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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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4 **A school-based, smartphone application-assisted, multi-component**
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6 **childhood obesity intervention: protocol of a cluster-randomized**
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8 **controlled trial (the DECIDE-children study)**
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18 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

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4 University Health Science Center. Results will be disseminated through publication in
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6 peer-reviewed journals, presentation at conferences and in lay summaries provided to
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8 school staff and participants.
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11 **Trial registration** ClinicalTrials.gov: NCT03665857.
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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

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4 China, there is promise for mobile technology-assisted childhood obesity prevention
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6 programs. Smartphone application (app) has been particularly promising due to its
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8 individualized and interactive characteristics, which might be greatly helpful in timely
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10 monitoring and feedback of children's nutritional status, diet and physical activity
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12 behaviors.
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17 In September 2018, we started to conduct the cluster-RCT that aims to develop an
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19 innovative, effective and scalable programme to prevent childhood obesity among
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21 primary school students.
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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 hHealth” (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

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4 their schools at follow-up visits.
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6 The inclusion criteria included that the school principal agreed to take part in the study,
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8 and the number of students recruited from grade 4 was no less than 50. If schools were
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10 located at different administrative districts, the number of schools in each
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12 administrative district should be even. Boarding schools, schools for children with
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14 special skills or minor ethnic groups were excluded. Schools that had conducted or
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16 would conduct other programme to prevent or treat childhood obesity during the study
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18 period were excluded. Schools were also not included if they had a definite plan for
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20 relocation or cancellation in the next two years.
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27 One or two classes of grade 4 were recruited. If the number of eligible students in each
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29 class was predicted to be no less than 40, one class was selected; otherwise, two classes
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31 were recruited.
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34 35 **Recruitment of students** 36

37 After recruiting schools, the research staff asked the class teachers to send informed
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39 consent forms to all students and their parents in the selected classes. All students and
40
41 their parents who provided written informed consent participated in this study. But
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43 students with one of the following conditions were excluded: ① medical history of
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45 heart disease, hypertension, diabetes, tuberculosis, asthma, hepatitis or nephritis; or ②
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47 obesity caused by endocrine diseases or side effects of drugs; or ③ abnormal physical
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49 development like dwarfism or gigantism; or ④ being physically incomplete and
50
51 deformed such as severe scoliosis, chicken breasts, limp, obvious O-leg or X-leg; or ⑤
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53 inability to participate in school sports activities; or ⑥ having been losing weight by
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4 vomiting or taking drugs during the past three months.
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9 ***Baseline and follow-up data collection***
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11 The primary outcomes are the differences between the intervention and control group
12 in the change of students' BMI and BMI-Z score after one academic year (9 months
13 after baseline). The secondary outcomes include the differences between two groups in
14 the changes of 1) students' BMI and BMI-Z score at 4 and 21 months after baseline, 2)
15 students' waist and hip circumferences at 4, 9 and 21 months after baseline, 3) students'
16 systolic and diastolic blood pressures at 4, 9 and 21 months after baseline, 4) students'
17 body fat percentage at 9 months after baseline, 5) students' physical fitness measures
18 (one-minute rope jumping, one-minute sit-up, standing jump and 50m*8 shuttle run) at
19 9 months after baseline, and 6) mediators and/or moderators of intervention effects
20 including students' knowledge-attitude-practice, family and school environment related
21 to obesity prevention at 9 months after baseline.
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40 According to the standard procedure, baseline data were collected by the trained project
41 personnel or physical education teachers (only for physical fitness measures). Follow-
42 up investigations will be undertaken according to the same standard procedures at 4
43 months after baseline (i.e. in the middle of intervention for the intervention group), 9-
44 month (i.e. immediately after intervention for the intervention group) and 21 months
45 after baseline (i.e. 12 months after 9-month intervention for the intervention group).
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56 The assessors measuring students' height and weight at follow-up investigations will
57 be blind for group allocation, i.e. they will not be told which schools were allocated to
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4 the intervention or control group. Descriptions of the outcome measures are shown in
5
6 Table 1.
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9 Questionnaires were developed based on previous studies, pilot study of the project and
10
11 found to be feasible and acceptable to students and parents [13-15]. Questions related
12
13 to dietary intake were designed based on the validated Block Kids Food Screener [13],
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15 and those related to duration of moderate-to-vigorous physical activity were based on
16
17 a validated 7-day physical activity questionnaire [14]. Other possible variables
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19 moderating or mediating students' nutritional status (e.g. children's eating behaviors
20
21 [15]) were also included in the questionnaires.
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26 27 ***Randomization procedures*** 28

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30 Randomization was stratified by administrative districts that the schools belong to. For
31
32 practical reasons, four schools were selected from each of the two districts (Dongcheng
33
34 and Mentougou District) of Beijing, respectively; four schools were recruited from each
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36 of the two districts (Shayiba and Shuimogou District) of Urumchi, respectively; all of
37
38 eight schools were selected from urban Changzhi (only one administrative district).
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40 Randomization was carried out using a computer-generated random number system by
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42 a researcher in the third-party organization who was not involved in the study.
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48 49 ***Intervention description*** 50

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

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4 Before implementation of the intervention, all of the participating school personnel
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6 have been trained by the project personnel. Two manuals (“An Implementation Manual
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8 for School Personnel Involving in the Multi-component Obesity Intervention among
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10 Primary School Students” and “An Implementation Manual for Project Personnel
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12 Involving in the Multi-component Obesity Intervention among Primary School
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14 Students”) have been developed for this complex intervention. They describe in details
15
16 the duty of both project personnel and school personnel in intervention schools
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18 delivering the intervention (school principals, class teachers, physical education
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20 teachers, school doctors), respectively. The manuals also describe the detailed
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22 workflow of implementation for each intervention component, i.e., who, when, how
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24 and to what extent the specific intervention element should be delivered. All of the
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26 school personnel have been required to carry out the intervention in accordance with
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28 the implementation manual.
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37 During implementation of the intervention, regular field observation and checking of
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39 smartphone app records will aid in strengthening quality of the intervention.
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43 ***Process evaluation***

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45 The process evaluation will be conducted in intervention schools throughout the project
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47 period to monitor and document the level of implementation of the intervention. It also
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49 aimed to aid in understanding the relationship between specific intervention elements
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51 and outcomes. Based on the steps and principles described in the conceptual framework
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53 by Saunders et al.[17], we identified the process evaluation elements including fidelity
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55 (the extent to which the intervention will be implemented as initially planned), dose
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4 delivered (the frequency and intensity of actual implementation of the program), dose
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6 received (the extent to which students/parents/teachers will be exposed to the
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8 intervention, as well as the degree of their satisfaction with intervention and materials),
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10 reach (the proportions and the characteristics of students/parents/teachers/schools
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12 completing or dropping out from the intervention) and context (family environment and
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14 school policies related to obesity prevention).
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19 The methods of process data collection will include: (1) direct regular field observation
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21 and records collected to control quality of the intervention (e.g., quality and quantity of
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23 the intervention sessions, number of students attending the lectures); (2) the users logs
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25 (e.g., frequency and duration) collected by the smartphone app; and (3) student- and
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27 parent-based questionnaires reporting the demographic information, family
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29 environment as well as their satisfaction with the intervention; (4) school questionnaires
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31 recording school policies related to obesity prevention.
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37 ***Health economic evaluation***

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40 A cost-effectiveness analysis will be employed in the health economic evaluation, and
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42 a societal perspective is used to examine whether the intervention is economically
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44 feasible. Intervention costs include times (research staff, participating school staff, and
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46 students' parents) for all the intervention activities and material expenses. Time costs
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48 are based on personal employment compensations if available or average
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50 compensations in the local areas for similar types of employees. Material expenses are
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52 based on real purchasing prices. An incremental cost-effectiveness ratio will be
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54 calculated and a sensitivity analysis will be used to vary key parameters to examine the
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4 robustness of health economic results.
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6 ***Sample size estimation*** 7

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9 We aim to recruit a total of 1,200 students from 24 schools with an average cluster size
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11 of 50 students per school. This sample size will provide 88% power at 5% significance
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13 level (two-sided) to detect a between-group difference of 0.50 kg/m² in BMI after the
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15 one-school-year intervention, assuming a standard deviation (SD) of 1.40 kg/m², an
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17 intra-cluster correlation coefficient of 0.05 and the 10% rate of attrition.
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20 ***Statistical analyses*** 21

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23 Statistical analyses will be performed using SAS version 9.4 (SAS Institute Inc., Cary,
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25 NC, USA). All statistical tests will be two-sided at 5% level of significance. Baseline
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27 characteristics at both school- and individual-level will be reported by using descriptive
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29 statistics. Continuous variables will be presented as means and SDs, and categorical
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31 variables will be presented as percentages.
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35 The primary analysis will be based on the intention-to-treat principle including all
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37 randomized schools and students recruited from each school. Generalized linear mixed
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39 models will be used to evaluate the intervention effect on primary and secondary
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41 outcomes measured at 4 and/or 9 and/or 21 months following baseline investigation,
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43 adjusting for baseline outcome value, age and sex. The cluster effect of school and
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45 repeated measures of the same participant will be taken into account in the multi-level
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47 modelling, and missing data will be treated in the maximum likelihood estimates
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49 assuming they are missing at random. The intra-cluster correlation coefficient will also
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51 be estimated. Sensitivity analysis will be considered on the primary outcome using the
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4 last-value-carry-forward (LVCF) imputation on missing data. Model-adjusted mean
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6 group differences will be reported on continuous outcomes. Adjusted odds ratio (OR)
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8 will be reported on binary outcomes using a logit link. The 95% confidence interval
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10 (CI) and associated *P*-value were calculated.
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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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Study team of the DECIDE-children study:

Beijing: Department of Maternal and Child Health, School of Public Health, Peking University (Hai-Jun Wang, Zheng Liu, Li-Zi Lin, Qiang Feng, Chen-Xiong Li, Shuang Zhou, Wen-Hao Li, Chu-Yao Jin, Qin Li, Yu Cheng, Di Wang, Lan Cheng, Yi Song, Hong Zhou, Xiang-Rong Xu, Jie-Yun Song); Dongcheng Primary and Secondary School Health Care Center, Beijing (Ai-Yu Gao, Hai-Hua Chen, Li-Jia Shang), Mentougou Primary and Secondary School Health Care Center, Beijing (Fang Zhang, Run-Ze Chen).

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.	

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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	<p>The following school policies are suggested:</p> <ol style="list-style-type: none"> 1. “Not selling”: Not selling unhealthy snack¹ 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”)	<ol style="list-style-type: none"> 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.

	<p>individualized feedback related to these behaviors.</p> <p>3. Weight management</p> <p>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.</p> <p>4. Assessment and feedback</p> <p>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.</p>	
Regular monitoring of students' weight and height	<p>1. Monthly monitoring</p> <p>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);</p> <p>2. Weekly monitoring</p> <p>Students' weight is monitored weekly by the students themselves in the classroom.</p>	<p>The trained school doctors with the help of the trained professionals (for monthly monitoring);</p> <p>The trained professionals (for data input of monthly monitoring)</p> <p>Students (for weekly monitoring)</p>

<p>Reinforcement of students' physical activity within and outside school</p>	<p>1. Reinforcement of students' physical activity within school</p> <p>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;</p> <p>Physical education teachers should teach students at least one sports game during each extracurricular activity.</p> <p>2. Reinforcement of students' physical activity outside school</p> <p>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;</p> <p>Recommendations for physical activity outside school are given through the smartphone app once every two months;</p> <p>Students are encouraged to do sports games outside school that are taught by their physical education teachers during extracurricular activities.</p>	<p>The trained physical education teachers (for students' physical activity within school);</p> <p>Students' parents assisted by the smartphone app (for students' physical activity outside school)</p>
<p>Health education activities</p>	<p>1. Health education activities towards parents (or other primary caregivers)</p> <p><u>1) Frequency and duration</u></p> <p>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.</p> <p><u>2) Contents</u></p> <p>➤ For the first activity</p> <p>Key messages are similar to health education activities towards students (described below).</p> <p>Parents (or other primary caregivers) are also taught to use the smartphone app.</p> <p>➤ For other activities</p>	<p>The trained research staff (for health education activities towards parents/other primary caregivers and school teachers);</p> <p>The trained class teachers (for health education activities towards students)</p>

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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

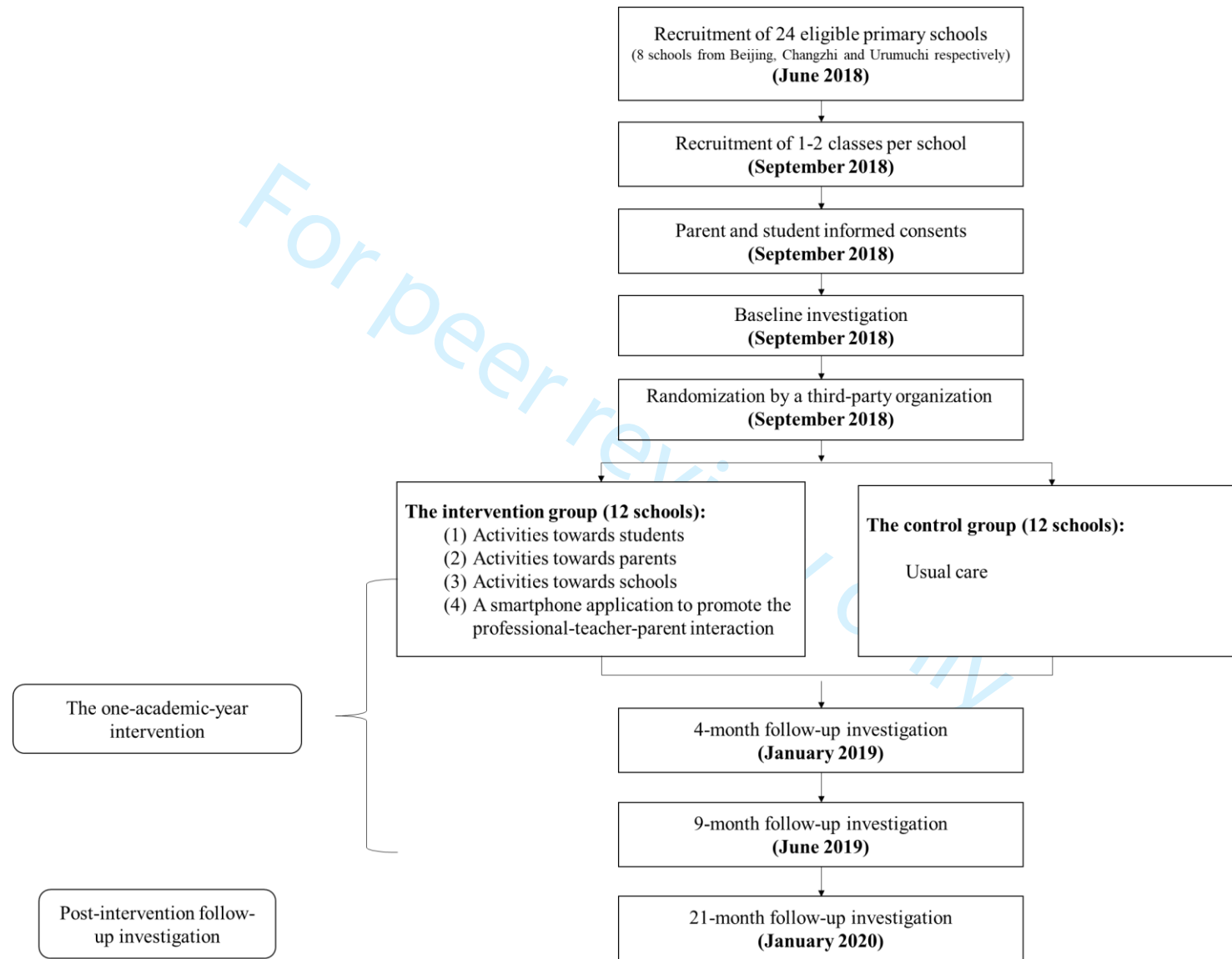
① Knowledge diffusion

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

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	<p>primary and middle school students” are delivered to students. Health education messages are also spread through posters in campus or classroom.</p> <p>② Promotion for translating knowledge into action</p> <p>“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.</p> <p>③ Feedback and encouragement for BMI and behavior change</p> <p>Feedback of regular monitoring results of students’ BMI and behaviors is provided in each health education activity. The students with good performance are encouraged.</p>	
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For peer review only



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Figure 1 Study flow chart of the DECIDE-children

For peer review only

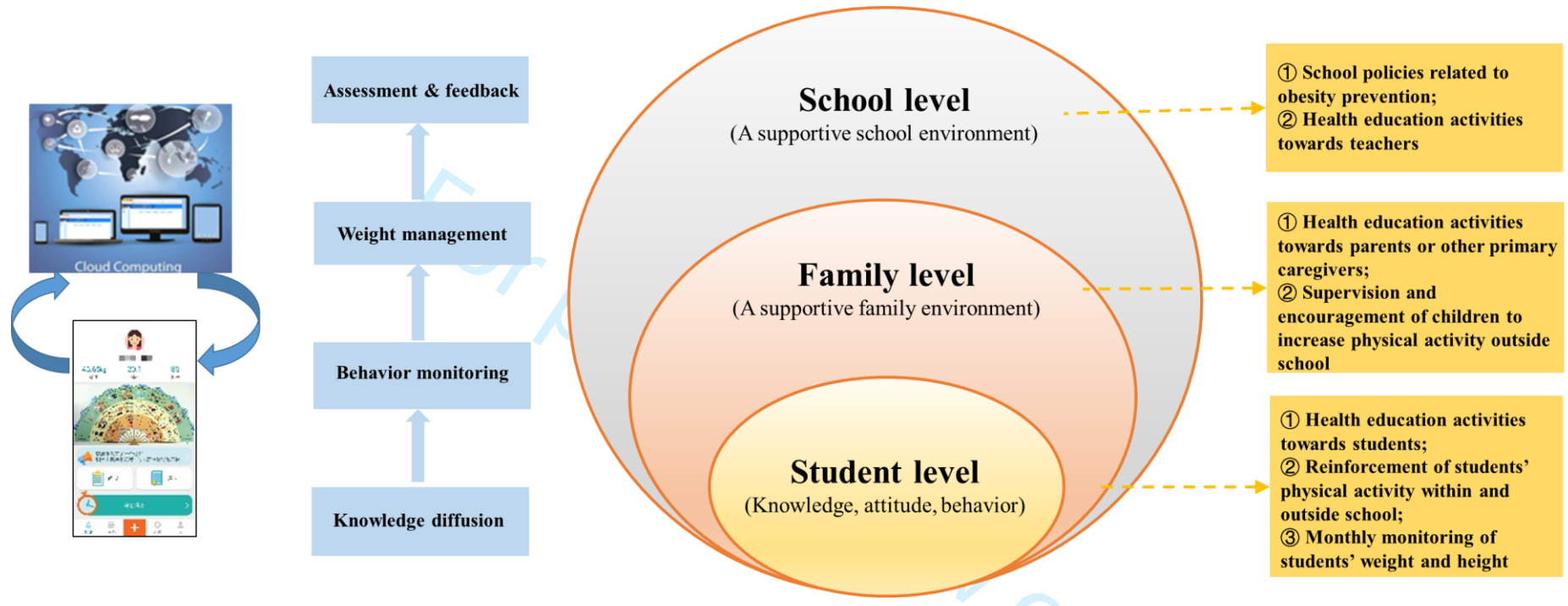


Figure 2 Theoretical framework of the DECIDE-children

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.

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			Page
		Reporting Item	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

1	Trial registration:	#2b	All items from the World Health Organization Trial	n/a
2				
3	data set		Registration Data Set	
4				
5				
6	Protocol version	#3	Date and version identifier	n/a
7				
8				
9	Funding	#4	Sources and types of financial, material, and other	22
10			support	
11				
12				
13				
14				
15	Roles and	#5a	Names, affiliations, and roles of protocol contributors	1,21,22
16				
17	responsibilities:			
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19	contributorship			
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23	Roles and	#5b	Name and contact information for the trial sponsor	22
24				
25	responsibilities:			
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27	sponsor contact			
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29	information			
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32	Roles and	#5c	Role of study sponsor and funders, if any, in study	n/a
33				
34	responsibilities:		design; collection, management, analysis, and	
35			interpretation of data; writing of the report; and the	
36	sponsor and funder		decision to submit the report for publication, including	
37			whether they will have ultimate authority over any of	
38			these activities	
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47	Roles and	#5d	Composition, roles, and responsibilities of the	22
48				
49	responsibilities:		coordinating centre, steering committee, endpoint	
50			adjudication committee, data management team, and	
51	committees		other individuals or groups overseeing the trial, if	
52			applicable (see Item 21a for data monitoring committee)	
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1	Background and	#6a	Description of research question and justification for	5-6
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3	rationale		undertaking the trial, including summary of relevant	
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5			studies (published and unpublished) examining benefits	
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7			and harms for each intervention	
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11	Background and	#6b	Explanation for choice of comparators	n/a
12				
13	rationale: choice of			
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15	comparators			
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18	Objectives	#7	Specific objectives or hypotheses	6
19				
20				
21				
22	Trial design	#8	Description of trial design including type of trial (eg,	7
23				
24			parallel group, crossover, factorial, single group),	
25				
26			allocation ratio, and framework (eg, superiority,	
27				
28			equivalence, non-inferiority, exploratory)	
29				
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32	Study setting	#9	Description of study settings (eg, community clinic,	7
33				
34			academic hospital) and list of countries where data will be	
35				
36			collected. Reference to where list of study sites can be	
37				
38			obtained	
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42	Eligibility criteria	#10	Inclusion and exclusion criteria for participants. If	8-9
43				
44			applicable, eligibility criteria for study centres and	
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46			individuals who will perform the interventions (eg,	
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48			surgeons, psychotherapists)	
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51	Interventions:	#11a	Interventions for each group with sufficient detail to allow	11-12,
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53	description		replication, including how and when they will be	25-29
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55			administered	
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1	Interventions:	#11b	Criteria for discontinuing or modifying allocated	n/a
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3	modifications		interventions for a given trial participant (eg, drug dose	
4			change in response to harms, participant request, or	
5			improving / worsening disease)	
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11	Interventions:	#11c	Strategies to improve adherence to intervention protocols,	12-13
12				
13	adherence		and any procedures for monitoring adherence (eg, drug	
14			tablet return; laboratory tests)	
15				
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19	Interventions:	#11d	Relevant concomitant care and interventions that are	n/a
20				
21	concomitant care		permitted or prohibited during the trial	
22				
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24	Outcomes	#12	Primary, secondary, and other outcomes, including the	9-10
25			specific measurement variable (eg, systolic blood	
26			pressure), analysis metric (eg, change from baseline, final	23-24
27			value, time to event), method of aggregation (eg, median,	
28			proportion), and time point for each outcome. Explanation	
29			of the clinical relevance of chosen efficacy and harm	
30			outcomes is strongly recommended	
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41	Participant timeline	#13	Time schedule of enrolment, interventions (including any	7,
42			run-ins and washouts), assessments, and visits for	
43			participants. A schematic diagram is highly recommended	Figure 1
44			(see Figure)	
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51	Sample size	#14	Estimated number of participants needed to achieve	14
52			study objectives and how it was determined, including	
53			clinical and statistical assumptions supporting any sample	
54			size calculations	
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1	Recruitment	#15	Strategies for achieving adequate participant enrolment to reach target sample size	7-8
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6	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
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23	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)
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33	Allocation: implementation	#16c	Who will generate the allocation sequence, who will enrol participants, and who will assign participants to interventions	10
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41	Blinding (masking)	#17a	Who will be blinded after assignment to interventions (eg, trial participants, care providers, outcome assessors, data analysts), and how	9-10
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48	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
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20 21 22 23 24 25 26 27 28 29	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
30 31 32 33 34 35 36 37 38 39 40 41	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
42 43 44 45 46 47 48 49	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
50 51 52 53 54 55 56 57 58 59 60	Statistics: additional analyses	#20b	Methods for any additional analyses (eg, subgroup and adjusted analyses)	14-15

1	Statistics: analysis	#20c	Definition of analysis population relating to protocol non-	14-15
2				
3	population and		adherence (eg, as randomised analysis), and any	
4				
5	missing data		statistical methods to handle missing data (eg, multiple	
6				
7			imputation)	
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11	Data monitoring:	#21a	Composition of data monitoring committee (DMC);	n/a
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13	formal committee		summary of its role and reporting structure; statement of	
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15			whether it is independent from the sponsor and	
16			competing interests; and reference to where further	
17			details about its charter can be found, if not in the	
18			protocol. Alternatively, an explanation of why a DMC is	
19			not needed	
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28	Data monitoring:	#21b	Description of any interim analyses and stopping	n/a
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30	interim analysis		guidelines, including who will have access to these	
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32			interim results and make the final decision to terminate	
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34			the trial	
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38	Harms	#22	Plans for collecting, assessing, reporting, and managing	n/a
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40			solicited and spontaneously reported adverse events and	
41				
42			other unintended effects of trial interventions or trial	
43				
44			conduct	
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48	Auditing	#23	Frequency and procedures for auditing trial conduct, if	n/a
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50			any, and whether the process will be independent from	
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52			investigators and the sponsor	
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55	Research ethics	#24	Plans for seeking research ethics committee / institutional	7
56				
57	approval		review board (REC / IRB) approval	
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1 2 3 4 5 6 7 8 9 10	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
11 12 13 14 15 16 17 18	Consent or assent	#26a	Who will obtain informed consent or assent from potential trial participants or authorised surrogates, and how (see Item 32)	9
19 20 21 22 23 24 25	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
26 27 28 29 30 31 32 33 34 35	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
36 37 38 39 40 41	Declaration of interests	#28	Financial and other competing interests for principal investigators for the overall trial and each study site	22
42 43 44 45 46 47 48	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
49 50 51 52 53 54 55 56 57 58 59 60	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

1	Dissemination	#31a	Plans for investigators and sponsor to communicate trial	2-3
2				
3	policy: trial results		results to participants, healthcare professionals, the	
4			public, and other relevant groups (eg, via publication,	
5			reporting in results databases, or other data sharing	
6			arrangements), including any publication restrictions	
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13	Dissemination	#31b	Authorship eligibility guidelines and any intended use of	n/a
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15	policy: authorship		professional writers	
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19	Dissemination	#31c	Plans, if any, for granting public access to the full	n/a
20				
21	policy: reproducible		protocol, participant-level dataset, and statistical code	
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23	research			
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26	Informed consent	#32	Model consent form and other related documentation	n/a
27				
28	materials		given to participants and authorised surrogates	
29				
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32	Biological specimens	#33	Plans for collection, laboratory evaluation, and storage of	n/a
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34			biological specimens for genetic or molecular analysis in	
35				
36			the current trial and for future use in ancillary studies, if	
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38			applicable	
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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)

Journal:	<i>BMJ Open</i>
Manuscript ID	bmjopen-2018-027902.R1
Article Type:	Protocol
Date Submitted by the Author:	01-Aug-2019
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Primary Subject Heading:	Epidemiology
Secondary Subject Heading:	Paediatrics, Public health
Keywords:	pediatric obesity, cluster, prevention, randomized controlled trial

SCHOLARONE™
Manuscripts

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4 1 **A school-based, multi-faceted health promotion programme to**
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6 2 **prevent obesity among children: protocol of a cluster-randomized**
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8 3 **controlled trial (the DECIDE-children study)**
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14 5 Zheng Liu¹, Yang-Feng Wu², Wen-Yi Niu³, Xiang-Xian Feng⁴, Yi Lin⁵, Ai-Yu Gao⁶,
15
16 6 Fang Zhang⁷, Hai Fang⁸, Pei Gao⁹, Hui-Juan Li², Hai-Jun Wang¹, the study team for
17
18 7 the DECIDE-children study
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4 23**Abstract**5
6 24 **Introduction** Obesity is an increasingly serious public health concern globally.7
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9 25 Effective and sustainable childhood obesity prevention strategies would have potential10
11 26 to help and may have impact on its lifelong health. However, few such strategies have12
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14 27 been rigorously evaluated for Chinese children in different regions of China.15
16 28 **Methods and analysis** DECIDE-Children is a cluster-randomized controlled trial that17
18
19 29 aims to assess the effectiveness and sustainability of a school-based, multi-faceted20
21 30 intervention to prevent obesity among Grade 4 primary school students (8 to 10 years22
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24 31 old) in China. Twenty-four schools (approximately 1200 students) from the more than25
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27 32 average, average and less than average developed regions in China will be randomized28
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30 33 to intervention (12 schools) or usual practice (12 schools). The intervention will last for31
32
33 34 one year and consist of activities towards students, parents and school environment. A34
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36 35 smartphone application will be used to assist in implementation of the intervention.36
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38 36 Data will be collected at baseline, 4 months, 9 months and 21 months. The primary38
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40 37 outcome is the difference between arms in the change of students' body mass index41
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43 38 (BMI) at 9 months after the baseline investigation. The secondary outcomes include the43
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45 39 differences between arms in the change of anthropometric measures, diet, physical46
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48 40 activity and other measures at follow-up visits. A range of process evaluation methods48
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50 41 will be used to determine implementation of the complex intervention.51
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53 42 **Ethics and dissemination** This study has been approved by the Peking University53
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55 43 Institution Review Board (IRB00001052-18021). Results will be disseminated through55
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57 44 publication in peer-reviewed journals, presentation at conferences and in lay summaries57
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45 provided to school staff and participants.

46 **Trial registration** ClinicalTrials.gov: NCT03665857.

For peer review only

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4 **47 Strengths and limitations of this study**

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7 48 1. This study will rigorously evaluate the effectiveness and scalability of a childhood
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9 49 obesity prevention programme in eastern, central and western regions with different
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11 50 levels of economic development in China.

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14 51 2. We will employ a smartphone application to assist in implementation of the complex
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16 52 intervention, including information diffusion, behavior monitoring, weight
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18 53 management, assessment and feedback.

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22 54 3. We will include an explicit process evaluation plan for both intervention and control
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24 55 groups, determining the implementation of the complex intervention.

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27 56 4. A follow-up investigation will be conducted to evaluate the sustainability of the
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29 57 intervention.

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32 58 5. This intervention is limited by a relatively short duration, but further funding will be
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34 59 sought for a potential longer-term intervention in future.
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60 **Introduction**

61 Childhood obesity is a significant public health concern worldwide [1, 2]. China has
62 seen a dramatic increase in childhood obesity with the economy fast growing over the
63 past decades. The prevalence of obesity among 7-18 y Chinese children increased from
64 0.1% in 1985 to 7.3% in 2014 [2]. Childhood obesity is not only associated with adverse
65 consequences on physical and mental health of children in the short term [3, 4], but also
66 increases risk of developing cardiovascular diseases in the long term [5, 6]. Accordingly,
67 effective strategies to curb and reduce childhood obesity prevalence would bear great
68 long-term potential to prevent cardiovascular diseases in whole population.

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

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4 82 the effectiveness of a childhood obesity intervention. Yet previous studies have been
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6 83 largely conducted in a single region, which limits the generalizability of study findings
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9 84 to other populations. Another weakness is that most studies examined outcomes only
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11 85 at the end of the intervention. Thus, it remains unclear whether healthy behaviors and
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14 86 weight continue beyond the period of the intervention.
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17 ***School system in China***

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19 88 In primary schools in China, there are six grades in total, with age of students ranging
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22 89 from 6 to 11 years. The usual size of a class is less than 45, but varies in different
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25 90 schools, ranging from 30 to 60. There are two school policies issued by Chinese
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27 91 government that are particularly relevant to prevention and management of childhood
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30 92 obesity. First, schools should have the school doctor or health care teachers who provide
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33 93 in-house school health care. Their routine practices include student health surveillance,
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36 94 health education for students, prevention and control of common diseases of students.
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38 95 Second, schools should implement ‘One-Hour Physical Activity On Campus Every
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41 96 School Day’. That is, the total time of physical activity (i.e. physical education classes,
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44 97 class-break exercise and extracurricular activities) per school day should be no less than
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47 98 one hour. However, implementation of these policies in school system is varying in
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50 99 different regions in China [14].

100 ***Development of a childhood obesity intervention***

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

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4 104 (2) we conducted focus group discussions and interviews with key informants (children,
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6 105 parents, teachers, school principals, local health and education officials) to further
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9 106 revise and refine the intervention approaches; (3) to test feasibility of the proposed
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12 107 intervention, we also undertook a three-month, before-after, pilot study at two primary
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14 108 schools in Beijing (one in the urban area and the other in the rural area) among 58 Grade
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17 109 4 students (mean age: 9.38 ± 0.49 years)[15]; (4) we further discussed the proposed
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20 110 intervention with multiple experts. Based on all the work mentioned, we finally
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22 111 developed the intervention elements used for this study.

112 *Aim and objectives*

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

124 **Methods and analysis**

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

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4 126 Recommendations for Interventional Trials (SPIRIT) statement [16, 17].
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7 127 ***Study design***
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9 128 DECIDE-Children is a cluster-randomized, parallel-group controlled trial. To
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11 129 accommodate with the social and economic variations within the country and increase
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13 130 the scalability of our interventions, we will intentionally select study schools from three
14
15 131 different regions of China, the more than average developed area in the east (Beijing),
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17 132 the average developed area in the central (Shanxi) and the less than average developed
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19 133 area in the west (Xinjiang). A total of 24 primary schools (clusters) equally distributed
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21 134 among three regions will be selected. In Beijing, 4 schools will be selected from
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23 135 Dongcheng district (located in the central city) and 4 from Mentougou district (located
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25 136 in a suburban rural area). In Xinjiang, all 8 schools will be selected in Urumchi, the
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27 137 capital city of the autonomous region; and half of the schools will be selected from
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29 138 Shayiba district (an urban district) and half from Shuimogou district (a rural district).
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31 139 In Shanxi, all 8 schools will be selected from only one urban district of Changzhi, a
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33 140 small to medium size city in the province. The reason for excluding rural schools in
34
35 141 Changzhi is that most of these schools were boarding schools. Thus, a total of 24
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37 142 primary schools from five sites in three regions will be selected and randomized into
38
39 143 two groups, one on the obesity prevention intervention and the other on usual practice.
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41 144 The intervention will be implemented for one school year from late September 2018 to
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43 145 June 2019, and the study will continue with a one-year follow-up investigation in June
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45 146 2020. Figure 1 shows the study flow.
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58 147 ***Recruitment***
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148 **Recruitment of schools**

149 The present study will be carried out in Grade 4 students (8 to 10 years old), as they are
150 old enough to understand health education information and able to remain in the same
151 school to complete the two-year study before they graduate. To be eligible, the school
152 principal should agree with randomization procedure and compliance with the study
153 protocol. The total number of Grade 4 students must be more than 50 in the school, and
154 the school have not implemented or are not going to implement an obesity prevention
155 or similar intervention program. Boarding schools, special schools for children with
156 talent skills or minority ethnic groups will be excluded. Schools will also not be
157 included if they have a definite plan for relocation or cancellation in the next two years.
158 For schools participating the program, the size of a class varies from less than 30 to
159 approximately 60 children a class. To meet the sample size requirement, we will recruit
160 two classes of the school if the number of students in each class is less than 50 and one
161 class otherwise. If the number of classes in one school is more than needed, the school
162 principal will recommend which classes to be selected.
163 Three steps will be undertaken for the recruitment of schools. First, project staff will
164 contact the local education authority to gain their opinion, support, approval and basic
165 information of the schools (type of schools, number of students and teachers). Second,
166 project staff will approach the schools by a phone call or a visit to understand the
167 eligibility of the potential schools for participation. Third, the final list of eligible
168 schools and classes will be made by the principal investigator and schools will be
169 invited by local research partners.

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4 **170 Recruitment of students**

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6 171 After recruiting schools and before the baseline examination, written informed consent
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9 172 will be provided to all students and their primary caregivers (parents in most cases) in
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11 173 the selected classes. Then parents with informed consent will be required to fill in a
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13 174 self-administrative questionnaire about health status of their children. The project staff
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15 175 will collect the questionnaires and if find one or more of the following conditions
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17 176 reported by parents, their children will be excluded: 1) medical history of heart disease,
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19 177 hypertension, diabetes, tuberculosis, asthma, hepatitis or nephritis; 2) obesity caused by
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21 178 endocrine diseases or side effects of drugs; 3) abnormal physical development like
22
23 179 dwarfism or gigantism; 4) being physically incomplete and deformed such as severe
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25 180 scoliosis, pectus carinatum, limp, obvious O-leg or X-leg; 5) inability to participate in
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27 181 school sports activities; 6) having been losing weight by vomiting or taking drugs
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29 182 during the past three months.

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37 183 ***Randomization procedures***

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40 184 The random sequence of allocation of schools (clusters) to intervention or control will
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42 185 be stratified by the study sites. Schools in the same study site will be randomly allocated
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44 186 in 1:1 ratio to either the intervention or control group using a computer-generated
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46 187 random number system (the simple random sampling method). Randomization will be
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48 188 performed by an independent person at the central coordinating center at Peking
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50 189 University Clinical Research Institute. The randomization will take place only after the
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52 190 baseline assessments complete to ensure the allocation concealment.

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58 191 ***Intervention***

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4 192 We used Social Ecological Model to identify intervention elements in this multi-faceted
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6 193 health promotion programme [18]. As shown in Figure 2, the programme will target
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9 194 the influencing factors of childhood obesity at both individual (student-focused
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11 195 activities) and environmental levels (providing a supportive family and school
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13 196 environment), with the intent to influence knowledge, attitude and behaviors of school
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15 197 children.

198 **Description of the intervention components**

199 The intervention components are described in Table 1 and 2.

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

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

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

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

212 **Quality control of the intervention**

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

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4 214 component Obesity Intervention among Primary School Students” and “An Operation
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6 215 Manual for School Team Members Involving in the Multi-component Obesity
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9 216 Intervention among Primary School Students”) have been developed for implementing
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12 217 and managing this complex intervention. They describe in detail the duties of project
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14 218 staff and school team members (school principals, class teachers, physical education
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17 219 teachers, school doctors/health care teachers) in delivering the intervention,
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20 220 respectively. The manuals also describe the detailed workflow of implementation for
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22 221 each intervention component, i.e., who, when, how and to what extent the specific
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24 222 intervention element should be delivered. All of the project staff and school team
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27 223 members will be required to carry out the intervention in accordance with the operation
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30 224 manuals.

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32 225 During implementation of the intervention, regular field observation and checking of
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35 226 smartphone app records will also be applied. To improve fidelity, if it is found that
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38 227 schools are not complying with the study protocol, project staff will timely
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41 228 communicate with school team members and continue with follow-up supervision.

42 43 229 ***Control group***

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45 230 The twelve schools in the control group will not carry out any interventions delivered
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48 231 by the study and will continue usual practice according to their own teaching curriculum
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51 232 during the study period (from September 2018 to June 2020). Participants in the control
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54 233 group will receive the health education materials that will have been delivered to those
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57 234 in the intervention group as soon as the 21-month follow-up investigation be completed
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60 235 in June 2020.

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4 236 ***Outcome evaluation***
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6 237 Table 3 describes what, when and how the study outcomes will be evaluated. Baseline
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8 238 measurements will be conducted in September 2018 for both intervention and control
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11 239 groups. Follow-up measurements will be undertaken at 4 months after baseline
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14 240 measurements in January (one school semester and in the half of the intervention), 9
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17 241 months after baseline measurements in June 2019 (one school year and immediately
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20 242 whole intervention program completed) and 21 months after baseline measurements in
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22 243 June 2020 (two school years and 12 months after the intervention completion).
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24 244 At the baseline and all follow-up visits, anthropometric measures (height, weight, waist
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27 245 and hip circumference, systolic and diastolic blood pressures, body fat percentage) and
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30 246 physical fitness measures (one-minute rope jumping, one-minute sit-up, long standing
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33 247 jump, shuttle run (50 m×8)) will be collected by the trained outcome assessors using
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36 248 uniform device and/or forms according to the standard methods and procedures. The
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38 249 assessors measuring students' height and weight will be blinded to group allocation of
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41 250 the schools. We will use questionnaires to measure students' behaviors (duration of
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44 251 moderate-to-vigorous physical activity, eating behavior, sedentary behavior), school
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47 252 policies for prevention and management of childhood obesity, and other potential
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50 253 moderators/mediators of the intervention (e.g. stage of change related to weight
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53 254 reduction behavior). Questionnaires were developed based on previous studies and the
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56 255 pilot study. They were found to be feasible and acceptable to students and their parents
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59 256 [20-22].
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60 257 ***Outcomes***

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4 258 The primary outcome is the difference between arms in the change of students' body
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6 259 mass index ($BMI = \text{weight (kg)} / (\text{height (m)})^2$) immediately after the intervention
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9 260 completion (9 months after the baseline examination). The secondary outcomes include
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11 261 the change of BMI in one year after the intervention completion. In addition, we will
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14 262 also compare the following indices between arms at follow-up visits: 1) change in
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17 263 students' BMI-Z (standard deviation score will be calculated based on World Health
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19 264 Organization criteria [23]); 2) change in prevalence and incidence of childhood
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22 265 overweight/obesity defined according to the criteria for Chinese children and
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25 266 adolescents [24]; 3) change in students' waist circumference, waist-to-hip
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27 267 circumference ratio and systolic and diastolic blood pressures; and 4) change in students'
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30 268 body fat percentage, physical fitness measures, behavioral and other outcomes.

31 32 269 *Sample size estimation*

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35 270 We assumed the difference between two groups in change in BMI (effect size) would
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37 271 be 0.50 kg/m^2 , a standard deviation (SD) of BMI would be 1.40 kg/m^2 , an intra-cluster
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40 272 correlation coefficient would be 0.05 and the rate of attrition would be 10% for sample
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43 273 size calculation in our study. We aimed to recruit a total of 1,200 students from 24
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46 274 schools with an average cluster size of 50 students per school. This sample size will
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48 275 provide 88% power with $\alpha = 0.05$ to detect a mean difference of 0.50 kg/m^2 in change of
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51 276 BMI between groups after the one-school-year intervention.

52 53 277 *Statistical analyses*

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56 278 Statistical analyses will be performed using SAS version 9.4 (SAS Institute Inc., Cary,
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58 279 NC, USA). All statistical tests will be two-sided at 5% level of significance. Baseline

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4 280 characteristics at both school- and individual-level will be reported by using descriptive
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6 281 statistics.

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9 282 The primary analysis will be based on the intention-to-treat principle including all
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11 283 students recruited with the baseline BMI measured. Generalized linear mixed models
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14 284 will be used to compare the primary and secondary outcomes at 4 and/or 9 and/or 21
15
16
17 285 months after the baseline, adjusting for the clustering effect and baseline outcome
18
19 286 values. The missing data will be treated in the maximum likelihood estimates assuming
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21
22 287 they are missing at random. The intra-cluster correlation coefficient will also be
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24
25 288 estimated. Sensitivity analysis will be considered on the primary outcome using the
26
27 289 last-value-carry-forward imputation if missing data exceeds 5%. For continuous
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30 290 outcomes, we will report pre-, post-intervention means for intervention and control
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32 291 groups, respectively, and model-adjusted mean differences between groups. For binary
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35 292 outcomes, we will report pre-, post-intervention percentages for intervention and
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38 293 control groups, respectively, and adjusted odds ratio (OR) between groups. The 95%
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40 294 confidence interval (CI) and associated *P*-value will be calculated. We will also
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43 295 examine whether any difference in outcomes between control and intervention arms
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46 296 varies by children sex, socioeconomic factor (mother's education), BMI status at
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48 297 baseline and primary caregivers of children (parents as compared with non-parents).

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50 298 ***Process evaluation***

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53 299 The process evaluation will be conducted in intervention schools throughout the project
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56 300 period to monitor and document the implementation of the intervention. It also aims to
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59 301 aid in understanding the relationship between specific intervention elements and
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4 302 outcomes. The control schools will also be monitored for “treatment as usual”.

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6 303 Based on the steps and principles described in the conceptual framework by Saunders

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9 304 et al.[25], we will identify the process evaluation elements including fidelity (the extent

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11 305 to which the intervention will be implemented as initially planned), dose delivered (the

12
13 306 frequency and intensity of actual implementation of the program), dose received (the

14
15 307 extent to which students/primary caregivers (parents in most cases)/teachers will be

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17 308 exposed to the intervention, as well as the degree of their satisfaction with intervention

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19 309 and materials), reach (the proportions and the characteristics of students/primary

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21 310 caregivers/teachers completing or dropping out of the intervention) and context (family

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23 311 environment and school policies related to obesity prevention and management).

24
25 312 The methods of process data collection will include: (1) direct regular field observation

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27 313 and records collected for quality control of the intervention (e.g., quality and quantity

28
29 314 of the intervention sessions, number of students attending the lectures); (2) the user logs

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31 315 (e.g., frequency and duration) collected by the smartphone app; and (3) student and

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33 316 parent questionnaires (Table 3) on students’ behaviors and family environment in both

34
35 317 intervention and control schools; (4) school questionnaires on school policies related to

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37 318 obesity prevention and management in both intervention and control schools; (5)

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39 319 interviews with participants (6~8 students per school) conducted in follow-up

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41 320 investigations in both intervention and control schools.

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43 321 ***Health economic evaluation***

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45 322 A cost-effectiveness analysis will be employed in the health economic evaluation, and

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47 323 a societal perspective is used to examine whether the intervention is economically

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4 324 feasible. Intervention costs include times (project staff, school staff, and students'
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6 325 primary caregivers (parents in most cases)) for all the intervention activities and
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9 326 material expenses. Only time of project staff spent in implementing the intervention
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11 327 will be included. Time costs are based on personal employment compensations if
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14 328 available or average compensations in the local areas for similar types of employees.
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17 329 Material expenses are based on real purchasing prices. An incremental cost-
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19 330 effectiveness ratio will be calculated and a sensitivity analysis will be used to vary key
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22 331 parameters to examine the robustness of health economic results.

332 **Patient and Public involvement**

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

342 **Trial status**

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

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4 346 in 2018 and completed in June 2019. The 4-month follow-up measurements started and
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6 347 completed in January 2019. The 9-month follow-up measurements started and
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9 348 completed in June 2019. The 21-month follow-up measurements will start and complete
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11
12 349 in June 2020.

13 14 350 **Ethics and dissemination**

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17 351 This study was reviewed and has been approved by the Peking University Institution
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19 352 Review Board (IRB00001052-18021). Any amendments to the study protocol will be
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22 353 submitted for IRB approval prior to implementation. Written informed consent will be
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24 354 obtained from all students and their parents. All data collected will be entered into
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27 355 electronic database with personal identification information de-identified. The database
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30 356 will be accessed only by designated staff with password. Results will be disseminated
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33 357 through publication in peer-reviewed journals, presentation at conferences and in lay
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35 358 summaries provided to school staff and participants. On completion of the trial, and
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38 359 after publication of these results, data would be available on request by contacting the
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41 360 corresponding author of this protocol.

42 43 361 **Discussion**

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45 362 Non-communicable diseases, especially cardiovascular diseases, have been the public
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48 363 health burden among the whole population. Preventing childhood obesity in early life
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51 364 could have the greatest long-term potential to curb this epidemic burden. Although
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54 365 several childhood obesity intervention studies have been conducted in China, research
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56 366 gaps existed in terms of methodological flaws, process measures, scalability and
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59 367 sustainability of the intervention. Based on a theory-driven and systematic development
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4 368 during its formative phase (e.g., systematic review [8], qualitative interviews, panel
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6 369 discussions and a piloted study [15]), the DECIDE-Children study provides one of the
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9 370 first examples of rigorous development and evaluation of a childhood obesity
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11 371 prevention programme implemented in eastern, central and western regions of China.
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14 372 This study has several distinguishing features: 1) randomization by an independent
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16 373 person not involved in the study, blinding of key outcome measures, and a detailed
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18 374 process evaluation plan will help to provide study results with high quality; 2) a follow-
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20 375 up investigation one year after the intervention completion will be conducted to
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22 376 determine the sustainability of the intervention; 3) a smartphone app with functions of
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24 377 information diffusion, behavior monitoring, weight management, assessment and
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26 378 feedback is employed to assist in implementation of the intervention; 4) three centers
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28 379 located in eastern, central and western regions of China will be involved to reflect
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30 380 different levels of economic development in China; 5) most of the intervention
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32 381 components (school polices, regular monitoring of students' weight and height,
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34 382 reinforcement of students' physical activity within school, health education activities
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36 383 for students) will be integrated into the regular academic schedule of each intervention
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38 384 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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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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4 **Competing interests statement**
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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	<p><u>1) Frequency and duration</u> 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).</p> <p><u>2) Different kinds of activities</u> 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”).</p> <p><u>3) Contents</u></p> <p>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.</p> <p>② Promotion for translating knowledge into action “Small hand in big hand” homework (e.g., “challenge of three days away from screen”) will</p>	The trained class teachers

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	<p>be arranged at the end of each health education activity.</p> <p>③ Feedback and encouragement for BMI and behavior change</p> <p>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.</p>	
<p>Reinforcement of students' physical activity within school</p>	<p>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;</p> <p>2) Physical education teachers will be advised to teach students at least one sports game during each extracurricular activity.</p>	<p>The trained physical education teachers</p>
<p>Regular monitoring of students' weight and height</p>	<p><u>1) Monthly monitoring</u></p> <p>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);</p> <p><u>2) Weekly monitoring</u></p> <p>Students' weight will be monitored weekly by the students themselves in the classroom.</p>	<p>The trained school doctors/health care teachers with the assistance of the trained project staff (for monthly monitoring);</p> <p>The trained project staff (for data input of monthly monitoring)</p> <p>Students (for weekly monitoring)</p>

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2. Activities towards parents (providing a supportive family environment)		
Health education activities for parents	<p><u>1) Frequency and duration</u> 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).</p> <p><u>2) Contents</u></p> <ul style="list-style-type: none"> ➤ 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	<ul style="list-style-type: none"> 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	<p>The following school policies will be suggested:</p> <ul style="list-style-type: none"> 1) "Not selling": 	<p>Trained school principal;</p> <p>Trained class teachers</p>

	<p>Not selling unhealthy snacks¹ or sugar-sweetened beverages within school;</p> <p>2) “Not eating”: Telling students not to eat unhealthy snacks or drink sugar-sweetened beverages within school;</p> <p>3) “Not buying”: Students being educated by class teachers not to buy unhealthy snacks or sugar-sweetened beverages around school.</p>	
<p>Health education activities for school teachers</p>	<p><u>1) Frequency and duration</u> 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.</p> <p><u>2) Contents</u> Key messages will be similar to health education activities for students (described above). School teachers will also be taught to use the smartphone app.</p>	The trained project staff
<p>4. A smartphone app assisted in implementation of the intervention</p>		
<p>The smartphone app (“Eat Wisely, Move Happily”)</p>	<p><u>1) Information diffusion (the behavior change technique (BCT) used: providing information on consequences of behavior)</u> The smartphone app will provide information to parents, class teachers and project staff in</p>	<p>The smartphone app (installed by parents, school teachers and project staff) and the computer management</p>

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.

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	<p>accordance with health education activities.</p> <p><u>2) Behavior monitoring (the BCT used: prompting self-monitoring of behavior)</u></p> <p>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).</p> <p><u>3) Weight management (the BCT used: prompting self-monitoring)</u></p> <p>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).</p> <p><u>4) Assessment and feedback (the BCT used: providing feedback on performance)</u></p> <p>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.</p>	<p>system (utilized by project staff)</p>
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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 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.	

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

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4 Figure 1 Study flow chart of the DECIDE-children
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7 Figure 2 Social Ecological Model of the DECIDE-children
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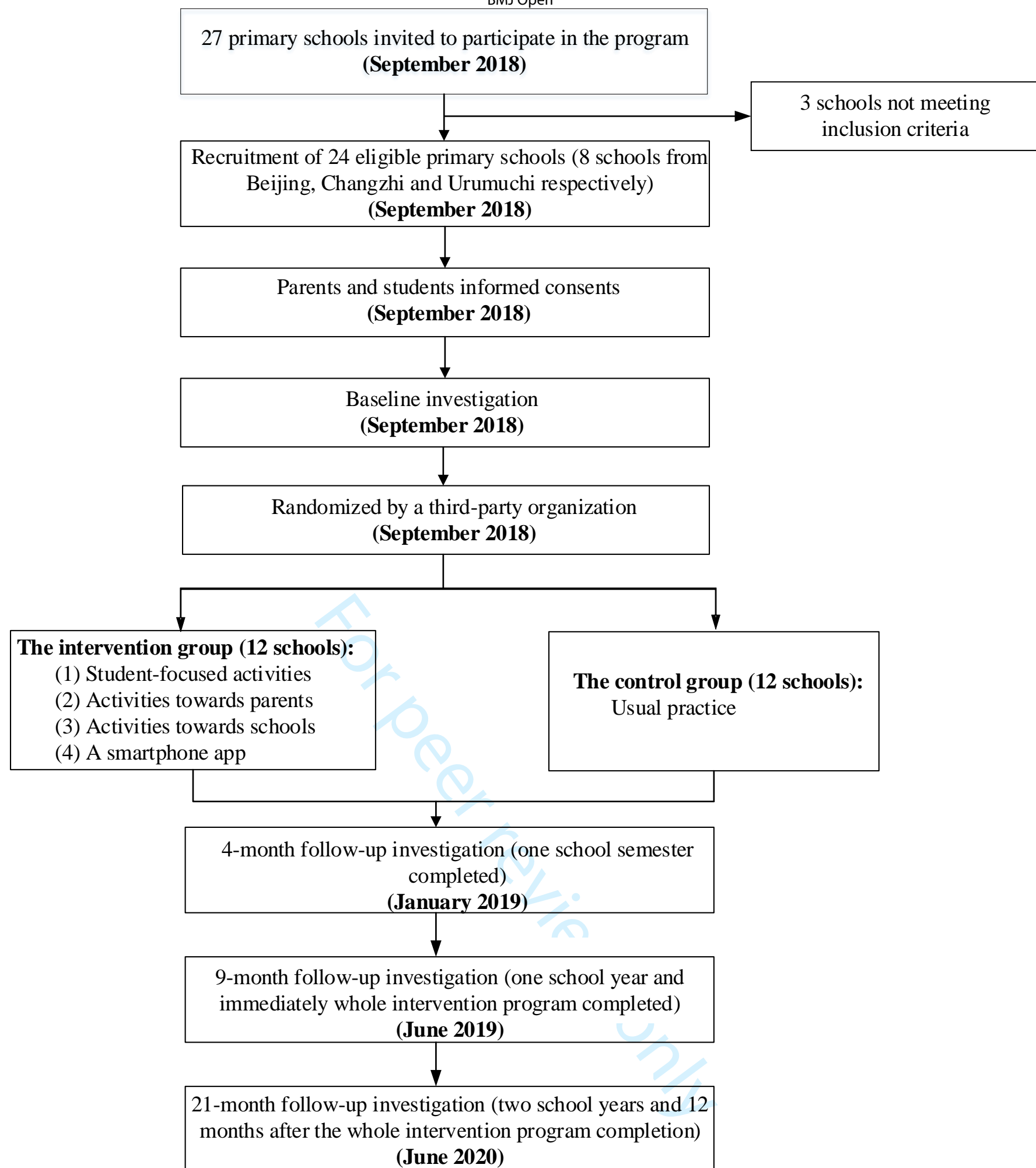


Figure 1 Study flow chart of the DECIDE-children

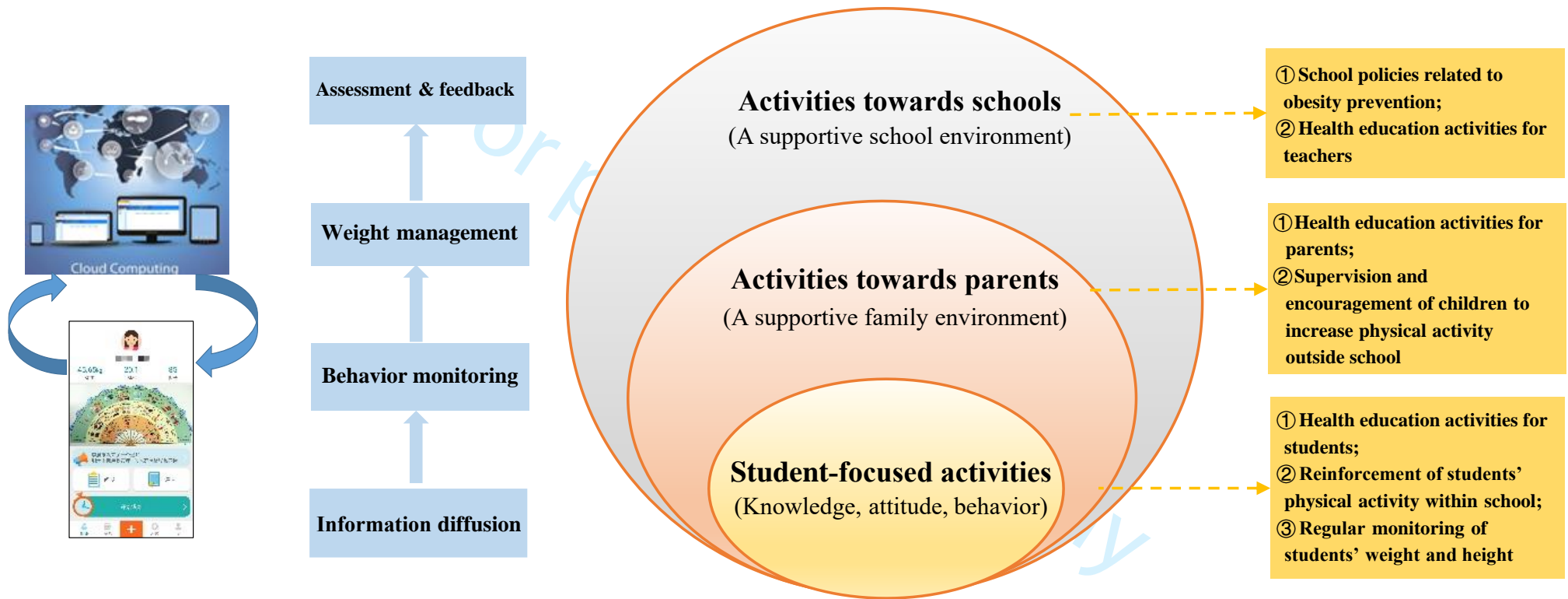


Figure 2 Social Ecological Model of the DECIDE-children

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

1 2 3 4 5 6 7	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.
8 9 10 11 12 13 14 15 16 17	Protocol version	#3	Date and version identifier	This information will be provided as soon as the manuscript revision is finally completed.
18 19 20 21 22 23	Funding	#4	Sources and types of financial, material, and other support	25
24 25 26 27 28 29 30	Roles and responsibilities: contributorship	#5a	Names, affiliations, and roles of protocol contributors	24-25
31 32 33 34 35 36 37 38 39 40 41 42 43 44 45 46	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.
47 48 49 50 51 52 53 54 55 56 57 58 59 60	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

1			report for publication, including whether	
2			they will have ultimate authority over	
3			any of these activities	
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8	Roles and	#5d	Composition, roles, and responsibilities	25
9	responsibilities:		of the coordinating centre, steering	
10			committee, endpoint adjudication	
11	committees		committee, data management team,	
12			and other individuals or groups	
13			overseeing the trial, if applicable (see	
14			Item 21a for data monitoring committee)	
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24	Background and	#6a	Description of research question and	5-7
25	rationale		justification for undertaking the trial,	
26			including summary of relevant studies	
27			(published and unpublished) examining	
28			benefits and harms for each intervention	
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37	Background and	#6b	Explanation for choice of comparators	6
38	rationale: choice			
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44	Objectives	#7	Specific objectives or hypotheses	7
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47	Trial design	#8	Description of trial design including type	8
48			of trial (eg, parallel group, crossover,	
49			factorial, single group), allocation ratio,	
50			and framework (eg, superiority,	
51			equivalence, non-inferiority, exploratory)	
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1 2 3 4 5 6 7 8 9 10 11 12	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
13 14 15 16 17 18 19 20 21 22 23 24	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
25 26 27 28 29 30 31 32 33 34	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
35 36 37 38 39 40 41 42 43 44 45 46 47 48 49 50 51 52 53 54 55 56 57 58 59 60	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.

1	Interventions:	#11c	Strategies to improve adherence to	11-12
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3	adherence		intervention protocols, and any	
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5			procedures for monitoring adherence	
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7			(eg, drug tablet return; laboratory tests)	
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11	Interventions:	#11d	Relevant concomitant care and	n/a.
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13	concomitant care		interventions that are permitted or	This is a childhood obesity
14				prevention intervention.
15			prohibited during the trial	Based on our previous
16				experiences, it is less likely
17				that concomitant care and
18				interventions will take place.
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20				
21				
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23				
24				
25				
26				
27				
28	Outcomes	#12	Primary, secondary, and other	13-14, Table 3
29				
30			outcomes, including the specific	
31				
32			measurement variable (eg, systolic	
33				
34			blood pressure), analysis metric (eg,	
35				
36			change from baseline, final value, time	
37				
38			to event), method of aggregation (eg,	
39				
40			median, proportion), and time point for	
41				
42			each outcome. Explanation of the	
43				
44			clinical relevance of chosen efficacy and	
45				
46			harm outcomes is strongly	
47				
48			recommended	
49				
50				
51				
52				
53				
54	Participant	#13	Time schedule of enrolment,	Figure 1
55				
56	timeline		interventions (including any run-ins and	
57				
58				
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washouts), assessments, and visits for participants. A schematic diagram is highly recommended (see Figure)

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7				
8	Sample size	#14	Estimated number of participants	14
9				
10			needed to achieve study objectives and	
11			how it was determined, including clinical	
12			and statistical assumptions supporting	
13			any sample size calculations	
14				
15				
16				
17				
18				
19				
20	Recruitment	#15	Strategies for achieving adequate	9-10
21			participant enrolment to reach target	
22			sample size	
23				
24				
25				
26				
27				
28	Allocation:	#16a	Method of generating the allocation	10
29	sequence		sequence (eg, computer-generated	
30			random numbers), and list of any	
31	generation		factors for stratification. To reduce	
32			predictability of a random sequence,	
33			details of any planned restriction (eg,	
34			blocking) should be provided in a	
35			separate document that is unavailable	
36			to those who enrol participants or	
37			assign interventions	
38				
39				
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51	Allocation	#16b	Mechanism of implementing the	10
52	concealment		allocation sequence (eg, central	
53			telephone; sequentially numbered,	
54	mechanism		opaque, sealed envelopes), describing	
55				
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1		any steps to conceal the sequence until	
2			
3		interventions are assigned	
4			
5			
6	Allocation:	#16c Who will generate the allocation	9-10
7			
8	implementation	sequence, who will enrol participants,	
9			
10		and who will assign participants to	
11			
12		interventions	
13			
14			
15			
16	Blinding (masking)	#17a Who will be blinded after assignment to	13
17			
18		interventions (eg, trial participants, care	
19			
20		providers, outcome assessors, data	
21			
22		analysts), and how	
23			
24			
25			
26	Blinding	#17b If blinded, circumstances under which	n/a.
27			
28	(masking):	unblinding is permissible, and	The assessors measuring
29			students' height and weight will
30	emergency	procedure for revealing a participant's	be blinded to group allocation of
31			the schools. We did not
32	unblinding	allocated intervention during the trial	anticipate any necessary
33			circumstances when unblinding
34			is permissible.
35			
36			
37			
38			
39			
40	Data collection	#18a Plans for assessment and collection of	13
41			
42	plan	outcome, baseline, and other trial data,	
43			
44		including any related processes to	
45			
46		promote data quality (eg, duplicate	
47			
48		measurements, training of assessors)	
49			
50		and a description of study instruments	
51			
52		(eg, questionnaires, laboratory tests)	
53			
54		along with their reliability and validity, if	
55			
56		known. Reference to where data	
57			
58			
59			
60			

1		collection forms can be found, if not in	
2			
3		the protocol	
4			
5			
6	Data collection	#18b Plans to promote participant retention	15
7			
8	plan: retention	and complete follow-up, including list of	
9			
10		any outcome data to be collected for	
11			
12		participants who discontinue or deviate	
13			
14		from intervention protocols	
15			
16			
17			
18	Data management	#19 Plans for data entry, coding, security,	3
19			
20		and storage, including any related	
21			
22		processes to promote data quality (eg,	
23			
24		double data entry; range checks for	
25			
26		data values). Reference to where	
27			
28		details of data management procedures	
29			
30		can be found, if not in the protocol	
31			
32			
33			
34	Statistics:	#20a Statistical methods for analysing	15
35			
36	outcomes	primary and secondary outcomes.	
37			
38		Reference to where other details of the	
39			
40		statistical analysis plan can be found, if	
41			
42		not in the protocol	
43			
44			
45			
46	Statistics:	#20b Methods for any additional analyses	15
47			
48	additional	(eg, subgroup and adjusted analyses)	
49			
50	analyses		
51			
52			
53			
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1	Statistics: analysis	#20c	Definition of analysis population relating	15
2				
3	population and		to protocol non-adherence (eg, as	
4				
5	missing data		randomised analysis), and any	
6				
7			statistical methods to handle missing	
8				
9			data (eg, multiple imputation)	
10				
11				
12				
13	Data monitoring:	#21a	Composition of data monitoring	18
14				
15	formal committee		committee (DMC); summary of its role	
16				
17			and reporting structure; statement of	
18				
19			whether it is independent from the	
20				
21			sponsor and competing interests; and	
22				
23			reference to where further details about	
24				
25			its charter can be found, if not in the	
26				
27			protocol. Alternatively, an explanation of	
28				
29			why a DMC is not needed	
30				
31				
32				
33				
34	Data monitoring:	#21b	Description of any interim analyses and	n/a.
35				
36	interim analysis		stopping guidelines, including who will	
37				
38			have access to these interim results and	This is a childhood obesity
39				prevention intervention.
40			make the final decision to terminate the	
41				Based on our previous
42			trial	
43				experiences, it is less likely
44				that discontinuing
45				interventions will take place.
46				
47				
48				
49				
50				
51				
52	Harms	#22	Plans for collecting, assessing,	16 (we will use
53				
54			reporting, and managing solicited and	questionnaires to collect and
55				
56			spontaneously reported adverse events	
57				
58				
59				
60				

		and other unintended effects of trial interventions or trial conduct	assess any adverse events or other process data)
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5			
6	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).
7			
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19			
20	Research ethics approval	#24 Plans for seeking research ethics committee / institutional review board (REC / IRB) approval	2-3
21			
22			
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26			
27			
28	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
29			
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41			
42	Consent or assent	#26a Who will obtain informed consent or assent from potential trial participants or authorised surrogates, and how (see Item 32)	10
43			
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51			
52	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.
53			
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1			and biological specimens in ancillary	
2			studies, if applicable	
3				
4				
5				
6	Confidentiality	#27	How personal information about	3
7				
8			potential and enrolled participants will	
9				
10			be collected, shared, and maintained in	
11				
12			order to protect confidentiality before,	
13				
14			during, and after the trial	
15				
16				
17				
18	Declaration of	#28	Financial and other competing interests	26
19	interests		for principal investigators for the overall	
20				
21			trial and each study site	
22				
23				
24				
25	Data access	#29	Statement of who will have access to	3
26				
27			the final trial dataset, and disclosure of	
28				
29			contractual agreements that limit such	
30				
31			access for investigators	
32				
33				
34				
35	Ancillary and post	#30	Provisions, if any, for ancillary and post-	n/a.
36	trial care		trial care, and for compensation to those	
37				
38			who suffer harm from trial participation	This is a childhood obesity
39				prevention intervention.
40				
41				Based on our experiences, it
42				is less likely that ancillary
43				and post-trial care will take
44				place.
45				
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47				
48				
49				
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53	Dissemination	#31a	Plans for investigators and sponsor to	3
54	policy: trial results		communicate trial results to participants,	
55				
56			healthcare professionals, the public,	
57				
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and other relevant groups (eg, via
 publication, reporting in results
 databases, or other data sharing
 arrangements), including any
 publication restrictions

12	Dissemination	#31b	Authorship eligibility guidelines and any	n/a
14	policy: authorship		intended use of professional writers	
18	Dissemination	#31c	Plans, if any, for granting public access	n/a
20	policy:		to the full protocol, participant-level	
22	reproducible		dataset, and statistical code	
24	research			
28	Informed consent	#32	Model consent form and other related	10
30	materials		documentation given to participants and	
32			authorised surrogates	
36	Biological	#33	Plans for collection, laboratory	n/a
38	specimens		evaluation, and storage of biological	
39			specimens for genetic or molecular	This study will not collect
41			analysis in the current trial and for future	biological specimens.
43			use in ancillary studies, if applicable	

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

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Manuscripts

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4 1 **A school-based, multi-faceted health promotion programme to**
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6 2 **prevent obesity among children: protocol of a cluster-randomized**
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8 3 **controlled trial (the DECIDE-Children study)**
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14 5 Zheng Liu¹, Yang-Feng Wu², Wen-Yi Niu³, Xiang-Xian Feng⁴, Yi Lin⁵, Ai-Yu Gao⁶,
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18 7 the DECIDE-children study
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1
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3
4 23**Abstract**

5
6 24 **Introduction** Obesity is a public health concern that is becoming increasingly more
7
8
9 25 serious worldwide. Effective and sustainable childhood obesity prevention strategies
10
11 26 may help to reduce the prevalence of obesity and may have an impact on lifelong health.
12
13
14 27 However, few such strategies have been rigorously evaluated for Chinese children in
15
16
17 28 different regions of China.

18
19 29 **Methods and analysis** DECIDE-Children is a cluster-randomized controlled trial that
20
21 30 aims to assess the effectiveness and sustainability of a school-based, multi-faceted
22
23 31 intervention to prevent obesity among Grade 4 primary school students (8 to 10 years
24
25 32 old) in China. Twenty-four schools (approximately 1200 students) from above average,
26
27 33 average and below average developed regions in China will be randomized to an
28
29 34 intervention (12 schools) or usual practice (12 schools) group. The intervention will last
30
31 35 for one year and consist of activities towards students, parents and school environment.
32
33 36 A smartphone application will be used to assist in providing information on, monitoring
34
35 37 and providing feedback on the behaviours and body weight of the students. Data will
36
37 38 be collected at baseline, 4 months, 9 months and 21 months. The primary outcome will
38
39 39 be the difference between groups in the change in students' body mass index (BMI) at
40
41 40 9 months after the baseline investigation. The secondary outcomes will include the
42
43 41 differences between groups in the changes in anthropometric measures, diet, physical
44
45 42 activity levels and other measures at the follow-up visits. A variety of process
46
47 43 evaluation methods will be used to evaluate the implementation process of the complex
48
49 44 intervention.

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4 45 **Ethics and dissemination** This study was approved by the Peking University
5
6 46 Institution Review Board (IRB00001052-18021). The results will be disseminated
7
8
9 47 through publication in peer-reviewed journals, presentations at conferences and in lay
10
11
12 48 summaries provided to school staff and participants.
13
14 49 **Trial registration** ClinicalTrials.gov: NCT03665857.
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For peer review only

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4 **50 Strengths and limitations of this study**

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6
7 51 1. This study will rigorously evaluate the effectiveness of a childhood obesity
8
9 52 prevention programme in eastern, central and western regions with different levels of
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11 53 economic development in China.
12
13
14 54 2. We will employ a smartphone application to assist in providing information on,
15
16 55 monitoring and providing feedback on the behaviours and body weight of the students.
17
18
19 56 3. We will include an explicit process evaluation plan for both the intervention and the
20
21 57 control groups, which will evaluate the implementation process of the complex
22
23 58 intervention.
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25
26
27 59 4. A follow-up investigation will be conducted to evaluate the sustainability of the
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29 60 intervention.
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31
32 61 5. This intervention is limited by a relatively short duration, but additional funding will
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35 62 be sought for the implementation of a long-term intervention in the future.
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63 **Introduction**

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

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

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4 85 achieve this, a thorough process evaluation of the intervention implementation is
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6 86 necessary. Furthermore, socioeconomic development is associated with patterns of
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8
9 87 childhood obesity [13] and may also affect the effectiveness of a childhood obesity
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11
12 88 intervention. Social disparities in the patterns of obesity differ between China and
13
14 89 Western countries. In China, socioeconomic development has been positively
15
16
17 90 associated with overweight and obesity prevalence in children [13]. However, previous
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20 91 studies have been largely conducted in a single region, which limits the generalizability
21
22
23 92 of study findings to other populations. Another weakness is that most studies examined
24
25
26 93 outcomes only at the end of the intervention. Thus, it remains unclear whether healthy
27
28
29 94 behaviours and a healthy weight are maintained beyond the period of the intervention.

30 95 *School system in China*

31
32
33 96 In primary schools in China, there are six grades in total, and the age of the students
34
35
36 97 ranges from 6 to 11 years. The typical size of a Chinese class is fewer than 45 students,
37
38
39 98 but varies in different schools, ranging from 30 to 60 students. There are two school
40
41
42 99 policies that have been issued by the Chinese government that are particularly relevant
43
44
45 100 to the prevention and management of childhood obesity. First, schools should have
46
47
48 101 school doctors or health care teachers who provide in-house school health care. The
49
50
51 102 routine practices include student health surveillance, health education for students, and
52
53
54 103 the prevention and control of common diseases in students. Second, schools should
55
56
57 104 implement 'One-Hour Physical Activity On Campus Every School Day'. That is, the
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59
60 105 total duration of physical activity (i.e., physical education classes, exercises during
106
breaks from class and extracurricular activities) per school day should be no less than

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3
4 107 one hour. However, the implementation of these policies in the school systems in China
5
6 108 varies by region [14].
7
8

9 109 ***Development of a childhood obesity intervention***

10
11 110 To fill in research gaps, in accordance with the school systems in China, we underwent
12
13
14 111 four stages to develop the intervention: (1) we systematically reviewed previous
15
16
17 112 literature to identify intervention elements related to intervention effectiveness; (2) we
18
19
20 113 conducted focus group discussions and interviews with key informants (children,
21
22 114 parents, teachers, school principals, local health and education officials) to further
23
24
25 115 revise and refine the intervention approaches; (3) we conducted a three-month, before-
26
27 116 after, pilot study at two primary schools in Beijing (one in an urban area and the other
28
29
30 117 in a rural area) involving 58 Grade 4 students (mean age: 9.38±0.49 years) to test the
31
32
33 118 feasibility of the proposed intervention [15]; and (4) we further discussed the proposed
34
35
36 119 intervention with multiple experts. Based on all the work mentioned, we finally
37
38 120 developed the intervention elements used for this study.
39

40 121 ***Aim and objectives***

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42
43 122 To develop effective lifestyle interventions for the prevention and control of
44
45
46 123 cardiovascular disease in China, the Diet, ExerCIse and CarDiovascular hEalth
47
48 124 (DECIDE) project was initiated in 2016. As one of five independent DECIDE studies,
49
50
51 125 the DECIDE-Children study aims to develop a school-based, multi-faceted childhood
52
53
54 126 obesity prevention programme targeting school children aged 8-10 years in three
55
56 127 different regions of China and rigorously test its effectiveness in preventing excessive
57
58 128 weight gain in Chinese primary school settings. The research objectives of the
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4 129 DECIDE-Children study were (1) to assess the effectiveness of the intervention
5
6 130 compared with the usual practice in preventing childhood overweight and obesity; (2)
7
8
9 131 to determine the sustainability of the intervention in preventing overweight and obesity;
10
11
12 132 and (3) to evaluate the process and health economics of the intervention.
13

14 133 **Methods and analysis**

15
16
17 134 This protocol has been prepared in accordance with the Standard Protocol Items:
18
19 135 Recommendations for Interventional Trials (SPIRIT) statement [16, 17].
20
21

22 136 *Study design*

23
24 137 DECIDE-Children is a cluster-randomized, parallel-group controlled trial. To
25
26
27 138 accommodate the social and economic variations within the country, we will
28
29
30 139 intentionally select schools from three different regions of China: the above average
31
32
33 140 developed area in the east (Beijing), the average developed area in central China
34
35 141 (Shanxi) and the below average developed area in the west (Xinjiang). A total of 24
36
37
38 142 primary schools (clusters) equally distributed among three regions will be selected. In
39
40 143 Beijing, 4 schools will be selected from the Dongcheng district (located in the centre of
41
42
43 144 the city), and 4 will be selected from the Mentougou district (located in a rural suburban
44
45 145 area). In Xinjiang, all 8 schools will be selected from Urumchi, the capital city of the
46
47
48 146 autonomous region; four of the schools will be selected from the Shayiba district (an
49
50
51 147 urban district), and the other four schools will be selected from the Shuimogou district
52
53
54 148 (a rural district). In Shanxi, all 8 schools will be selected from only one urban district,
55
56 149 Changzhi, a small- to medium-sized city in the province. The reason for excluding rural
57
58
59 150 schools in Changzhi is that most of the rural schools are boarding schools, and parents
60

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4 151 are difficult to reach in boarding schools. Thus, a total of 24 primary schools from five
5
6 152 sites in three regions will be selected and randomized into two groups, the obesity
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8
9 153 prevention intervention group and the usual practice group. The intervention will be
10
11 154 implemented for one school year from late September 2018 to June 2019, and the study
12
13
14 155 will continue with a one-year follow-up investigation in June 2020. Figure 1 shows the
15
16
17 156 flow of the study.

19 157 ***Recruitment***

22 158 **Recruitment of the schools**

24 159 The present study will be carried out in Grade 4 students (8 to 10 years old), as they are
25
26
27 160 sufficiently mature to understand health education information and are able to remain
28
29
30 161 in the same school to complete the two-year study before they graduate. For a school
31
32
33 162 to be eligible, the school principal must agree with the randomization procedure and
34
35
36 163 comply with the study protocol. The total number of Grade 4 students must be greater
37
38 164 than 50 in the school, and schools that have implemented or are planning to implement
39
40
41 165 an obesity prevention intervention or similar intervention programme will not be
42
43 166 eligible. Boarding schools and specialty schools for children with talents or minority
44
45
46 167 ethnic groups will be excluded. Schools will also not be included if they have a definite
47
48 168 plan for relocation or cancellation in the next two years. For the schools participating
49
50
51 169 in the programme, the size of a class will vary between fewer than 30 children and
52
53
54 170 approximately 60 children per class. If the number of students in each class is less than
55
56 171 50, we will recruit two classes from the school, and if the number of students is greater
57
58
59 172 than 50, we will recruit one class to meet the sample size requirement. If there are more
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4 173 classes in one school than needed for the study, the school principal will recommend
5
6 174 which classes we should select.

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8
9 175 Three steps will be followed for the recruitment of the schools. First, project staff will
10
11 176 contact the local education authorities to gain their opinion, support, and approval of
12
13 177 the study and basic information of the schools (type of schools and the number of
14
15 178 students and teachers). Second, project staff will contact the schools by phone or visit
16
17 179 the schools to determine the eligibility of the selected schools for the study. Third, the
18
19 180 final list of eligible schools and classes will be made by the principal investigator and
20
21 181 schools will be invited to participate in the study by local research partners.

22 182 **Recruitment of the students**

23
24
25 183 After recruiting the schools and before conducting the baseline measurements, written
26
27 184 informed consent will be provided by all students and their primary caregivers (parents
28
29 185 in most cases) in the selected classes. Then, the parents who provide informed consent
30
31 186 will be required to complete a self-administrative questionnaire about the health status
32
33 187 of their children. The project staff will collect the questionnaires and if a parent reports
34
35 188 one of the following conditions, his or her children will be excluded: 1) medical history
36
37 189 of heart disease, hypertension, diabetes, tuberculosis, asthma, hepatitis or nephritis; 2)
38
39 190 obesity caused by endocrine diseases or side effects of drugs; 3) abnormal physical
40
41 191 development like dwarfism or gigantism; 4) physical deformity such as severe scoliosis,
42
43 192 pectus carinatum, limp, obvious O-leg or X-leg; 5) inability to participate in school
44
45 193 sport activities; 6) a loss in weight by vomiting or taking drugs during the past three
46
47 194 months.

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4 195 ***Randomization procedures***

5
6 196 The random sequence of allocation of the schools (clusters) to the intervention or
7
8
9 197 control group will be stratified by the study sites. Schools in the same study site will be
10
11
12 198 randomly allocated in a 1:1 ratio to either the intervention or control group using a
13
14 199 computer-generated random number system (the simple random sampling method).
15
16
17 200 Randomization will be performed by an independent person at the central coordinating
18
19 201 centre at Peking University Clinical Research Institute. The randomization will take
20
21
22 202 place only after the baseline measurements are completed to ensure allocation
23
24
25 203 concealment.

26
27 204 ***Intervention***

28
29
30 205 We used the Social Ecological Model to identify intervention elements in this multi-
31
32 206 faceted health promotion programme [18]. As shown in Figure 2, the programme will
33
34
35 207 target the influencing factors of childhood obesity at both individual (student-focused
36
37
38 208 activities) and environmental levels (a supportive family and school environment), with
39
40 209 the intent to influence the knowledge, attitude and behaviours of school children.

41
42
43 210 **Description of the intervention components**

44
45 211 The intervention components are described in Tables 1 and 2.

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47
48 212 ***Student-focused activities:*** These activities will include health education activities for
49
50 213 students, the reinforcement of students' physical activity at school and the regular
51
52
53 214 monitoring of students' weight and height.

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55
56 215 ***Activities towards parents:*** These activities will include health education activities for
57
58 216 parents and the supervision and encouragement of children to increase their physical
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4 217 activity level outside of school.
5

6 218 **Activities towards schools:** These activities will include school policies related to
7
8
9 219 obesity prevention and health education activities for teachers.
10

11 220 **The smartphone app:** Project staff, school teachers and parents will be suggested to
12
13
14 221 install the app titled “Eat Wisely, Move Happily”. The app, which was developed based
15
16
17 222 on behaviour change techniques [19], will aid in information diffusion, behaviour
18
19
20 223 monitoring, weight management, assessment and feedback.
21

22 224 **Quality control of the intervention**

23
24 225 Two manuals (“An Operation Manual for Project Staff Involved in the Multi-
25
26
27 226 component Obesity Intervention among Primary School Students” and “An Operation
28
29
30 227 Manual for School Team Members Involved in the Multi-component Obesity
31
32
33 228 Intervention among Primary School Students”) have been developed for implementing
34
35
36 229 and managing this complex intervention. The manuals describe in detail the duties of
37
38
39 230 project staff and school team members (school principals, class teachers, physical
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41
42 231 education teachers, school doctors/health care teachers) in delivering the intervention.
43
44
45 232 The manuals also describe the detailed workflow of the implementation of each
46
47
48 233 intervention component, i.e., by whom, when, how and to what extent the specific
49
50
51 234 intervention element should be delivered. All of the project staff and school team
52
53
54 235 members will be required to conduct the intervention in accordance with the operation
55
56
57 236 manuals.

58 237 During implementation of the intervention, regular field observations will be made and
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60 238 the smartphone app records will be checked. If it is found that schools are not complying

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4 239 with the study protocol, project staff will communicate with school team members in a
5
6 240 timely manner and conduct follow-ups to improve the fidelity of the study results.
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8

9 241 ***Control group***

10
11 242 The twelve schools in the control group will not carry out any of the DECIDE-Children
12
13 243 intervention components and will continue their usual practice according to their own
14
15 244 teaching curriculum during the study period (from September 2018 to June 2020).
16
17 245 Participants in the control group will receive the same health education materials that
18
19 246 will have been delivered to those in the intervention group immediately after the 21-
20
21 247 month follow-up investigation is completed in June 2020.
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26
27 248 ***Outcome evaluation***

28
29 249 Table 3 describes the study outcomes, including when and how the study outcomes will
30
31 250 be evaluated. Baseline measurements will be conducted in September 2018 for both the
32
33 251 intervention and the control groups. Follow-up measurements will be conducted 4
34
35 252 months after the baseline measurements are conducted in January (after one school
36
37 253 semester and half way through the intervention), 9 months after the baseline
38
39 254 measurements are conducted in June 2019 (after one school year and immediately after
40
41 255 the whole intervention programme is completed) and 21 months after the baseline
42
43 256 measurements are conducted in June 2020 (after two school years and 12 months after
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45 257 the intervention is completed).
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53 258 At the baseline and all follow-up visits, anthropometric measures (height, weight, waist
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55 259 and hip circumference, systolic and diastolic blood pressures, body fat percentage) and
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57 260 physical fitness measures (one-minute rope jumping, one-minute sit-up, long standing
58
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4 261 jump, shuttle run (50 m×8)) will be collected by the trained outcome assessors using
5
6 262 the same device and/or forms according to the standard methods and procedures. The
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9 263 assessors measuring students' height and weight will be blinded to the group allocation
10
11 264 of the schools. We will use questionnaires to measure students' behaviours (duration of
12
13 265 moderate-to-vigorous physical activity, eating behaviour, sedentary behaviour), school
14
15 266 policies for prevention and management of childhood obesity, and other potential
16
17 267 moderators/mediators of the intervention (e.g., stage of readiness for behaviour change
18
19 268 related to weight reduction). The questionnaires were developed based on previous
20
21 269 studies and the pilot study. The questionnaires were found to be feasible for this study
22
23 270 and acceptable to students and their parents [20-22].
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30 **Outcomes**

31
32 272 The primary outcome is the difference between groups in the change in students' body
33
34 273 mass index ($BMI = \text{weight (kg)} / (\text{height (m)})^2$) immediately after the intervention
35
36 274 completion (9 months after the baseline measurements are conducted). The secondary
37
38 275 outcomes include the change in BMI one year after the intervention is completed (21
39
40 276 months after the baseline measurements are conducted). In addition, we will compare
41
42 277 the following indices between groups at the follow-up visits: 1) change in students'
43
44 278 BMI z-score (standard deviation score will be calculated based on the World Health
45
46 279 Organization criteria [23]); 2) change in prevalence and incidence of childhood
47
48 280 overweight/obesity defined according to the criteria for Chinese children and
49
50 281 adolescents [24]; 3) change in students' waist circumference, waist-to-hip
51
52 282 circumference ratio and systolic and diastolic blood pressures; and 4) change in students'
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4 283 body fat percentage, physical fitness measures, behavioural outcomes and other
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6 284 outcomes.

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9 285 ***Sample size estimation***

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11 286 We assumed that the difference between the two groups in the change in BMI (effect
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13
14 287 size) would be 0.50 kg/m², the standard deviation (SD) of the BMI would be 1.40 kg/m²,
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16
17 288 the intra-cluster correlation coefficient would be 0.05 and the rate of attrition would be
18
19
20 289 10% for the sample size calculation in our study. We aimed to recruit a total of 1,200
21
22
23 290 students from 24 schools with an average cluster size of 50 students per school. This
24
25
26 291 sample size will provide 88% power with $\alpha=0.05$ to detect a mean difference of 0.50
27
28
29 292 kg/m² in the change in BMI between groups after the intervention lasting one school
30
31
32 293 year.

33 294 ***Statistical analyses***

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35 295 Statistical analyses will be performed using SAS version 9.4 (SAS Institute Inc., Cary,
36
37
38 296 NC, USA). All statistical tests will be two-sided at the 5% level of significance.
39
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41 297 Baseline characteristics at both the school and individual levels will be reported by
42
43
44 298 using descriptive statistics.

45
46 299 The primary analysis will be based on the intention-to-treat principle and include all
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48
49 300 students recruited with the baseline BMIs measured. Generalized linear mixed models
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51
52 301 will be used to compare the primary and secondary outcomes at 4, 9, and 21 months
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54
55 302 after the baseline measurements are conducted, and the models will adjust for the
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57
58 303 clustering effect and baseline outcome values. The missing data will be treated in the
59
60 304 maximum likelihood estimates assuming they are missing at random. The intra-cluster

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4 305 correlation coefficient will also be estimated. Sensitivity analysis will be performed on
5
6 306 the primary outcome using the last-value-carry-forward imputation if the percentage of
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9 307 missing data exceeds 5%. For continuous outcomes, we will report pre-, and post-
10
11 308 intervention means for the intervention and control groups and model-adjusted mean
12
13
14 309 differences between groups. For binary outcomes, we will report pre- and post-
15
16
17 310 intervention percentages for the intervention and control groups and adjusted odds
18
19 311 ratios (ORs) between groups. The 95% confidence intervals (CIs) and associated *P*-
20
21 312 values will be calculated. We will also examine whether the differences in the outcomes
22
23 313 between the control and intervention groups vary by the three regions (Beijing, Shanxi,
24
25 314 Xinjiang), the sex of children, socioeconomic status (mother's education), BMI status
26
27 315 at baseline and primary caregivers of the children (parents compared with non-parents).
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316 *Process evaluation*

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

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4 327 The intervention process data collection procedure will include (1) direct regular field
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6 328 observation and records which will be collected for the quality control of the
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9 329 intervention (e.g., quality and quantity of the intervention sessions and number of
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11 330 students attending the lectures) and will be recorded by the trained project staff; (2) the
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13
14 331 user logs (e.g., frequency and duration) which will be collected by the smartphone app;
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16
17 332 (3) school policies related to obesity prevention and management, which will be
18
19 333 collected by the questionnaires (Table 3) in both the intervention and the control groups;
20
21
22 334 and (4) interviews with participants (6~8 students per school) which will be conducted
23
24
25 335 in both the intervention and the control groups.

27 336 *Health economics evaluation*

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29
30 337 A cost-effectiveness analysis will be employed in the health economics evaluation, and
31
32 338 a societal perspective will be used to examine whether the intervention is economically
33
34
35 339 feasible. Intervention costs will include hours spent by project staff, school staff, and
36
37
38 340 students' primary caregivers (parents in most cases) for all the intervention activities
39
40
41 341 and material expenses. Only the time spent by the project staff in implementing the
42
43 342 intervention will be included. Time costs will be based on personal employment
44
45 343 compensations if available or average compensations in the local areas for similar types
46
47
48 344 of employees. Material expenses will be based on the actual purchasing prices. An
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51 345 incremental cost-effectiveness ratio will be calculated and a sensitivity analysis will be
52
53 346 used to vary key parameters to examine the robustness of the health economics results.

56 347 **Patient and Public involvement**

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58 348 We will conduct focus group discussions and interviews with key stakeholders
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4 349 (children, parents, teachers, school principals, local health, and education officials) by
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6 350 refining the intervention approach. We will not involve any of the stakeholders in other
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9 351 aspects of the research study, including idea development, design of the study,
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11 352 implementation of the protocol, data collection, and analysis and interpretation of the
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14 353 results. The results of the study will be disseminated through publication in peer-
15
16
17 354 reviewed journals, presentations at conferences and in lay summaries provided to
18
19 355 school staff, students and parents. The benefits and burden of the intervention will be
20
21
22 356 assessed by children and their primary caregivers through self-reported questionnaires
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24
25 357 at the end of the intervention.

26 27 358 **Trial status**

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29
30 359 The trial started and the recruitment of schools and children was completed in
31
32 360 September 2018. Baseline measurements were conducted in the last few weeks in
33
34
35 361 September 2018. The intervention lasting one school year started at the end of
36
37
38 362 September 2018 and was completed in June 2019. The 4-month follow-up
39
40 363 measurements started and were completed in January 2019. The 9-month follow-up
41
42 364 measurements started and were completed in June 2019. The 21-month follow-up
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44
45 365 measurements will start and will be completed in June 2020.

46 47 48 366 **Ethics and dissemination**

49
50 367 This study was reviewed and approved by the Peking University Institution Review
51
52 368 Board (IRB00001052-18021). Any amendments to the study protocol will be submitted
53
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55 369 for IRB approval prior to implementation. Written informed consent will be obtained
56
57
58 370 from all students and their parents. All data collected will be entered into an electronic
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4 371 database with de-identified information. The database will be accessed only by
5
6 372 designated staff with a password. The results will be disseminated through publication
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9 373 in peer-reviewed journals, presentation at conferences and in lay summaries provided
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11 374 to school staff and participants. Upon completion of the trial and after the publication
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14 375 of these results, the data will be made available upon request by contacting the
15
16
17 376 corresponding author of this protocol.

19 377 **Discussion**

22 378 Non-communicable diseases, especially cardiovascular diseases, have contributed to
23
24 379 the public health burden worldwide. Preventing childhood obesity in early life may
25
26
27 380 have the greatest long-term effects in curbing this widespread burden. Although several
28
29
30 381 childhood obesity intervention studies have been conducted in China, research gaps
31
32 382 exist in terms of methodological flaws, process measures, and sustainability of the
33
34
35 383 intervention. The DECIDE-Children study is based on theory-driven and systematic
36
37
38 384 developments (e.g., systematic review [8], qualitative interviews, panel discussions and
39
40 385 a pilot study [15]) and serves as one of the first examples of a rigorously developed and
41
42
43 386 evaluated childhood obesity prevention programme that will be implemented in eastern,
44
45
46 387 central and western regions of China.

48 388 Our DECIDE-Children study can overcome poor adherence to the intervention
49
50 389 components, which is a weakness of most previous studies, due to our favourable
51
52
53 390 collaborations with local education authorities as well as the rigorous quality control of
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55
56 391 implementing the intervention. This study also has several other distinguishing features:
57
58 392 1) randomization by an independent person not involved in the study, blinding of key
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4 393 outcome measures, and a detailed process evaluation plan will help to provide study
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6 394 results of high quality; 2) a follow-up investigation will be conducted one year after the
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8
9 395 intervention is completed to determine the sustainability of the effects of the
10
11 396 intervention; 3) a smartphone app will be employed to assist in providing information
12
13
14 397 on, monitoring and providing feedback on the behaviours and body weight of the
15
16
17 398 children; 4) three centres located in eastern, central and western regions of China will
18
19 399 be involved in the study to reflect the different levels of economic development in
20
21
22 400 China; and 5) most of the intervention components (school polices, regular monitoring
23
24
25 401 of students' weight and height, reinforcement of students' physical activity at school,
26
27 402 health education activities for students) will be integrated into the regular academic
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29
30 403 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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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.

For peer review only

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	<p><u>(1) Frequency and duration</u> 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).</p> <p><u>(2) Different kinds of activities</u> 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”).</p> <p><u>(3) Content</u> 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.</p>	The trained class teachers

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	<p>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.</p> <p>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.</p>	
<p>Reinforcement of students’ physical activity within school</p>	<p>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;</p> <p>2) Physical education teachers will be advised to teach students at least one sports game during each extracurricular activity.</p>	<p>The trained physical education teachers</p>
<p>Regular monitoring of students’ weight and height</p>	<p>1) <u>Monthly monitoring</u> 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);</p> <p>2) <u>Weekly monitoring</u></p>	<p>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</p>

	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	<p><u>1) Frequency and duration</u> 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).</p> <p><u>2) Contents</u></p> <ul style="list-style-type: none"> ➤ 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	<ol style="list-style-type: none"> 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)		

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<p>School policies related to obesity prevention</p>	<p>The following school policies will be suggested:</p> <p>1) “Not selling”: Not selling unhealthy snacks¹ or sugar-sweetened beverages within school;</p> <p>2) “Not eating”: Telling students not to eat unhealthy snacks or drink sugar-sweetened beverages at school;</p> <p>3) “Not buying”: Students being educated by class teachers not to buy unhealthy snacks or sugar-sweetened beverages around school.</p>	<p>The trained school principal; The trained class teachers</p>
<p>Health education activities for school teachers</p>	<p><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.</p> <p><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.</p>	<p>The trained project staff</p>
<p>4. A smartphone app assisted in implementation of the intervention</p>		
<p>The smartphone app (“Eat Wisely, Move</p>	<p><u>1) Information diffusion (the behaviour change technique (BCT) used: providing information on consequences of behaviours)</u></p>	<p>The smartphone app (installed by parents, school teachers and project</p>

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.

<p>Happily”)</p>	<p>The smartphone app will provide information to parents, class teachers and project staff in accordance with the health education activities.</p> <p><u>2) Behaviour monitoring (the BCT used: prompting the self-monitoring of behaviours)</u></p> <p>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).</p> <p><u>3) Weight management (the BCT used: prompting self-monitoring)</u></p> <p>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).</p> <p><u>4) Assessment and feedback (the BCT used: providing feedback on performance)</u></p> <p>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.</p>	<p>staff) and the computer management system (utilized by project staff)</p>
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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!”

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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.	

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One-minute sit-up	√	√	
Long standing jump	√	√	
Shuttle run (50 m×8)	√	√	
Behavioural measures and other measures			
Students' knowledge related to energy balance	√	√	<p>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).</p> <p>Students should finish the questionnaires in the classroom in the presence of the trained outcome assessors, who can provide guidance and help.</p> <p>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].</p> <p>Students should finish the questionnaires in the classroom in the presence of the trained outcome assessors, who can provide guidance and help.</p>
Students' duration of moderate-to-vigorous physical activity	√	√	<p>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</p>

1				good reliability [22].
2				The questionnaires should be self-reported by parents or other primary
3				caregivers of the students.
4				We will use a self-designed questionnaire to determine the average duration of
5				completing homework, watching television and playing electronic devices per
6				day during the last week.
7				Students should finish the questionnaires in the classroom in the presence of
8				the trained outcome assessors, who can provide guidance and help.
9				The questionnaires should be filled by the trained investigators after face-to-
10				face interviews with school principals, doctors/health care teachers and
11	Students' sedentary	√	√	physical education teachers.
12	behaviour			We will use two items for the assessment. First, we will ask "Have you taken
13				action to reduce your weight during the last three months?" Yes/no choices
14				will be provided. In addition, we will ask "Do you currently intend to reduce
15				your weight?" Five choices ranging from "completely do not intend" to "intend
16				to very much" will be provided.
17	School policies for the			Students should finish the questionnaires in the classroom in the presence of
18	prevention and	√	√	the trained outcome assessors, who can provide guidance and help.
19	management of			The questionnaires should be filled by the trained investigators after face-to-
20	childhood obesity			face interviews with school principals, doctors/health care teachers and
21				physical education teachers.
22				We will use two items for the assessment. First, we will ask "Have you taken
23				action to reduce your weight during the last three months?" Yes/no choices
24				will be provided. In addition, we will ask "Do you currently intend to reduce
25	Stage of readiness for			your weight?" Five choices ranging from "completely do not intend" to "intend
26	behaviour change	√	√	to very much" will be provided.
27	related to weight			Students should finish the questionnaires in the classroom in the presence of
28	reduction			the trained outcome assessors, who can provide guidance and help.
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Figure 1 Flow of the DECIDE-Children study

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

For peer review only

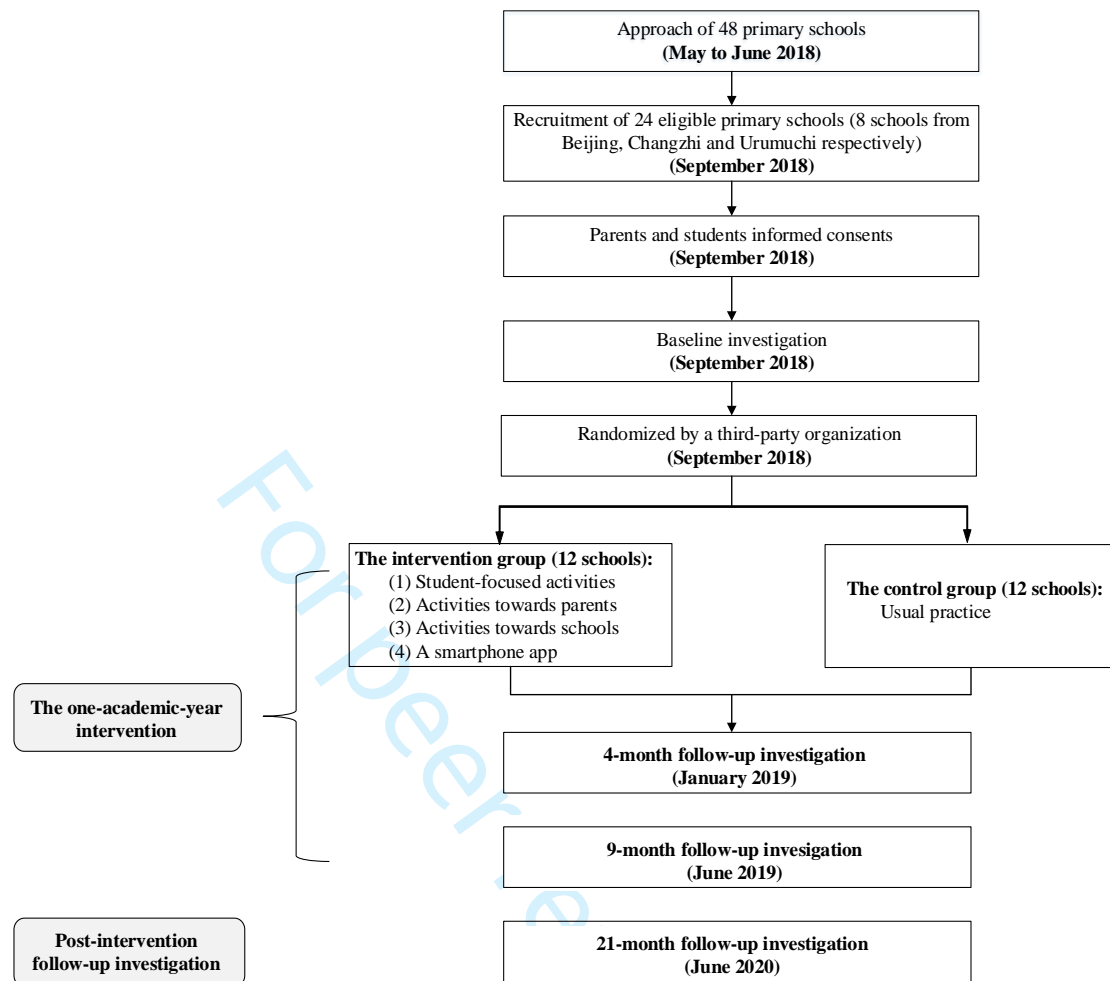


Figure 1 Flow of the DECIDE-Children study

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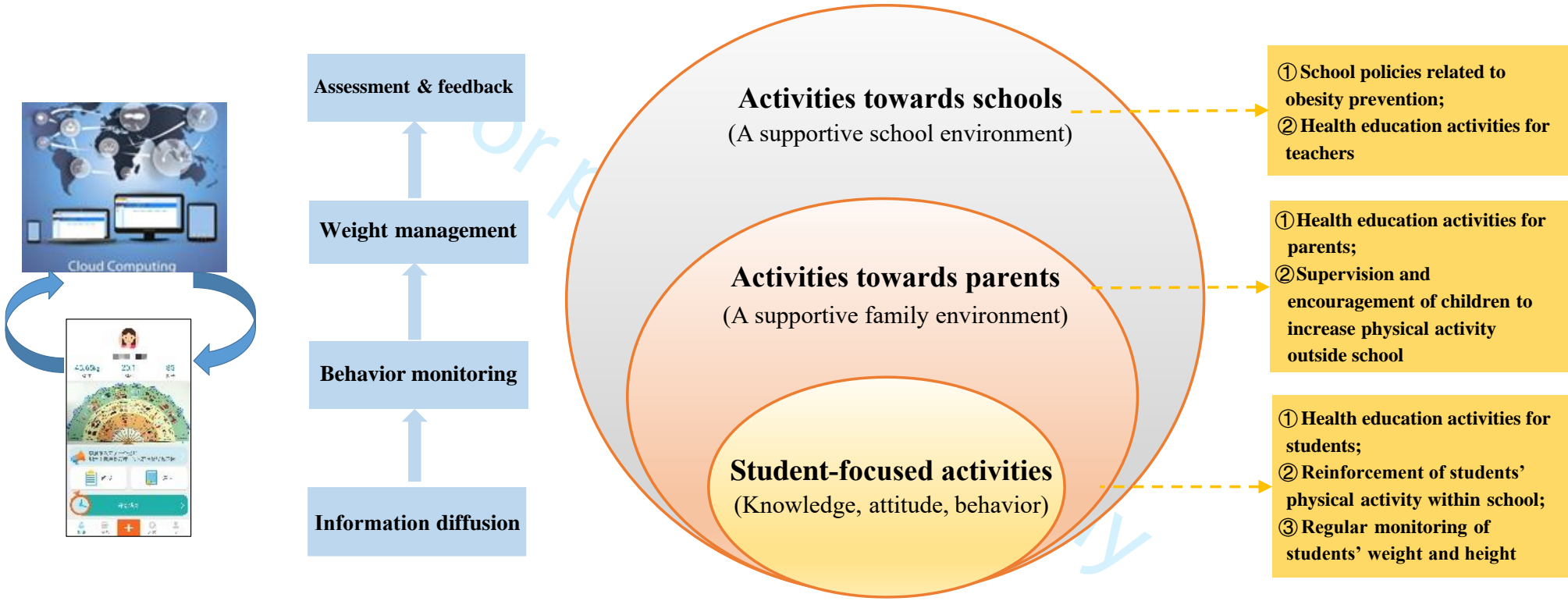


Figure 2 The Social Ecological Model as applied to the DECIDE-Children study

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

1	Trial registration:	#2b	All items from the World Health	This information is provided
2				
3	data set		Organization Trial Registration Data Set	in the trial registration
4				website.
5				
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7				
8	Protocol version	#3	Date and version identifier	This information will be
9				provided as soon as the
10				manuscript revision is finally
11				completed.
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18	Funding	#4	Sources and types of financial, material,	25
19			and other support	
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24	Roles and	#5a	Names, affiliations, and roles of protocol	24-25
25	responsibilities:		contributors	
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27	contributorship			
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31	Roles and	#5b	Name and contact information for the	n/a.
32	responsibilities:		trial sponsor	
33				
34	sponsor contact			This study was not
35				sponsored by any individuals
36				or companies. The funder
37	information			name and number has been
38				provided in Page 25.
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47	Roles and	#5c	Role of study sponsor and funders, if	26
48	responsibilities:		any, in study design; collection,	
49			management, analysis, and	
50	sponsor and		interpretation of data; writing of the	
51			report; and the decision to submit the	
52	funder			
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report for publication, including whether they will have ultimate authority over any of these activities

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8	Roles and	#5d	Composition, roles, and responsibilities	25
9	responsibilities:		of the coordinating centre, steering	
10			committee, endpoint adjudication	
11	committees		committee, data management team,	
12			and other individuals or groups	
13			overseeing the trial, if applicable (see	
14			Item 21a for data monitoring committee)	
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24	Background and	#6a	Description of research question and	5-7
25	rationale		justification for undertaking the trial,	
26			including summary of relevant studies	
27			(published and unpublished) examining	
28			benefits and harms for each intervention	
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37	Background and	#6b	Explanation for choice of comparators	6
38	rationale: choice			
39	of comparators			
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44	Objectives	#7	Specific objectives or hypotheses	7
45				
46				
47	Trial design	#8	Description of trial design including type	8
48			of trial (eg, parallel group, crossover,	
49			factorial, single group), allocation ratio,	
50			and framework (eg, superiority,	
51			equivalence, non-inferiority, exploratory)	
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1 2 3 4 5 6 7 8 9 10 11 12	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
13 14 15 16 17 18 19 20 21 22 23 24	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
25 26 27 28 29 30 31 32 33 34	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
35 36 37 38 39 40 41 42 43 44 45 46 47 48 49 50 51 52 53 54 55 56 57 58 59 60	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.

1	Interventions:	#11c	Strategies to improve adherence to	11-12
2				
3	adherence		intervention protocols, and any	
4				
5			procedures for monitoring adherence	
6				
7			(eg, drug tablet return; laboratory tests)	
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11	Interventions:	#11d	Relevant concomitant care and	n/a.
12				
13	concomitant care		interventions that are permitted or	This is a childhood obesity
14				prevention intervention.
15			prohibited during the trial	Based on our previous
16				experiences, it is less likely
17				that concomitant care and
18				interventions will take place.
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28	Outcomes	#12	Primary, secondary, and other	13-14, Table 3
29				
30			outcomes, including the specific	
31				
32			measurement variable (eg, systolic	
33				
34			blood pressure), analysis metric (eg,	
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36			change from baseline, final value, time	
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38			to event), method of aggregation (eg,	
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40			median, proportion), and time point for	
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42			each outcome. Explanation of the	
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44			clinical relevance of chosen efficacy and	
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46			harm outcomes is strongly	
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48			recommended	
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54	Participant	#13	Time schedule of enrolment,	Figure 1
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56	timeline		interventions (including any run-ins and	
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washouts), assessments, and visits for participants. A schematic diagram is highly recommended (see Figure)

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8	Sample size	#14	Estimated number of participants	14
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10			needed to achieve study objectives and	
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12			how it was determined, including clinical	
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14			and statistical assumptions supporting	
15			any sample size calculations	
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20	Recruitment	#15	Strategies for achieving adequate	9-10
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22			participant enrolment to reach target	
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24			sample size	
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28	Allocation:	#16a	Method of generating the allocation	10
29				
30	sequence		sequence (eg, computer-generated	
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32	generation		random numbers), and list of any	
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34			factors for stratification. To reduce	
35			predictability of a random sequence,	
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37			details of any planned restriction (eg,	
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39			blocking) should be provided in a	
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41			separate document that is unavailable	
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43			to those who enrol participants or	
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45			assign interventions	
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51	Allocation	#16b	Mechanism of implementing the	10
52				
53	concealment		allocation sequence (eg, central	
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55	mechanism		telephone; sequentially numbered,	
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57			opaque, sealed envelopes), describing	
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1		any steps to conceal the sequence until	
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3		interventions are assigned	
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6	Allocation:	#16c Who will generate the allocation	9-10
7			
8	implementation	sequence, who will enrol participants,	
9			
10		and who will assign participants to	
11			
12		interventions	
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16	Blinding (masking)	#17a Who will be blinded after assignment to	13
17			
18		interventions (eg, trial participants, care	
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20		providers, outcome assessors, data	
21			
22		analysts), and how	
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26	Blinding	#17b If blinded, circumstances under which	n/a.
27			
28	(masking):	unblinding is permissible, and	The assessors measuring
29			students' height and weight will
30	emergency	procedure for revealing a participant's	be blinded to group allocation of
31			the schools. We did not
32	unblinding	allocated intervention during the trial	anticipate any necessary
33			circumstances when unblinding
34			is permissible.
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40	Data collection	#18a Plans for assessment and collection of	13
41			
42	plan	outcome, baseline, and other trial data,	
43			
44		including any related processes to	
45			
46		promote data quality (eg, duplicate	
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48		measurements, training of assessors)	
49			
50		and a description of study instruments	
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52		(eg, questionnaires, laboratory tests)	
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54		along with their reliability and validity, if	
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56		known. Reference to where data	
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1		collection forms can be found, if not in	
2			
3		the protocol	
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6	Data collection	#18b Plans to promote participant retention	15
7			
8	plan: retention	and complete follow-up, including list of	
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10		any outcome data to be collected for	
11			
12		participants who discontinue or deviate	
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14		from intervention protocols	
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18	Data management	#19 Plans for data entry, coding, security,	3
19			
20		and storage, including any related	
21			
22		processes to promote data quality (eg,	
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24		double data entry; range checks for	
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26		data values). Reference to where	
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28		details of data management procedures	
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30		can be found, if not in the protocol	
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34	Statistics:	#20a Statistical methods for analysing	15
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36	outcomes	primary and secondary outcomes.	
37			
38		Reference to where other details of the	
39			
40		statistical analysis plan can be found, if	
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42		not in the protocol	
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46	Statistics:	#20b Methods for any additional analyses	15
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48	additional	(eg, subgroup and adjusted analyses)	
49			
50	analyses		
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1	Statistics: analysis	#20c	Definition of analysis population relating	15
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3	population and		to protocol non-adherence (eg, as	
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5	missing data		randomised analysis), and any	
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7			statistical methods to handle missing	
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9			data (eg, multiple imputation)	
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13	Data monitoring:	#21a	Composition of data monitoring	18
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15	formal committee		committee (DMC); summary of its role	
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17			and reporting structure; statement of	
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19			whether it is independent from the	
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21			sponsor and competing interests; and	
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23			reference to where further details about	
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25			its charter can be found, if not in the	
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27			protocol. Alternatively, an explanation of	
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29			why a DMC is not needed	
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34	Data monitoring:	#21b	Description of any interim analyses and	n/a.
35				
36	interim analysis		stopping guidelines, including who will	
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38			have access to these interim results and	This is a childhood obesity
39				prevention intervention.
40			make the final decision to terminate the	
41				Based on our previous
42			trial	experiences, it is less likely
43				that discontinuing
44				interventions will take place.
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52	Harms	#22	Plans for collecting, assessing,	16 (we will use
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54			reporting, and managing solicited and	questionnaires to collect and
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56			spontaneously reported adverse events	
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1			and other unintended effects of trial	assess any adverse events
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3			interventions or trial conduct	or other process data)
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6	Auditing	#23	Frequency and procedures for auditing	7 (This study is one of the
7			trial conduct, if any, and whether the	five independent studies of
8			process will be independent from	the overall DECIDE project.
9				
10			investigators and the sponsor	This overall project is audited
11				by the funder (National Key
12				R&D Program of China).
13				
14				
15				
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18				
19				
20	Research ethics	#24	Plans for seeking research ethics	2-3
21				
22	approval		committee / institutional review board	
23				
24			(REC / IRB) approval	
25				
26				
27				
28	Protocol	#25	Plans for communicating important	2-3
29				
30	amendments		protocol modifications (eg, changes to	
31			eligibility criteria, outcomes, analyses)	
32			to relevant parties (eg, investigators,	
33			REC / IRBs, trial participants, trial	
34			registries, journals, regulators)	
35				
36				
37				
38				
39				
40				
41				
42	Consent or assent	#26a	Who will obtain informed consent or	10
43				
44			assent from potential trial participants or	
45			authorised surrogates, and how (see	
46			Item 32)	
47				
48				
49				
50				
51				
52	Consent or	#26b	Additional consent provisions for	n/a.
53				
54	assent: ancillary		collection and use of participant data	
55				This study will not collect
56				biological specimens.
57	studies			
58				
59				
60				

1		and biological specimens in ancillary	
2		studies, if applicable	
3			
4			
5			
6	Confidentiality	#27 How personal information about	3
7		potential and enrolled participants will	
8		be collected, shared, and maintained in	
9		order to protect confidentiality before,	
10		during, and after the trial	
11			
12			
13			
14			
15			
16			
17			
18	Declaration of	#28 Financial and other competing interests	26
19	interests	for principal investigators for the overall	
20		trial and each study site	
21			
22			
23			
24			
25			
26	Data access	#29 Statement of who will have access to	3
27		the final trial dataset, and disclosure of	
28		contractual agreements that limit such	
29		access for investigators	
30			
31			
32			
33			
34			
35			
36	Ancillary and post	#30 Provisions, if any, for ancillary and post-	n/a.
37	trial care	trial care, and for compensation to those	
38		who suffer harm from trial participation	This is a childhood obesity
39			prevention intervention.
40			Based on our experiences, it
41			is less likely that ancillary
42			and post-trial care will take
43			place.
44			
45			
46			
47			
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49			
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51			
52			
53	Dissemination	#31a Plans for investigators and sponsor to	3
54	policy: trial results	communicate trial results to participants,	
55		healthcare professionals, the public,	
56			
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and other relevant groups (eg, via
 publication, reporting in results
 databases, or other data sharing
 arrangements), including any
 publication restrictions

Dissemination [#31b](#) Authorship eligibility guidelines and any n/a
 policy: authorship intended use of professional writers

Dissemination [#31c](#) Plans, if any, for granting public access n/a
 policy: to the full protocol, participant-level
 reproducible dataset, and statistical code
 research

Informed consent [#32](#) Model consent form and other related 10
 materials documentation given to participants and
 authorised surrogates

Biological [#33](#) Plans for collection, laboratory n/a
 specimens evaluation, and storage of biological
 specimens for genetic or molecular This study will not collect
 analysis in the current trial and for future biological specimens.
 use in ancillary studies, if applicable

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 by the [EQUATOR Network](#) in collaboration with [Penelope.ai](#)

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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Keywords:	pediatric obesity, cluster, prevention, randomized controlled trial

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Manuscripts

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4 1 **A school-based, multi-faceted health promotion programme to**
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6 2 **prevent obesity among children: protocol of a cluster-randomized**
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8 3 **controlled trial (the DECIDE-Children study)**
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14 5 Zheng Liu¹, Yang-Feng Wu², Wen-Yi Niu³, Xiang-Xian Feng⁴, Yi Lin⁵, Ai-Yu Gao⁶,
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16 6 Fang Zhang⁷, Hai Fang⁸, Pei Gao⁹, Hui-Juan Li², Hai-Jun Wang¹, the study team for
17
18 7 the DECIDE-children study
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1
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3
4 23**Abstract**

5
6 24 **Introduction** Obesity is a public health concern that is becoming increasingly more
7
8
9 25 serious worldwide. Effective and sustainable childhood obesity prevention strategies
10
11 26 may help to reduce the prevalence of obesity and may have an impact on lifelong health.
12
13
14 27 However, few such strategies have been rigorously evaluated for Chinese children in
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16
17 28 different regions of China.

18
19 29 **Methods and analysis** DECIDE-Children is a cluster-randomized controlled trial that
20
21
22 30 aims to assess the effectiveness and sustainability of a school-based, multi-faceted
23
24
25 31 intervention to prevent obesity among Grade 4 primary school students (8 to 10 years
26
27
28 32 old) in China. Twenty-four schools (approximately 1200 students) from above average,
29
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31 33 average and below average developed regions in China will be randomized to an
32
33
34 34 intervention (12 schools) or usual practice (12 schools) group. The intervention will last
35
36
37 35 for one school year (9 months) and consist of activities towards students, parents and
38
39
40 36 school environment. A smartphone application will be used to assist in providing
41
42
43 37 information on, monitoring and providing feedback on the behaviours and body weight
44
45
46 38 of the students. Data will be collected at baseline, 4 months, 9 months and 21 months.
47
48
49 39 The primary outcome will be the difference between groups in the change in students'
50
51
52 40 body mass index (BMI) at 9 months after the baseline investigation. The secondary
53
54
55 41 outcomes will include the differences between groups in the changes in anthropometric
56
57
58 42 measures, diet, physical activity levels and other measures at the follow-up visits. A
59
60 43 variety of process evaluation methods will be used to evaluate the implementation
44 process of the complex intervention.

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4 45 **Ethics and dissemination** This study was approved by the Peking University
5
6 46 Institution Review Board (IRB00001052-18021). The results will be disseminated
7
8
9 47 through publication in peer-reviewed journals, presentations at conferences and in lay
10
11
12 48 summaries provided to school staff and participants.
13
14 49 **Trial registration** ClinicalTrials.gov: NCT03665857.
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For peer review only

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4 **50 Strengths and limitations of this study**

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7 51 1. This study will rigorously evaluate the effectiveness of a childhood obesity
8
9 52 prevention programme in eastern, central and western regions with different levels of
10
11 53 economic development in China.
12
13
14 54 2. We will employ a smartphone application to assist in providing information on,
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16 55 monitoring and providing feedback on the behaviours and body weight of the students.
17
18
19 56 3. We will include an explicit process evaluation plan for both the intervention and the
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21 57 control groups, which will evaluate the implementation process of the complex
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23 58 intervention.
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26
27 59 4. A follow-up investigation will be conducted to evaluate the sustainability of the
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29 60 intervention.
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32 61 5. This intervention is limited by a relatively short duration, but additional funding will
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35 62 be sought for the implementation of a long-term intervention in the future.
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63 **Introduction**

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

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

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4 85 achieve this, a thorough process evaluation of the intervention implementation is
5
6 86 necessary. Furthermore, socioeconomic development is associated with patterns of
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9 87 childhood obesity [13] and may also affect the effectiveness of a childhood obesity
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11
12 88 intervention. Social disparities in the patterns of obesity differ between China and
13
14 89 Western countries. In China, socioeconomic development has been positively
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16
17 90 associated with overweight and obesity prevalence in children [13]. However, previous
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20 91 studies have been largely conducted in a single region, which limits the generalizability
21
22
23 92 of study findings to other populations. Another weakness is that most studies examined
24
25
26 93 outcomes only at the end of the intervention. Thus, it remains unclear whether healthy
27
28
29 94 behaviours and a healthy weight are maintained beyond the period of the intervention.

30 95 *School system in China*

31
32
33 96 In primary schools in China, there are six grades in total, and the age of the students
34
35
36 97 ranges from 6 to 11 years. The typical size of a Chinese class is fewer than 45 students,
37
38
39 98 but varies in different schools, ranging from 30 to 60 students. There are two school
40
41
42 99 policies that have been issued by the Chinese government that are particularly relevant
43
44
45 100 to the prevention and management of childhood obesity. First, schools should have
46
47
48 101 school doctors or health care teachers who provide in-house school health care. The
49
50
51 102 routine practices include student health surveillance, health education for students, and
52
53
54 103 the prevention and control of common diseases in students. Second, schools should
55
56
57 104 implement 'One-Hour Physical Activity On Campus Every School Day'. That is, the
58
59
60 105 total duration of physical activity (i.e., physical education classes, exercises during
106 breaks from class and extracurricular activities) per school day should be no less than

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4 107 one hour. However, the implementation of these policies in the school systems in China
5
6 108 varies by region [14].
7
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9 109 ***Development of a childhood obesity intervention***

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11 110 To fill in research gaps, in accordance with the school systems in China, we underwent
12
13
14 111 four stages to develop the intervention: (1) we systematically reviewed previous
15
16
17 112 literature to identify intervention elements related to intervention effectiveness; (2) we
18
19
20 113 conducted focus group discussions and interviews with key informants (children,
21
22 114 parents, teachers, school principals, local health and education officials) to further
23
24
25 115 revise and refine the intervention approaches; (3) we conducted a three-month, before-
26
27 116 after, pilot study at two primary schools in Beijing (one in an urban area and the other
28
29
30 117 in a rural area) involving 58 Grade 4 students (mean age: 9.38±0.49 years) to test the
31
32
33 118 feasibility of the proposed intervention [15]; and (4) we further discussed the proposed
34
35
36 119 intervention with multiple experts. Based on all the work mentioned, we finally
37
38 120 developed the intervention elements used for this study.
39

40 121 ***Aim and objectives***

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42
43 122 To develop effective lifestyle interventions for the prevention and control of
44
45 123 cardiovascular disease in China, the Diet, ExerCIse and CarDiovascular hEalth
46
47
48 124 (DECIDE) project was initiated in 2016. As one of five independent DECIDE studies,
49
50
51 125 the DECIDE-Children study aims to develop a school-based, multi-faceted childhood
52
53 126 obesity prevention programme targeting school children aged 8-10 years in three
54
55
56 127 different regions of China and rigorously test its effectiveness in preventing excessive
57
58 128 weight gain in Chinese primary school settings. The research objectives of the
59
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4 129 DECIDE-Children study were (1) to assess the effectiveness of the intervention
5
6 130 compared with the usual practice in preventing childhood overweight and obesity; (2)
7
8
9 131 to determine the sustainability of the intervention in preventing overweight and obesity;
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11
12 132 and (3) to evaluate the process and health economics of the intervention.
13

14 133 **Methods and analysis**

15
16
17 134 This protocol has been prepared in accordance with the Standard Protocol Items:
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19 135 Recommendations for Interventional Trials (SPIRIT) statement [16, 17].
20
21

22 136 *Study design*

23
24 137 DECIDE-Children is a cluster-randomized, parallel-group controlled trial. To
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26
27 138 accommodate the social and economic variations within the country, we will
28
29
30 139 intentionally select schools from three different regions of China: the above average
31
32
33 140 developed area in the east (Beijing), the average developed area in central China
34
35 141 (Shanxi) and the below average developed area in the west (Xinjiang). A total of 24
36
37
38 142 primary schools (clusters) equally distributed among three regions will be selected. In
39
40 143 Beijing, 4 schools will be selected from the Dongcheng district (located in the centre of
41
42
43 144 the city), and 4 will be selected from the Mentougou district (located in a rural suburban
44
45
46 145 area). In Xinjiang, all 8 schools will be selected from Urumchi, the capital city of the
47
48 146 autonomous region; four of the schools will be selected from the Shayiba district (an
49
50
51 147 urban district), and the other four schools will be selected from the Shuimogou district
52
53
54 148 (a rural district). In Shanxi, all 8 schools will be selected from only one urban district,
55
56 149 Changzhi, a small- to medium-sized city in the province. The reason for excluding rural
57
58
59 150 schools in Changzhi is that most of the rural schools are boarding schools, and parents
60

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4 151 are difficult to reach in boarding schools. Thus, a total of 24 primary schools from five
5
6 152 sites in three regions will be selected and randomized into two groups, the obesity
7
8
9 153 prevention intervention group and the usual practice group. The intervention will be
10
11 154 implemented for one school year from late September 2018 to June 2019, and the study
12
13
14 155 will continue with a one-year follow-up investigation in June 2020. Figure 1 shows the
15
16
17 156 flow of the study.

19 157 ***Recruitment***

22 158 **Recruitment of the schools**

24 159 The present study will be carried out in Grade 4 students (8 to 10 years old), as they are
25
26
27 160 sufficiently mature to understand health education information and are able to remain
28
29
30 161 in the same school to complete the two-year study before they graduate. For a school
31
32 162 to be eligible, the school principal must agree with the randomization procedure and
33
34
35 163 comply with the study protocol. The total number of Grade 4 students must be greater
36
37 164 than 50 in the school, and schools that have implemented or are planning to implement
38
39
40 165 an obesity prevention intervention or similar intervention programme will not be
41
42 166 eligible. Boarding schools and specialty schools for children with talents or minority
43
44
45 167 ethnic groups will be excluded. Schools will also not be included if they have a definite
46
47
48 168 plan for relocation or cancellation in the next two years. For the schools participating
49
50
51 169 in the programme, the size of a class will vary between fewer than 30 children and
52
53 170 approximately 60 children per class. If the number of students in each class is less than
54
55
56 171 50, we will recruit two classes from the school, and if the number of students is greater
57
58
59 172 than 50, we will recruit one class to meet the sample size requirement. If there are more
60

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3
4 173 classes in one school than needed for the study, the school principal will recommend
5
6 174 which classes we should select.

7
8
9 175 Three steps will be followed for the recruitment of the schools. First, project staff will
10
11 176 contact the local education authorities to gain their opinion, support, and approval of
12
13 177 the study and basic information of the schools (type of schools and the number of
14
15 178 students and teachers). Second, project staff will contact the schools by phone or visit
16
17 179 the schools to determine the eligibility of the selected schools for the study. Third, the
18
19 180 final list of eligible schools and classes will be made by the principal investigator and
20
21 181 schools will be invited to participate in the study by local research partners.

22 182 **Recruitment of the students**

23
24
25 183 After recruiting the schools and before conducting the baseline measurements, written
26
27 184 informed consent will be provided by all students and their primary caregivers (parents
28
29 185 in most cases) in the selected classes. Then, the parents who provide informed consent
30
31 186 will be required to complete a questionnaire about the health status of their children.
32
33 187 The project staff will collect the questionnaires and if a parent reports one of the
34
35 188 following conditions, his or her children will be excluded: 1) medical history of heart
36
37 189 disease, hypertension, diabetes, tuberculosis, asthma, hepatitis or nephritis; 2) obesity
38
39 190 caused by endocrine diseases or side effects of drugs; 3) abnormal physical
40
41 191 development like dwarfism or gigantism; 4) physical deformity such as severe scoliosis,
42
43 192 pectus carinatum, limp, obvious O-leg or X-leg; 5) inability to participate in school
44
45 193 sport activities; 6) a loss in weight by vomiting or taking drugs during the past three
46
47 194 months.

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4 195 ***Randomization procedures***

5
6 196 The random sequence of allocation of the schools (clusters) to the intervention or
7
8
9 197 control group will be stratified by the study sites. Schools in the same study site will be
10
11
12 198 randomly allocated in a 1:1 ratio to either the intervention or control group using a
13
14 199 computer-generated random number system (the simple random sampling method).
15
16
17 200 Randomization will be performed by an independent person at the central coordinating
18
19 201 centre at Peking University Clinical Research Institute. The randomization will take
20
21
22 202 place only after the baseline measurements are completed to ensure allocation
23
24
25 203 concealment.

26
27 204 ***Intervention***

28
29
30 205 We used the Social Ecological Model to identify intervention elements in this multi-
31
32 206 faceted health promotion programme [18]. As shown in Figure 2, the programme will
33
34
35 207 target the influencing factors of childhood obesity at both individual (student-focused
36
37 208 activities) and environmental levels (a supportive family and school environment), with
38
39
40 209 the intent to influence the knowledge, attitude and behaviours of school children.

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42
43 210 **Description of the intervention components**

44
45 211 The intervention components are described in Tables 1 and 2.

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47
48 212 ***Student-focused activities:*** These activities will include health education activities for
49
50 213 students, the reinforcement of students' physical activity at school and the regular
51
52 214 monitoring of students' weight and height.

53
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55 215 ***Activities towards parents:*** These activities will include health education activities for
56
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58 216 parents and the supervision and encouragement of children to increase their physical
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4 217 activity level outside of school.
5

6 218 **Activities towards schools:** These activities will include school policies related to
7
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9 219 obesity prevention and health education activities for teachers.
10

11 220 **The smartphone app:** Project staff, school teachers and parents will be suggested to
12
13
14 221 install the app titled “Eat Wisely, Move Happily”. The app, which was developed based
15
16
17 222 on behaviour change techniques [19], will aid in information diffusion, behaviour
18
19 223 monitoring, weight management, assessment and feedback.
20

21 22 224 **Quality control of the intervention**

23
24 225 Two manuals (“An Operation Manual for Project Staff Involved in the Multi-
25
26
27 226 component Obesity Intervention among Primary School Students” and “An Operation
28
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30 227 Manual for School Team Members Involved in the Multi-component Obesity
31
32 228 Intervention among Primary School Students”) have been developed for implementing
33
34
35 229 and managing this complex intervention. The manuals describe in detail the duties of
36
37
38 230 project staff and school team members (school principals, class teachers, physical
39
40 231 education teachers, school doctors/health care teachers) in delivering the intervention.
41
42
43 232 The manuals also describe the detailed workflow of the implementation of each
44
45
46 233 intervention component, i.e., by whom, when, how and to what extent the specific
47
48
49 234 intervention element should be delivered. All of the project staff and school team
50
51 235 members will be required to conduct the intervention in accordance with the operation
52
53 236 manuals.
54

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56 237 During implementation of the intervention, regular field observations will be made and
57
58 238 the smartphone app records will be checked. If it is found that schools are not complying
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4 239 with the study protocol, project staff will communicate with school team members in a
5
6 240 timely manner and conduct follow-ups to improve the fidelity of the study results.
7
8

9 241 ***Control group***

10
11 242 The twelve schools in the control group will not carry out any of the DECIDE-Children
12
13 243 intervention components and will continue their usual practice according to their own
14
15 244 teaching curriculum during the study period (from September 2018 to June 2020).
16
17 245 Participants in the control group will receive the same health education materials that
18
19 246 will have been delivered to those in the intervention group immediately after the 21-
20
21 247 month follow-up investigation is completed in June 2020.
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26
27 248 ***Outcome evaluation***

28
29 249 Table 3 describes the study outcomes, including when and how the study outcomes will
30
31 250 be evaluated. Baseline measurements will be conducted in September 2018 for both the
32
33 251 intervention and the control groups. Follow-up measurements will be conducted 4
34
35 252 months after the baseline measurements are conducted in January (after one school
36
37 253 semester and half way through the intervention), 9 months after the baseline
38
39 254 measurements are conducted in June 2019 (after one school year and immediately after
40
41 255 the whole intervention programme is completed) and 21 months after the baseline
42
43 256 measurements are conducted in June 2020 (after two school years and 12 months after
44
45 257 the intervention is completed).
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53 258 At the baseline and all follow-up visits, anthropometric measures (height, weight, waist
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55 259 and hip circumference, systolic and diastolic blood pressures, body fat percentage) and
56
57 260 physical fitness measures (one-minute rope jumping, one-minute sit-up, long standing
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4 261 jump, shuttle run (50 m×8)) will be collected by the trained outcome assessors using
5
6 262 the same device and/or forms according to the standard methods and procedures. The
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8
9 263 assessors measuring students' height and weight will be blinded to the group allocation
10
11 264 of the schools. We will use questionnaires to measure students' behaviours (duration of
12
13 265 moderate-to-vigorous physical activity, eating behaviour, sedentary behaviour), school
14
15 266 policies for prevention and management of childhood obesity, and other potential
16
17 267 moderators/mediators of the intervention (e.g., stage of readiness for behaviour change
18
19 268 related to weight reduction). The questionnaires were developed based on previous
20
21 269 studies and the pilot study. The questionnaires were found to be feasible for this study
22
23 270 and acceptable to students and their parents [20-22].
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29

30 **Outcomes**

31
32 272 The primary outcome is the difference between groups in the change in students' body
33
34 273 mass index ($BMI = \text{weight (kg)} / (\text{height (m)})^2$) immediately after the intervention
35
36 274 completion (9 months after the baseline measurements are conducted). The secondary
37
38 275 outcomes include the change in BMI one year after the intervention is completed (21
39
40 276 months after the baseline measurements are conducted). In addition, we will compare
41
42 277 the following indices between groups at the follow-up visits: 1) change in students'
43
44 278 BMI z-score (standard deviation score will be calculated based on the World Health
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46 279 Organization criteria [23]); 2) change in prevalence and incidence of childhood
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48 280 overweight/obesity defined according to the criteria for Chinese children and
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50 281 adolescents [24]; 3) change in students' waist circumference, waist-to-hip
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52 282 circumference ratio and systolic and diastolic blood pressures; and 4) change in students'
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4 283 body fat percentage, physical fitness measures, behavioural outcomes (including
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6 284 students' duration of moderate-to-vigorous physical activity, students' eating behaviour
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8
9 285 and students' sedentary behaviour) and other outcomes (including students' knowledge
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11 286 related to energy balance, school policies for the prevention and management of
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14 287 childhood obesity and stage of readiness for behaviour change related to weight
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17 288 reduction).

18 19 289 ***Sample size estimation***

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22 290 We assumed that the difference between the two groups in the change in BMI (effect
23
24 291 size) would be 0.50 kg/m², the standard deviation (SD) of the BMI would be 1.40 kg/m²,
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26
27 292 the intra-cluster correlation coefficient would be 0.05 and the rate of attrition would be
28
29
30 293 10% for the sample size calculation in our study. We aimed to recruit a total of 1,200
31
32 294 students from 24 schools with an average cluster size of 50 students per school. This
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34
35 295 sample size will provide 88% power with $\alpha=0.05$ to detect a mean difference of 0.50
36
37 296 kg/m² in the change in BMI between groups after the intervention lasting one school
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40 297 year.

41 42 43 298 ***Statistical analyses***

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45 299 Statistical analyses will be performed using SAS version 9.4 (SAS Institute Inc., Cary,
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47
48 300 NC, USA). All statistical tests will be two-sided at the 5% level of significance.
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51 301 Baseline characteristics at both the school and individual levels will be reported by
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53 302 using descriptive statistics.
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56 303 The primary analysis will be based on the intention-to-treat principle and include all
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58 304 students recruited with the baseline BMIs measured. Generalized linear mixed models

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4 305 will be used to compare the primary and secondary outcomes at 4, 9, and 21 months
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6 306 after the baseline measurements are conducted, and the models will adjust for the
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9 307 clustering effect and baseline outcome values. The missing data will be treated in the
10
11 308 maximum likelihood estimates assuming they are missing at random. The intra-cluster
12
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14 309 correlation coefficient will also be estimated. Sensitivity analysis will be performed on
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16
17 310 the primary outcome using the last-value-carry-forward imputation if the percentage of
18
19 311 missing data exceeds 5%. For continuous outcomes, we will report pre-, and post-
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21
22 312 intervention means for the intervention and control groups and model-adjusted mean
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24 313 differences between groups. For binary outcomes, we will report pre- and post-
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26
27 314 intervention percentages for the intervention and control groups and adjusted odds
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29
30 315 ratios (ORs) between groups. The 95% confidence intervals (CIs) and associated *P*-
31
32 316 values will be calculated. We will also examine whether the differences in the outcomes
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34
35 317 between the control and intervention groups vary by the three regions (Beijing, Shanxi,
36
37 318 Xinjiang), the sex of children, socioeconomic status (mother's education), BMI status
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39
40 319 at baseline and primary caregivers of the children (parents compared with non-parents).

41 42 43 320 ***Process evaluation***

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45 321 Based on the steps and principles described in the conceptual framework by Saunders
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47
48 322 et al.[25], we will identify the process evaluation elements including fidelity (the extent
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51 323 to which the intervention will be implemented as initially planned), dose delivered (the
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53 324 frequency and intensity of the actual implementation of the programme), dose received
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56 325 (the extent to which students/primary caregivers (parents in most cases)/teachers will
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59 326 be exposed to the intervention, as well as the degree of their satisfaction with the

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4 327 intervention and materials), reach (the proportions and the characteristics of
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6 328 students/primary caregivers/teachers completing or dropping out of the intervention)
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9 329 and context (family environment and school policies related to obesity prevention and
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11 330 management).

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14 331 The implementation process data collection procedure will include (1) direct regular
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16 332 field observation and records which will be collected for the quality control of the
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18 333 intervention (e.g., quality and quantity of the intervention sessions and number of
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20 334 students attending the lectures) and will be recorded by the trained project staff; (2) the
21
22 335 user logs (e.g., frequency and duration) which will be collected by the smartphone app;
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24 336 (3) school policies related to obesity prevention and management, which will be
25
26 337 collected by the questionnaires (Table 3) in both the intervention and the control groups;
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28 338 and (4) interviews with participants (6~8 students per school) which will be conducted
29
30 339 in both the intervention and the control groups.

340 ***Health economics evaluation***

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

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4 349 incremental cost-effectiveness ratio will be calculated and a sensitivity analysis will be
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6 350 used to vary key parameters to examine the robustness of the health economics results.
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9 351 **Patient and Public involvement**

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11 352 We will conduct focus group discussions and interviews with key stakeholders
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14 353 (children, parents, teachers, school principals, local health, and education officials) by
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17 354 refining the intervention approach. We will not involve any of the stakeholders in other
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20 355 aspects of the research study, including idea development, design of the study,
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22 356 implementation of the protocol, data collection, and analysis and interpretation of the
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24
25 357 results. The results of the study will be disseminated through publication in peer-
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28 358 reviewed journals, presentations at conferences and in lay summaries provided to
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30
31 359 school staff, students and parents. The benefits and burden of the intervention will be
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33 360 assessed by children and their primary caregivers through self-reported questionnaires
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35 361 at the end of the intervention.
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37 362 **Trial status**

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40 363 The trial started and the recruitment of schools and children was completed in
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42
43 364 September 2018. Baseline measurements were conducted in the last few weeks in
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46 365 September 2018. The intervention lasting one school year started at the end of
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48
49 366 September 2018 and was completed in June 2019. The 4-month follow-up
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51 367 measurements started and were completed in January 2019. The 9-month follow-up
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53 368 measurements started and were completed in June 2019. The 21-month follow-up
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56 369 measurements will be completed in June 2020.

57 58 370 **Ethics and dissemination**

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4 371 This study was reviewed and approved by the Peking University Institution Review
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6 372 Board (IRB00001052-18021). Any amendments to the study protocol will be submitted
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9 373 for IRB approval prior to implementation. Written informed consent will be obtained
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11 374 from all students and their parents. All data collected will be entered into an electronic
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14 375 database with de-identified information. The database will be accessed only by
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17 376 designated staff with a password. The results will be disseminated through publication
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19 377 in peer-reviewed journals, presentation at conferences and in lay summaries provided
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22 378 to school staff and participants. Upon completion of the trial and after the publication
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25 379 of these results, the data will be made available upon request by contacting the
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27 380 corresponding author of this protocol.

30 381 **Discussion**

32 382 Non-communicable diseases, especially cardiovascular diseases, have contributed to
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35 383 the public health burden worldwide. Preventing childhood obesity in early life may
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38 384 have the greatest long-term effects in curbing this widespread burden. Although several
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41 385 childhood obesity intervention studies have been conducted in China, research gaps
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43 386 exist in terms of methodological flaws, process measures, and sustainability of the
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46 387 intervention. The DECIDE-Children study is based on theory-driven and systematic
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48 388 developments (e.g., systematic review [8], qualitative interviews, panel discussions and
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51 389 a pilot study [15]) and serves as one of the first examples of a rigorously developed and
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54 390 evaluated childhood obesity prevention programme that will be implemented in eastern,
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56 391 central and western regions of China.

58 392 Our DECIDE-Children study can overcome poor adherence to the intervention

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4 393 components, which is a weakness of most previous studies, due to our favourable
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6 394 collaborations with local education authorities as well as the rigorous quality control of
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9 395 implementing the intervention. This study also has several other distinguishing features:
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11 396 1) randomization by an independent person not involved in the study, blinding of key
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14 397 outcome measures, and a detailed process evaluation plan will help to provide study
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17 398 results of high quality; 2) a follow-up investigation will be conducted one year after the
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20 399 intervention is completed to determine the sustainability of the effects of the
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22 400 intervention; 3) a smartphone app will be employed to assist in providing information
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25 401 on, monitoring and providing feedback on the behaviours and body weight of the
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28 402 children; 4) three centres located in eastern, central and western regions of China will
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31 403 be involved in the study to reflect the different levels of economic development in
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33 404 China; and 5) most of the intervention components (school polices, regular monitoring
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35 405 of students' weight and height, reinforcement of students' physical activity at school,
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38 406 health education activities for students) will be integrated into the regular academic
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40 407 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.

For peer review only

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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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6 **Competing interests statement**
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9 None.
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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	<p><u>(1) Frequency and duration</u> 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).</p> <p><u>(2) Different kinds of activities</u> 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”).</p> <p><u>(3) Content</u> 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.</p>	The trained class teachers

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	<p>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.</p> <p>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.</p>	
<p>Reinforcement of students’ physical activity within school</p>	<p>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;</p> <p>2) Physical education teachers will be advised to teach students at least one sports game during each extracurricular activity.</p>	<p>The trained physical education teachers</p>
<p>Regular monitoring of students’ weight and height</p>	<p><u>1) Monthly monitoring</u> 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);</p> <p><u>2) Weekly monitoring</u></p>	<p>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</p>

	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	<p><u>1) Frequency and duration</u> 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).</p> <p><u>2) Contents</u></p> <ul style="list-style-type: none"> ➤ 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	<ol style="list-style-type: none"> 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)		

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School policies related to obesity prevention	<p>The following school policies will be suggested:</p> <p>1) “Not selling”: Not selling unhealthy snacks¹ or sugar-sweetened beverages within school;</p> <p>2) “Not eating”: Telling students not to eat unhealthy snacks or drink sugar-sweetened beverages at school;</p> <p>3) “Not buying”: Students being educated by class teachers not to buy unhealthy snacks or sugar-sweetened beverages around school.</p>	<p>The trained school principal; The trained class teachers</p>
Health education activities for school teachers	<p><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.</p> <p><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.</p>	<p>The trained project staff</p>
4. A smartphone app assisted in implementation of the intervention		
<p>The smartphone app (“Eat Wisely, Move</p>	<p><u>1) Information diffusion (the behaviour change technique (BCT) used: providing information on consequences of behaviours)</u></p>	<p>The smartphone app (installed by parents, school teachers and project</p>

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.

<p>Happily”)</p>	<p>The smartphone app will provide information to parents, class teachers and project staff in accordance with the health education activities.</p> <p><u>2) Behaviour monitoring (the BCT used: prompting the self-monitoring of behaviours)</u></p> <p>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).</p> <p><u>3) Weight management (the BCT used: prompting self-monitoring)</u></p> <p>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).</p> <p><u>4) Assessment and feedback (the BCT used: providing feedback on performance)</u></p> <p>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.</p>	<p>staff) and the computer management system (utilized by project staff)</p>
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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.	

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One-minute sit-up	√	√	
Long standing jump	√	√	
Shuttle run (50 m×8)	√	√	
Behavioural measures and other measures			
Students' knowledge related to energy balance	√	√	<p>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).</p> <p>Students should finish the questionnaires in the classroom in the presence of the trained outcome assessors, who can provide guidance and help.</p> <p>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].</p> <p>Students should finish the questionnaires in the classroom in the presence of the trained outcome assessors, who can provide guidance and help.</p>
Students' duration of moderate-to-vigorous physical activity	√	√	<p>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</p>

1				good reliability [22].
2				The questionnaires should be self-reported by parents or other primary
3				caregivers of the students.
4				We will use a self-designed questionnaire to determine the average duration of
5				completing homework, watching television and playing electronic devices per
6				day during the last week.
7				Students should finish the questionnaires in the classroom in the presence of
8				the trained outcome assessors, who can provide guidance and help.
9				The questionnaires should be filled by the trained investigators after face-to-
10				face interviews with school principals, doctors/health care teachers and
11	Students' sedentary	√	√	physical education teachers.
12	behaviour			We will use two items for the assessment. First, we will ask "Have you taken
13				action to reduce your weight during the last three months?" Yes/no choices
14				will be provided. In addition, we will ask "Do you currently intend to reduce
15				your weight?" Five choices ranging from "completely do not intend" to "intend
16				to very much" will be provided.
17	School policies for the			Students should finish the questionnaires in the classroom in the presence of
18	prevention and	√	√	the trained outcome assessors, who can provide guidance and help.
19	management of			The questionnaires should be filled by the trained investigators after face-to-
20	childhood obesity			face interviews with school principals, doctors/health care teachers and
21				physical education teachers.
22				We will use two items for the assessment. First, we will ask "Have you taken
23				action to reduce your weight during the last three months?" Yes/no choices
24				will be provided. In addition, we will ask "Do you currently intend to reduce
25	Stage of readiness for			your weight?" Five choices ranging from "completely do not intend" to "intend
26	behaviour change	√	√	to very much" will be provided.
27	related to weight			Students should finish the questionnaires in the classroom in the presence of
28	reduction			the trained outcome assessors, who can provide guidance and help.
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Figure 1 Flow of the DECIDE-Children study

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

For peer review only

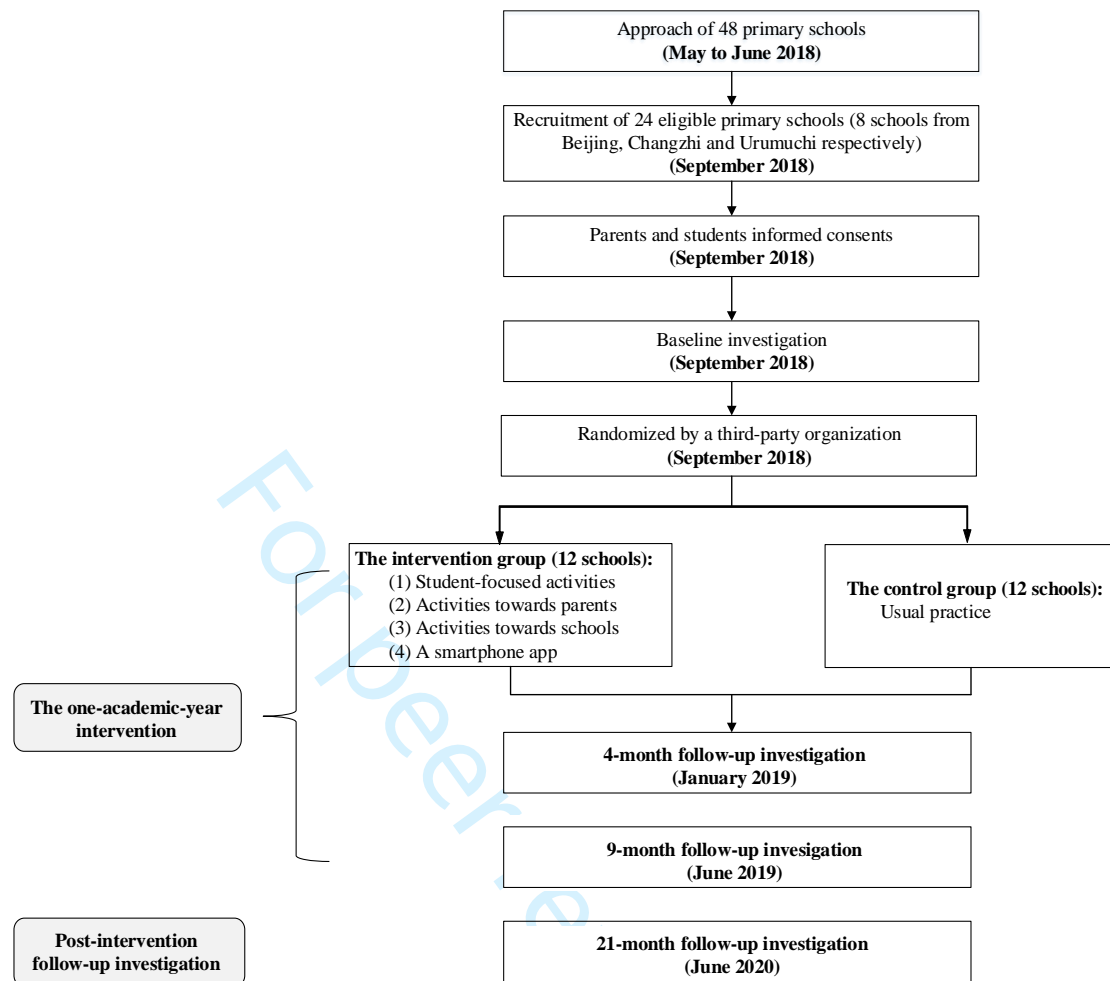


Figure 1 Flow of the DECIDE-Children study

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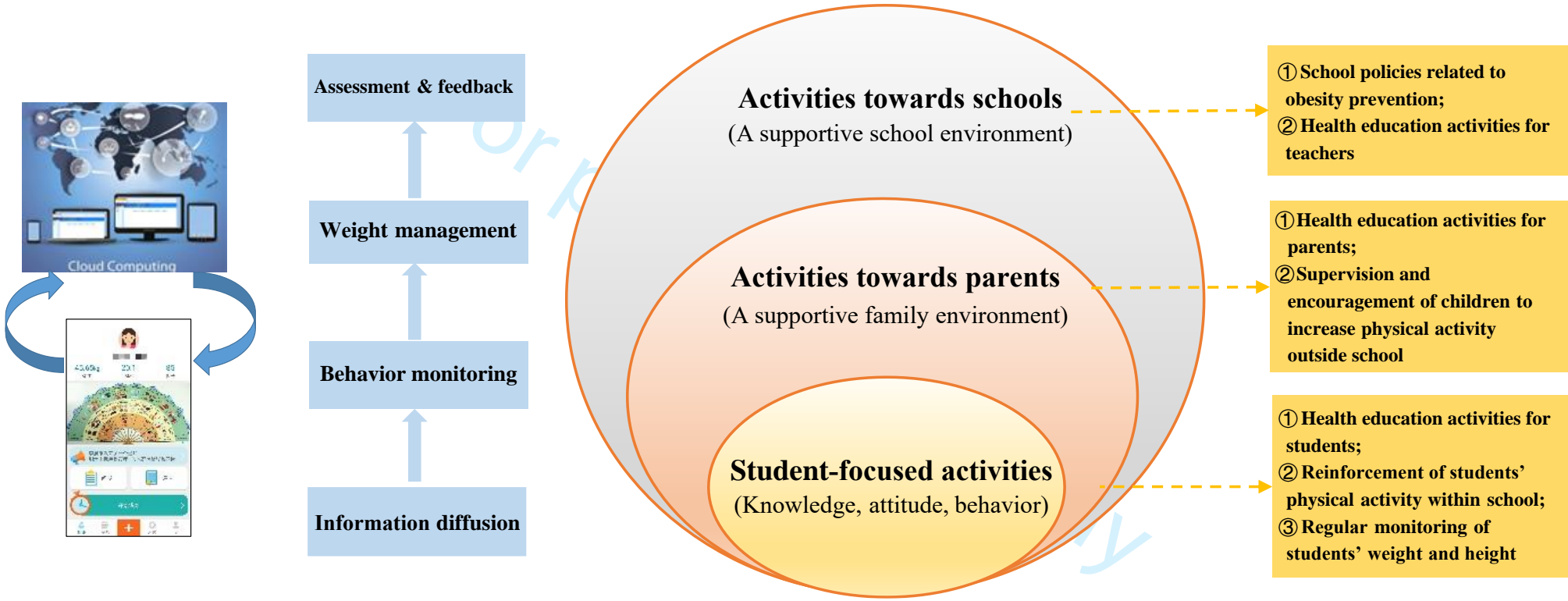


Figure 2 The Social Ecological Model as applied to the DECIDE-Children study

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

1	Trial registration:	#2b	All items from the World Health	This information is provided
2				
3	data set		Organization Trial Registration Data Set	in the trial registration
4				website.
5				
6				
7				
8	Protocol version	#3	Date and version identifier	This information will be
9				provided as soon as the
10				manuscript revision is finally
11				completed.
12				
13				
14				
15				
16				
17				
18	Funding	#4	Sources and types of financial, material,	25
19			and other support	
20				
21				
22				
23				
24	Roles and	#5a	Names, affiliations, and roles of protocol	24-25
25	responsibilities:		contributors	
26				
27	contributorship			
28				
29				
30				
31	Roles and	#5b	Name and contact information for the	n/a.
32	responsibilities:		trial sponsor	
33				
34	sponsor contact			This study was not
35				sponsored by any individuals
36				or companies. The funder
37	information			name and number has been
38				provided in Page 25.
39				
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47	Roles and	#5c	Role of study sponsor and funders, if	26
48	responsibilities:		any, in study design; collection,	
49			management, analysis, and	
50	sponsor and		interpretation of data; writing of the	
51			report; and the decision to submit the	
52	funder			
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report for publication, including whether they will have ultimate authority over any of these activities

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8	Roles and	#5d	Composition, roles, and responsibilities	25
9				
10	responsibilities:		of the coordinating centre, steering	
11			committee, endpoint adjudication	
12	committees		committee, data management team,	
13			and other individuals or groups	
14			overseeing the trial, if applicable (see	
15			Item 21a for data monitoring committee)	
16				
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24	Background and	#6a	Description of research question and	5-7
25			justification for undertaking the trial,	
26	rationale		including summary of relevant studies	
27			(published and unpublished) examining	
28			benefits and harms for each intervention	
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37	Background and	#6b	Explanation for choice of comparators	6
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39	rationale: choice			
40				
41	of comparators			
42				
43				
44	Objectives	#7	Specific objectives or hypotheses	7
45				
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47	Trial design	#8	Description of trial design including type	8
48			of trial (eg, parallel group, crossover,	
49			factorial, single group), allocation ratio,	
50			and framework (eg, superiority,	
51			equivalence, non-inferiority, exploratory)	
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1 2 3 4 5 6 7 8 9 10 11 12	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
13 14 15 16 17 18 19 20 21 22 23 24	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
25 26 27 28 29 30 31 32 33 34	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
35 36 37 38 39 40 41 42 43 44 45 46 47 48 49 50 51 52 53 54 55 56 57 58 59 60	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.

1	Interventions:	#11c	Strategies to improve adherence to	11-12
2				
3	adherence		intervention protocols, and any	
4				
5			procedures for monitoring adherence	
6				
7			(eg, drug tablet return; laboratory tests)	
8				
9				
10				
11	Interventions:	#11d	Relevant concomitant care and	n/a.
12				
13	concomitant care		interventions that are permitted or	This is a childhood obesity
14				prevention intervention.
15			prohibited during the trial	Based on our previous
16				experiences, it is less likely
17				that concomitant care and
18				interventions will take place.
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28	Outcomes	#12	Primary, secondary, and other	13-14, Table 3
29				
30			outcomes, including the specific	
31				
32			measurement variable (eg, systolic	
33				
34			blood pressure), analysis metric (eg,	
35				
36			change from baseline, final value, time	
37				
38			to event), method of aggregation (eg,	
39				
40			median, proportion), and time point for	
41				
42			each outcome. Explanation of the	
43				
44			clinical relevance of chosen efficacy and	
45				
46			harm outcomes is strongly	
47				
48			recommended	
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54	Participant	#13	Time schedule of enrolment,	Figure 1
55				
56	timeline		interventions (including any run-ins and	
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washouts), assessments, and visits for participants. A schematic diagram is highly recommended (see Figure)

1 2 3 4 5 6 7				
8 9 10 11 12 13 14 15 16 17 18 19	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
20 21 22 23 24 25 26 27	Recruitment	#15	Strategies for achieving adequate participant enrolment to reach target sample size	9-10
28 29 30 31 32 33 34 35 36 37 38 39 40 41 42 43 44 45 46 47 48 49	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
50 51 52 53 54 55 56 57 58 59 60	Allocation concealment mechanism	#16b	Mechanism of implementing the allocation sequence (eg, central telephone; sequentially numbered, opaque, sealed envelopes), describing	10

1		any steps to conceal the sequence until	
2			
3		interventions are assigned	
4			
5			
6	Allocation:	#16c Who will generate the allocation	9-10
7			
8	implementation	sequence, who will enrol participants,	
9			
10		and who will assign participants to	
11			
12		interventions	
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14			
15			
16	Blinding (masking)	#17a Who will be blinded after assignment to	13
17			
18		interventions (eg, trial participants, care	
19			
20		providers, outcome assessors, data	
21			
22		analysts), and how	
23			
24			
25			
26	Blinding	#17b If blinded, circumstances under which	n/a.
27			
28	(masking):	unblinding is permissible, and	The assessors measuring
29			students' height and weight will
30	emergency	procedure for revealing a participant's	be blinded to group allocation of
31			the schools. We did not
32	unblinding	allocated intervention during the trial	anticipate any necessary
33			circumstances when unblinding
34			is permissible.
35			
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40	Data collection	#18a Plans for assessment and collection of	13
41			
42	plan	outcome, baseline, and other trial data,	
43			
44		including any related processes to	
45			
46		promote data quality (eg, duplicate	
47			
48		measurements, training of assessors)	
49			
50		and a description of study instruments	
51			
52		(eg, questionnaires, laboratory tests)	
53			
54		along with their reliability and validity, if	
55			
56		known. Reference to where data	
57			
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1		collection forms can be found, if not in	
2			
3		the protocol	
4			
5			
6	Data collection	#18b Plans to promote participant retention	15
7			
8	plan: retention	and complete follow-up, including list of	
9			
10		any outcome data to be collected for	
11			
12		participants who discontinue or deviate	
13			
14		from intervention protocols	
15			
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18	Data management	#19 Plans for data entry, coding, security,	3
19			
20		and storage, including any related	
21			
22		processes to promote data quality (eg,	
23			
24		double data entry; range checks for	
25			
26		data values). Reference to where	
27			
28		details of data management procedures	
29			
30		can be found, if not in the protocol	
31			
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34	Statistics:	#20a Statistical methods for analysing	15
35			
36	outcomes	primary and secondary outcomes.	
37			
38		Reference to where other details of the	
39			
40		statistical analysis plan can be found, if	
41			
42		not in the protocol	
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46	Statistics:	#20b Methods for any additional analyses	15
47			
48	additional	(eg, subgroup and adjusted analyses)	
49			
50	analyses		
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1	Statistics: analysis	#20c	Definition of analysis population relating	15
2				
3	population and		to protocol non-adherence (eg, as	
4				
5	missing data		randomised analysis), and any	
6				
7			statistical methods to handle missing	
8				
9			data (eg, multiple imputation)	
10				
11				
12				
13	Data monitoring:	#21a	Composition of data monitoring	18
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15	formal committee		committee (DMC); summary of its role	
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17			and reporting structure; statement of	
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19			whether it is independent from the	
20				
21			sponsor and competing interests; and	
22				
23			reference to where further details about	
24				
25			its charter can be found, if not in the	
26				
27			protocol. Alternatively, an explanation of	
28				
29			why a DMC is not needed	
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34	Data monitoring:	#21b	Description of any interim analyses and	n/a.
35				
36	interim analysis		stopping guidelines, including who will	
37				
38			have access to these interim results and	This is a childhood obesity
39				prevention intervention.
40			make the final decision to terminate the	
41				Based on our previous
42			trial	
43				experiences, it is less likely
44				that discontinuing
45				interventions will take place.
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52	Harms	#22	Plans for collecting, assessing,	16 (we will use
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54			reporting, and managing solicited and	questionnaires to collect and
55				
56			spontaneously reported adverse events	
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1			and other unintended effects of trial	assess any adverse events
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3			interventions or trial conduct	or other process data)
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6	Auditing	#23	Frequency and procedures for auditing	7 (This study is one of the
7			trial conduct, if any, and whether the	five independent studies of
8			process will be independent from	the overall DECIDE project.
9				
10			investigators and the sponsor	This overall project is audited
11				by the funder (National Key
12				R&D Program of China).
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20	Research ethics	#24	Plans for seeking research ethics	2-3
21				
22	approval		committee / institutional review board	
23				
24			(REC / IRB) approval	
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27				
28	Protocol	#25	Plans for communicating important	2-3
29				
30	amendments		protocol modifications (eg, changes to	
31			eligibility criteria, outcomes, analyses)	
32			to relevant parties (eg, investigators,	
33			REC / IRBs, trial participants, trial	
34			registries, journals, regulators)	
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42	Consent or assent	#26a	Who will obtain informed consent or	10
43				
44			assent from potential trial participants or	
45			authorised surrogates, and how (see	
46			Item 32)	
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52	Consent or	#26b	Additional consent provisions for	n/a.
53				
54	assent: ancillary		collection and use of participant data	
55				This study will not collect
56				biological specimens.
57	studies			
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1		and biological specimens in ancillary	
2		studies, if applicable	
3			
4			
5			
6	Confidentiality	#27 How personal information about	3
7			
8		potential and enrolled participants will	
9			
10		be collected, shared, and maintained in	
11			
12		order to protect confidentiality before,	
13			
14		during, and after the trial	
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18	Declaration of	#28 Financial and other competing interests	26
19			
20	interests	for principal investigators for the overall	
21			
22		trial and each study site	
23			
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25	Data access	#29 Statement of who will have access to	3
26			
27		the final trial dataset, and disclosure of	
28			
29		contractual agreements that limit such	
30			
31		access for investigators	
32			
33			
34			
35	Ancillary and post	#30 Provisions, if any, for ancillary and post-	n/a.
36			
37	trial care	trial care, and for compensation to those	
38			
39		who suffer harm from trial participation	This is a childhood obesity
40			prevention intervention.
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44			Based on our experiences, it
45			
46			is less likely that ancillary
47			
48			and post-trial care will take
49			
50			place.
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53	Dissemination	#31a Plans for investigators and sponsor to	3
54			
55	policy: trial results	communicate trial results to participants,	
56			
57		healthcare professionals, the public,	
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59			
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and other relevant groups (eg, via
 publication, reporting in results
 databases, or other data sharing
 arrangements), including any
 publication restrictions

Dissemination [#31b](#) Authorship eligibility guidelines and any n/a
 policy: authorship intended use of professional writers

Dissemination [#31c](#) Plans, if any, for granting public access n/a
 policy: to the full protocol, participant-level
 reproducible dataset, and statistical code
 research

Informed consent [#32](#) Model consent form and other related 10
 materials documentation given to participants and
 authorised surrogates

Biological [#33](#) Plans for collection, laboratory n/a
 specimens evaluation, and storage of biological
 specimens for genetic or molecular This study will not collect
 analysis in the current trial and for future biological specimens.
 use in ancillary studies, if applicable

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 by the [EQUATOR Network](#) in collaboration with [Penelope.ai](#)