

Original Article

Comprehensive school-based intervention to control overweight and obesity in China: a cluster randomized controlled trial

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Background and Objectives: With prevalence of childhood obesity increasing rapidly, developing of effective and sustainable intervention strategies is becoming more and more important for the prevention of childhood obesity in China. A trial was developed to evaluate the effect of comprehensive school-based intervention on childhood obesity. **Methods and Study Design:** A multi-center cluster randomized controlled trial was conducted among urban children (n=9,867) aged 6-13 years in 38 primary schools from six large cities. Comprehensive intervention, nutrition education and physical activity interventions were carried out among children. Nutrition education was also targeted towards teachers, parents and health workers in intervention schools. The program was implemented for 2 semesters from May 2009 to May 2010. **Results:** The combined prevalence of overweight and obesity increased by 1.5 percent (22.7% vs 24.2%, $p<0.001$) in control group while 0.2 percent in comprehensive intervention group (23.6% vs 23.8%, $p=0.954$) after intervention ($p=0.067$). The effect was significantly stronger among girls than boys (-1.4% vs -0.9%, $p=0.028$). A significant intervention effect was found on BMI for -0.3 kg/m² (95% confidence interval (CI): -0.4, -0.2; $p<0.001$), BMI z scores for -0.14 (95% CI: -0.18, -0.11; $p<0.001$), body fat for -0.8 percent (95% CI: -0.9, -0.6; $p<0.001$), waist circumference for -0.5 cm (95% CI: -0.6, -0.3; $p<0.001$), blood serum glucose for -0.20 mmol/L (95% CI: -0.24, -0.16; $p<0.001$) and cholesterol for -0.32 mmol/L (95% CI: -0.34, -0.30; $p<0.001$). **Conclusions:** We observed moderately significant effects on combined prevalence of overweight and obesity, BMI, BMI z scores, waist circumference, percentage body fat, glucose and lipid for a comprehensive school-based intervention of childhood obesity in China.

Key Words: childhood obesity, comprehensive intervention, physical activity, nutrition, lipids

INTRODUCTION

With the changing of dietary practices and increasing of sedentary lifestyles, the prevalence of obesity-related non-communicable chronic diseases (NCD) has been rapidly increasing in both developed and developing countries.¹⁻⁹ The increasing trend of childhood obesity has appeared globally.¹⁰⁻¹⁴ About 10% of 5-17 years old children have been overweight worldwide, and 2%-3% were obese.¹⁵ The rapid increase in unhealthy body weight in school children has led to obese prevalence in some developing countries as high as or even higher than that in developed countries.¹⁵⁻¹⁷ The same increasing trend for

childhood obesity has also happened in China, which has caused significant direct medical costs. As reported by Zhao et al, the estimated total medical costs of hypertension, diabetes, coronary heart disease and strokes that

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could be attributed to overweight and obesity was 21.11 billion Yuan (RMB) in China in 2003, accounting for 25.5% of the total medical costs of these four primary chronic diseases, or 3.7% of the national total medical costs.¹⁸

Obese children are more likely to be obese adults¹⁹⁻²¹ and suffer from obesity-related NCD, psychosocial problems, social stigmatization, and poor self-image.²² Prevention is of the most importance to curb the rise in obesity-related NCD, because treatment is expensive and it will drain the limited public health resources.²³

Nutrition education and physical activity interventions have considerable potential to prevent weight gain in the general population. School-based intervention programs have emerged increasingly as an important strategy in obesity prevention. School provides an ideal opportunity in terms of both physical and social environment for preventing and treating obesity. Therefore, school-based obesity interventions have been applied worldwide as well as in China. Most of the available evidence, however, originates from studies conducted in developed countries and few in developing countries.^{24,25}

We have previously developed a school-based physical activity intervention strategy for childhood obesity in China, and it showed a good effectiveness and sustainability in an intervention study of 20 schools in Beijing.²⁶ In China, a few studies indicated that school based comprehensive intervention combined with nutrition and physical activity programs were effective.^{27,28} However, whether it would be successful when expanded to a larger scale (from more regions to nation-wide) still remains unclear. So we have designed a multi-center randomized controlled trial of comprehensive nutrition-based intervention study on childhood obesity in China (NISCOC),²⁹ which combined nutrition education and physical activity interventions and was applied to 30 schools in 5 study sites. The analysis of cost-effectiveness based on NISCOC indicated that the school-based integrated intervention was cost-effective on childhood obesity prevention in urban China,³⁰ but it is not clear if there are intervention effects on biochemical indicators. A study based on the selected study population (overweight and obese children, $n=438$) in one study site (Beijing) of NISCOC observed that the comprehensive program had superior positive effects on body fat percentage compared with the diet only or physical activity only intervention.³¹ However, it is not clear whether this is the same in the whole study population, by including other study sites and by including the normal weight and underweight children who were involved in the same intervention project.^{30,31}

The objective of this study was to comprehensively evaluate the intervention effects of NISCOC on a national level. If it is effective, it will provide the basis for the development childhood obesity prevention policies.

METHODS

This study was a multi-center cluster randomized control trial. Six centers, including Shanghai, Chongqing, Guangzhou, Jinan, Harbin and Beijing, were recruited. Two-step cluster sampling method was used for subjects' selection. Firstly, 8 schools from Beijing and 6 schools from each other city were randomly chosen into the trial.

The selected schools were randomly divided into three groups in Beijing (3 schools for nutrition education intervention, 3 schools for physical activity intervention and 2 schools for control) and two groups in each other city (3 schools for comprehensive intervention and 3 schools for control). In total, there were 15 comprehensive intervention schools, 3 nutrition education intervention schools, 3 physical activity intervention schools and 17 control schools. Secondly, 2 classes from each grade (1st to 5th) were selected randomly in every school. 390 classes were selected. All recruited students were from urban districts. This trial information was registered at Chinese Clinical Trial Register (number ChiCTR-PRC-09000402).

Inclusion criteria for selecting school: 1) non-boarding school; 2) the prevalence of obesity, based on the routine physical examination records, was above 10%; 3) Providing school lunch feeding, and more than 50% students have lunch at school. All the students in the selected classes were invited to participate in the study.

Exclusion criteria for subjects: 1) students who suffered from serious illnesses (such as congenital heart disease, the body carried out fixation or joint replacement surgery, and so on) or couldn't withstand severe physical activity or diet control were excluded. 2) Students who participated in the past one year or planned to participate in other similar intervention projects in the next year were excluded.

This study was approved by the Ethical Review Committee of National Institute for Nutrition and Food Safety (renamed "National Institute for Nutrition and Health"), Chinese Center for Disease Control and Prevention. The informed consent voluntarily was signed by participants' parents or their guardians.

Interventions

Nutrition education intervention, physical activity intervention and the comprehensive intervention including nutrition education and physical activity intervention were designed for childhood obesity prevention. The program was implemented for 2 semesters from May 2009 to May 2010. Detailed information on the interventions can be found in a previous published article.²⁹

Nutrition education intervention

A nutrition handbook was developed.³² Cartoon pamphlets were distributed to each student in the intervention schools. Courses on nutrition and health were given 6 times for the students, 2 times for the parents and 4 times for teachers and health workers. The contents included healthy eating proportions of three meals, how to choose the beverage and snacks, reducing eating out and Western-style fast food, and so on. Nutrition professionals gave the lectures to teachers, parents and workers firstly, and then the trained teachers were responsible for teaching students. Each lecture lasted a minimum of 40 min. Furthermore, "Dietary Pagoda for Chinese people" posters were displayed on the walls of all participating classrooms. Cartoon handbooks containing all of this information were distributed to all participants in the nutrition education group to help clarify the concepts presented in the lectures. The school lunch cafeteria menu for students was evaluated periodically and specific nutrition sugges-

tions were provided accordingly.

Physical activity intervention

A classroom-based physical activity program for elementary students named "Happy 10" was used in physical activity (PA) intervention. The Happy 10 program was developed as a classroom-based intervention to promote physical activity among primary school students. The Happy 10 program has been implemented and promoted in urban Beijing since 2004 and is a useful strategy for increasing PA among school children. On each school day, students conducted Happy 10 organized by teachers to do a 10-min segment of moderate intensity, age- and space-appropriate physical activity twice at school. The forms of PA includes game, dance or rhythmic gymnastics, such as "invisible rope skipping", "imitating animals", and the "squat and multiplication table", were linked with the core curriculum objectives and were conducted during breaks. The 10-minute sessions consisted of four parts: 1) the teacher or student selected the cards to determine the activities; 2) several children were chosen to model the exercises in the front of the classroom and the other students followed along (one to three activities were performed at each session); 3) a cool-down period took place after the activities; and 4) the students were taught a health message. The average energy expenditure of 10-mins PA ranged from 25.0-35.1 kcal.³³ Students were also encouraged to develop different forms of PA that they liked. Furthermore, education about PA was provided to students, parents, health workers and teachers.

In order to improve the home environment, we also involved the parents in our intervention study, including, but not limited to, sending them nutrition education bulletins. We also applied the supervising strategies to make sure the interventions would be fully implemented by frequent visiting without notice to intervention schools. There were also some competing activities and seminars held between centers and schools.

Assessment of intervention effects

The physical examination was carried out in school. Height was measured to an accuracy of 1 mm with a free standing stadiometer mounted on a rigid tripod (GMCS-I, Xindong Huateng Sports Equipment Co. Ltd., Beijing, China). One overnight fasting body weight was measured to the nearest 0.1 kg on a digital scale (RGT-140, Wujin Hengqi Co. Ltd., Changzhou, China). Body mass index (BMI) was calculated as weight in kilograms divided by height in meters squared (kg/m^2). The BMI z scores, based on age and sex, were calculated for each subject using World Health Organization growth references. Overweight was defined as BMI between the 85th and the 95th percentiles, whereas obesity was defined as $\text{BMI} \geq 95$ th percentile, using age- and sex-specific BMI cutoff points developed by the Working Group for Obesity in China (WGOC).³⁴ Children with malnutrition was defined as the China national standard for screening of malnutrition in children and adolescents.³⁵

Waist circumference (WC) was measured mid-way between the lower rib margin and the iliac crest with flexible anthropometric tape (Myotape). The WC was meas-

ured twice to the nearest 0.1 cm. If the variation between these two measurements was greater than 0.5 cm, a third measurement was taken and the mean was calculated by using the two closest measurements.

After an overnight fast, body composition was measured in the morning using a single frequency (50 Hz) hand to foot bioelectrical impedance device (ImpDF50, Impedimed Pty Ltd., Qld, Australia), with subjects in a calm state considering the effects of physical activity and meals. The bioimpedance measurement required careful placement of our electrodes on the hand and foot. Resistance (R) and reactance (X_c) were determined. Body impedance was calculated as the square root of ($R^2 + X_c^2$). The body fat percentage was calculated using the prediction equations developed by Deurenberg.³⁶

Fasting venous blood samples (5 mL) were drawn in the morning after 10-14 h of overnight fasting. Serum glucose was determined by the glucose-oxidase method (Daiichi Pharmaceutical Co., Ltd, Tokyo, Japan) within 4 h after the sample was obtained. Total cholesterol (Chol), triglycerides (TG), low-density lipoprotein cholesterol (LDL-C) and high-density lipoprotein cholesterol (HDL-C) were determined by enzymatic methods using commercial kits (Daiichi Pharmaceutical Co., Ltd, Tokyo, Japan).

Statistical analysis

The variable used for the calculation of sample size was the BMI changes. To detect a difference of $0.7 \text{ kg}/\text{m}^2$ of BMI changes between the intervention and control groups, the minimum number required would be 3 schools in each center with 250 students in each school.²⁶ The interclass correlation is assumed to be 0.05. The sample size of 7500 students from 30 schools located in 5 centers has 90% power to detect a mean between-group difference in BMI of 0.7 units with an effect size of 0.64. Statistical significance level was set at 0.05 (two-sided).

The continuous variables were expressed as mean and standard deviation. Linear Growth Model (LGM) adjusting for confounding factors was used for comparison of the means and the changes of continuous variables among intervention group and control group. Mixed Model was used for comparison of the means between post-intervention and baseline for each group. The percentage of overweight and obesity were compared with Generalized Linear Mixed Model (GLMM). Procedure GLMM was used with school as random effect variable. The fixed effect variables included sex, age, and intervention types. Daily energy intake was taken as adjusted variable. Statistical significance level was set at $p < 0.05$. SAS software package version 9.1 (SAS Institute Inc, Cary, NC) was used for analysis.

RESULTS

Baseline characteristics

We had collected baseline anthropometric measures from 9,867 children (2,150 in Beijing, 7,717 in five other cities). Of whom, 8,573 children (4,205 girls) were re-measured one year later with a follow-up rate of 86.9% (Figure 1). At least 1 teacher in every class and 1 parent in every family participated in the program. Table 1 shows the characteristics of the subjects including age,

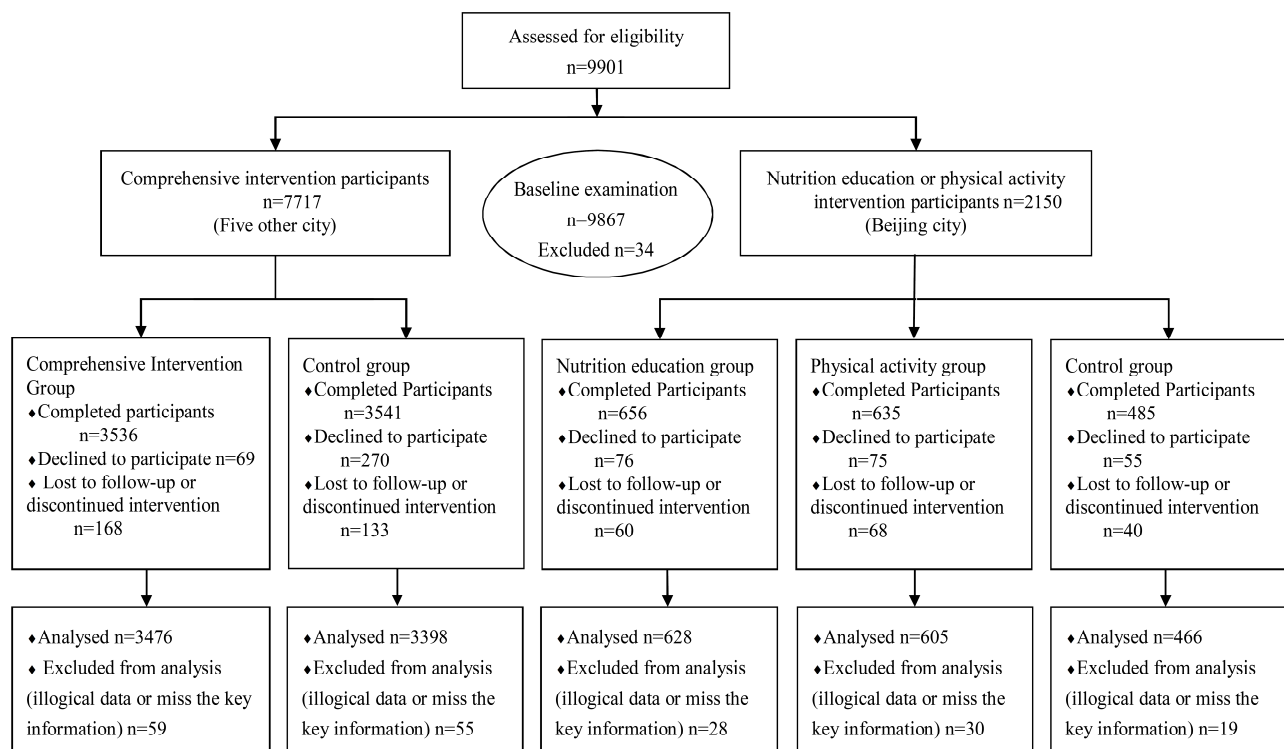


Figure 1. Trial profile for follow-up data

sex, mother's educational level and family's economic level. No significant difference was found between intervention and control groups. Except for the gender proportion of students in Beijing, there was no significant difference between the retained students and the lost students for the basic characteristics.

Changes of nutrition knowledge, attitude, practice and physical activity

Participants' nutrition knowledge in the comprehensive intervention group improved significantly as compared with the control group. The increased proportion of students with correct responses of nutrition knowledge included "Eating single food is not good for health increased" (comparing comprehensive intervention group to control group: 8.9% vs. 0.8%, $p=0.001$), "More nutrition for coarse grains than refined grains" (2.6% vs. -1.6%, $p=0.028$), "Having more milk and soy products is beneficial to health" (3.1% vs. 0.8%, $p=0.013$), "Moderate exercise could be good for learning" (21.0% vs. 12.0%, $p<0.001$), "Exercising less could be prone to be obese" (5.6% vs. 1.9%, $p=0.003$). We did not observe significant improvement for attitude and practice. The physical activity time significantly increased from 815.9±420.6 mins/week to 855.1±405.6 minutes/week in the comprehensive intervention group with no significant changes in the control group, with a significant intervention effect of 46.0 mins/week.

Weight-related outcomes

Table 2 shows the main intervention effects on BMI, BMI z scores, body fat percentage, WC and prevalence of overweight & obesity. The changes of BMI, BMI z scores, body fat percentage and WC were all significantly different between control group and intervention group. Com-

pared with the control group, the comprehensive intervention effects could be found -0.3 kg/m² (95% confidence interval (CI): -0.4, -0.2; $p<0.001$) for BMI, -0.14 (95% CI: -0.18, -0.11; $p<0.001$) for BMI z scores, -0.8% (95% CI: -0.9, -0.6; $p<0.001$) for percentage body fat and -0.5 cm (95% CI: -0.6, -0.3; $p<0.001$) for WC in the intervention group. The combined prevalence of overweight and obesity increased in control group by 1.5% (22.7% vs. 24.2%, $p<0.001$) but only 0.2% in the comprehensive intervention group (23.6% vs. 23.8%, $p=0.954$) after one school year. The odds ratio (OR) value of the comprehensive intervention group being overweight or obese was 0.9 (95% CI: 0.7, 1.0) compared with control group. There was almost no significant intervention effect in nutrition education group and physical activity group except the waist circumference (-0.40 cm, 95% CI: -0.77, -0.02, $p=0.036$) in nutrition education group.

Table 3 presents the different intervention effects between boys and girls. Although the positive effects on BMI, BMI z scores, body fat percentage and WC were found among both boys and girls, the boys decreased more body fat (-1.0%) and less WC (-0.3 cm) than girls (-0.5%, $p=0.008$; -0.7 cm, $p<0.001$). For the combined prevalence of overweight and obesity, the intervention effects were also significantly different. Compared with control group, the odds of being overweight or obese after intervention reduced 10% (OR=0.9; 95% CI: 0.8, 1.0) for boys and 20% for girls (OR=0.8; 95% CI: 0.7, 0.9).

The comprehensive intervention effect among different weight status children was also significantly different on BMI, BMI z scores, body fat percentage and WC. More obvious effects on BMI, BMI z scores, body fat percentage and WC were found among overweight/obese children and normal weight children ($p<0.001$), but there were no significant effects for malnourished children

Table 1. Characteristics of the subjects at baseline

	Comprehensive intervention				Nutrition education or physical activity intervention				
	Intervention group	Control group	Retained	Lost	Nutrition education group	Physical activity group	Control	Retained	Lost
Total, N	3773	3944	6874	843	792	778	580	1699	451
Age (year), mean (SD)	9.0 (1.4)	9.0 (1.4)	9.0 (1.4)	9.0 (1.4)	9.2 (1.5)	9.2 (1.6)	9.3 (1.6)	9.1 (1.5)	9.4 (1.6)
Sex, N (%)									
Boys	2006 (50.9)	1908 (50.6)	3476 (50.6)	438 (52.0)	417 (52.7)	425 (54.5)	343 (59.1)	892 (52.5)	293 (64.9)** †
Girls	1938 (49.1)	1865 (49.4)	3398 (49.4)	405 (48.0)	375 (47.3)	353 (45.5)	237 (40.9)	807 (47.5)	158 (35.1)
Mother's educational level, (N (%))									
Low (illiterate)	7 (0.2)	12 (0.4)	17 (0.3)	2 (0.4)	4 (0.7)	2 (0.3)	5 (1.1)	10 (0.8)	1 (0.3)
Middle (Primary or junior middle school)	976 (33.1)	1113 (39.4)	1909 (36.5)	180 (33.5)	332 (56.0)	376 (63.5)	294 (66.2)	802 (60.8)	200 (64.7)
High (Senior middle school or above)	1964 (66.6)	1699 (60.2)	3307 (63.2)	356 (66.2)	257 (43.3)	214 (36.1)	145 (32.7)	508 (38.5)	108 (35.0)
Family's economic level (Yuan/month/per family member), N (%)									
≤1,500	1205 (41.0)	1266 (44.9)	2254 (43.1)	217 (40.6)	278 (47.4)	305 (52.0)	240 (54.8)	673 (51.4)	150 (49.5)
1,501-2,500	829 (28.2)	757 (26.8)	1439 (27.5)	147 (27.5)	161 (27.4)	158 (26.9)	107 (24.4)	344 (26.3)	82 (27.1)
>2,500	904 (30.8)	798 (28.3)	1531 (29.3)	171 (32.0)	148 (25.2)	124 (21.1)	91 (20.8)	292 (22.3)	71 (23.4)
BMI (kg/m ²), mean (SD)	17.1 (3.3)	17.0 (3.1)	17.1 (3.2)	17.1 (3.3)	16.6 (2.9)	16.9 (3.2)	16.4 (2.6)	16.6 (2.9)	16.8 (3.0)

†Comparison between students being retained and lost.

** $p < 0.01$.

Table 2. The overall outcomes for intervention

	Baseline	End of study	Change ^{††}	Intervention effect (Beta (95% CI), <i>p</i>)
BMI (kg/m²), mean±SD				
Control group [†]	17.1±3.2	17.9±3.6	0.8±1.5 ^{**}	
Intervention group [§]	17.0±3.3	17.6±3.5	0.6±1.7 ^{**}	-0.3 (-0.4, -0.2), <0.001
Control group [‡]	16.4±2.7	17.1±2.6	0.7±2.2 ^{**}	
Nutrition education group [¶]	16.7±2.9	17.4±2.9	0.7±2.2 ^{**}	0.00 (-0.26, 0.26), 0.990
Physical activity group ^{††}	16.9±3.2	17.7±2.9	0.8±2.2 ^{**}	0.07 (-0.19, 0.34), 0.584
BMI z score, mean±SD				
Control group [†]	0.19±1.30	0.22±1.39	0.03±0.66 ^{**}	
Intervention group [§]	0.23±1.37	0.12±1.40	-0.11±0.75 ^{**}	-0.15 (-0.18, -0.11), <0.001
Control group [‡]	-0.11±1.14	-0.04±1.11	0.08±0.91	
Nutrition education group [¶]	-0.03±1.18	0.03±1.18	0.05±0.88	-0.02 (-0.13, 0.08), 0.678
Physical activity group ^{††}	0.04±1.3	0.16±1.15	0.13±0.92 ^{**}	0.05 (-0.06, 0.16), 0.377
Body Fat (%), mean±SD				
Control group [†]	26.8±7.2	28.6±6.8	1.8±3.2 ^{**}	
Intervention group [§]	26.9±7.1	28.0±7.0	1.1±3.6 ^{**}	-0.8 (-0.9, -0.6), <0.001
Control group [‡]	25.7±7.2	27.3±6.7	1.7±3.7 ^{**}	
Nutrition education group [¶]	26.6±6.9	28.8±6.3	2.2±4.1 ^{**}	0.56 (0.09, 1.04), 0.019
Physical activity group ^{††}	27.0±7.0	28.4±6.4	1.4±3.8 ^{**}	-0.26 (-0.71, 0.20), 0.269
Waist circumference (cm), mean±SD				
Control group [†]	57.5±8.9	61.1±10.1	3.6±3.7 ^{**}	
Intervention group [§]	57.9±8.8	61.0±9.9	3.1±3.7 ^{**}	-0.5 (-0.6, -0.3), <0.001
Control group [‡]	56.1±7.7	58.9±8.6	2.9±3.1 ^{**}	
Nutrition education group [¶]	57.0±8.7	59.4±9.5	2.5±3.1 ^{**}	-0.40 (-0.77, -0.02), 0.036
Physical activity group ^{††}	57.4±9.1	60.1±9.9	2.7±3.5 ^{**}	-0.20 (-0.60, 0.21), 0.337
Overweight, %				
Control group [†]	11.8	12.0	0.2	
Intervention group [§]	12.7	11.5	-1.2	0.9 (0.8, 1.1), 0.198
Control group [‡]	5.1	10.7	5.6	
Nutrition education group [¶]	8.5	10.8	2.4	0.59 (0.26, 1.36), 0.413
Physical activity group ^{††}	6.7	13.0	6.4 [#]	0.89 (0.54, 1.47), 0.517
Obese, %				
Control group [†]	10.9	12.2	1.3 ^{**}	
Intervention group [§]	10.9	12.3	1.4 ^{**}	1.0 (0.9, 1.1), 0.972
Control group [‡]	6.6	5.4	-1.3	
Nutrition education group [¶]	6.4	7.8	1.4	1.57 (0.74, 3.31), 0.151
Physical activity group ^{††}	10.2	7.4	-2.8	0.86 (0.45, 1.65), 0.774
Overweight and obese, %				
Control group [†]	22.7	24.2	1.5 [*]	
Intervention group [§]	23.6	23.8	0.2	0.9 (0.7, 1.0), 0.061
Control group [‡]	11.1	17.6	6.5	
Nutrition education group [¶]	14.3	19.8	5.5	0.93 (0.57, 1.51), 0.572
Physical activity group ^{††}	16.1	21.9	5.8	0.89 (0.54, 1.47), 0.637
Glucose (mmol/L), mean±SD				
Control group [†]	4.53±0.51	4.68±0.49	0.15±0.58 ^{**}	
Intervention group [§]	4.58±0.54	4.53±0.43	-0.05±0.64 ^{**}	-0.20 (-0.24, -0.16), <0.001
Control group [‡]	3.98±0.72	5.02±0.44	1.05±0.95 ^{**}	
Nutrition education group [¶]	4.32±0.54	5.04±0.36	0.72±0.61 ^{**}	-0.32 (-0.42, -0.22), <0.001
Physical activity group ^{††}	4.49±0.55	4.95±0.44	0.46±0.58 ^{**}	-0.59 (-0.68, -0.49), <0.001
Insulin (mU/mL), mean±SD				
Control group [†]	6.03±3.58	6.31±4.18	0.15±4.04 [*]	
Intervention group [§]	6.20±3.89	6.34±4.20	0.18±4.58	-0.06 (-0.30, 0.18), 0.620
Control group [‡]	5.24±3.03	4.72±3.06	-0.47±3.52 [*]	
Nutrition education group [¶]	5.24±3.2	5.13±3.5	0.02±3.47	0.23 (0.00, -0.91), 0.051
Physical activity group ^{††}	5.97±3.87	5.14±3.63	-0.79±4.07 ^{**}	-0.27 (-0.82, 0.28), 0.327
HDL-c (mmol/L), mean±SD				
Control group [†]	1.47±0.29	1.68±0.37	0.21±0.33 ^{**}	
Intervention group [§]	1.50±0.32	1.62±0.39	0.13±0.37 ^{**}	-0.09 (-0.11, -0.07), <0.001
Control group [‡]	1.39±0.24	1.42±0.31	0.02±0.25	
Nutrition education group [¶]	1.42±0.29	1.69±0.32	0.27±0.32 ^{**}	0.24 (0.21, 0.28), <0.001
Physical activity group ^{††}	1.39±0.28	1.47±0.29	0.08±0.26 ^{**}	0.054 (0.02, 0.09), 0.001

[†]The control group for comprehensive intervention. [‡]The control group for only nutrition education intervention group or only physical activity intervention group. [§]The comprehensive intervention group. [¶]The only nutrition education intervention group. ^{††}The only physical activity intervention group.

^{†††}The difference between baseline and end of study for the same group.

n*<0.05; *n*<0.01.

Table 2. The overall outcomes for intervention (cont.)

	Baseline	End of study	Change ^{‡‡}	Intervention effect (Beta (95% CI), <i>p</i>)
LDL-C (mmol/L), mean±SD				
Control group [†]	2.23±0.63	2.34±0.67	0.11±0.51 ^{**}	
Intervention group [§]	2.25±0.61	2.33±0.70	0.08±0.60 ^{**}	-0.02 (-0.04, 0), 0.131
Control group [‡]	1.73±0.46	1.79±0.44	0.06±0.30	
Nutrition education group [¶]	1.68±0.44	1.81±0.46	0.13±0.47 ^{**}	0.07 (0.02, 0.12), 0.004
Physical activity group ^{††}	1.68±0.42	1.8±0.46	0.12±0.31 ^{**}	0.06 (0.02, 0.10), 0.002
Chol (mmol/L), mean±SD				
Control group [†]	4.00±0.82	4.18±0.74	0.18±0.61 ^{**}	
Intervention group [§]	4.24±0.77	4.10±0.79	-0.14±0.58 ^{**}	-0.32 (-0.34, -0.30), <0.001
Control group [‡]	3.96±0.66	3.51±0.58	-0.45±0.44 ^{**}	
Nutrition education group [¶]	3.95±0.62	3.78±0.53	-0.17±0.68 ^{**}	0.27 (0.20, 0.34), <0.001
Physical activity group ^{††}	3.93±0.65	3.79±0.64	-0.15±0.48 ^{**}	0.30 (0.24, 0.36), <0.001
TG (mmol/L), mean±SD				
Control group [†]	0.83±0.48	0.89±0.43	0.05±0.54 ^{**}	
Intervention group [§]	0.80±0.41	0.86±0.51	0.07±0.50 ^{**}	0.01 (-0.01, 0.03), 0.329
Control group [‡]	0.72±0.36	0.69±0.4	-0.03±0.38	
Nutrition education group [¶]	0.81±0.38	0.69±0.38	-0.12±0.41 ^{**}	-0.09 (-0.14, -0.03), 0.001
Physical activity group ^{††}	0.72±0.35	0.7±0.47	-0.03±0.44	0.01 (-0.05, 0.06), 0.837

[†]The control group for comprehensive intervention. [‡]The control group for only nutrition education intervention group or only physical activity intervention group. [§]The comprehensive intervention group. [¶]The only nutrition education intervention group. ^{††}The only physical activity intervention group.

^{‡‡}The difference between baseline and end of study for the same group.

p*<0.05; *p*<0.01.

(Table 4).

Glucose, insulin and lipids

For glucose level, there was a 0.05 units (mmol/L) decrease in intervention group and 0.15 units (mmol/L) increase in control group after intervention (*p*<0.001), resulting in a significant intervention effect of -0.20 mmol/L in the comprehensive intervention group (Table 2). The significant comprehensive intervention effect on glucose was found in both boys (-0.17 mmol/L) and girls (-0.17 mmol/L) (Table 3). We did not observe a significant intervention effect on serum insulin. We observed significant intervention effect on comprehensive intervention on Chol level with an intervention effect of -0.32 mmol/L (0.14 mmol/L decrease in intervention group and 0.18 mmol/L increase in control group, *p*<0.001). Significant intervention effects on HDL-c and TG were only observed in nutrition education group with an intervention effect of 0.24 mmol/l for HDL-c and -0.09 mmol/L for TG (Table 2).

DISCUSSION

In this large scale, multi-center, school-based randomised clinical trial, we observed significant intervention effects of the comprehensive nutrition education and physical activity intervention in China. This study was the largest multi-center comprehensive childhood obesity intervention study in primary schools in China. The large sample size provided sufficient power to detect a relatively small effect. Another strength of the study was the extensive and precise measurements of intervention effects, including not only broad anthropometric index of BMI, BMI z scores, body fat percentage, WC and the prevalence of overweight combined with obesity, but also biomarkers of glucose and lipids.

Our findings were consistent with previous studies. One meta-analysis based on 32 studies showed that

school-based prevention interventions could be effective in reducing BMI in children.³⁷ Another meta-analysis, including 17 childhood obesity prevention programmes, found that childhood obesity prevention programmes had a significant desirable effect on blood lipids.³⁸ A school-based intervention program in Netherlands found a significant positive effect for overweight percent though no significant effect for BMI.³⁹ After one school year intervention, the prevalence of overweight and obesity increased only 0.2% in the intervention group, but 1.5% in the control group. Compared with control group, the odds of being overweight or obese were reduced by 10% for the intervention group. Although BMI increased in both groups, a greater increment in the control group was observed. Some studies have indicated little effect in controlling obesity and overweight with short time interventions.¹⁵ We observed a significant effect which might be due to the fact that the interventions were comprehensive in combination with the effect of the knowledge, attitude and practice of nutrition and obesity intervention among children.

Significant gender differences of intervention effect were observed in the current study. Another similar intervention study found a greater effect in boys than girls;⁴⁰ however, the opposite result occurred in this intervention, with more effect in preventing the combined prevalence of overweight and obesity among girls than that among boys. Plausible explanations for this difference could be as follows. Firstly, girls are basically less physically active; adding our exercise program into girls' daily activities might have produced a substantial effect on their energy expenditure. Secondly, girls are more inactive than boys and easier to comply with their teachers or parents generally, so girls could do better than boys in conducting the interventions. Thirdly, the post-exercise eating behavior may have been different according to gender. Girls may need more body fat than boys after puberty and they

Table 3. The effects of comprehensive intervention for different gender

	Boys			Girls			<i>P</i> for gender difference
	Baseline	End of study	Change	Baseline	End of study	Change	
BMI (kg/m ²), mean±SD							
Control group	17.5±3.4	18.3±3.9	0.8±1.6**	16.6±2.8	17.2±3.2	0.7±1.3**	
Intervention group	17.6±3.5	18.1±3.7	0.5±1.9**	16.7±2.9	17.0±3.2	0.4±1.6**	
Intervention effect, beta (95% CI)			-0.3 (-0.4, -0.2)			-0.3 (-0.4, -0.2)	0.546
<i>p</i> value [†]			<0.001			<0.001	
BMI z score, mean±SD							
Control group	0.41±1.4	0.46±1.51	0.06±0.72**	-0.03±1.15	-0.02±1.22	0.01±0.58	
Intervention group	0.46±1.46	0.38±1.47	-0.09±0.81**	0.00±1.22	-0.14±1.27	-0.14±0.68**	
Intervention effect, beta (95% CI)			-0.14 (-0.20, -0.09)			-0.15 (-0.19, -0.10)	0.773
<i>p</i> value [†]			<0.001			<0.001	
Body fat (%), mean±SD							
Control group	22.3±6.9	24.8±7.1	2.5±3.6**	31.5±3.5	32.5±3.7	1.0±2.6**	
Intervention group	22.4±6.9	24.0±7.2	1.7±4.0**	31.5±3.6	32.1±3.9	0.6±3.0**	
Intervention effect, beta (95% CI)			-1.0 (-1.3, -0.8)			-0.5 (-0.7, -0.3)	0.008
<i>p</i> value [†]			<0.001			<0.001	
Waist circumference (cm), mean±SD							
Control group	59.2±9.7	63.2±11.0	3.9±3.9**	55.8±7.7	59.0±8.5	3.3±3.4**	
Intervention group	59.5±9.5	63.1±10.6	3.6±3.8**	56.3±7.7	58.8±8.5	2.6±3.6**	
Intervention effect, beta (95% CI)			-0.3 (-0.6, 0)			-0.7 (-0.9, -0.4)	<0.001
<i>p</i> value [†]			0.029			<0.001	
Overweight, %							
Control group	14.5	14.6	0.1	9.6	9.8	0.2	
Intervention group	15.0	15.0	0.0	10.7	8.7	-2.0**	
Intervention effect, beta (95% CI)			1.0 (0.8, 1.2)			0.7 (0.5, 0.9)	0.094
<i>p</i> value [†]			0.929			<0.006	
Obese, %							
Control group	13.6	16.4	2.8**	8.6	8.5	-0.1	
Intervention group	13.1	15.1	2.0*	8.7	9.4	0.7	
Intervention effect, beta (95% CI)			0.9 (0.8, 1.0)			1.0 (0.8, 1.2)	0.427
<i>p</i> value [†]			0.055			0.883	
Overweight and obese, %							
Control group	28.1	31.0	2.9**	18.2	18.3	0.1	
Intervention group	28.1	30.1	2.0*	19.4	18.1	-1.3*	
Intervention effect, beta (95% CI)			0.9 (0.8, 1.0)			0.8 (0.7, 0.9)	0.029
<i>p</i> value [†]			0.129			0.004	
Glucose (mmol/L), mean±SD							
Control group	4.58±0.50	4.72±0.48	0.14±0.58**	4.47±0.50	4.63±0.49	0.16±0.57**	
Intervention group	4.66±0.52	4.58±0.42	-0.08±0.63**	4.50±0.55	4.48±0.42	-0.02±0.63	
Intervention effect, beta (95% CI)			-0.21 (-0.25, -0.17)			-0.17 (-0.21, -0.13)	0.073
<i>p</i> value [†]			<0.001			<0.001	

[†]The difference between baseline and end of study for the same group. [‡]*p* value for intervention effect.

p*<0.01; *p*<0.01.

Table 3. The effects of comprehensive intervention for different gender (cont.)

	Boys			Girls			<i>P</i> for gender difference
	Baseline	End of study	Change [†]	Baseline	End of study	Change [†]	
Insulin (mU/mL), mean±SD							
Control group	5.93±3.56	6.21±4.13	0.19±3.98	6.11±3.6	6.39±4.23	0.09±4.05	
Intervention group	6.14±3.87	6.17±4.14	0.06±4.6	6.26±3.94	6.43±4.19	0.23±4.54	
Intervention effect, beta (95% CI)			-0.17 (-0.50,0.16)			0.02 (-0.31,0.35)	0.557
<i>p</i> value [‡]			0.306			0.882	
HDL-c (mmol/L), mean±SD							
Control group	1.48±0.30	1.70±0.38	0.22±0.35**	1.45±0.28	1.66±0.37	0.21±0.31**	
Intervention group	1.51±0.32	1.65±0.40	0.14±0.37**	1.48±0.31	1.61±0.38	0.13±0.38**	
Intervention effect, beta (95% CI)			-0.08±0.01 (-0.10,-0.06)			-0.08 (-0.10,-0.06)	0.702
<i>p</i> value [‡]			<0.001			<0.001	
LDL-C (mmol/L), mean±SD							
Control group	2.20±0.60	2.31±0.64	0.12±0.49**	2.28±0.65	2.37±0.70	0.09±0.53**	
Intervention group	2.21±0.58	2.32±0.67	0.11±0.59**	2.30±0.64	2.38±0.73	0.09±0.62**	
Intervention effect, beta (95% CI)			-0.01 (-0.05,0.03)			-0.01 (-0.05,0.03)	0.367
<i>p</i> value [‡]			0.516			0.553	
CHO (mmol/L), mean±SD							
Control group	3.96±0.79	4.16±0.71	0.20±0.61**	4.04±0.85	4.20±0.76	0.16±0.61**	
Intervention group	4.23±0.74	4.10±0.75	-0.14±0.56**	4.27±0.80	4.13±0.82	-0.14±0.59**	
Intervention effect, beta (95% CI)			-0.34 (-0.38,-0.30)			-0.30 (-0.34,-0.26)	0.215
<i>p</i> value [‡]			<0.001			<0.001	
TG (mmol/L), mean±SD							
Control group	0.82±0.49	0.86±0.44	0.04±0.56**	0.86±0.46	0.91±0.41	0.05±0.51**	
Intervention group	0.78±0.42	0.83±0.43	0.05±0.44**	0.81±0.39	0.88±0.55	0.07±0.54**	
Intervention effect, beta (95% CI)			0.01 (-0.03,0.05)			0.02 (-0.02,0.06)	0.577
<i>p</i> value [‡]			0.534			0.291	

[†]The difference between baseline and end of study for the same group. [‡]*p* value for intervention effect.

p*<0.01; *p*<0.01.

Table 4. The effects of comprehensive intervention for different weight status children (mean±SD)

	Malnutrition			Normal weight			Overweight/Obesity			<i>p</i> for weight status difference
	Baseline	End of study	Change [†]	Baseline	End of study	Change [†]	Baseline	End of study	Change [†]	
BMI (kg/m ²)										
Control group	13.5±0.6	14.1±1.4	0.7±1.3**	16.0±1.4	16.7±2.1**	0.7±1.3**	21.5±3.0	22.5±3.3	1.0±2.0**	<0.001
Intervention group	13.4±0.7	14.2±1.9	0.8±1.6**	16.1±1.4	16.5±2.0	0.4±1.3**	21.5±3.3	22.0±3.2	0.5±2.6**	
Intervention effect, beta (95% CI) <i>p</i> value [‡]			0.1 (-0.2, 0.3) 0.521			-0.3 (-0.3, -0.2) <0.001			-0.6 (-0.8, -0.3) <0.001	
BMI z score										
Control group	-1.87±0.47	-1.66±0.88	0.21±0.87**	-0.15±0.67	-0.11±0.93	0.04±0.62**	2.01±0.75	1.97±0.86	-0.04±0.64	<0.001
Intervention group	-1.94±0.57	-1.72±1.03	0.22±1.08**	-0.10±0.67	-0.21±0.92	-0.12±0.64**	2.03±0.93	1.83±0.85	-0.20±0.81**	
Intervention effect, beta (95% CI) <i>p</i> value [‡]			0.01 (-0.16, 0.17) 0.922			-0.16 (-0.20, -0.12) <0.001			-0.16 (-0.24, -0.09) <0.001	
Body fat (%)										
Control group	22.5±7.1	24.4±6.7	1.9±3.4**	25.2±6.6	27.2±6.3	2.1±3.2**	33.2±4.3	34.5±4.5	1.3±3.6**	<0.001
Intervention group	23.0±6.9	24.5±6.8	1.7±4.3**	25.1±6.6	26.3±6.5	1.4±3.5**	33.1±4.2	33.5±4.8	0.5±3.8**	
Intervention effect, beta (95% CI) <i>p</i> value [‡]			-0.2 (-0.8, 0.3) 0.442			-0.8 (-1.0, -0.6) <0.001			-0.9 (-1.3, -0.5) <0.001	
Waist circumference (cm)										
Control group	49.5±3.2	52.3±4.3	2.7±2.6	54.7±5.0	58.0±6.3	3.3±3.4**	69.1±9.2	73.8±9.6	4.7±4.3**	<0.001
Intervention group	50.2±4.9	52.8±6.2	2.6±2.8	55.0±5.0	57.9±6.2	2.9±3.4**	69.0±8.7	73.0±9.3	3.9±4.7**	
Intervention effect, beta (95% CI) <i>p</i> value [‡]			-0.1 (-0.6, 0.3) 0.510			-0.4 (-0.6, 0.2) <0.001			-0.8 (-1.3, -0.4) <0.001	

[†]The difference between baseline and end of study for the same group. [‡]*p* value for intervention effect.

p*<0.01; *p*<0.01.

may store more fat in their body (the girls had more body fat percentage than boys at baseline), which could make girls reduce less body fat than boys.

We found significant intervention effects on glucose and lipids. Although some school-based interventions have positive effects on overweight or obesity,⁴¹⁻⁴³ most have not.⁴⁴⁻⁴⁶ Several short-term school-based programs altered glucose and/or insulin levels,^{47,48} even though they had no effect on the BMI. In our study, positive effects were found both on the BMI and also on the levels of glucose and lipids. The intervention effect sizes we observed were significant but small, which raise the concerns about clinical relevance. However, our intervention effect was population based. The slight improvement of the population distribution might result in a large decrease of disease prevalence. Comparing the 2002 and 2012 China National Nutrition and Health Surveys, the mean level of glucose, Chol and TG increased by 0.75 mmol/L, 0.69 mmol/L and 0.28 mmol/L, respectively, in 10 years, which were paralleled by an increased prevalence of diabetes from 2.0% in 2002 to 9.7% in 2012, dyslipidemia from 18.6% in 2002 to 40.4% in 2012.⁴⁹ We observed an intervention effect of NISCOC of -0.2 mmol/L glucose and -0.32 mmol/L total cholesterol with comprehensive intervention and -0.09 mmol/L TG by nutrition education intervention in one year; if these intervention effects were sustainable over 10 years, theoretically, the potential long term intervention effect would counter balance the increasing magnitude of the mean population increasing trend of glucose and dyslipidemia. A similar inference for childhood obesity was observed. From 2002 to 2012, the 10-year increased BMI ranged from 0.4 to 1.8 kg/m²,⁴⁹ with a mean value of 0.14 kg/m²/year, among children aged 6-13 years, which was much less than our intervention effects of 0.3 kg/m²/year of comprehensive intervention.

One popular concern of childhood obesity intervention trials is that the intervention on preventing obesity may cause harmful effect for malnourished students. So we stratified our analysis of intervention effect by BMI status in this study. We didn't observe any negative effect among stunting participants. Although there's less body fat and waist circumference increase (not significantly), there was a greater BMI and BMI z scores increase among malnutrition students in intervention group than control group.

The limitations of our study included that the intervention was only in urban and not in rural areas, and the BMI z scores were slightly different between control and intervention group at baseline. Also, H1N1 spread in the second half year of 2009, just at the beginning of the intervention study. Many schools refused the staff members from our study group to enter the schools for supervising the intervention implementation, which at least in part, weakened the intervention effect. Another fact, which we have to consider, is that Happy 10 activity may not be added to the normal PA of the students, but somehow replaced some other kinds of activities, which also could weaken our intervention effect from the theoretical level. So we insisted that the Happy 10 program should be conducted twice a day instead of the sedentary activity to reduce the sedentary time. No long-term follow-up is

available, so it is not known whether these intervention effects will persist once the obligatory school-based PA stops.

In conclusion, we observed significantly moderate intervention effects on the prevalence of overweight and obesity, BMI, BMI z scores, waist circumference, body fat percentage, plasma glucose and lipid index. The school-based comprehensive intervention could be used for prevention of childhood obesity in China.

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