A multifaceted intervention to prevent obesity in primary school children:

protocol of a cluster-randomized controlled trial (the DECIDE-Children study)

Zheng Liu, Yang-Feng Wu, Wen-Yi Niu, Xiang-Xian Feng, Yi Lin, Ai-Yu Gao, Fang Zhang, Hai Fang, Pei Gao, Hui-Juan Li, Hai-Jun Wang, the study team for the DECIDE-children study[*]

[*] **The study team for 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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Background

The global prevalence of obesity among children and adolescents has increased eightfold in the last four decades.[1] The increase has recently plateaued in high-income countries, but continued to accelerate in low- and middle-income countries.[1] Childhood obesity can affect a child's physical and psychological health,[2] academic attainment,[3] and quality of life[4] and, in the longer term, heighten risks for cardio-metabolic diseases, musculoskeletal problems, and cancer.[5,6] From an economic perspective, an investment in preventing childhood obesity is cost-effective considering the lifetime health benefits and improved quality of life.[7] Since 2017, the World Health Organization (WHO) has called for all countries to take greater action to end childhood obesity.[8]

China's recent economic growth has been accompanied by a rapid increase in overweight and obesity among school-aged children and growing interest in its prevention. Earlier Chinese obesity intervention studies in school-aged children were generally poorly evaluated with unclear reporting of randomisation, non-blinding of primary outcome assessments, attrition bias, selective reporting of outcomes, and the failure to consider clustering effects.[9] Subsequent school-based obesity prevention studies in various cities across China[10-12], have had inconsistent findings possible due to the use of heterogeneous intervention packages (different combination of intervention elements). Moreover, each of these studies took place in single developed city, limiting generalisability. To date, there has been no Chinese multi-center trial of a multifaceted intervention for prevention of childhood obesity, which is the strategy most likely to bring sustained gains across the child and adolescent years.[8]

Objectives

Overall Objective:

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

Specific Objectives:

The specific objectives of the DECIDE-Children study will be

(1) to assess the effectiveness of the intervention compared with the usual practice in preventing childhood overweight and obesity;

(2) to evaluate the process of the intervention.

Design

DECIDE-Children is a cluster-randomized, parallel-group controlled trial. The intervention will be implemented for one school year from late September 2018 to June 2019. Figure 1 shows the flow of the study. The study has been registered at ClinicalTrials.gov (number NCT03665857).

Setting

To accommodate the social and economic variations within the country, we will intentionally select

schools from three different regions of China: the above average developed area in the east (Beijing), the average developed area in central China (Shanxi) and the below average developed area in the west (Xinjiang). A total of 24 primary schools (clusters) equally distributed among three regions will be selected. In Beijing, 4 schools will be selected from the Dongcheng district (located in the centre of the city), and 4 will be selected from the Mentougou district (located in a rural suburban area). In Xinjiang, all 8 schools will be selected from Urumchi, the capital city of the autonomous region; four of the schools will be selected from the Shayiba district (an urban district), and the other four schools will be selected from the Shuimogou district (a rural district). In Shanxi, all 8 schools will be selected from only one urban district, Changzhi, a small- to medium-sized city in the province. The reason for excluding rural schools in Changzhi is that most of the rural schools are boarding schools, and parents are difficult to reach in boarding schools. Thus, a total of 24 primary schools from five sites in three regions will be selected and randomized into two groups, the obesity prevention intervention group and the usual practice group.

Recruitment of Participants

Recruitment of schools

The present study will be carried out in Grade 4 students (8 to 10 years old), as they are sufficiently mature to understand health education information and are able to remain in the same school to complete the two-year study before they graduate. For a school to be eligible, the school principal must agree with the randomization procedure and comply with the study protocol. The total number of Grade 4 students must be greater than 50 in the school, and schools that have implemented or are planning to implement an obesity prevention intervention or similar intervention programme will

not be eligible. Boarding schools and specialty schools for children with talents or minority ethnic groups will be excluded. Schools will also not be included if they have a definite plan for relocation or cancellation in the next two years. For the schools participating in the programme, the size of a class will vary between fewer than 30 children and approximately 60 children per class. If the number of students in each class is less than 50, we will recruit two classes from the school, and if the number of students is greater than 50, we will recruit one class to meet the sample size requirement. If there are more classes in one school than needed for the study, the school principal will recommend which classes we should select.

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

Recruitment of children

After school recruitment, written informed consent will be provided by all children and their primary caregivers (parents in most cases) in the selected classes. Then, the parents who provide informed consent will be required to complete a questionnaire about the health status of their children. The project staff will collect the questionnaires and if a parent reports one of the following conditions, his or her child will be excluded:

1) medical history of heart disease, hypertension, diabetes, tuberculosis, asthma, hepatitis or nephritis;

2) obesity caused by endocrine diseases or side effects of drugs;

3) abnormal physical development like dwarfism or gigantism;

4) physical deformity such as severe scoliosis, pectus carinatum, limp, obvious O-leg or X-leg;

5) inability to participate in school sport activities;

6) a loss in weight by vomiting or taking drugs during the past three months.

Randomization

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

Intervention

We used the Social Ecological Model to identify intervention elements in this multifaceted health promotion programme[13]. As shown in Figure 2, the programme will target the influencing factors of childhood obesity at both individual (child-focused activities) and environmental levels (a supportive family and school environment), with the intent to influence the knowledge, attitude and

behaviours of school children.

Description of the intervention components

The intervention components are described in Tables 1 and 2.

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

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

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

The smartphone app: Project staff, school teachers and parents will be suggested to install the app titled "Eat Wisely, Move Happily". The app, which was developed based on behaviour change techniques[14], will aid in information diffusion, behaviour monitoring, weight management, assessment and feedback.

Quality control of the intervention

Two manuals ("An Operation Manual for Project Staff Involved in the Multi-component Obesity Intervention among Primary School Students" and "An Operation Manual for School Team Members Involved in the Multi-component Obesity Intervention among Primary School Students") have been developed for implementing and managing this complex intervention. The manuals describe in detail the duties of project staff and school team members (school principals, class

teachers, physical education teachers, school doctors/health care teachers) in delivering the intervention. The manuals also describe the detailed workflow of the implementation of each intervention component, i.e., by whom, when, how, and to what extent the specific intervention element should be delivered. All of the project staff and school team members will be required to conduct the intervention in accordance with the operation manuals.

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

Control

The twelve schools in the control group will not carry out any of the DECIDE-Children intervention components and will continue their usual practice according to their own teaching curriculum during the study period. Participants in the control group will receive the same health education materials that will have been delivered to those in the intervention group immediately after the trial ends.

Outcomes

Primary outcome

The primary outcome is the difference between groups in the change in children's body mass index (BMI=weight (kg)/(height (m))^2) immediately after the intervention completion (9 months after the baseline measurements are conducted).

Secondary outcomes

The secondary outcomes include the following indices between groups at the 4-month and 9-month follow-up investigations: 1) change in BMI z-score (standard deviation score will be calculated based on the WHO criteria[15]); 2) change in prevalence and incidence of overweight/obesity defined according to the criteria for Chinese children and adolescents[16]; 3) change in waist circumference, waist-to-hip circumference ratio and systolic and diastolic blood pressures; and 4) change in body fat percentage, physical fitness measures, behavioural outcomes (including screen time, duration of moderate-to-vigorous physical activity, eating behaviour and sedentary behaviour) and other outcomes (including knowledge related to energy balance and stage of readiness for behaviour change related to weight management).

Outcome evaluation

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

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

measures (one-minute rope jumping, one-minute sit-up, long standing jump, shuttle run (50 m×8)) will be collected by the trained outcome assessors using the same device and/or forms according to the standard methods and procedures. The assessors measuring children's height and weight will be blinded to the group allocation of the schools. We will use questionnaires to measure children's behaviours (duration of moderate-to-vigorous physical activity, eating behaviour, sedentary behaviour), and other potential moderators/mediators of the intervention (e.g., stage of readiness for behaviour change related to weight management). The questionnaires were developed based on previous studies and the pilot study. The questionnaires were found to be feasible for this study and acceptable to children and their parents.

Sample size estimation

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

Statistical analyses

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

the school and individual levels will be reported by using descriptive statistics.

The primary analysis will be based on the intention-to-treat principle and include all children recruited with the baseline BMIs measured. Generalized linear mixed models will be used to compare the primary and secondary outcomes at 4 and 9 months after the baseline measurements are conducted, and the models will adjust for the clustering effect and baseline outcome values. The missing data will be treated in the maximum likelihood estimates assuming they are missing at random. The intra-cluster correlation coefficient will also be estimated. Sensitivity analysis will be performed on the primary outcome using the last-value-carry-forward imputation if the percentage of missing data exceeds 5%. For continuous outcomes, we will report pre-, and post-intervention means for the intervention and control groups and model-adjusted mean differences between groups. For binary outcomes, we will report pre- and post-intervention percentages for the intervention and control groups and adjusted odds ratios (ORs) between groups. The 95% confidence intervals (CIs) and associated *P*-values will be calculated. We will also examine whether the differences in the outcomes between the control and intervention groups vary by the three regions (Beijing, Shanxi, Xinjiang), the sex of children, socioeconomic status (mother's education), BMI status at baseline (overweight or obese, not overweight or obese), and primary caregivers of the children (parents compared with non-parents).

Process evaluation

Based on the steps and principles described in the conceptual framework by Saunders et al.,[17] we will identify the process evaluation elements including fidelity (the extent to which the intervention

will be implemented as initially planned), dose delivered (the frequency and intensity of the actual implementation of the programme), dose received (the extent to which children/primary caregivers (parents in most cases)/teachers will be exposed to the intervention, as well as the degree of their satisfaction with the intervention and materials), reach (the proportions and the characteristics of children/primary caregivers/teachers completing or dropping out of the intervention) and context (family environment and school policies related to obesity prevention and management).

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

Ethical consideration

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

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

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

	(described below); 2) Weekly monitoring Children's weight will be monitored weekly by the children themselves in the classroom.	monthly monitoring); The trained project staff (for data input of monthly monitoring) Children (for weekly monitoring)
2. Activities towards parents (providing a supportive family environment)		
Health education activities for parents	1) Frequency and duration At least one activity (lasting for approximately 40-60 minutes) will be held at the beginning of each semester. One more activity will be held in the middle of the first semester. Another activity will also be held in the middle of the second semester if necessary (for example, if the fidelity of the data is unsatisfactory). 2) Contents ➢ For the first activity Key messages will be similar to those for the health education activities for children (described above). Parents will also be taught to use the smartphone app. ➢ For other activities Project staff will provide feedback about children's 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 children's physical activity outside school	1) Parents will be instructed to encourage children 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) Children will be encouraged to participate in sports games outside of school that will be taught by their physical education teachers during extracurricular activities.	Parents
3. Activities towards schools (providing a supportive school environment)		

School policies related to obesity prevention	The following school policies will be suggested: 1) "Not selling": Not selling unhealthy snacks or sugar-sweetened beverages within school; 2) "Not eating": Telling students not to eat unhealthy snacks or drink sugar-sweetened beverages at school; 3) "Not buying": Children being educated by class teachers not to buy unhealthy snacks or sugar-sweetened beverages around school.	The trained school principal; The trained class teachers
Health education activities for school teachers	1) Frequency and duration 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. 2) Content Key messages will be similar to those for the health education activities for children (described above). School teachers will also be taught to use the smartphone app.	The trained project staff
4. A smartphone app assisted in implementation of the intervention		
The smartphone app ("Eat Wisely, Move Happily")	1) Information diffusion (the behaviour change technique (BCT) used: providing information on consequences of behaviours) The smartphone app will provide information to parents, class teachers and project staff in accordance with the health education activities. 2) Behaviour monitoring (the BCT used: prompting the self-monitoring of behaviours) Parents together with their children will be asked to record the diet and physical activity behaviours of students in the app weekly, and then they will receive individualized feedback related to these behaviours (described in Table	The smartphone app (installed by parents, school teachers and project staff) and the computer management system (utilized by project staff)

	2).	
	3) Weight management (the BCT used: prompting self-monitoring)	
	According to the monthly monitoring of children's weight and height (described above), parents, school teachers and project staff will view the recent weight status (categorized according to the BMI percentile criteria), changes compared with previous records of the children and the individualized feedback related to weight management (described in Table 2).	
	4) Assessment and feedback (the BCT used: providing feedback on performance)	
	The smartphone app will also provide a synthetic and individualized assessment that will combine changes in the behaviours and weight status of the children. The four kinds of feedback are shown in Table 2.	

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 in the DECIDE-Children study

Measurements	Time points			Instrument	Number of measures at each time point	Method of assessment	Outcome variables
	Baseline	4 months	9 months				
Adiposity							
Height	Yes	Yes	Yes	Stadiometer (Huateng GMCS-1)	Twice (third measure if difference > 0.5 cm)[1]	Measured to the nearest 0.1 cm	BMI, BMI Z-score (together with children's sex and date of birth) [1], prevalence of overweight or obesity, prevalence of obesity, incidence of overweight or obesity, incidence of obesity, remission of overweight or obesity, remission of obesity (BMI status was defined according to both Chinese national screening criteria [2] and WHO criteria [1])
Weight	Yes	Yes	Yes	Lever scale (Wujin RGT-140)	Twice (third measure if difference > 0.1 kg) [2]	Measured to the nearest 0.1 kg	
Body fat percentage	Yes	No	Yes	Body component instrument (Tanita MC-780 MA)	Once	According to instructions of the instrument	Body fat percentage
Waist circumference	Yes	Yes	Yes	Tape (MyoTape)	Twice (third measure if difference > 1.0 cm) [3]	Measured to the nearest 0.1 cm	Waist circumference, waist-to-hip ratio

Hip circumference	Yes	Yes	Yes	Tape (MyoTape)	Twice (third measure if difference > 1.0 cm) [3]	Measured to the nearest 0.1 cm	

Physical activity and dietary behaviors

Stage of behavior change for weight management	Yes	No	Yes	The validated items measuring stages (in the action stage versus in the pre-action stage) of behavior change for the purpose of weight management [9]	Once		Percentage of children in the action stage of behavior change for weight management (children actually being initiated come behavioral change, in comparison with those in the pre-contemplation (i.e., not thinking about becoming engaged in the behavior change) or contemplation (i.e., not involved in the behavior change but was considering getting involved in the behavior in the near future) stage)
Screen viewing behavior	Yes	No	Yes	An updated version of a previously validated screen viewing questionnaire [5]	Once	Children finished the questionnaires in the classroom in the presence of the trained outcome assessors who can provide guidance and help.	Time spent on screen viewing [6]
Physical activity	Yes	No	Yes	An updated version of a previously validated Youth Risk Behavior Survey questionnaire [3]	Once		Number of days performing moderate-to-vigorous physical activity ≥1 hour per week (this cut-off was defined based on "Global Recommendations on Physical Activity for Health" [4])

Eating behavior	Yes	No	Yes	An updated version of a previously validated Block Kids Food Screener questionnaire [7]; previously validated Children Eating Behavior Questionnaire [8]	Once		Percentage of children who did not drink sugar-sweetened beverages, percentage of children who did not eat high-energy food (fried food, western fast food), excessive eating behavior (scores of satiety responsiveness, scores of emotional over-eating scores)
Obesity-related knowledge							
Obesity-related knowledge	Yes	No	Yes	Items designed based on the key messages of health education activities [4]	Once	Children finished the questionnaires in the classroom in the presence of the trained outcome assessors who can provide guidance and help.	Scores of obesity-related knowledge
Physical fitness							
One-minute rope jump	Yes	No	Yes	Not applicable	Once	Measured to unit of number	Number of rope jumps within one minute
One-minute sit-up	Yes	No	Yes	Not applicable	Once	Measured to unit of number	Number of sit-ups within one minute
Long standing jump	Yes	No	Yes	Not applicable	Third [5]	Measured to the nearest 1 cm	Distance of long standing jump

Shuttle run (50 m ×8)	Yes	No	Yes	Not applicable	Once	Measured to the nearest 0.1 s	Duration of shuttle run (50 m×8)
Blood pressure							
Systolic and diastolic blood pressures	Yes	Yes	Yes	Electronic sphygmomanometer (Omron HBP-1300)	Twice (third measure if difference >5 mmHg)[6]	Measured to the nearest 1 mmHg	Systolic blood pressure, diastolic blood pressure

1 Where two values were ≤ 0.5 cm, a definitive measurement value was calculated as the average of the two. For individuals with three values recorded, a definitive measurement value was calculated as average of the closest pair or average of all three readings (if there were no two closest readings). 2 Where two values were ≤ 0.1 kg, a definitive measurement value was calculated as the average of the two. For individuals with three values recorded, a definitive measurement value was calculated as average of the closest pair or average of all three readings (if there were no two closest readings). 3 Where two values were ≤ 1.0 cm, a definitive measurement value was calculated as the average of the two. For individuals with three values recorded, a definitive measurement value was calculated as average of the closest pair or average of all three readings (if there were no two closest readings). 4 For example, children were asked "*Is it correct that drinking sugar-sweetened beverage cannot substitute drinking water*?" and three choices were provided (*"correct"; "wrong"; "unknown"*). Children who chose "correct" would be given 1 score, and those choosing "wrong" or "unknown" would be given 0 score. 5 A definitive measurement value was obtained from the maximum of the three measurements. 6 Where two values were ≤ 5 mmHg, a definitive measurement value was calculated as the average of the two. For individuals with three values recorded, a definitive measurement value was calculated as average of the closest pair or average of all three readings (if there were no two closest readings).
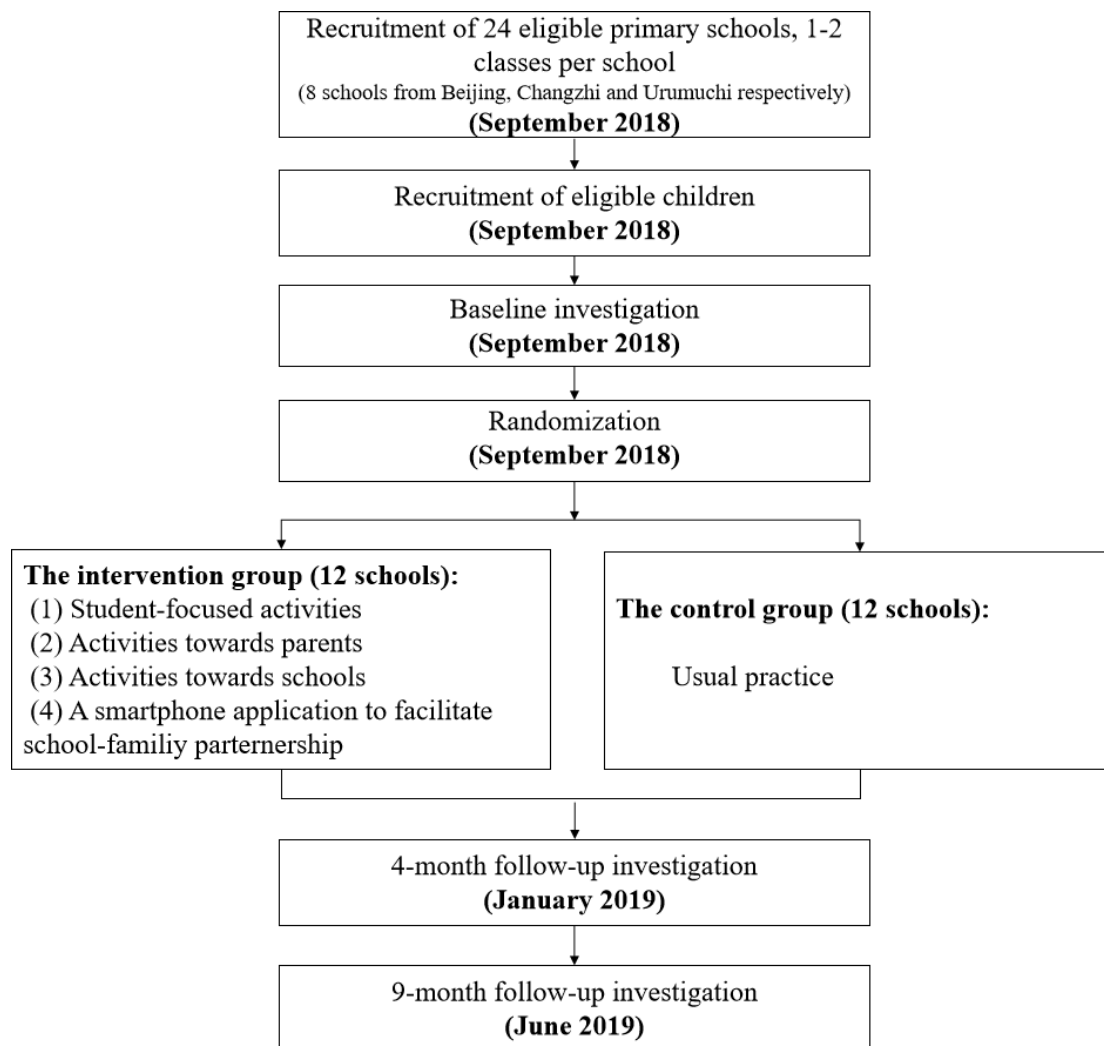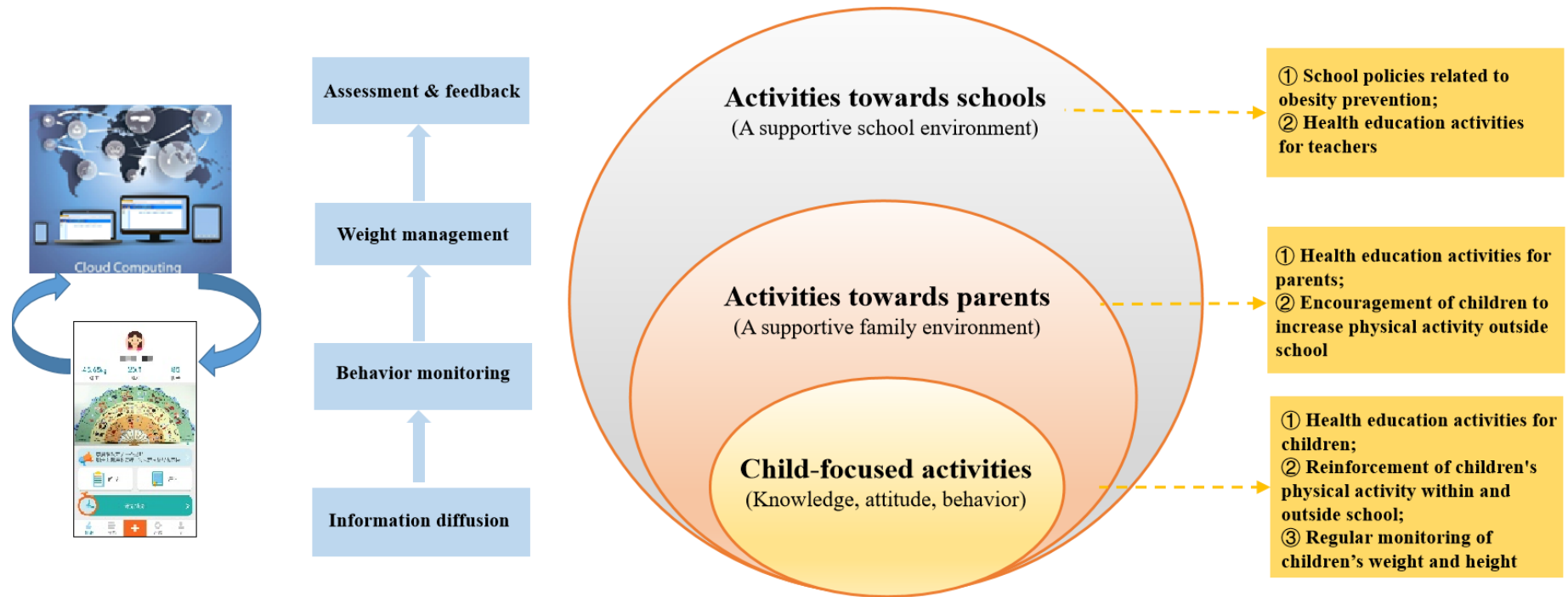
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┌─────────────────────────────────────────────────┐
│     Recruitment of 24 eligible primary schools, 1-2│
│                  classes per school                 │
│  (8 schools from Beijing, Changzhi and Urumuchi respectively)│
│                 (September 2018)                    │
└─────────────────────────────────────────────────┘
                         │
                         ▼
┌─────────────────────────────────────────────────┐
│          Recruitment of eligible children           │
│                 (September 2018)                    │
└─────────────────────────────────────────────────┘
                         │
                         ▼
┌─────────────────────────────────────────────────┐
│              Baseline investigation                 │
│                 (September 2018)                    │
└─────────────────────────────────────────────────┘
                         │
                         ▼
┌─────────────────────────────────────────────────┐
│                  Randomization                      │
│                 (September 2018)                    │
└─────────────────────────────────────────────────┘
```

The intervention group (12 schools):
(1) Student-focused activities
(2) Activities towards parents
(3) Activities towards schools
(4) A smartphone application to facilitate school-familiy parternership

The control group (12 schools):

Usual practice

```
┌─────────────────────────────────────────────────┐
│         4-month follow-up investigation             │
│                 (January 2019)                      │
└─────────────────────────────────────────────────┘
                         │
                         ▼
┌─────────────────────────────────────────────────┐
│         9-month follow-up investigation             │
│                  (June 2019)                        │
└─────────────────────────────────────────────────┘
```

Figure 1 Study flow

Figure 2 The social ecological model as applied to the DECIDE-Children study