The Diet, ExerCIse and CarDiovascular hEalth study (DECIDE) study for children: DECIDE-Children

STATISTICAL ANALYSIS PLAN

Version 3

2018/07/0

Contents

1 Study objective

To assess the effectiveness of a multifaceted intervention to prevent obesity among Grade 4 primary school children (8-10 years old) in China.

2 Study design

This is a cluster randomized clinical trial with 24 schools among approximately 1200 children from 5 study sites selected from 3 regions across China.

3 Study period and settings

- Study period: September 2018~June 2019
- Study settings: A total of 24 schools from 5 study sites in Beijing, Changzhi of Shanxi province, and Urumuqi of Xinjiang province in China.

4 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). Randomisation will be performed by an independent person at the central coordinating centre at Peking University Clinical Research Institute. The randomisation will take place only after the baseline measurements are completed to ensure allocation concealment.

5 Intervention

Multifaceted health promotion programme was designed and will be used as the intervention. Detailed description of the intervention was provided in the study protocol.

6 Outcomes

6.1 Primary outcome

The primary outcome is defined as the between-group difference in children's change of body mass index (BMI) from baseline to 9 months (immediately after the intervention completion), where BMI (kg/m^2) = weight (kg)/(height $(m)^2$.

6.2 Secondary outcomes

(1) The outcomes between groups at 4 and 9 months:

- Change in BMI Z-score[1]
- Change in prevalence and incidence of overweight/obesity[2]
- Change in waist circumference (cm)
- Change in waist-to-hip circumference ratio
- Change in systolic blood pressures (mmHg)
- Change in diastolic blood pressures (mmHg)

(2) The outcomes between groups at 9 months:

- Change in body fat percentage
- Change in physical fitness measures, including number of rope jumps within one minute, duration of shuttle run (50 m × 8, unit: s), distance of long standing jump, and number of sit-ups within one minute.

- Change in screen time
- Change in moderate-to-vigorous-intensity physical activity
- Change in dietary behaviours[3]
- Change in knowledge related to energy balance
- Change in stage of readiness for behaviour change related to weight management[4]

7 Methods

7.1 Sample size calculation

We assumed that the between-group difference in the change of BMI from baseline to 9 months would be 0.50 kg/m^2, standard deviation (SD) of the BMI would be 1.40 kg/m^2, the intra-cluster correlation coefficient would be 0.05 and the attrition rate would be 10%[5]. We estimated that a total of 1200 students from 24 schools with an average cluster size of 50 students per school would provide 88% power with α=0.05 to detect the assumed difference between the intervention and control groups.

7.2 Analysis set

The primary analysis will be based on the intention-to-treat principle and will include all children recruited with the baseline BMIs measured. If the percentage of missing data exceeds 5%, sensitivity analysis will be performed on the primary outcome using the last-value-carry-forward imputation.

7.3 Statistical models

A mixed-effect model will be used, with adjustment for the school-clustering effect

(the random effect).

Using BMI as an example, the model was shown as below:

$$Y_{ij} = \beta_0 + b_i + \beta_1 Group + \beta_2 BMI_{baseline} + \beta_3 Age_{baseline} + \beta_4 Sex + \varepsilon_{ij},$$

$$i = 1, 2, \dots, 24, \quad j = 1, 2, \dots, n_i, \quad b_i \sim N(0, \sigma_b^2), \ \varepsilon_{ij} \sim N(0, \sigma^2)$$

where Y_{ij} is the change in BMI from baseline to 9 months (BMI at 9 months – BMI at baseline) for observation j on school i, β_0 is the mean BMI across the population of schools being sampled, b_i is a random variable representing the deviation from the population mean of the mean BMI for the ith school, and ε_{ij} is a random variable representing the deviation in BMI for observation j on school i from the mean BMI for school i. $Group$ represents the group allocation (i.e., 1=intervention and 0=control), and β_1 is the effect of interest.

7.4 Estimation of intra-cluster correlation coefficient

We will estimate the intra-cluster correlation coefficient for the primary outcome to compare the between-cluster variance as a fraction of the total variance (intra-cluster correlation coefficient = (between-cluster variance)/(between-cluster variance + within-cluster variance)).

7.5 Subgroup analysis

We will examine whether the primary outcome varies by region (Beijing, Changzhi of Shanxi province, Urumuqi of Xinjiang province), sex of children (boy, girl), maternal education (high school or below, above high school), BMI status at baseline (overweight/obese, not overweight/obese), and primary caregivers of the children (parents, non-parents).

8 Statistical software

Statistical analyses will be performed using SAS version 9.4 (SAS Institute Inc., Cary, NC, USA).

9 Proposed main tables

(1) Table 1 will describe baseline characteristics of schools and children participating in the DECIDE-Children study, including

- Number of schools and children, overall and by trial arm
- Median (range) number of children per school
- Number of children in three regions, overall and by trial arm
- Sex-specific number of children, overall and by trial arm
- Number of children whose primary caregivers were parents or non-parents, overall and by trial arm
- Number of children in varying levels of maternal education, overall and by trial arm
- Mean and SD of age, height, weight, BMI, and BMI Z-score

The mocked table 1 is shown below:

Mock Table 1 The baseline characteristics of schools and children participating in the DECIDE-Children study, overall and by trial arm

	All	**Intervention group**	**Control group**
Cluster level			
Number of schools	xx	xx	xx
Median (range) number of children/school	xx (xx-xx)	xx (xx-xx)	xx (xx-xx)
Individual level			

Number of children	xxxx	xxx	xxx
Region, n (%)			
Beijing	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)
Shanxi	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)
Xinjiang	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)
Sex, n (%)			
Male	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)
Female	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)
Primary caregiver, n (%)			
Parents	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)
Non-parents	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)
Maternal education, n (%)			
High school or below	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)
Above high school	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)
Mean age (SD), year	x.x (x.x)	x.x (x.x)	x.x (x.x)
Mean height (SD), cm	xxx.x (x.x)	xxx.x (x.x)	xxx.x (x.x)
Mean weight (SD), kg	xx.x (x.x)	xx.x (x.x)	xx.x (x.x)
Mean BMI (SD), kg/m^2	xx.x (x.x)	xx.x (x.x)	xx.x (x.x)
Mean BMI Z-score (SD)	x.x (x.x)	x.x (x.x)	x.x (x.x)

Abbreviations: BMI=body mass index; SD=standard deviation.

(2) Table 2 will show intervention effects in the DECIDE-Children study

- For continuous outcomes, we will report pre/post-intervention means for the intervention and control groups, adjusted differences between groups, and the associated *P* values.
- For binary outcomes, we will report pre/post-intervention percentages for the intervention and control groups and adjusted odds ratios (ORs) between groups, 95% confidence intervals (CIs), and the associated *P* values.
- The mocked table is shown below:

Mocked Table 2 Intervention effects in the DECIDE-Children study

Outcomes	N*	Intervention		Control		Main comparison between groups (intervention- control)	
		Mean (SD)/n (%) at baseline	Mean (SD)/n (%) at 4/9 months	Mean (SD)/n (%) at baseline	Mean (SD)/n (%) at 4/9 months	Adjusted mean difference/ OR (95% CI)	*P* value
Adiposity							
BMI	xxx/xxx	xx.x (x.x)	xx.x (x.x)	xx.x (x.x)	xx.x (x.x)	x.xx (x.xx, x.xx)	x.xxx
BMI Z-score	xxx/xxx	x.x (x.x)	x.x (x.x)	x.x (x.x)	x.x (x.x)	x.xx (x.xx, x.xx)	x.xxx
Obese	xxx/xxx	xxx (xx.x%)	xxx (xx.x%)	xxx (xx.x%)	xxx (xx.x%)	x.xx (x.xx, x.xx)	x.xxx
Overweight or obese	xxx/xxx	xxx (xx.x%)	xxx (xx.x%)	xxx (xx.x%)	xxx (xx.x%)	x.xx (x.xx, x.xx)	x.xxx
Body fat percentage	xxx/xxx	xx.xx (xx.xx)	xx.xx (xx.xx)	xx.xx (xx.xx)	xx.xx (xx.xx)	x.xx (x.xx, x.xx)	x.xxx
Waist circumference, cm	xxx/xxx	xx.x (x.x)	xx.x (x.x)	xx.x (x.x)	xx.x (x.x)	x.xx (x.xx, x.xx)	x.xxx
Waist-to-hip ratio	xxx/xxx	x.xx (x.xx)	x.xx (x.xx)	x.xx (x.xx)	x.xx (x.xx)	x.xx (x.xx, x.xx)	x.xxx
Physical activity and dietary behaviours							
In the action stage of behaviour change	xxx/xxx	xxx (xx.x%)	xxx (xx.x%)	xxx (xx.x%)	xxx (xx.x%)	x.xx (x.xx, x.xx)	x.xxx
screen time<2 hours/day	xxx/xxx	xxx (xx.x%)	xxx (xx.x%)	xxx (xx.x%)	xxx (xx.x%)	x.xx (x.xx, x.xx)	x.xxx
Days performing MVPA ≥1 hour per week, days	xxx/xxx	x.x (x.x)	x.x (x.x)	x.x (x.x)	x.x (x.x)	x.xx (x.xx, x.xx)	x.xxx
Not drinking sugar-sweetened beverages	xxx/xxx	xxx (xx.x%)	xxx (xx.x%)	xxx (xx.x%)	xxx (xx.x%)	x.xx (x.xx, x.xx)	x.xxx
Not eating fried food	xxx/xxx	xxx (xx.x%)	xxx (xx.x%)	xxx (xx.x%)	xxx (xx.x%)	x.xx (x.xx, x.xx)	x.xxx
Not eating western fast food	xxx/xxx	xxx (xx.x%)	xxx (xx.x%)	xxx (xx.x%)	xxx (xx.x%)	x.xx (x.xx, x.xx)	x.xxx
Emotional over-eating, score	xxx/xxx	x.x (x.x)	x.x (x.x)	x.x (x.x)	x.x (x.x)	x.xx (x.xx, x.xx)	x.xxx
Satiety responsiveness, score	xxx/xxx	xx.x (x.x)	xx.x (x.x)	xx.x (x.x)	xx.x (x.x)	x.xx (x.xx, x.xx)	x.xxx
Obesity-related knowledge							
Obesity-related knowledge, score	xxx/xxx	x.x (x.x)	x.x (x.x)	x.x (x.x)	x.x (x.x)	x.xx (x.xx, x.xx)	x.xxx
Physical fitness							
Number of rope jumps within one minute	xxx/xxx	xxx.x (xx.x)	xxx.x (xx.x)	xxx.x (xx.x)	xxx.x (xx.x)	xx.xx (xx.xx, xx.xx)	x.xxx

Duration of shuttle run (50 m × 8), s	xxx/xxx	xxx.x (xx.x)	xxx.x (xx.x)	xxx.x (xx.x)	xxx.x (xx.x)	xx.xx (xx.xx, xx.xx)	x.xxx
Distance of long standing jump, cm	xxx/xxx	xxx.x (xx.x)	xxx.x (xx.x)	xxx.x (xx.x)	xxx.x (xx.x)	x.xx (x.xx, x.xx)	x.xxx
Number of sit-ups within one minute, s	xxx/xxx	xx.x (x.x)	xx.x (x.x)	xx.x (x.x)	xx.x (x.x)	x.xx (x.xx, x.xx)	x.xxx
Blood pressure							
SBP, mmHg	xxx/xxx	xxx.x (xx.x)	xxx.x (xx.x)	xxx.x (xx.x)	xxx.x (xx.x)	x.xx (x.xx, x.xx)	x.xxx
DBP, mmHg	xxx/xxx	xx.x (x.x)	xx.x (x.x)	xx.x (x.x)	xx.x (x.x)	x.xx (x.xx, x.xx)	x.xxx

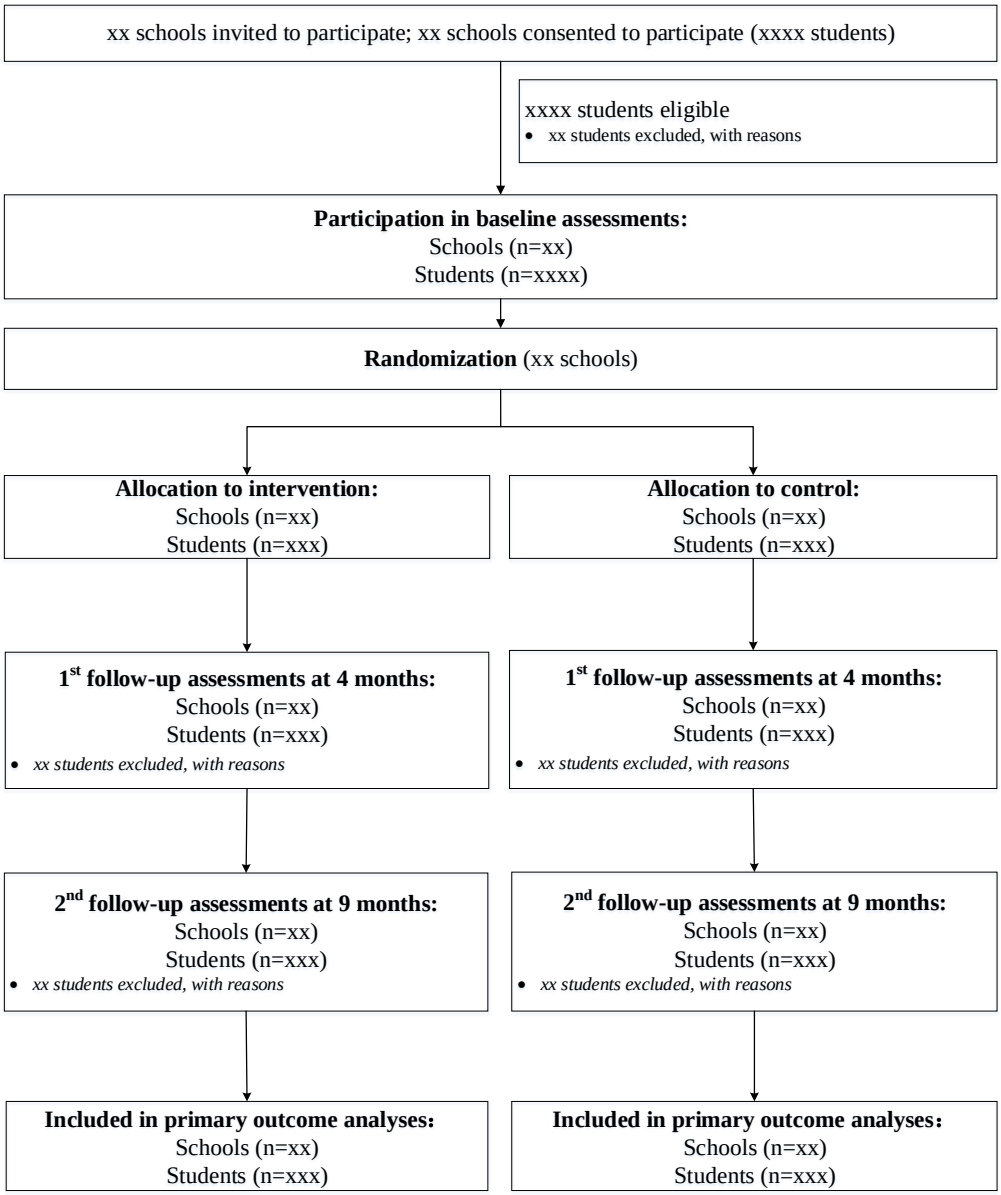
[*] The number before "/" refers to that of the intervention group, and the number after "/" refers to that of the control group.

Abbreviations: BMI=body mass index; CI=confidence interval; DBP=diastolic blood pressure; MVPA=moderate-to-vigorous physical activity; OR=odds ratio; SBP=Systolic blood pressure; SD=standard deviation.

10 Proposed main figures

(1) Figure 1 will show trial profile of the DECIDE-Children study according to the CONSORT guidelines, including enrolment, allocation, follow-up, and analysis phases of this cluster-randomized controlled trial of the intervention and control groups.

The mocked figure 1 is shown below:



Mocked Figure 1 Trial profile of the DECIDE-Children study

(2) Figure 2 will show results of subgroup analyses for the primary outcome.

- Forest plots will be used to show the subgroup analyses of the primary outcome.
- Number of children, adjusted mean difference (95% CI), and *P* values for interaction by different subgroups will be reported.

Reference

1 de Onis M, Onyango A, Borghi E. Development of a who growth reference for school- aged children and adolescents. Bull World Health Organ 2007;85:660–7.

2 National Health Commission of the People's Republic of China. Screening for overweight and obesity among school-age children and adolescents (WS/T 586-2018). Beijing, China; 2018.

3 Wardle J, Guthrie CA, Sanderson S, et al. Development of the children's eating behaviour questionnaire. J Child Psychol & Psychiat 2001;42:963–70.

4 Prochaska J, Di Clemente C, Norcross H. In search of how people change: applications to addictive behavior. Am Psychol 1992;47:1102–14.

5 Liu Z, Li Q, Maddison R, et al. A school-based comprehensive intervention for childhood obesity in China: a cluster randomized controlled trial. Child Obes 2019; 15: 105–15.