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Effectiveness of a kindergarten-based intervention for preventing childhood obesity

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Effectiveness of a kindergarten-based intervention for preventing childhood obesity in China

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Abbreviations:

Randomized controlled trial (RCT);Body mass index (BMI); Working Group on Obesity in China (WGOC)

Table of Contents Summary: We have demonstrated the feasibility of implementing a multifaceted, culturally appropriate preschool-based obesity intervention program in Guangzhou, China.

What's Known on This Subject: As a country with an emerging obesity epidemic, few

large-scale obesity prevention programs have been conducted among children and adolescents in China. There has also yet to be definitive evidence of what constitutes effective approaches for childhood obesity intervention.

What This Study Adds: We have piloted an intervention program designed for preschool children in Guangzhou. This 12-month long multifaceted program was simple to implement and well-received by stakeholders and appeared to be effective in reducing obesity prevalence.



Contributors' Statements:

Xiu Qiu and Huimin Xia: Dr. Qiu and Dr. Xia conceptualized and designed the study, and approved the final manuscript as submitted.

Yan Hu: Ms. Hu carried out the entire intervention process, performed the initial analyses, drafted the initial manuscript, and approved the final manuscript as submitted.

Jianrong He: Mr. He performed the initial analyses, drafted the initial manuscript, and approved the final manuscript as submitted.

Fanghua Liu: Ms. Liu coordinated and supervised data collection, critically reviewed the manuscript, and approved the final manuscript as submitted.

Weidong Li: Mr. Li coordinated and supervised data collection, critically reviewed the manuscript, and approved the final manuscript as submitted.

Jinghua Lu: Ms. Lu coordinated and supervised data collection, critically reviewed the manuscript, and approved the final manuscript as submitted.

Yanfei Xing: Ms. Xing carried out the intervention project, and approved the final manuscript as submitted.

Suifang Lin: Ms. Lin carried out the intervention project, and approved the final manuscript as submitted.

Qiong Feng: Ms. Feng carried out the intervention project, and approved the final manuscript as submitted.

Suzanne Bartington: Dr. Bartington interpreted the data, critically reviewed the manuscript, and approved the final manuscript as submitted.

Kin Bong Hubert Lam: Dr. Lam interpreted the data, critically reviewed the manuscript, and approved the final manuscript as submitted.

Kar Keung Cheng: Dr. Cheng interpreted the data, critically reviewed the manuscript, and approved the final manuscript as submitted.

Abstract

Background and Objectives: Interventions to prevent childhood obesity targeting school age children have mostly reported limited effectiveness, suggesting such prevention programs may need to start at an earlier age, but evidence has been scarce. We reported a pilot study aiming to demonstrate the feasibility of a multifaceted intervention for preschool children and to provide a preliminary assessment of the effectiveness.

Methods: This non-randomized controlled trial recruited children aged 3-6 years from six kindergartens in Guangzhou, China. Based on the preference of the School and Parents Committees, four kindergartens (648 children) received a three-component intervention (training of kindergarten staff, instigating a curriculum promoting healthy diet and lifestyle, and close collaboration between families and kindergartens) over 12 months, while the other two kindergartens (336 children), serving as controls, received routine health care provision. Outcome measures were the changes in body mass index (BMI) z-score between baseline and the end of 12 months, and the prevalence of post-intervention overweight/obese children.

Results: By 12 months, children within the intervention group had a smaller BMI z-score increase (0.24) compared to the control (0.41), with a difference of -0.31 (95% CI -0.47 to -0.15) (p<0.0001). The prevalence of overweight/obesity was also lower among the intervention group at the end of the study (OR: 0.43, 95% CI 0.19 to 0.96), adjusted for baseline overweight/obesity status.

Conclusions: Our results indicated a multi-component health behavior intervention might be effective in reducing the prevalence of obesity, but the longer term effects will need confirmation from randomized controlled trials.

Introduction

Childhood obesity is an important public health issue because of its association with a number of adverse health outcomes in adulthood,¹ not only in Western countries, but also in low- and middle-income countries.^{2,3} With lifestyle and dietary changes brought about by rapid economic growth and urbanization, the childhood obesity epidemic has spread to low- and middle-income countries, such as China.^{2,3,4} Data from a nationwide survey in 2010 revealed 15% of Chinese children and adolescents were overweight or obese,⁵ prompting an urgent need for effective primary prevention strategies to curb the progression of the obesity epidemic in China.

Previous prospective studies have suggested the potential origins of obesity in early life, ⁶⁻⁹ during which exposures such as fetal stressors, maternal smoking and formula feeding may contribute to rapid weight gain during the first year of life, ¹⁰ predisposing to the development of obesity in childhood, which persists into adulthood. ¹¹ Although there is evidence suggesting that obesity, as a chronic condition, develops in early childhood years, ¹² most childhood obesity intervention studies have been conducted among school age children, ¹³⁻¹⁵ and few have targeted the preschool population, especially in China. ¹⁶⁻¹⁸

Community-based weight management programs, which facilitate weight loss through long term health-related behavioral changes in nutrition and physical activity, ^{17,19} may play an important role in the prevention and control of childhood obesity. However, little research into this area has been conducted in China. ²⁰ While there is some evidence to suggest such programs require a multidisciplinary approach, including the use of cognitive behavioral strategies and the involvement of multiple stakeholders and sectors, ¹⁰ in order to achieve and

maintain healthy lifestyle,²¹ it is unclear how such intervention strategies can be formulated and implemented in China, because of the heterogeneity in policies on health and well-being of pre-school children across contemporary urban China. ^{22,23,24}

We conducted a pilot study in Guangzhou, the largest city in southern China, aiming to develop a feasible, multidisciplinary kindergarten-based obesity prevention trial among preschool children, and to evaluate the acceptability among stakeholders and the effectiveness of the program. The experience and information obtained in this pilot study would inform the design of a definitive (phase III) cluster randomized controlled trial (RCT).

Methods

Setting and recruitment

A cluster, non-randomized controlled pilot trial was conducted between January 2012 and December 2013 in three districts (Liwan, Haizhu, and Panyu) of Guangzhou. All 65 kindergartens (a brief description of preschool education in Guangzhou is given in Appendix 1) in these districts were screened for eligibility, of which 22 met the inclusion criteria: (i) run by the government (public kindergarten); (ii) located in the central area of the district; (iii) had no less than 100 students; and (iv) had no less than two school doctors. Invitation letters were sent to the principals of the eligible kindergartens, six of whom agreed to participate in the trial. Based on the preference of the School and Parents Committee and the availability of the catering software in the kindergartens, four kindergartens were allocated to the intervention group and the remaining two were assigned as the control. All children 3 to 6 years of age enrolled in the participating preschools and their parents or legal guardians were

invited to participate in the study.

The study protocol was approved by the Ethical Committee for Biomedical Research in Guangzhou Women and Children Medical Centre and Guangzhou Health and Family Planning Commission of the Peoples' Republic of China. The study was registered in ClinicalTrials.gov (NCT03022474). Written informed consent was obtained from the parents/guardians of all participating children.

Intervention

The intervention protocol was developed by an expert group from the National Children Obesity Intervention Team, comprising pediatricians, child health specialists, preschool teachers, and nutritionists, and included three integrated components (Table 1):

Component 1- training of kindergarten staff: Before the start of the program, two members of the intervention team (a nutritionist and a physician) delivered eight 40-min sessions (twice a week for a month) on dietary management in children and daily food purchasing for school doctors and kitchen staff. During the trial, two physicians (qualified in health education) gave lectures every two months on general nutrition knowledge to all preschool staff, focusing on the promotion of healthy food and restriction of unhealthy food. To understand the dietary intake of children from school meals in this trial, we first conducted a dietary survey in all 6 preschools at baseline. Kitchen staff were trained to use the dietary software to develop balanced menus specifically for preschool children, in line with the prevailing nutritional guidelines (Appendix 2). At approximately six months into the trial we repeated the survey. Overall, the nutrient content of modified menus was largely consistent with the Chinese Nutrition Society guidance for preschool children (Supplementary Table 3).

Component 2- a curriculum promoting healthy diet and lifestyle: Children in the intervention group received a 20-minute health education lesson every week, delivered through a curriculum designed by the Expert Group (with accompanying picture books), where they had learning activities and games covering healthy food choice, dietary habit, and reduction of sedentary behaviors. The curriculum also introduced daily, short (<10 min) activities and dance sessions after lunch to increase children's physical activity levels.

Component 3 - collaboration between families and kindergartens: We organized lectures designed for parents delivered every two months during the intervention period. Topics covered included childhood obesity prevention measures and how to use growth curves. We produced a handbook for communication between families and schools, to be distributed on a weekly basis and, in which children's health behaviors were documented and reviewed by teachers and parents. Finally, parents were notified of their children's height and weight every three months, so that they could plot and interpret their children's growth curves.

Children in the control group received regular healthcare as per the routine practice.

Apart from the anthropometric measurements at baseline and every three months thereafter, they did not receive any other intervention.

Outcome Measures

Our primary outcome measures were the changes in body mass index (BMI) z-score between baseline and the end of 12 months, and the prevalence of post-intervention overweight/obese children. Weight and height were measured every three months from the beginning of the project by trained preschool doctors. Weight was determined in minimal clothing without shoes to the nearest 0.5 kg, and height to the nearest 0.5 cm using a calibrated stadiometer

provided by the research team. BMI was calculated as weight (kg) divided by height (m) squared. BMI z-scores (SD score), representing the deviation compared with an average child of the same sex and age, were calculated for each child based on standardized growth charts from the Working Group on Obesity in China (WGOC). Children with BMI values between 85th and 94th percentiles (z-scores between 1.036 and 1.645) were considered overweight and those with BMI ≥95th percentile (z-score ≥1.645) were considered obese, following the BMI reference developed by WGOC. We combined the overweight and obese children in our subsequent analyses.

The secondary outcomes were the feasibility and acceptability of the intervention, which were qualitatively described. We used a number of techniques to evaluate the intervention components, including direct observation, collection of uptake data, questionnaires administered to parents and preschool staff, and interviews with key school doctors and teachers to discuss explored delivery, development and optimization of the complex intervention components.

Covariates

Parents (or legal guardians) were requested to complete a questionnaire covering socio-demographic information, mode of infant feeding, daily activities, birth weight and length of their children, as well as parental height and weight.

Statistical Analysis

Baseline characteristics between intervention and control groups were compared and assessed by Chi-squared and t-tests where appropriate. The difference in prevalence of overweight/obesity (expressed as odds ratios [OR] and associated 95% confidence intervals

[CIs]) between the intervention and control groups was compared both at baseline and at the end of the intervention period using multivariate regression analysis with PROC SURVEYLOGISTIC procedures (SAS Institute Inc.) after adjusting for gender, maternal BMI, dietary factors and physical activity measures as covariates and baseline status of overweight/obesity. For BMI and BMI z-scores, we built multiple linear regression models with PROG SURVEYREG procedures to assess the intervention effect, after adjustment for the potential confounders aforementioned. The SAS Survey Procedures (PROC SURVEYLOGISTIC/ PROG SURVEYREG) has been widely used in previous studies. ²⁶⁻²⁸ to account for complex sampling structure (including clustering). Multilevel models were not used because the intraclass correlation coefficient (ICC) for all three outcomes (an indicator of the extent of clustering of data at school level) were negligibly small (0.003 for overweight/obesity, 0.01 for BMI, and 0.02 for BMI z-score), and that the number of clusters (preschools) was too small (n=6) for multilevel models to be effective (Maas and Hox suggested there should be at least 30 groups for unbiased estimation²⁹). Likewise, as only 30% of the children in the control group had quarterly anthropometric measurements (as this was not part of the routine practice) we did not compute longitudinal models to avoid bias. A two-tailed p-value of 0.05 was considered statistically significant. All statistical analyses were based on the intention-to-treat population at the end of the final follow-up assessment and performed using SAS 9.1 software (SAS Institute, Cary, NC, USA).

Results

Baseline Characteristics

Among the 65 kindergartens, 59 were excluded for the following reasons: having <100 students (n=15), having <2 school doctors (n=19), not located in the central area of the district (n=9), and were not willing to participate (n=16). Supplementary Table 1 shows the characteristics of the eligible preschools, including the 16 that did not participate in the study. The participating preschools tended to have smaller school size, younger children and a better staff to children ratio. Overall, 6 kindergartens located in Liwan (n=2), Haizhu (n=2), and Panyu (n=2), comprising a total of 1063 children aged 3 to 6 years participated in the study. We excluded 79 children with missing baseline information and 67 who were lost to follow up, resulting 917 children in the final analysis (Figure 1). There were no material differences in baseline characteristics between children who were included in final analysis and those who were excluded (data not shown).

Table 2 and Supplementary Table 2 summarize the baseline characteristics of the intervention and control groups, and for each participating preschool, respectively. Four kindergartens were assigned to receive the intervention, and the remaining two served as the control. Although the two groups did not differ statistically in gender distribution, birth length, and family structure, children in the intervention group were younger (49 vs 52 months), more likely to be exclusively breastfed before 6 months (45% vs 42%). The absolute differences in other characteristics were insubstantial both between and within the two groups.

Main Outcomes

The main outcomes of interest in the trial are the changes in the prevalence of overweight/obesity and the absolute differences in BMI and BMI z-scores at follow-up. Table

3 and Figure 2 show the change of prevalence of overweight/obesity for both intervention and control groups at baseline and after 12 months. At the start of the trial, the prevalence of overweight/obesity was slightly higher in the control (20.8%) compared to the intervention group (15.5%), although this difference was not statistically significant (OR 0.92; 95% CI 0.65, 1.31; p=0.66). At the end of the study, while the prevalence increased in both groups, the extent of increase was less prominent in the children who received intervention (+4.4%) compared to those who did not (+12.4%). Adjusting for baseline overweight/obesity status and other relevant confounders, the risk of becoming overweight/obesity in the intervention group was more than halved (OR 0.43; 95% CI 0.19, 0.96). The effect was stronger among boys (OR 0.40; 95% CI 0.19, 0.85) than in girls (0.47; 0.17, 1.31).

With respect to the BMI and BMI z-scores, there were no statistically significant differences between intervention and control (15.6 kg/m² vs 16.0kg/m², p=0.051 for BMI; and 0.12 vs 0.56, p=0.118 for BMI z-score) at baseline. After 12 months, the increase in BMI was more than doubled in the control group (0.49 kg/m²) compared to the interventions (0.22 kg/m²), with a mean difference of -0.27 kg/m² after adjusting for maternal BMI, gender, age, feeding mode before 6 months, time spent eating, sleeping time and time spent in outdoor activities (95% CI -0.46, -0.08; p=0.002). The results were similar for BMI z-score, with a difference of 0.31 (95% CI, -0.47, -0.15; p<0.0001) between the two groups.

Secondary Outcomes

As a pilot study, we explored the acceptability and feasibility of specific intervention components delivered in the preschool setting. Findings of the evaluation are shown in Table 5. Overall, most of the components were deemed appropriate by the kindergarten staff and

parents, reflected in very high attendance levels and positive feedback throughout the trial. Nevertheless, two components were found to be less suitable in this setting. Exercise sessions after lunch received mixed feedback as (i) it was logistically challenging to assemble children after lunch and (ii) they shortened the break time. Although parents had expressed interest in attending bimonthly health promotion lectures, they were too busy to attend all sessions.

Discussion

We have, to our knowledge for the first time, demonstrated the feasibility of running a weight management trial in a kindergarten setting in China, where children are exposed to an increasing obesogenic environment as a result of recent rapid economic development. ³⁰ This 12-month multidisciplinary pilot program, which aims to increase parental awareness of their children's weight and to discourage unhealthy behaviors, could significantly slow down the progression to overweight/obesity among preschool children.

Previous studies have reported comparable intervention effect sizes in older children. 31-33 In this study, the progression to overweight/obese BMI among girls appeared to be less sensitive to the intervention measures; a finding which is somewhat consistent with other studies. 33-35 It is possible that socio-cultural factors account for these observed gender differences. Males are expected to be physically stronger and parents (especially grandparents) frequently associate this with having large appetite and may be more likely to overfeed male children. 36 Therefore, it is possible that our intervention has exerted a stronger beneficial effect on boys who might have an otherwise higher risk of unhealthy dietary habit and behaviors than girls.

We also found that children who received the intervention had a smaller increase in BMI/BMI z-score, which was consistent with other childhood obesity intervention studies, ³⁷⁻³⁹ despite of the difference in their objectives, designs, mode, and setting of intervention delivery. A systematic review of interventions targeting children of 0-5 years reported to have an effect of -0.26 kg/m² (95% CI 0.53, 0.00) in BMI compared to the control. ¹⁶ However, the majority of previous studies targeted children aged 6 to 12 years, with interventions predominantly based on behavior change theories and implemented in education settings.⁴⁰ Some major fundamental changes were required to implement these comprehensive approaches, including the integration of healthy lifestyle promotion into the regular curriculum, improvement of nutritional quality of food provided to children, and provision of support for people who may be influential to children's growth. 41 Evidence has suggested that multicomponent methods may be more effective in prevention of overweight among children compared to community-based single-component interventions, irrespective of the study design (i.e. RCT or non-RCT). 42-44 In our current study, modification of behavioral elements was emphasized throughout the whole semester, creating a supportive environment and culture, and a home-preschool association was set up for parents to implement health promotion strategies and activities. The use of multiple strengthened component designs would be more likely to improve the outcomes.

Our findings have important public health implications, as we have demonstrated the feasibility of implementing interventions in a kindergarten setting through the use of multiple tactics (monitoring and feedback) to encourage participants' self-motivation. ⁴⁵ Most previous intervention programs were conducted in elementary and middle schools where food was

provided by commercial caterers; whereas we were able to monitor children's diet through school doctors and chefs, since food choice and quality in Chinese preschools is monitored by the government, allowing full adherence to the nutritional goals. ^{16,46} We also found the participation of parents in the intervention program was instrumental to the success as they paid more attention to their children's diet and lifestyle due to their increased awareness of the consequences of childhood obesity. By asking parents to monitor their children's growth curves regularly, families became more involved and compliant to the intervention regimen. Therefore it is important that future studies incorporate health education lectures and other relevant tools as core components of obesity prevention intervention to engage family members and to encourage active lifestyle and healthy eating within the family.

As a pilot trial, there were some limitations in the current study. Our trial has relatively insufficient power to detect the intervention efficacy compared to a large-scale RCT. Kindergartens were allocated to the intervention group on a voluntary basis, and, therefore, randomization was not possible and resulted in imbalance of confounding factors between the two groups and allocation bias. It is possible that the kindergartens (and parents) opting in for the intervention had stronger intentions and health behaviors to tackle childhood obesity than the control kindergartens, hence our observed effect size might have been over-estimated. Nevertheless, our findings (from a non-randomized trial) were similar to those obtained from randomized studies.⁴⁷ Our intervention was limited to 12 months, and we do not have long-term follow-up data to assess compliance after the intervention. However, one of our purposes was to evaluate the feasibility of the intervention and to inform optimization in this setting. We demonstrated the feasibility and acceptability of delivering a multi-component

obesity intervention in preschool, which provided opportunity to refine and modify the program. This information will form part of the strategy plan for the future phase 3 RCT to provide definitive evidence. Finally, we did not perform a formal sample size calculation because this was a pilot study and we have included all eligible kindergartens of the targeted area which agreed to take part in the study.

Conclusion

This kindergarten-based comprehensive intervention, consisting of regular BMI monitoring by preschool doctors and parents, and education to increase awareness among parents and teachers on obesity and healthy dietary and lifestyle, has led to a reduced prevalence of obesity in a sample of preschool children attending kindergarten in Guangzhou, China. The findings have demonstrated the feasibility of implementing an effective multidisciplinary preschool-based obesity intervention program. A large, definitive RCT trial is now required to determine the long-term effectiveness of children obesity interventions.

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Figure legends

Figure 1. Trial profile for one year follow-up

Figure 2. Mean change in proportion of overweight and obese children from baseline to follow up at 12 months according to clusters



Table 1 Details of the three components of the intervention program

Component	Aims	Description
1. Training of kindergarten staff	To increase knowledge base, skills and confidence for planning and cooking of healthy meals to influence dietary behavior	i) Before the start of the trial, eight 40-min sessions (twice a week for a month) on dietary management in children and daily food purchasing were organized for school doctors and kitchen staff.
		ii) During the trial, lectures (every two months) on general knowledge in nutrition focusing on the promotion of healthy food and restriction of unhealthy food were given to all preschool staff.
		iii) Kitchen staffs were trained to use the dietary software for planning balanced menus appropriate for preschool children.
2. A curriculum promoting healthy diet and lifestyle	i) To promote a habit of healthy eating among childrenii) To increase the amount of time for	i) An additional weekly 20-min health education lesson was included in the curriculum, where children had learning activities and games covering healthy food choice, appropriate portion sizes and eating pace. This involved the use of various learning aids
	physical activity	such as picture story books, cards, food models, and nursery rhymes. ii) Physical activities were mandatory in in the intervention group. Teachers were trained to act as play group leaders and organize activities after lunch. Daily 10-min dance sessions were included. Children were asked to dance in rhythm music in the activity room.
3. Collaboration between families and schools	i) To equip families with the knowledge about children development and healthy lifestyle and skills to monitor their children's growth	i) A series of lectures designed for parents were organized every two months during the intervention period, covering topics such as what body mass index (BMI) is, reference BMI for preschool children, how to use growth curves, the cause and harms of childhood obesity, advice on healthy diet (increasing consumption of vegetables and fruit, reducing consumption of meat, snacks, and fast food, and avoiding sugary drinks).
	ii) To improve communications between the school and parents	ii) A handbook was issued to every family, in which children's health behaviors were documented to be reviewed by teachers and parents weekly.
	iii) To engage parents as facilitators of their children's health after the intervention period	iii) Parents were notified of their children's anthropometric measurements every three months, so that they could plot and interpret their children's growth curves themselves.

Table 2 Demographic characteristics of the children and families at baseline by intervention status

	Intervention	Control	p-value
n	619	298	.0.004
Age (month); mean (SD)	48.8 (7.6)	52.0 (7.1)	< 0.001
Gender; n (%)	 / ·		0.54
Male	317 (51.2)	159 (53.4)	
Female	302 (48.8)	139 (46.6)	
Birth weight (kg); mean (SD)	3.2 (0.4)	3.2 (0.5)	0.041
Birth length (cm); mean (SD)	49.9 (1.8)	49.7 (2.0)	0.27
Feeding mode before 6 months; n (%)			0.004
Exclusive breastfeeding	279 (45.1)	120 (41.7)	
Partial breastfeeding	234 (37.9)	92 (31.9)	
Formula feeding	105 (17.0)	76 (26.4)	
Time spent outdoors (h); mean (SD)	1.7 (1.1)	1.8 (1.0)	0.038
Time spent watching TV (h); mean (SD)	1.1 (0.7)	1.3 (1.0)	0.005
Nighttime sleep duration (h); mean (SD)	9.0(0.8)	9.6 (1.3)	< 0.001
Average feeding time for a meal (min); mean	32.4 (11.6)	30.5 (9.0)	0.016
(SD)	,	,	
Mother's BMI (kg/m ²); mean (SD)	20.7 (2.3)	21.1 (2.5)	0.030
Father's BMI (kg/m²); mean (SD)	23.4 (2.7)	23.5 (3.1)	0.75
Family structure; n (%)	()	()	0.24
Nuclear family	224 (38.2)	104 (39.7)	
Extended	332 (56.6)	150 (57.3)	
Other	31 (5.3)	8 (3.1)	

Table 3 Changes in the prevalence of overweight/obesity after 12 months by gender and group

			Intervention vs Control		
	Intervention	Control	Difference (95% CI)	Adjusted odds ratio (95% CI)	
All					
n	619	298			
Baseline	15.5%	20.8%	-5.3% (-10.7,0.1)	$0.92 (0.65, 1.31)^a$	
12 months	19.9%	33.2%	-13.4% (-19.6, -7.2)	$0.43 (0.19, 0.96)^{b}$	
Change after 12 months	+4.4%	+12.4%			
Male					
n	317	159			
Baseline	19.2%	22.6%	-3.4% (-11.2, 4.4)	$1.19(0.76, 1.87)^{a}$	
12 months	21.1%	37.1%	-16.0% (-24.5, -7.2)	$0.40 (0.19, 0.85)^{b}$	
Change after 12	+1.9%	+14.5%			
months					
Female					
n	302	139			
Baseline	11.6%	18.7%	-7.1% (-14.5, -0.3)	$0.77 (0.56, 1.05)^a$	
12 months	18.5%	28.8%	-10.2% (-18.9, -1.5)	$0.47 (0.17, 1.31)^{b}$	
Change after 12 months	+6.9%	+10.1%		, , ,	

^aAdjusted for maternal BMI, feeding mode before 6 months, gender (where appropriate), time spent eating, sleeping time and time spent in outdoor activities

^bAdditionally adjusted for baseline status of overweight/obesity

Table 4 Adjusted differences in anthropometric indices at different time points

			Intervention vs Control	
	Intervention	Control	Difference (95% CI)	p-value
Baseline				
BMI (kg/m ²); mean (SE) ^a	15.6 (1.5)	16.0 (1.4)	-0.22 (-0.47, 0.03)	0.051
BMI z-score; mean (SE) ^b	0.12 (1.44)	0.56 (1.25)	-0.16 (-0.38, 0.06)	0.118
12 months				
BMI (kg/m ²); mean (SE) ^c	15.0 (1.5)	16.4 (1.8)	-0.44 (-0.68, -0.19)	< 0.0001
BMI z-score; mean (SE) ^d	0.36 (1.41)	0.97 (1.51)	-0.45 (-0.64, -0.26)	< 0.0001
Change after 12 months				
BMI (kg/m ²); mean (SE) ^c	0.2 (1.1)	0.5 (1.1)	-0.27 (-0.46, -0.08)	0.002
BMI z-score; mean (SE) ^d	0.24 (1.11)	0.41 (1.05)	-0.31 (-0.47, -0.15)	< 0.0001

^aAdjusted for gender, age, feeding mode before 6 months, time spent eating, sleeping time and time spent in outdoor activities

^bSame as (a) but without adjusting for age

age, feeding m rout in outdoor activities ^cAdjusted for maternal BMI, baseline status of overweight/obesity, gender, age, feeding mode before 6 months, time spent eating, sleeping time and time spent in outdoor activities

^bSame as (c) but without adjusting for age

Table 5 Methods and findings of the evaluation of the intervention program

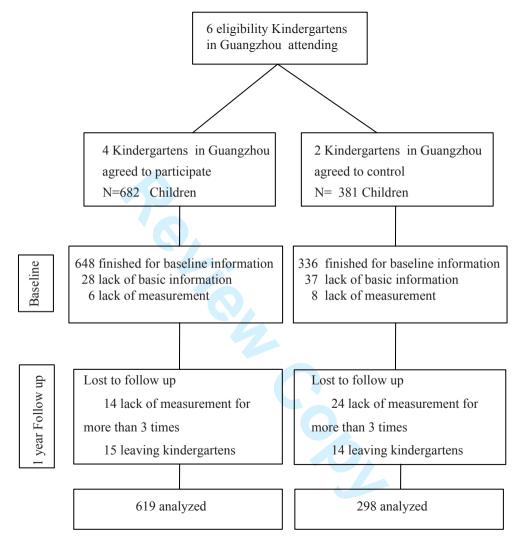
Component	Methods of evaluation	Key findings
1. Training of kindergarten staff	i) Interview of preschool staff focusing on	i) Acceptability for the course on general nutrition knowledge was high. Preschool staff
	the appropriateness of the content	found it useful and the level was appropriate. Some kitchen staff thought the catering
		software was too advanced for them due to their relatively lower educational level.
	ii) Pre- and post-course questionnaires	
	testing the understanding of core content	ii) Nonetheless, after training, 76% of the kitchen staff were able to operate the software
	and the use of the catering software	on their own.
	iii) Awareness and attendance of preschool	iii) Overall 96% of the preschool staff were aware of the courses. Attendance was also
	staff in the courses	high at 93%.
2. A curriculum promoting	i) Interview of preschool staff focusing on	i) Teachers who were responsible for delivering the health education lessons had
healthy diet and lifestyle	the appropriateness of the curriculum	positive feedback and thought the content was appropriate.
	ii) Observation of sessions to learn	ii) The "healthy activities", while being acceptable by the children, the timing (after
	satisfaction and acceptance of teachers and	lunch) was impractical as it shortened the lunch break (which includes a nap).
	children.	Nevertheless dancing in the activity room was highly acceptable to children and
		preschool staff.
	iii) Questionnaires for parents on their	
	knowledge of their children's dietary habits	iii) Parents' response showed that they were familiar with their children's dietary habit
	and health behaviors	and health knowledge.
3. Collaboration between families	i) Interview of parents and preschool staff	i) Parents were too busy to attend all the lectures. They were more prepared to attend
and schools		twice – at the start and during the intervention.
	ii) Awareness and attendance of parents in	
	the courses	ii) This was reflected by a high awareness at 92%, but a lower attendance rate at 69%.
	iii) Compliance and usefulness of the	iii) Parents would welcome the feedback to be sent via text messages or a smartphone
	handbook	app. However, they still preferred to use handbook as a means to communicate with the

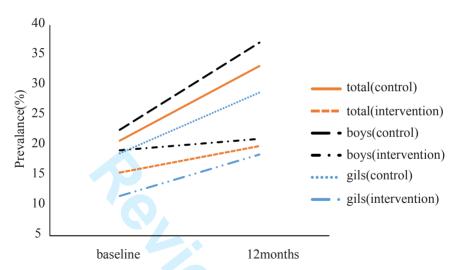
iv) Pre- and post-course questionnaires testing the understanding of core content

teachers. On average 96% of the handbooks were handed in on time.

iv) Parents liked the idea of tracing their children's growth curve, although they found the lecture material difficult. 99% of the children in the intervention group had a complete set of BMI records.







Checklist of items to include when reporting a randomized trial (56-58)

PAPER SECTION And topic	Item	Description	Reported on page #
TITLE & ABSTRACT	1	How participants were allocated to interventions (e.g., "random allocation", "randomized", or "randomly assigned").	
INTRODUCTION Background	2	Scientific background and explanation of rationale.	
METHODS Participants	3	Eligibility criteria for participants and the settings and locations where the data were collected.	
Interventions	4	Precise details of the interventions intended for each group and how and when they were actually administered.	
Objectives	5	Specific objectives and hypotheses.	
Outcomes	6	<u>Clearly defined primary and secondary outcome measures</u> and, when applicable, any <u>methods used to enhance the quality of measurements</u> (e.g., multiple observations, training of assessors).	
Sample size	7	How sample size was determined and, when applicable, explanation of any interim analyses and stopping rules.	
Randomization Sequence generation	8	Method used to generate the random allocation sequence, including details of any restriction (e.g., blocking, stratification).	
Randomization Allocation concealment	9	Method used to implement the random allocation sequence (e.g., numbered containers or central telephone), clarifying whether the sequence was concealed until interventions were assigned.	
Randomization Implementation	10	Who generated the allocation sequence, who enrolled participants, and who assigned participants to their groups.	
Blinding (masking)	11	Whether or not participants, those administering the interventions, and those assessing the outcomes were blinded to group assignment. When relevant, how the success of blinding was evaluated.	
Statistical methods	12	Statistical methods used to compare groups for primary outcome(s); Methods for additional analyses, such as subgroup analyses and adjusted analyses.	
RESULTS Participant flow	13	Flow of participants through each stage (a diagram is strongly recommended). Specifically, for each group report the numbers of participants randomly assigned, receiving intended treatment, completing the study protocol, and analyzed for the primary outcome. Describe protocol deviations from study as planned, together with reasons.	
Recruitment	14	Dates defining the periods of recruitment and follow-up.	
Baseline data	15	Baseline demographic and clinical characteristics of each group.	
Numbers analyzed	16	Number of participants (denominator) in each group included in each analysis and whether the analysis was by "intention-to-treat". State the results in absolute numbers when feasible (e.g., 10/20, not 50%).	
Outcomes and estimation	17	For each primary and secondary outcome, a summary of results for each group, and the estimated effect size and its precision (e.g., 95% confidence interval).	
Ancillary analyses	18	Address multiplicity by reporting any other analyses performed, including subgroup analyses and adjusted analyses, indicating those pre-specified and those exploratory.	
Adverse events	19	All important adverse events or side effects in each intervention group.	
DISCUSSION Interpretation	20	Interpretation of the results, taking into account study hypotheses, sources of potential bias or imprecision and the dangers associated with multiplicity of analyses and outcomes.	
Generalizability	21	Generalizability (external validity) of the trial findings.	
Overall evidence	22	General interpretation of the results in the context of current evidence.	

Appendix 1 A brief introduction of preschool education in Guangzhou

Kindergartens are educational establishments or learning space offering early childhood education, usually between the ages of three and six, prior to the commencement of compulsory (and free) primary education. In Guangzhou they may be run by municipal government or private enterprises, providing mainly full-day program with two semesters every year. In 2016, 511,417 children (out of 540,821 eligible or 95%) were enrolled in kindergartens across the city. Most kindergartens are staffed by fully qualified teachers who have a degree in early childhood education. At the same time, a training framework has been in place for existing pre-school teachers.

While there is yet to have a uniform consensus on the areas of development covered by preschool education curriculum, the following main themes emerge, revolving around health and physical development, emotional and spiritual well-being, social competence, intellectual development and communication skills.

Currently, a reform in curriculum is taking place in Guangzhou aiming to improve kindergarten teachers' professional knowledge, such as their understanding of the concept of play and pedagogy, and perceptions of inclusion and kindergarten-based curriculum. Involvement of parents and family in supporting preschool education has been emphasized and the collaborative partnership between kindergarten and family has been strengthened considerably in recent years.

Supplementary Table 1 Characteristics of eligible preschools at baseline by participation status

	Preschools that took part in the study (n = 6)	Preschools that did not take part in the study $(n = 16)$
Preschool setting		
Government run; n (%)	5 (83.3)	12 (75.0)
Years of running since establishment; mean (SD)	25.0 (20.2)	31.6 (20.8)
Full-day education; n (%)	6 (100)	16 (100)
Children	` '	, ,
Number of children		
Mean (SD)	177.2 (62.1)	209.0 (50.7)
Range	117-277	112-289
Age (month); mean (SD)	49.8 (7.6)	51.2 (6.1)
% male; mean (SD)	51.9 (0.2)	53.4 (1.4)
Staff		
Teachers		
Number; mean (SD)	24.0 (7.8)	21.8 (6.6)
Teacher: children ratio; mean (SD)	0.14 (0.01)	0.10 (0.01)
Years of service; mean (SD)	7.6 (1.4)	6.1 (1.3)
Medical staff		
Number; mean (SD)	2.5 (0.5)	2.1 (0.3)
Years of service; mean (SD)	4.3 (1.1)	4.8 (2.3)
Kitchen staff		
Number; mean (SD)	7.2 (2.4)	6.9 (1.4)
Years of service; mean (SD)	3.7 (0.7)	3.6 (1.0)

Supplementary Table 2 Demographic characteristics of the children and families at baseline by school

		Intervention preschools			Control p	reschools
	A	В	С	D	E	F
n	261	155	130	73	208	90
Age (month); mean (SD)	48.6 (8.5)	49.4 (7.6)	50.1 (5.9)	45.9 (6.7)	52.2 (7.1)	51.5 (7.1)
Gender; n (%)						
Male	130 (49.8)	82 (52.9)	67 (51.5)	38 (52.1)	120 (57.7)	39 (43.3)
Female	131 (50.2)	73 (47.1)	63 (48.5)	35 (47.9)	88 (42.3)	51 (56.7)
Birth weight (kg); mean (SD)	3.3 (0.4)	3.3 (0.5)	3.2 (0.5)	3.1 (0.4)	3.1 (0.5)	3.2 (0.4)
Birth length (cm); mean (SD)	50.0 (1.5)	49.7 (1.9)	49.7 (2.0)	50.0 (1.8)	49.6 (2.0)	49.9 (1.6)
Feeding mode before 6 months; n (%)	` ′	` ,	` ′	` '	` /	` /
Exclusive breastfeeding	119 (45.6)	75 (48.7)	68 (52.3)	17 (23.3)	71 (35.7)	49 (55.1)
Partial breastfeeding	101 (38.7)	51 (33.1)	49 (37.7)	33 (45.2)	74 (37.2)	18 (20.2)
Formula feeding	41 (15.7)	28 (18.2)	13 (10.0)	23 (31.5)	54 (27.1)	22 (24.7)
Time spent outdoors (h); mean (SD)	1.8 (1.1)	1.5 (1.0)	1.6 (1.0)	1.6(0.9)	1.9(0.7)	1.6(1.4)
Time spent watching TV (h); mean (SD)	1.1 (0.7)	1.2 (0.8)	1.1 (0.6)	1.1(0.7)	1.1 (0.9)	1.7(1.2)
Nighttime sleep duration (h); mean (SD)	8.9 (0.6)	9.0 (0.8)	9.1 (0.7)	9.2 (1.2)	9.6 (1.3)	9.3 (1.3)
Average feeding time for a meal (min); mean (SD)	34.6 (11.8)	30.5 (10.6)	32.1 (12.2)	29.1 (10.2)	30.9 (7.6)	29.6 (11.9)
Mother's BMI (kg/m ²); mean (SD)	20.6 (2.3)	20.8 (2.3)	20.9 (2.6)	20.9 (2.3)	21.2 (2.7)	20.8 (2.2)
Father's BMI (kg/m ²); mean (SD)	23.5 (2.8)	23.3 (2.7)	23.2 (2.7)	23.4 (2.5)	23.6 (3.3)	23.0 (2.6)
Family structure; n (%)	` ,	` ′		` '	` /	. ,
Nuclear family	99 (38.8)	49 (33.6)	48 (40.0)	28 (40.6)	80 (41.2)	24 (35.3)
Extended	149 (58.4)	89 (61.0)	70 (58.3)	24 (34.8)	109 (56.2)	41 (60.3)
Other	7 (2.8)	8 (5.4)	2(1.7)	14 (20.3)	5 (2.6)	3 (4.6)

Appendix 2 Component 1: Dietary intervention

Children attending preschools in Guangzhou are provided with meals (breakfast, lunch, and snacks); the dietary standard of which is based on the Chinese dietary guidelines set by the Chinese Nutrition Society, which aim to achieve a balanced diet as shown in the "dietary pagoda" in Figure S1. To understand the dietary intake of children from school meals in this trial, we conducted a dietary survey in all 6 preschools at baseline. During a four-day period, food was weighed before and after cooking, and after meals (for the leftovers), and was analyzed for nutritional intake of the children by food groups (as per the dietary pagoda). A summary of the daily nutrient intake at baseline (and the recommended intake) is given in Supplementary Table 3. The following issues were identified:

- Protein content exceeded recommended intake;
- Vegetable oil was also excessive;
- However, vegetable intake was insufficient in most preschools;
- Fruit was served 2-3 times every week;
- Too much sugar was added to a local traditional soup.

We designed the intervention component to specifically target these areas, with an aim to enhance the nutritional quality of the food served in the preschools in the intervention group, to comply with the Chinese Nutrition Society guidance for preschool children dietary intake. Kitchen staff in the preschools receiving intervention were given lectures on the fundamentals in children nutritional needs and a dietary software was provided to assist the planning of healthy and balanced meals and snacks.

At approximately six months into the trial, the dietary survey was repeated in all preschools in the intervention group. Supplementary Table 3 shows the daily nutrient intake of children, calculated from the weight of food provided by the preschools, assuming 35% and 40% of intake come from breakfast and lunch, respectively. Macronutrient content became closer to the reference daily intake values, with slightly reduced energy, protein, and fat content and a higher proportion of carbohydrates compared to the baseline. There were substantial changes in micronutrients such as calcium (from 332.8 to 612.5 mg), sodium (780.9 to 801.44 mg), and vitamin C (50.8 to 64.9 mg). Of note, phosphorus content, which was essentially unchanged in the intervention, far exceeded the recommended intake value.



Figure S1 Dietary Pagoda for Preschool Children

Supplementary Table 3 Daily nutrient intake before and during intervention (6 months into the trial) in preschools

	Daily	intake ^a	Daile na fanana a intaleab
	Pre-intervention	During intervention	 Daily reference intake^b
Macronutrients			
Energy (kcal)	1509.0	1461.9	1466.1
Carbohydrate (g)	190.3	199.1	197.3
Protein (g)	55.1	49.6	50.0
Fat (g)	58.6	51.9	53.0
Micronutrients			
Sodium (mg)	780.9	801.4	816.8
Calcium (mg)	332.8	612.5	733.4
Phosphorus (mg)	717.6	712.1	483.4
Selenium (mg)	33.7	30.2	23.3
Iron (mg)	14.9	11.8	12.0
Zinc (mg)	8.2	7.6	11.0
Vitamin A (IU)	524.8	515.7	566.7
Thiamine (mg)	0.9	0.8	0.7
Riboflavin (mg)	0.7	0.7	0.7
Niacin (mg)	8.1	7.8	6.7
Vitamin C (mg)	50.8	64.9	66.7

^a Daily intake was measured from the breakfast and lunch provided by the preschools using the weighing method, and calculated based on the assumption that 35% and 40% of total daily intake come from breakfast and lunch, respectively.

^b Daily intake level of a nutrient that is considered to be sufficient to meet the requirements of 97-98% of healthy preschool children.

List word counts below (do not paste the text here). Please see the Decision Letter Attachment for allowances as they pertain to your manuscript type.

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EDITOR/REVIEWER COMMENTS	AUTHOR'S RESPONSE	REFERENCE PAGE	CHANGE
Paste each of the editor and reviewer	Paste your answer to the editor and reviewer queries here.	State where* the change	APPROVED?
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		manuscript.	USE ONLY
Editor's comment: Please make sure to	Please refer to our response below.		
adjust for clustering in the analysis.			
The introduction (or the Methods, where	We have now included as a supplementary material (Appendix 1) a brief	Appendix 1	
the schools and participants are described)	description of the preschool education in Guangzhou, which we hope to give		
would benefit from a brief background	readers outside China improved contextual background of the study.		
about preschool and kindergarten			
programs in China (e.g., length of school			
day and school year, rates of attendance			
among population, educational			
requirements for classroom teachers).			
The Introduction would also benefit from	We have carefully read through the manuscript and have corrected the	Throughout the	
another careful read with an eye toward	grammatical and typographical errors.	manuscript	
basic grammar, etc. There are numerous			
easy-to-fix typographical errors.			
What is known about the differences, if	We have prepared supplementary tables to show the characteristics of the	Supplementary Table 1	
any, between the eligible kindergartens	kindergartens that have or have not participated in the study (Supplementary	Page 11, Line 3-6	
that participated and the eligible	Table 1, referred in Page 11, Line 3-6):		
kindergartens that did not participate in	"Supplementary Table 1 shows the characteristics of the eligible preschools,	Supplementary Table 2	
the research? What are the demographic	including the 16 that did not participate in the study. The participating	Page 11, Line 12-13	
characteristics of the families for each of	preschools tended to have smaller school size, younger children and a better	1 480 11, 2 12 13	
the participating schools (that is, not in the	, ,		
aggregate, as shown in Table 2)?	staff to children ratio."		
aggregate, as shown in Table 2)!			

Γ		W-1		
		We also revised the statements reporting the demographic characteristics of the families in the participating kindergartens (Supplementary Table 2, referred in		
		Page 11, Line 12-13):		
		"Table 2 and Supplementary Table 2 summarize the baseline characteristics of		
		the intervention and control groups, and for each participating preschool,		
		respectively."		
	Component 1: Were any pre-intervention	We conducted dietary surveys before and during the intervention (6 months into	Appendix 2	
	data gathered about the school nutrition	the trial) to measure the nutrient content of the meals provided by the preschools	Page 7, Line 17-20	
	environment? Without information about	(breakfast and lunch). Further information is given in Appendix 2 (referred in	1 age 7, Line 17-20	
	typical meal plans and patterns (similar to	Page 7, Line 17-20) and Supplementary Table 3(referred in Page 7, Line 20-22).	Supplementary Table 3	
)	the USDA's National School Lunch		Page 7, Line 20-22	
,	program and the Child and Adult Care	first conducted a dietary survey in all 6 preschools at baseline. Kitchen staffs	1 age 7, Eme 20 22	
5	Food Program), it is difficult to know	were trained to use the dietary software to develop balanced menus specifically		
)	what needed to be changed/improved.	for preschool children, in line with the prevailing nutritional guidelines		
		(Appendix 2). Overall, the nutrient content of modified menus was largely		
3		consistent with the Chinese Nutrition Society guidance for preschool children		
,		(Supplementary Table 3)."		
3	Component 2: The last sentence of this	We have revised the statement to clarify the meaning. It now reads (Page 8, Line	Page 8, Lines 5-6	
)	paragraph is unclear; specifically, what is			
)	meant by "less than 10 minutes during	"The curriculum also introduced daily, short (<10 min) activities and dance		
	break"?	sessions after lunch to increase children's physical activity levels."		
2				
3	Component 3: Can the authors include	We have revised our tables so that a new Table 5 now includes the attendance	Table 5	
	attendance data for the parent lectures?	data for the parent lectures:		
		"This was reflected by a high awareness at 92%, but a lower attendance rate at		
,		69%."		
3				
, [The secondary outcomes described on pp	The original Table 1 has included aspects of the evaluation and the findings. We	Table 5	
)	8-9 are very interesting; are there plans	agree with the reviewer that the information initially presented was limited and	Page 12, Line 22	
	for dissemination? If so, please include a	we have since inserted a new Table 5 documenting secondary outcomes,	Page 13, Line 1-5	
2	citation for interested parties to learn	providing comprehensive information for interested parties and presented a		
3	more. The limited information included	summary of findings in Table 5 as follows (Page 12,Line 22; Page 13, Line 1-5):		
1	in this manuscript does not provide a	"Overall, most of the components were deemed appropriate by the kindergarten		
5	sufficient understanding of this aspect of	staff and parents, reflected in very high attendance levels and positive feedback		
,	the evaluation.	throughout the trial. Nevertheless, two components were found to be less suitable		
		in this setting. Exercise sessions after lunch received mixed feedback as (i) it was		
5		logistically challenging to assemble children after lunch and (ii) they shortened		
7		the break time. Although parents had expressed interest in attending bimonthly health promotion lectures, they were too busy to attend all sessions."		
<u> </u>		health promotion tectures, they were too busy to attend all sessions.		
2	TILL: 12 A	W. L	D 0 I in . 21 22	
3	This is my primary concern with the		Page 9, Line 21-22	
, L	study. The authors' analytic approach	coefficient (ICC) for our outcomes, which is an indirect measure of the extent of	Page 10,Line 1-14	

does not account for the clustered nature of the data (i.e., at the school level). Use of multilevel models would acknowledge the non-random similarity of children attending the same schools and produce better estimates of standard errors.

clustering, are all negligibly small (0.003 for overweight/obesity, 0.01 for BMI, and 0.02 for BMI z-score), and (ii) the number of clusters was also too small for multilevel model to be effective (Maas and Hox [1] suggested there should be at least 30 groups for unbiased estimation), we decided to use multivariate regression analysis for complex sampling design (PROC URVEYLOGISTIC /PROG SURVEYREG) [2] instead, which could account for complex sampling structure (including clustering) and has been widely used in previous studies [3-6].

We have modified the description of statistical method as follows (Page 9 Line 21-22, Page 10,Line 1-14):

"The difference in prevalence of overweight/obesity (expressed as odds ratios [OR] and associated 95% confidence intervals [CIs]) between the intervention and control groups was compared both at baseline and at the end of the intervention period using multivariate regression analysis with PROC SURVEYLOGISTIC procedures (SAS Institute Inc.) after adjusting for gender, maternal BMI, dietary factors and physical activity measures as covariates and baseline status of overweight/obesity. For BMI and BMI z-scores, we built multiple linear regression models with PROG SURVEYREG procedures to assess the intervention effect, after adjustment for the potential confounders aforementioned. The SAS Survey Procedures (PROC SURVEYLOGISTIC/PROG SURVEYREG) has been widely used in previous studies, to account for complex sampling structure (including clustering). Multilevel models were not used because the intraclass correlation coefficient (ICC) for all three outcomes (an indicator of the extent of clustering of data at school level) were negligibly small (0.003 for overweight/obesity, 0.01 for BMI, and 0.02 for BMI z-score), and that the number of clusters (preschools) was too small (n=6) for multilevel models to be effective (Maas and Hox suggested there should be at least 30 groups for unbiased estimation)."

Reference:

- 1.Maas CJM, Hox JJ. Sufficient Sample Sizes for Multilevel Modeling. Methodology 2005; 1(3): 86–92.
- 2.An A B. Performing Logistic Regression on Survey Data with the New SURVEYLOGISTIC Procedure.
- 3.Graubard BI, Korn EL. Conditional logistic regression with survey data. Statistics in Biopharmaceutical Research 2010; DOI: 10.1198/sbr.2010.10002.
- 4.Curtin C, Anderson S E, Must A, et al. The prevalence of obesity in children with autism: a secondary data analysis using nationally representative data from the National Survey of Children's Health[J]. BMC Pediatrics, 2010, 10(1):11.
- 5.Rosner B, Cook N R, Daniels S, et al. Childhood Blood Pressure Trends and Risk Factors for High Blood Pressure: The NHANES experience 1988–2008[J]. Hypertension, 2013, 62(2):247-254.
- 6. Tietjen G E, Peterlin B L, Brandes J L, et al. Depression and anxiety: effect on

		T T			
	the migraine-obesity relationship.[J]. Headache the Journal of Head & Face Pain,				
	2007, 47(6):866.				
Additionally, because the authors	The rationale for not using longitudinal models is due to the relatively high	Page 10, Line 14-17			
gathered height and weight data every	proportion of missing measurement data within the control group. This is due to				
three months, I was surprised that					
longitudinal models were not computed.	default the process of routine practice, i.e. measurements only at baseline and at				
The authors have a huge amount of data	12 months, was followed. With 30% of the measurement data missing in the				
available.	control group, we felt (i) it would be underpowered given we only had two				
avanable.					
	control preschools, and (ii) the values were unlikely to be missing at random and				
	therefore would introduce further bias.				
	We have added following contents in the statistical method section (Page 10,				
	Line 14-17):				
	"as only 30% of the children in the control group had quarterly anthropometric				
	measurements (as this was not part of the routine practice) we did not compute				
	longitudinal models to avoid bias."				
longitudinal models to avoid bias."					