Effectiveness of School-Based Time-Restricted Eating for the Prevention and Control of Obesity in Children: A Cluster-Randomized Controlled Trial

(SCHOOL-TRE)

Study Protocol

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Contents

1. Summary

Title	Effectiveness of School-Based Time-Restricted Eating for the Prevention and Control of Obesity in Children: A Cluster-Randomized Controlled Trial
Background	The prevalence of childhood obesity in China has risen from 0.1% in 1985 to 7.3% in 2024. It does not only affect children's physical and mental health during childhood but also persist into adulthood, significantly increasing the risk of cardiovascular disease (CVD). Therefore, effective prevention and control of childhood obesity can shift the prevention window forward and promote the prevention of CVD. Childhood obesity is highly prevalent between 7 and 12 years of age, when children are spending half their time at school and exhibiting strong behavioral plasticity, making this a critical period for prevention and control of this debilitating disorder. Previous trials have demonstrated that comprehensive school-based interventions (primarily including reducing overeating, high-energy diets, and sedentary behavior, while increasing physical activity) can significantly reduce BMI and childhood obesity prevalence, but their feasibility is limited. Recently, time-restricted eating (TRE) has gained attention in adult studies for its feasibility, as it involves “time control without calorie restriction,” demonstrating weight loss effects comparable to energy restriction and higher feasibility. Therefore, we hypothesize that a 12-hour TRE program implemented in schools may enhance the prevention and control of childhood obesity, but there is currently a lack of empirical evidence, particularly regarding its preventive effects on childhood obesity.
Objectives	The overall objective of this study is to test the effectiveness of 12-hour TRE on the prevention and control of childhood obesity in school-aged children. The secondary objective is to test its long-term weight-controlling effect in children.
Study Design	The SCHOOL-TRE study is a school-based cluster randomized controlled trial designed to investigate the effectiveness of 12-hour TRE in the prevention and control of obesity in children. Schools were randomly

assigned to either the intervention group or the control group, and participants were recruited from each school at the class level, ensuring that each group included at least 690 children (8-10 years old). The control group received routine health education, while the intervention group received 12-hour TRE in addition to routine health education. The primary effect of TRE will be evaluated after a 9-month intervention period (one academic year) by comparing the magnitude of BMI-Z reduction from baseline between the two groups. Then, the intervention will be stopped, but the follow-up will be extended to one additional academic year to test its long-term effects.

Study Subjects

Eligibility criteria for schools:

- ☑ The principal agrees to accept the randomization process and adhere to the study protocol.
- ☑ The total number of fourth-year students in the school must be over 50.
- ☑ Schools that have not implemented or plan to implement obesity prevention interventions.
- ☑ Non-boarding schools, Ethnic minority schools, or specialty schools.
- ☑ Schools that have no clear plans to relocate or close within the next 2 years.

Eligibility criteria for classes:

- ☑ Class teachers are willing and actively involved in home-school liaison.
- ☑ Class sizes should be between 30 and 60 students.
- ☑ The class consists of fourth-grade students.
- ☑ There is at least one student with childhood obesity.
- ☑ Classes that have no clear plan to be merged or canceled in the next 2 years.

Exclusion criteria for students:

All students in the classes selected will be the subjects of the study after signing the informed consents, unless they have the following conditions:

	☒ Students with a history of heart disease, hypertension, diabetes, tuberculosis, asthma, hepatitis, or nephritis. ☒ Students with secondary obesity due to endocrine disorders or side effects of medications. ☒ Students with abnormal growth development, such as dwarfism, gigantism, etc. ☒ Students with physical deformities, including severe scoliosis, chicken breasts, claudication, and significant O-leg/X-shaped legs. ☒ Students with limited athletic ability or an inability to participate in physical activities. ☒ Students who have lost weight by inducing vomiting or taking medications in the past 3 months. ☒ Students who have undergone bariatric surgery. ☒ Students with mental disorders, intellectual developmental disabilities, or aphasia. ☒ Students who have taken medications that affect appetite or weight within three months (e.g., antipsychotics, hypnotics, weight loss medications, insulin). ☒ Students who plan to transfer in the next 2 years.
Interventions	**Interventions for the control group:** The current standard health education programs will be adopted according to the Chinese guidelines for health education in primary and secondary schools. **Interventions for the experimental group:** In addition to the standard health education programs, the subjects in the experimental group will also receive training in 12-hour TRE. The core contents of 12-hour TRE include (1) the eating time window is limited to 12 hours/day, (2) the last meal is no later than 19:00, (3) the subjects can freely choose the eating time window, (4) the subjects do not restrict energy intake

	during eating window, and (5) the subjects are allowed to drink non-calorie, sugar-free drinks (water, tea, coffee) during the fasting period.
Outcomes	The short-term outcome is the magnitude of weight loss after one academic year (9 months) of intervention, and then the intervention will be stopped, but the follow-up will be extended to one additional academic year (21 months) to test its long-term effects on obesity prevention. **Primary outcome:** Change in BMI-Z score from baseline to the end of 9 months of intervention **Secondary outcome:** • Change in BMI-Z score from baseline to the end of 21 months after intervention • Change in the prevalence of overweight or obesity • Weight attainment (BMI-Z<2) rate • Change in blood pressure • Change in waist-to-hip ratio • Change in quality of life • Change in eating behavior • Change in physical activity
Sample Size	The DECIDE-Children study demonstrated that a comprehensive school-based intervention reduced BMI-Z values by an additional 0.2. Our TRECO study showed a reduction of 0.3 in BMI-Z values, with an SD of 0.6, after 12 weeks of the TRE intervention in obese children. Based on these results, we assumed that the difference in BMI-Z values between the two groups after the intervention would be 0.2 (SD = 0.6). We therefore planned to include 690 students from six schools in each group, with an average of 115 students per school. This was calculated using a two-sided test at a level of significance of $\alpha = 0.05$, with 80% statistical power ($1 - \beta = 0.8$), an intra-group correlation coefficient (ICC) of 0.025, and a 10% loss to follow-up rate.

Statistical Analysis	This study will be analyzed on an intent-to-order basis. A generalized linear mixed-effects model was used to correct for cluster effect, i.e., class and school as random effects, for comparison of baseline characteristics of study subjects between groups. Subgroup analyses will be used to test for the presence of effector modifications. All tests were performed by bilateral test, and the P-value <0.05 indicated statistical differences, and all statistical analyses were performed using SAS 9.4 statistical software.

2. Background

With the rapid socio-economic development and the great transformation of residents' lifestyles, overweight and obesity are increasingly prevalent in children all over the world, particularly in China [1]. There are currently nearly 34 million school-age children who are overweight or obese in China, accounting for an estimated prevalence of 20% [2]. Moreover, childhood obesity is an important and modifiable risk factor for cardiovascular and metabolic diseases, and about 80% of childhood obesity persists into adulthood, significantly increasing the risk of chronic diseases, diabetes, and cardiovascular diseases in particular [3]. In addition, childhood obesity is highly prevalent between 7 and 12 years, when children spend half of their time at school and their behavior is highly malleable. Therefore, prevention and control of childhood obesity at school may be one of the main strategies for advancing the window of opportunity for chronic disease prevention and control.

Several studies have confirmed that school-based interventions such as dietary and health education programs have a positive effect on the prevention and control of childhood obesity. For example, a cluster-randomized controlled trial involving 1,392 school-aged children aged 8–10 years found that a one-year multidimensional comprehensive intervention (including systematic health education, enhanced physical activity programs within schools, and regular BMI monitoring with personalized feedback) resulted in a 27.0% reduction in the prevalence of obesity in the intervention group. This improvement was significantly greater than the 5.6% decrease observed in the control group [4]. Similarly, the U.S. “Healthy Schools Program” reduced the annual increase in BMI-z scores among students in intervention schools by 0.15 (95% CI: -0.21 to -0.09) by restricting the supply of sugary beverages [5]. A cluster-randomized controlled trial in the UK involving 2,000 primary school students found that a one-year

"Food Exploration Course" (including cooking practice and interpretation of nutritional labels) increased the proportion of intervention group students choosing fruits as snacks from 32% to 58%, while the control group only increased by 6% [6], indicating that school-based interventions may indirectly influence family dietary decisions through children. Additionally, in the Swedish "School Healthy Meals" study, researchers randomly assigned 30 schools to an intervention group (providing Mediterranean diet-based meals) and a control group (standard meals). After a two-year follow-up, the intervention group's insulin resistance index (HOMA-IR) was significantly lower than the control group (1.7 vs. 2.3, P=0.02), validating the protective effect of long-term school dietary interventions on metabolic health [7]. Overall, school-based interventions can effectively optimize students' dietary structure, increase intake of healthy foods, and reduce consumption of high-calorie snacks. However, such interventions still have limitations, as their effects may be offset by external environments even if they yield short-term benefits. An analysis of 27 global studies found that approximately 40% of school-based intervention effects gradually declined within 2–3 years after the intervention ended [8]. A French longitudinal study showed that school-based dietary interventions reduced obesity rates by 18%, but obesity rates rebounded to baseline levels within two years after students entered middle school (outside the intervention environment). As such, the scalability and long-term effects of intervention measures are often constrained by implementation challenges and insufficient follow-up resources. Some studies indicate that family factors such as low parental education levels or occupational types may weaken intervention effectiveness, and that translating health knowledge into behavior is particularly challenging. Therefore, while school-based dietary intervention strategies hold public health value in theory, their practical implementation faces multidimensional barriers that significantly undermine the feasibility of such measures. There is an urgent need to introduce more feasible dietary behavior training measures to establish and reshape students' healthy eating habits.

Childhood obesity is largely attributable to an irrational dietary structure, unhealthy dietary behaviors, and inappropriate feeding practices during infancy and early childhood. Calorie-restricted diet (CRD) represents the primary treatment for childhood obesity [9]. However, adherence to this dietary regimen is challenging for most children and their families, with poor compliance negatively impacting the management of childhood obesity, particularly in the long term [10]. This underscores the need for the development of more efficacious dietary intervention strategies for childhood obesity to provide a broader range of treatment options.

Recently, there has been a growing interest in changing dietary patterns, particularly the proposal and popularity of intermittent fasting programs, which have demonstrated positive effects on metabolic control, weight management, and symptom improvement [11]. They are also more easily accepted by the public and have higher compliance [12]. Intermittent fasting is a simple and practical dietary management tool that limits calorie intake during a specific period of time. The main types of fasting programs currently in use include alternate-day fasting, periodic fasting, and time-restricted eating (TRE). These programs have been shown to induce comparable weight loss to that of CRD, with an approximate weight loss of 3-8% over a period of 8-12 weeks [13]. However, most of these findings are from adults and the intervention duration is relatively short. Consequently, the long-term effects of intermittent fasting remain inconclusive, and there is currently no evidence of its efficacy in reducing weight in children with obesity.

Two pilot studies have been conducted to examine the feasibility, effectiveness, and adherence of intermittent fasting for the treatment of childhood obesity. One single-arm trial including 30 obese children aged 12-17 years found that BMI and lipids were reduced and vascular endothelial function, healthy eating behaviors, and quality of life were improved after intervention [14]. The other trial including 50 obese children aged 14-18 years found a significant reduction in BMI after 12 weeks of 16-hour TRE compared with the control group (no restriction of energy intake). The fasting program was completed 5.3 days per week without any adverse effects such as compensatory eating [15]. These findings suggest that intermittent fasting is feasible and effective for children with obesity. Further, an ongoing RCT will compare BMI reductions between CRD and 16-hour TRE after 8 weeks of intervention in patients with childhood obesity aged 8-18 years [16]. Moreover, in consideration of the real circumstances for school-age children in China, e.g., heavy schoolwork, high expected body height, and sumptuous dinners with their family, neither alternate-day fasting nor periodic fasting may be applicable for Chinese children. TRE only requires control of the eating time window and no energy restriction, and thus is simple and easy to implement and is expected to be a feasible and compliant dietary intervention for childhood obesity in China. However, there is a shortage of evidence from trial studies on adherence and efficacy, especially the long-term effect, of TRE in childhood obesity.

In the TRE program, participants only need to consider two dietary elements: the timing of meals and the duration of fasting. As for the first element, the evidence remains

inconclusive, but available evidence suggests that the earlier dinner ends, the better. For example, a crossover trial study including twenty healthy volunteers confirmed that those who ate dinner at 10:00 p.m. had higher blood glucose levels and lower overnight fat burning compared to those who ate dinner at 6:00 p.m [17]. Another crossover trial study of 18 overweight or obese individuals also confirmed that those who ate dinner at 9:00 p.m. had increased hunger and decreased energy expenditure during the day compared to those who ate dinner at 5:00 p.m [18]. Regarding the second element, how many hours of fasting is best for weight loss is either not clear. Existing TRE-related trials have confirmed that fasting for 12-16 hours can all produce a weight loss of 2.6-8% [19]. Further, an RCT including 60 obese adults found that 8 weeks of 12-hour TRE and 14-hour TRE resulted in 6.6% and 7.8% weight loss, respectively, with no group differences [20]. Another study extended the duration of fasting to 18 and 20 hours and found only 3.2% weight loss in both groups after 8 weeks of intervention [21]. It can be seen that the duration of fasting is not as long as it should be, and the longer it is, the worse compliance may be. Taking into account the available evidence, the optimal program for TRE may be to fast for 12-16 hours, with the last meal preferably at 7:00 p.m.

In summary, the 12-hour TRE may be the healthy dietary behavior pattern we are seeking, potentially offering a viable approach to improving the effectiveness of obesity prevention and control among children in China. Therefore, this study plans to conduct a school-based cluster randomized controlled trial to evaluate the effectiveness of the 12-hour TRE in preventing and controlling childhood obesity. We hypothesize that the adoption of the 12-hour TRE as a dietary behavior habit may yield better outcomes in preventing and controlling childhood obesity compared to current comprehensive interventions based on learning.

3. Study Design

SCHOOL-TRE is a cluster-randomized controlled trial in which 12 primary schools (campuses) in Suzhou will be randomly assigned to the intervention (6 schools) and control arms (6 schools). At each school, study subjects will be recruited in a class unit, ensuring that at least 690 children will be enrolled in each arm. The control group will undergo routine health education, and the intervention group will additionally receive a 12-hour TRE training. After 9 months (1 school year) of intervention, weight management and prevalence of childhood obesity will be compared between the two groups. Then the intervention will be stopped, but follow-up will be continued, and the sustained effect of the intervention will be evaluated at 1 year after the intervention (2 school years). The design is illustrated in **Figure 1**.

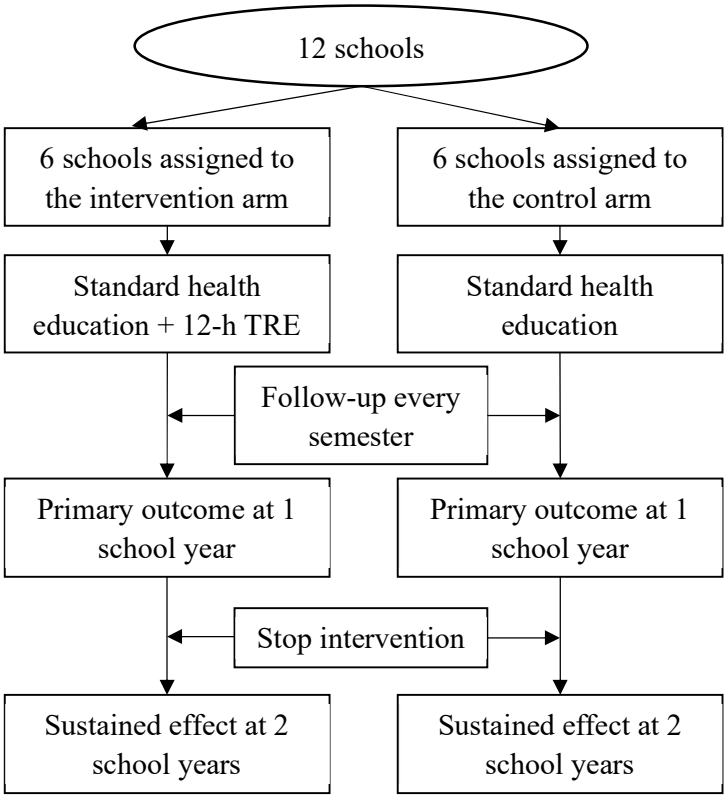

Figure 1. A flowchart illustrating the study design

4. Objectives

The primary objective of the SCHOOL-TRE is to evaluate the effectiveness of the 12-h TRE on the prevention and management of childhood obesity in school-aged children. In addition, the sustained effect of 12-h TRE will be examined at 1 school year after intervention. This implementation study will provide trial evidence for the usefulness of 12-h TRE in the

prevention and management of childhood obesity.

5. Study participants

This study plans to recruit the fourth-grade students from 12 elementary schools or campuses by randomly selecting 3-4 classes in each school/campus. Typically, all students in the selected classes will be invited to participate in the study, ensuring at least 115 students will be included in each school.

5.1 Eligibility criteria for schools:

☑ The principal agrees to accept the randomization process and adhere to the study protocols.

☑ The total number of fourth-year students in the school must be more than 50.

☑ Schools that have not or plan to implement obesity prevention interventions.

☑ Schools that are not boarding schools, ethnic minority schools, or specialty schools.

☑ Schools that have no clear plans to relocate or close within the next 2 years.

5.2 Eligibility criteria for classes:

☑ The class head teacher is willing to actively participate in home-school liaison.

☑ Class size should be between 30 and 60 students.

☑ The class consists of fourth-grade students.

☑ There are students with childhood obesity in the class.

☑ Classes that have no clear plan to be merged or canceled within the next 2 years.

5.3 Eligibility criteria for students:

All students in the class will typically be the subjects of the study after their patients sign the informed consent forms, unless they have the following circumstances:

☒ Students with a history of heart disease, high blood pressure, diabetes, tuberculosis, asthma, hepatitis, or nephritis.

☒ Students with secondary obesity due to endocrine disorders or side effects of medications.

☒ Students with abnormal growth and development, such as dwarfism, gigantism, etc.

☒ Students with physical deformities, such as severe scoliosis, chicken breasts, claudication, and significant O-leg/X-shaped legs.

☒ Students with limited athletic ability who are unable to participate in school physical activities.

☒ Students who have lost weight by inducing vomiting or taking medication in the past

3 months.

☒ Students who have undergone prior bariatric surgery.

☒ Students with mental disorders, intellectual developmental disabilities, and aphasia.

☒ Students who have taken medications that affect appetite or weight within three months (e.g., antipsychotics, hypnotics, weight loss medications, insulin).

☒ Students who plan to transfer within the next 2 years.

6. Randomization and recruitment

In this trial, 12 primary schools or campuses will be randomly assigned to two groups using the simple randomization method. The School of Public Health at Suzhou Medical College of Soochow University will complete the randomization strategy, and the random coding will be generated using the PROC PLAN program in the SAS software. The ratio of the experimental group to the control group is 1:1.

To facilitate the study procedures, we will recruit participants from fourth-grade students, with classes as the unit. This approach takes into account the students' comprehension ability and the age at which childhood obesity most commonly occurs. This study plans to select a Year 4 class (8–10 years old) from each school, comprising 30–60 students per class and a total of at least 115 students per school. Once the students' guardians have been fully informed of the research protocol and have signed the informed consent form, the study subjects will be provided with a free health assessment to determine whether they meet the inclusion criteria. All eligible students will then be included in the study.

7. Interventions

7.1 Interventions for the control group:

Standard health education procedures are in place. Health education will be conducted in accordance with the "Guiding Outline for Health Education in Primary and Secondary Schools."

7.2 Interventions for the experimental group:

In addition to the standard health education procedures, subjects in the experimental group will undergo 12 hours of TRE training. The core content of the propaganda and education on the 12-hour TRE feeding model is that the eating time window is limited to 12 hours per day, and the last meal must be finished by 19:00. The study subjects can freely choose their eating time window and are not restricted in terms of energy intake during mealtimes. During the

fasting period, they are allowed to drink non-calorie, sugar-free beverages such as water, tea, and coffee. The time of eating should be recorded every day.

8. Data collection

Data collection at the screening, baseline, and follow-up visits will be conducted by trained and qualified staff. The schedule of data collection is outlined in **Table 1.** At each visit, data on sociodemographic, behaviors, and disease history of individuals and families will be collected through questionnaires and clinical examinations. Data on adverse events will be actively monitored during follow-up. The specific data collection and the corresponding procedures are detailed below:

Table 1. The schedule of data collection

Data collection	Baseline visit	Intervention		Follow-up
		4 months	9 months	21 months
Informed consent	×			
General characteristics	×			
Anthropometry	×	×	×	×
Blood pressure	×	×	×	×
Physical activity	×		×	×
Diet behavior	×		×	×
Quality of life	×		×	×
Adverse events	×	×	×	

8.1 Questionnaire survey

- Demographic information: Age, gender, student ID, national ID number.
- Socioeconomic factors: parental education level, household income.
- Fetal development: gestational age at birth, birth weight, mode of delivery, and feeding method.
- Personal medical history: diabetes, constipation, OSAS, bariatric surgery, antipsychotics, hypnotics, weight-loss medications, insulin, etc.
- Family history of disease: obesity, hypertension, diabetes.
- Lifestyle: physical activity, dietary habits, sedentary time.
- Psychological factors: quality of life.
- Adverse events: dizziness, fatigue, etc.

8.2 Clinical examination

Body weight and height, waist circumference, hip circumference, and upper arm circumference will be measured by standard methods. Blood pressure will be measured three times at each visit. The average of the three readings constitutes the blood pressure value for that measurement.

9. Methods of data measurement

9.1 Questionnaire survey

A face-to-face survey is conducted by a trained and qualified investigator with each participant, using a standardized, self-administered questionnaire to collect demographic information (age, sex), fetal development (gestational week of birth, birth weight, delivery, feeding), and personal and family history of disease (obesity, hypertension, diabetes). Standardized scales are used to assess the lifestyle (physical activity, eating behaviors), and quality of life of the study subjects. Specifically, the Physical Activity Questionnaire for Adolescents (PAQ–A), a self-report scale designed for use with school students, will be used to assess the physical activity in our study. It contains eight items intended to capture adolescents' recollections of their physical activity over the preceding 7 days. The first and last of the PAQ–A's eight items each contain a number of subitems from which a mean is initially calculated, and those two means are added to responses on the other six items to obtain a total from which the mean is calculated to produce a composite score ranging from 1 to 5, with higher scores indicating greater physical activity. A ninth question seeks information about anything that would have prevented respondents from engaging in their “normal physical activities” during the previous week. The Child Eating Behavior Questionnaire (CEBQ), designed to assess children’s eating scale styles, will be used in our study. It is a parent-report measure comprised of 35 items, each rated on a five-point Likert scale that ranges from never to always. It is made up of eight scales: Food responsiveness, Emotional over-eating, Enjoyment of food, Desire to drink, Satiety responsiveness, Slowness in eating, Emotional under-eating, and Food fussiness. The instrument is ideal for use in research investigating the early precursors of eating disorders or obesity. The Quality of Life Scale for Children and Adolescents (QLSCA) is a Chinese version of the quality of life Scale for Children and Adolescents, consisting of 49 items for measuring 13 dimensions of students’ lives, such as their relationships with teachers and parents, partnership with fellow students, learning abilities and attitudes, self-perception, physical well-being, negative emotions, attitudes towards homework, living environment convenience, social

activities, sports capacity, self-satisfaction, and other unspecified factors. The QLSCA uses a five-point Likert-type scale to measure either frequency or intensity, with a recall period of two weeks. Scores were calculated for each dimension, with higher scores indicating a better quality of life.

9.2 Anthropometry

Body weight and height were measured using a regularly calibrated stadiometer and balance-beam scale with participants wearing light clothing and no shoes. Body mass index (BMI) was calculated as weight in kilograms divided by height in meters squared. The BMI-Z score was calculated based on the WHO growth charts. Waist circumference was measured at 1 cm above the umbilicus. Hip circumference is measured by taking a tape measure and wrapping it around the widest part of the hips, which is typically around the buttocks. Arm circumference was measured at the midpoint between the acromion and the olecranon of the right arm.

9.3 Blood pressure

Three consecutive sitting blood pressure measurements (with 30 sec in-between) were taken by trained staff using a digital blood pressure measuring device (HBP-1320, Omron, Japan), after the subjects had been resting for at least 5 min. All participants were required to avoid exercise, smoking, drinking alcohol, and tea for at least 30 min before the measurement.

10. Outcomes

This study is designed to test both long-term and sustained effectiveness of 12-h TRE on obesity management, with the long-term outcome being the magnitude of weight loss after 9 months (one academic year) of intervention. The intervention was then stopped but follow-up was extended to 21 months (one academic year after intervention) to assess the sustained effects, with the same outcome events as the long-term outcome.

Primary outcome:

Change in BMI-Z score

Secondary outcome:

- Change in BMI
- Change in the prevalence of childhood overweight or obesity (BMI-Z>2)
- Change in blood pressure
- Change in waist-to-hip ratio
- Change in quality of life

- Change in eating behavior
- Change in physical activity

11. Assessment of Outcomes

In this study, outcomes are assessed using standardized, internationally accepted measures. Blindness (the follow-up assessors are unaware of the grouping of study subjects) is used in the outcome assessment process.

12. Statistical Power and Sample Size

The DECIDE-Children study demonstrated that a comprehensive school-based intervention reduced BMI-Z values by an additional 0.2. Our TRECO study showed a reduction of 0.3 in BMI-Z values, with an SD of 0.6, after 12 weeks of the TRE intervention in obese children. Based on these results, we assumed that the difference in BMI-Z values between the two groups after the intervention would be 0.2 (SD = 0.6). We therefore planned to include 690 students from six schools in each group, with an average of 115 students per school. This was calculated using a two-sided test at a level of significance of $\alpha = 0.05$, with 80% statistical power ($1 - \beta = 0.8$), an intra-group correlation coefficient (ICC) of 0.025, and a 10% loss to follow-up rate.

13. Data management

All data are entered into the electronic database in the School of Public Health, Suzhou Medical College of Soochow University by trained and qualified nurses or investigators using an epidemic survey system (https://edc.gwxy.suda.edu.cn). The data entered are reviewed for a final data check and quality control.

14. Statistical analysis plan

This study will be analyzed on an intent-to-treat basis. A generalized linear mixed-effects model was used to correct for cluster effect, i.e., class and school as random effects, for comparison of baseline characteristics of study subjects between groups. Subgroup analyses will be used to test for the presence of effector modifications. All tests were performed by bilateral test, and the P-value <0.05 indicated statistical differences, and all statistical analyses were performed using SAS 9.4 statistical software.

15. Quality control

Quality control will be conducted by a team of investigators, key research staff, and project inspectors. Strict quality control will be implemented at every step of the study including project preparation, training, screening, intervention, and data collection. A manual of procedures will

be developed to detail the standardized approaches used in the study, such as participant recruitment, intervention, doctor training (protocol-based treatment, health coaching, and follow-up), health education (self-diet monitoring methods, lifestyle changes, and medication adherence), and other procedures of the study. All study personnel will be required to participate in a study training session prior to the initiation of any study procedures. The quality control team will review the study data regularly to ensure that all phases of the project are strictly implemented according to the study protocol and the authenticity, completeness, accuracy, and reliability of the research data.

15.1 Preparation phase

A manual of procedures will include detailed descriptions of all trial procedures and will be used for training purposes and as a reference for all study investigators and staff. Standard forms, devices, and procedures in the field for energy intake diary and other data collection procedures will be standardized. Furthermore, standard event definitions and event validation procedures will be used. The project will purchase the devices used in the study which pass the national quality inspection and provide these to local research teams. We will calibrate each device before they are distributed to study sites. The study protocol, manual of procedures, study forms, training materials, and other written materials will be prepared centrally.

15.2 Screening and recruitment phase

- To carry out obesity-related health education for children and their families, to ensure that they fully understand the hazards of childhood obesity, to establish confidence that obesity is preventable and controllable, and to try to include all eligible children.
- The enrolled children are trained to ensure that they are able to complete and upload a diet time diary and a weekly physical activity diary.

15.3 Implementation stage

- Dedicated participants are responsible for the collection of diet diaries and weekly physical activity diaries, and quality control participants assess the completion of the interventions and provided timely feedback to the attending physician in order to facilitate his or her supervision of the completion of the medical prescriptions.
- Dedicated follow-up appointments to reduce missed appointments.
- Follow-up outcomes are assessed by applying a blinded method (the assessor is unaware of the grouping of study subjects).

16. Security monitoring

16.1 Adverse events and reports

The intervention program in this study is more feasible. Possible adverse events include compensatory eating and reduced physical activity, which have been monitored at follow-up, and other adverse events not listed are reported and registered by the study subjects and their families with the nutritional counsellor.

16.2 Data security

After reviewing and confirming that the database created is correct, the data are locked by the principal investigator, the sponsor, and the statistical analyst. No further changes are made to the data files after locking. Problems identified after data locking should be followed strictly by the process of unlocking and re-locking the data. The Data Safety Committee and Ethics Committee are responsible for monitoring.

17. Study organization

SCHOOL-TRE is conducted jointly by the School of Public Health, Medical College of Soochow University, the Children's Hospital of Soochow University, and Wujiang Children's Hospital, forming a multidisciplinary and multi-departmental collaborative team of researchers (**Figure 3**). Decision-making, protocol design, overall organization, management and coordination of the study are carried out by the study steering committee, screening, recruitment and intervention management of the study subjects are implemented by the intervention team, blinded assessment of the outcome is implemented by the follow-up team, data quality control is implemented by the quality control team, and statistical analysis and reporting of the results is carried out by the Data Analysis Centre. Statistical analysis and reporting of results are carried out by the Data Analysis Centre, and the Data Safety Management Committee supervised the entire implementation of the project. Adopting a management model of overall coordination and division of labor and responsibility, and implementing a job responsibility system.

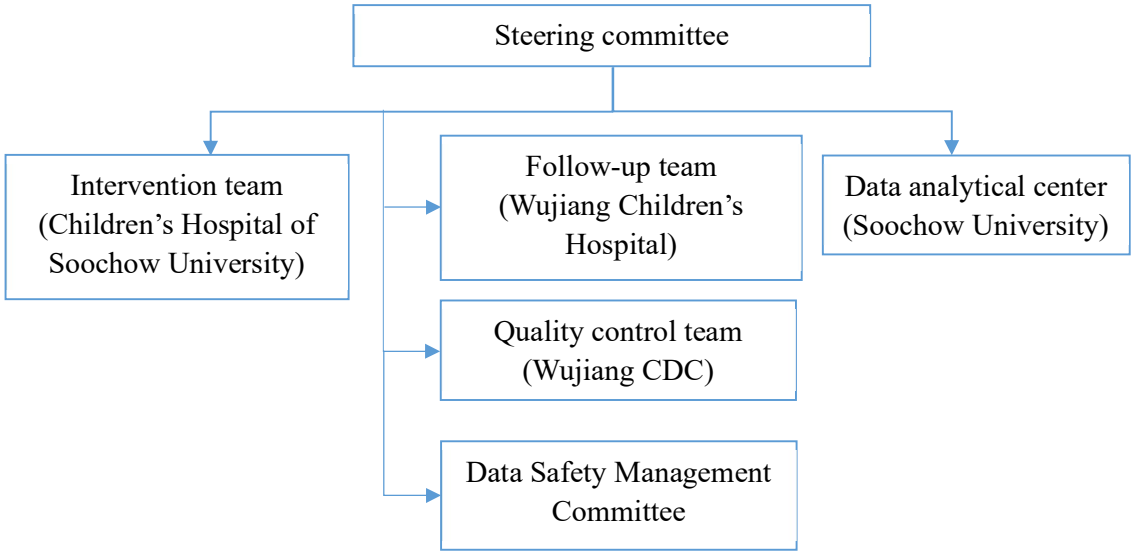

Figure 2. Study Organization Structure

18. Ethnic consideration

It is the responsibility of the principal investigator to ensure that this trial will be conducted in full compliance with the Declaration of Helsinki and the Chinese Code for Quality Management of Clinical Trials, as well as other relevant regulations. The study protocol was reviewed by the Ethics Committee of Soochow University and the Ethics Committee of Affiliated Children's Hospital of Soochow University, and all study subjects and their guardians signed an informed consent form.

19. Schedule

SCHOOL-TRE will last for two years and the schedule is shown in **Table 2**.

Table 2. Timeline and workplan

Research tasks	2025				2026				2027		
	5-6	7-8	9-10	11-12	1-2	3-6	7-8	9-12	1-8	9-10	11-12
registration, research tools	■	■									
Development of workbooks		■									
Preparations, training		■									
Recruitment of study participants, baseline data collection			■								
Interventions and quality			■	■	■	■	■				

control											
Follow-up											
Data analysis, writing papers											

20. References

1. 张娜 and 马冠生. 《中国儿童肥胖报告》解读. *营养学报*. 2017;39:530-534.
2. 《中国儿童肥胖的评估、治疗和预防指南》专家组. 中国儿童肥胖的评估、治疗和预防指南. *中国妇幼健康研究*. 2021;32:1716-1722.
3. Bjerregaard LG and Baker JL. Change in Overweight from Childhood to Early Adulthood and Risk of Type 2 Diabetes. *N Engl J Med*. 2018;378:2537-2538.
4. Liu Z, Gao P, Gao AY, Lin Y, Feng XX, Zhang F, Xu LQ, Niu WY, Fang H and Zhou S. Effectiveness of a Multifaceted Intervention for Prevention of Obesity in Primary School Children in China. *JAMA Pediatrics*. 2022;176:e214375-.
5. Johnson DB, Podrabsky M, Rocha A and Otten JJ. Effect of the Healthy Hunger-Free Kids Act on the Nutritional Quality of Meals Selected by Students and School Lunch Participation Rates. *JAMA Pediatrics*. 2016;170:e153918-e153918.
6. Aydin G, Booth A, Margerison C and Worsley A. Food and nutrition education in Australian primary schools: parents' views. *Health Education*. 2021;ahead-of-print.
7. Serra-Majem L, Roman B and Estruch R. Scientific evidence of interventions using the Mediterranean diet: a systematic review. *Nutrition Reviews*. 2006;64.
8. Kropski JA, Keckley PH and Jensen GL. School-based obesity prevention programs: an evidence-based review. *Obesity*. 2012;16:1009-1018.
9. Juonala M, Magnussen CG, Berenson GS, Venn A, Burns TL, Sabin MA, Srinivasan SR, Daniels SR, Davis PH, Chen W, Sun C, Cheung M, Viikari JS, Dwyer T and Raitakari OT. Childhood adiposity, adult adiposity, and cardiovascular risk factors. *N Engl J Med*. 2011;365:1876-85.
10. Sherzai A, Heim LT, Boothby C and Sherzai AD. Stroke, food groups, and dietary patterns: a systematic review. *Nutr Rev*. 2012;70:423-35.
11. Kim J and Lim H. Nutritional Management in Childhood Obesity. *J Obes Metab Syndr*. 2019;28:225-235.
12. Wilhelmi de Toledo F, Buchinger A, Burggrabe H, Hölz G, Kuhn C, Lischka E, Lischka N, Lützner H, May W, Ritzmann-Widderich M, Stange R, Wessel A, Boschmann M, Peper E and Michalsen A. Fasting therapy - an expert panel update of the 2002 consensus guidelines. *Forsch Komplementmed*. 2013;20:434-43.
13. de Cabo R and Mattson MP. Effects of Intermittent Fasting on Health, Aging, and Disease. *N Engl J Med*. 2019;381:2541-2551.
14. Varady KA, Cienfuegos S, Ezpeleta M and Gabel K. Clinical application of intermittent fasting for weight loss: progress and future directions. *Nat Rev Endocrinol*. 2022;18:309-321.
15. Middleton KR, Anton SD and Perri MG. Long-Term Adherence to Health Behavior Change. *Am J Lifestyle Med*. 2013;7:395-404.
16. Trepanowski JF, Kroeger CM, Barnosky A, Klempel M, Bhutani S, Hoddy KK, Rood J, Ravussin E and Varady KA. Effects of alternate-day fasting or daily calorie restriction on body composition, fat distribution, and circulating adipokines: Secondary analysis of a randomized controlled trial. *Clin Nutr*. 2018;37:1871-1878.
17. Kroeger CM, Trepanowski JF, Klempel MC, Barnosky A, Bhutani S, Gabel K and Varady KA. Eating behavior traits of successful weight losers during 12 months of alternate-day fasting: An exploratory analysis of a randomized controlled trial. *Nutr Health*. 2018;24:5-10.

18. Cai H, Qin YL, Shi ZY, Chen JH, Zeng MJ, Zhou W, Chen RQ and Chen ZY. Effects of alternate-day fasting on body weight and dyslipidaemia in patients with non-alcoholic fatty liver disease: a randomised controlled trial. *BMC Gastroenterol*. 2019;19:219.

19. Razavi R, Parvaresh A, Abbasi B, Yaghoobloo K, Hassanzadeh A, Mohammadifard N, Clark CCT and Morteza Safavi S. The alternate-day fasting diet is a more effective approach than a calorie restriction diet on weight loss and hs-CRP levels. *Int J Vitam Nutr Res*. 2021;91:242-250.

20. Xu S, Jiang Y, Zhang Y, Xu W, Zhang H, Yan Q, Gao L and Shang L. Dietary recommendations for fasting days in an alternate-day intermittent fasting pattern: A randomized controlled trial. Nutrition. 2022;102:111735.

21. Jebeile H, Gow ML, Lister NB, Mosalman Haghighi M, Ayer J, Cowell CT, Baur LA and Garnett SP. Intermittent Energy Restriction Is a Feasible, Effective, and Acceptable Intervention to Treat Adolescents with Obesity. J Nutr. 2019;149:1189-1197.