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

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Abbreviations: None.

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

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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.

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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

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2
3 maintain healthy lifestyle,²¹ it is unclear how such intervention strategies can be formulated
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5
6 and implemented in China, because of the heterogeneity in policies on health and well-being
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9 of pre-school children across contemporary urban China.^{22,23,24}
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11 We conducted a pilot study in Guangzhou, the largest city in southern China, aiming to
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13 develop a feasible, multidisciplinary kindergarten-based obesity prevention trial among
14
15 preschool children, and to evaluate the acceptability among stakeholders and the
16
17 effectiveness of the program. The experience and information obtained in this pilot study
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19 would inform the design of a definitive (phase III) cluster randomized controlled trial (RCT).
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26 **Methods**

27 **Setting and recruitment**

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29 A cluster, non-randomized controlled pilot trial was conducted between January 2012 and
30
31 December 2013 in three districts (Liwan, Haizhu, and Panyu) of Guangzhou. All 65
32
33 kindergartens (a brief description of preschool education in Guangzhou is given in Appendix
34
35 1) in these districts were screened for eligibility, of which 22 met the inclusion criteria: (i) run
36
37 by the government (public kindergarten); (ii) located in the central area of the district; (iii)
38
39 had no less than 100 students; and (iv) had no less than two school doctors. Invitation letters
40
41 were sent to the principals of the eligible kindergartens, six of whom agreed to participate in
42
43 the trial. Based on the preference of the School and Parents Committee and the availability of
44
45 the catering software in the kindergartens, four kindergartens were allocated to the
46
47 intervention group and the remaining two were assigned as the control. All children 3 to 6
48
49 years of age enrolled in the participating preschools and their parents or legal guardians were
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4 invited to participate in the study.

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6 The study protocol was approved by the Ethical Committee for Biomedical Research in
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8 Guangzhou Women and Children Medical Centre and Guangzhou Health and Family
9
10 Planning Commission of the Peoples' Republic of China. The study was registered in
11
12 ClinicalTrials.gov (NCT03022474). Written informed consent was obtained from the
13
14 parents/guardians of all participating children.
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18 **Intervention**

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20 The intervention protocol was developed by an expert group from the National Children
21
22 Obesity Intervention Team, comprising pediatricians, child health specialists, preschool
23
24 teachers, and nutritionists, and included three integrated components (Table 1):
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28
29 Component 1- training of kindergarten staff: Before the start of the program, two
30
31 members of the intervention team (a nutritionist and a physician) delivered eight 40-min
32
33 sessions (twice a week for a month) on dietary management in children and daily food
34
35 purchasing for school doctors and kitchen staff. During the trial, two physicians (qualified in
36
37 health education) gave lectures every two months on general nutrition knowledge to all
38
39 preschool staff, focusing on the promotion of healthy food and restriction of unhealthy food.
40
41 To understand the dietary intake of children from school meals in this trial, we first conducted
42
43 a dietary survey in all 6 preschools at baseline. Kitchen staff were trained to use the dietary
44
45 software to develop balanced menus specifically for preschool children, in line with the
46
47 prevailing nutritional guidelines (Appendix 2). At approximately six months into the trial we
48
49 repeated the survey. Overall, the nutrient content of modified menus was largely consistent
50
51 with the Chinese Nutrition Society guidance for preschool children (Supplementary Table 3).
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4 Component 2- a curriculum promoting healthy diet and lifestyle: Children in the
5
6 intervention group received a 20-minute health education lesson every week, delivered
7
8 through a curriculum designed by the Expert Group (with accompanying picture books),
9
10 where they had learning activities and games covering healthy food choice, dietary habit, and
11
12 reduction of sedentary behaviors. The curriculum also introduced daily, short (<10 min)
13
14 activities and dance sessions after lunch to increase children's physical activity levels.
15
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19 Component 3 - collaboration between families and kindergartens: We organized lectures
20
21 designed for parents delivered every two months during the intervention period. Topics
22
23 covered included childhood obesity prevention measures and how to use growth curves. We
24
25 produced a handbook for communication between families and schools, to be distributed on a
26
27 weekly basis and, in which children's health behaviors were documented and reviewed by
28
29 teachers and parents. Finally, parents were notified of their children's height and weight every
30
31 three months, so that they could plot and interpret their children's growth curves.
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36 Children in the control group received regular healthcare as per the routine practice.
37
38 Apart from the anthropometric measurements at baseline and every three months thereafter,
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40 they did not receive any other intervention.
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43 44 **Outcome Measures**

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46 Our primary outcome measures were the changes in body mass index (BMI) z-score between
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48 baseline and the end of 12 months, and the prevalence of post-intervention overweight/obese
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50 children. Weight and height were measured every three months from the beginning of the
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52 project by trained preschool doctors. Weight was determined in minimal clothing without
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54 shoes to the nearest 0.5 kg, and height to the nearest 0.5 cm using a calibrated stadiometer
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3 provided by the research team. BMI was calculated as weight (kg) divided by height (m)
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5 squared. BMI z-scores (SD score), representing the deviation compared with an average child
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7 of the same sex and age, were calculated for each child based on standardized growth charts
8
9 from the Working Group on Obesity in China (WGOC).²⁵ Children with BMI values between
10
11 85th and 94th percentiles (z-scores between 1.036 and 1.645) were considered overweight
12
13 and those with BMI \geq 95th percentile (z-score \geq 1.645) were considered obese, following the
14
15 BMI reference developed by WGOC.²⁵ We combined the overweight and obese children in
16
17 our subsequent analyses.
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24 The secondary outcomes were the feasibility and acceptability of the intervention, which
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26 were qualitatively described. We used a number of techniques to evaluate the intervention
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28 components, including direct observation, collection of uptake data, questionnaires
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30 administered to parents and preschool staff, and interviews with key school doctors and
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32 teachers to discuss explored delivery, development and optimization of the complex
33
34 intervention components.
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38 **Covariates**

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

49
50 Baseline characteristics between intervention and control groups were compared and assessed
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52 by Chi-squared and t-tests where appropriate. The difference in prevalence of
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54 overweight/obesity (expressed as odds ratios [OR] and associated 95% confidence intervals
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4 [CIs]) between the intervention and control groups was compared both at baseline and at the
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6 end of the intervention period using multivariate regression analysis with PROC
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8 SURVEYLOGISTIC procedures (SAS Institute Inc.) after adjusting for gender, maternal
9
10 BMI, dietary factors and physical activity measures as covariates and baseline status of
11
12 overweight/obesity. For BMI and BMI z-scores, we built multiple linear regression models
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14 with PROC SURVEYREG procedures to assess the intervention effect, after adjustment for
15
16 the potential confounders aforementioned. The SAS Survey Procedures (PROC
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18 SURVEYLOGISTIC/ PROC SURVEYREG) has been widely used in previous studies,²⁶⁻²⁸
19
20 to account for complex sampling structure (including clustering). Multilevel models were not
21
22 used because the intraclass correlation coefficient (ICC) for all three outcomes (an indicator
23
24 of the extent of clustering of data at school level) were negligibly small (0.003 for
25
26 overweight/obesity, 0.01 for BMI, and 0.02 for BMI z-score), and that the number of clusters
27
28 (preschools) was too small (n=6) for multilevel models to be effective (Maas and Hox
29
30 suggested there should be at least 30 groups for unbiased estimation²⁹). Likewise, as only 30%
31
32 of the children in the control group had quarterly anthropometric measurements (as this was
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34 not part of the routine practice) we did not compute longitudinal models to avoid bias. A
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36 two-tailed p-value of 0.05 was considered statistically significant. All statistical analyses
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38 were based on the intention-to-treat population at the end of the final follow-up assessment
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40 and performed using SAS 9.1 software (SAS Institute, Cary, NC, USA).
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54 **Results**

56 **Baseline Characteristics**

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4 Among the 65 kindergartens, 59 were excluded for the following reasons: having <100
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6 students (n=15), having <2 school doctors (n=19), not located in the central area of the
7
8 district (n=9), and were not willing to participate (n=16). Supplementary Table 1 shows the
9
10 characteristics of the eligible preschools, including the 16 that did not participate in the study.
11
12 The participating preschools tended to have smaller school size, younger children and a better
13
14 staff to children ratio. Overall, 6 kindergartens located in Liwan (n=2), Haizhu (n=2), and
15
16 Panyu (n=2), comprising a total of 1063 children aged 3 to 6 years participated in the study.
17
18 We excluded 79 children with missing baseline information and 67 who were lost to follow
19
20 up, resulting 917 children in the final analysis (Figure 1). There were no material differences
21
22 in baseline characteristics between children who were included in final analysis and those
23
24 who were excluded (data not shown).
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31 Table 2 and Supplementary Table 2 summarize the baseline characteristics of the
32
33 intervention and control groups, and for each participating preschool, respectively. Four
34
35 kindergartens were assigned to receive the intervention, and the remaining two served as the
36
37 control. Although the two groups did not differ statistically in gender distribution, birth length,
38
39 and family structure, children in the intervention group were younger (49 vs 52 months),
40
41 more likely to be exclusively breastfed before 6 months (45% vs 42%). The absolute
42
43 differences in other characteristics were insubstantial both between and within the two
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45 groups.
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51 **Main Outcomes**

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53 The main outcomes of interest in the trial are the changes in the prevalence of
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55 overweight/obesity and the absolute differences in BMI and BMI z-scores at follow-up. Table
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4 3 and Figure 2 show the change of prevalence of overweight/obesity for both intervention and
5
6 control groups at baseline and after 12 months. At the start of the trial, the prevalence of
7
8 overweight/obesity was slightly higher in the control (20.8%) compared to the intervention
9
10 group (15.5%), although this difference was not statistically significant (OR 0.92; 95% CI
11
12 0.65, 1.31; $p=0.66$). At the end of the study, while the prevalence increased in both groups,
13
14 the extent of increase was less prominent in the children who received intervention (+4.4%)
15
16 compared to those who did not (+12.4%). Adjusting for baseline overweight/obesity status
17
18 and other relevant confounders, the risk of becoming overweight/obesity in the intervention
19
20 group was more than halved (OR 0.43; 95% CI 0.19, 0.96). The effect was stronger among
21
22 boys (OR 0.40; 95% CI 0.19, 0.85) than in girls (0.47; 0.17, 1.31).
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29 With respect to the BMI and BMI z-scores, there were no statistically significant
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31 differences between intervention and control (15.6 kg/m² vs 16.0kg/m², $p=0.051$ for BMI;
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33 and 0.12 vs 0.56, $p=0.118$ for BMI z-score) at baseline. After 12 months, the increase in BMI
34
35 was more than doubled in the control group (0.49 kg/m²) compared to the interventions (0.22
36
37 kg/m²), with a mean difference of -0.27 kg/m² after adjusting for maternal BMI, gender, age,
38
39 feeding mode before 6 months, time spent eating, sleeping time and time spent in outdoor
40
41 activities (95% CI -0.46, -0.08; $p=0.002$). The results were similar for BMI z-score, with a
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43 difference of 0.31 (95% CI, -0.47, -0.15; $p<0.0001$) between the two groups.
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48 49 **Secondary Outcomes**

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51 As a pilot study, we explored the acceptability and feasibility of specific intervention
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53 components delivered in the preschool setting. Findings of the evaluation are shown in Table
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55 5. Overall, most of the components were deemed appropriate by the kindergarten staff and
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4 parents, reflected in very high attendance levels and positive feedback throughout the trial.
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6 Nevertheless, two components were found to be less suitable in this setting. Exercise sessions
7
8 after lunch received mixed feedback as (i) it was logistically challenging to assemble children
9
10 after lunch and (ii) they shortened the break time. Although parents had expressed interest in
11
12 attending bimonthly health promotion lectures, they were too busy to attend all sessions.
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19 **Discussion**

20
21 We have, to our knowledge for the first time, demonstrated the feasibility of running a weight
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23 management trial in a kindergarten setting in China, where children are exposed to an
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25 increasing obesogenic environment as a result of recent rapid economic development.³⁰ This
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27 12-month multidisciplinary pilot program, which aims to increase parental awareness of their
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29 children's weight and to discourage unhealthy behaviors, could significantly slow down the
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31 progression to overweight/obesity among preschool children.
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36 Previous studies have reported comparable intervention effect sizes in older
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38 children.³¹⁻³³ In this study, the progression to overweight/obese BMI among girls appeared to
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40 be less sensitive to the intervention measures; a finding which is somewhat consistent with
41
42 other studies.³³⁻³⁵ It is possible that socio-cultural factors account for these observed gender
43
44 differences. Males are expected to be physically stronger and parents (especially grandparents)
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46 frequently associate this with having large appetite and may be more likely to overfeed male
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48 children.³⁶ Therefore, it is possible that our intervention has exerted a stronger beneficial
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50 effect on boys who might have an otherwise higher risk of unhealthy dietary habit and
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52 behaviors than girls.
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4 We also found that children who received the intervention had a smaller increase in
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6 BMI/BMI z-score, which was consistent with other childhood obesity intervention studies,
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8 ³⁷⁻³⁹ despite of the difference in their objectives, designs, mode, and setting of intervention
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10 delivery. A systematic review of interventions targeting children of 0-5 years reported to have
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12 an effect of -0.26 kg/m² (95% CI 0.53, 0.00) in BMI compared to the control. ¹⁶ However, the
13
14 majority of previous studies targeted children aged 6 to 12 years, with interventions
15
16 predominantly based on behavior change theories and implemented in education settings.⁴⁰
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18 Some major fundamental changes were required to implement these comprehensive
19
20 approaches, including the integration of healthy lifestyle promotion into the regular
21
22 curriculum, improvement of nutritional quality of food provided to children, and provision of
23
24 support for people who may be influential to children's growth.⁴¹ Evidence has suggested that
25
26 multicomponent methods may be more effective in prevention of overweight among children
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28 compared to community-based single-component interventions, irrespective of the study
29
30 design (i.e. RCT or non-RCT).⁴²⁻⁴⁴ In our current study, modification of behavioral elements
31
32 was emphasized throughout the whole semester, creating a supportive environment and
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34 culture, and a home-preschool association was set up for parents to implement health
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36 promotion strategies and activities. The use of multiple strengthened component designs
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38 would be more likely to improve the outcomes.
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49 Our findings have important public health implications, as we have demonstrated the
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51 feasibility of implementing interventions in a kindergarten setting through the use of multiple
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53 tactics (monitoring and feedback) to encourage participants' self-motivation.⁴⁵ Most previous
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55 intervention programs were conducted in elementary and middle schools where food was
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3 provided by commercial caterers; whereas we were able to monitor children's diet through
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5 school doctors and chefs, since food choice and quality in Chinese preschools is monitored
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7 by the government, allowing full adherence to the nutritional goals.^{16,46} We also found the
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9 participation of parents in the intervention program was instrumental to the success as they
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11 paid more attention to their children's diet and lifestyle due to their increased awareness of
12
13 the consequences of childhood obesity. By asking parents to monitor their children's growth
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15 curves regularly, families became more involved and compliant to the intervention regimen.
16
17 Therefore it is important that future studies incorporate health education lectures and other
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19 relevant tools as core components of obesity prevention intervention to engage family
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21 members and to encourage active lifestyle and healthy eating within the family.
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29 As a pilot trial, there were some limitations in the current study. Our trial has relatively
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31 insufficient power to detect the intervention efficacy compared to a large-scale RCT.
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33 Kindergartens were allocated to the intervention group on a voluntary basis, and, therefore,
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35 randomization was not possible and resulted in imbalance of confounding factors between the
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37 two groups and allocation bias. It is possible that the kindergartens (and parents) opting in for
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39 the intervention had stronger intentions and health behaviors to tackle childhood obesity than
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41 the control kindergartens, hence our observed effect size might have been over-estimated.
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43 Nevertheless, our findings (from a non-randomized trial) were similar to those obtained from
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45 randomized studies.⁴⁷ Our intervention was limited to 12 months, and we do not have
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47 long-term follow-up data to assess compliance after the intervention. However, one of our
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49 purposes was to evaluate the feasibility of the intervention and to inform optimization in this
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51 setting. We demonstrated the feasibility and acceptability of delivering a multi-component
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3 obesity intervention in preschool, which provided opportunity to refine and modify the
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5 program. This information will form part of the strategy plan for the future phase 3 RCT to
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7 provide definitive evidence. Finally, we did not perform a formal sample size calculation
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9 because this was a pilot study and we have included all eligible kindergartens of the targeted
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11 area which agreed to take part in the study.
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15 16 **Conclusion**

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18 This kindergarten-based comprehensive intervention, consisting of regular BMI monitoring
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20 by preschool doctors and parents, and education to increase awareness among parents and
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22 teachers on obesity and healthy dietary and lifestyle, has led to a reduced prevalence of
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24 obesity in a sample of preschool children attending kindergarten in Guangzhou, China. The
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26 findings have demonstrated the feasibility of implementing an effective multidisciplinary
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28 preschool-based obesity intervention program. A large, definitive RCT trial is now required
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30 to determine the long-term effectiveness of children obesity interventions.
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37 38 **Acknowledgements**

39
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41
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44 to the study who are listed in full in the published study report.
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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

Review Copy

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	<p>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.</p> <p>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.</p> <p>iii) Kitchen staffs were trained to use the dietary software for planning balanced menus appropriate for preschool children.</p>
2. A curriculum promoting healthy diet and lifestyle	<p>i) To promote a habit of healthy eating among children</p> <p>ii) To increase the amount of time for physical activity</p>	<p>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 such as picture story books, cards, food models, and nursery rhymes.</p> <p>ii) Physical activities were mandatory 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.</p>
3. Collaboration between families and schools	<p>i) To equip families with the knowledge about children development and healthy lifestyle and skills to monitor their children's growth</p> <p>ii) To improve communications between the school and parents</p> <p>iii) To engage parents as facilitators of their children's health after the intervention period</p>	<p>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).</p> <p>ii) A handbook was issued to every family, in which children's health behaviors were documented to be reviewed by teachers and parents weekly.</p> <p>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.</p>

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

	Intervention	Control	p-value
n	619	298	
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 (SD)	32.4 (11.6)	30.5 (9.0)	0.016
Mother's BMI (kg/m ²); mean (SD)	20.7 (2.3)	21.1 (2.5)	0.030
Father's BMI (kg/m ²); 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	Control	Intervention vs 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 months	+1.9%	+14.5%		
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	Control	Intervention vs 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

^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

^dSame 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 the appropriateness of the content	i) Acceptability for the course on general nutrition knowledge was high. Preschool staff 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 and the use of the catering software	ii) Nonetheless, after training, 76% of the kitchen staff were able to operate the software on their own.
	iii) Awareness and attendance of preschool staff in the courses	iii) Overall 96% of the preschool staff were aware of the courses. Attendance was also high at 93%.
2. A curriculum promoting healthy diet and lifestyle	i) Interview of preschool staff focusing on the appropriateness of the curriculum	i) Teachers who were responsible for delivering the health education lessons had positive feedback and thought the content was appropriate.
	ii) Observation of sessions to learn satisfaction and acceptance of teachers and children.	ii) The “healthy activities”, while being acceptable by the children, the timing (after lunch) was impractical as it shortened the lunch break (which includes a nap). 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 and health behaviors	iii) Parents’ response showed that they were familiar with their children’s dietary habit and health knowledge.
3. Collaboration between families and schools	i) Interview of parents and preschool staff	i) Parents were too busy to attend all the lectures. They were more prepared to attend 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 handbook	iii) Parents would welcome the feedback to be sent via text messages or a smartphone app. However, they still preferred to use handbook as a means to communicate with the

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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.

Review Copy

6 eligibility Kindergartens
in Guangzhou attending

4 Kindergartens in Guangzhou
agreed to participate
N=682 Children

2 Kindergartens in Guangzhou
agreed to control
N= 381 Children

Baseline

648 finished for baseline information
28 lack of basic information
6 lack of measurement

336 finished for baseline information
37 lack of basic information
8 lack of measurement

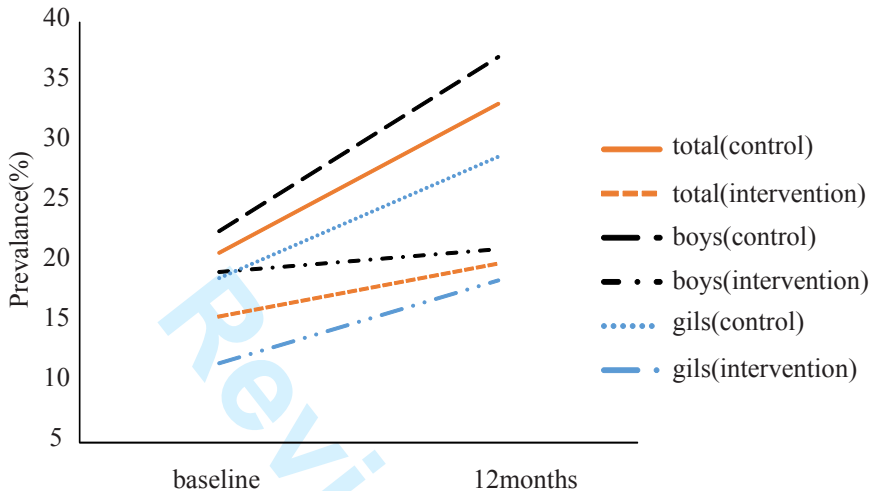
1 year Follow up

Lost to follow up
14 lack of measurement for
more than 3 times
15 leaving kindergartens

Lost to follow up
24 lack of measurement for
more than 3 times
14 leaving kindergartens

619 analyzed

298 analyzed



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

PAPER SECTION And topic	Item	Description	Reported on page #
<i>TITLE & ABSTRACT</i>	1	How participants were allocated to interventions (e.g., "random allocation", "randomized", or "randomly assigned").	
<i>INTRODUCTION</i> Background	2	Scientific background and explanation of rationale.	
<i>METHODS</i> 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	Clearly defined primary and secondary outcome measures and, when applicable, any methods used to enhance the quality of measurements (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 preschools	
	A	B	C	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		Daily reference intake ^b
	Pre-intervention	During intervention	
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.

of words in Abstract: **248** (250 words allowed)

of words in Manuscript Body: **3054** (3000 allowed for Regular Articles/Quality Reports; 4000 Reviews/Special Articles; 800 Commentaries; 1200 Perspectives)

of characters in Main Title: **92** characters (97 characters allowed, including spaces)

of characters in Short Title: **45** (55 characters allowed, including spaces)

of words in "Table of Contents Summary": **18** (25 words allowed; this section appears in all articles with abstracts)

of words in "What's Known on this Subject": **39** (40 words allowed; this section appears in Regular Articles only)

of words in "What this Study Adds": **34** (40 words allowed; this section appears in Regular Articles only)

2017-1221.R1 – Effectiveness of a kindergarten-based intervention for preventing childhood obesity in China -- by Hu Y et al.

EDITOR/REVIEWER COMMENTS <i>Paste each of the editor and reviewer queries here.</i>	AUTHOR'S RESPONSE <i>Paste your answer to the editor and reviewer queries here. If you alter your manuscript to address this query, you MUST paste the relevant altered text here – verbatim as it appears in the manuscript.</i>	REFERENCE PAGE <i>State where* the change now appears in your newly revised manuscript.</i>	CHANGE APPROVED? FOR EDITORIAL USE ONLY
Editor's comment: Please make sure to adjust for clustering in the analysis.	Please refer to our response below.		
The introduction (or the Methods, where the schools and participants are described) would benefit from a brief background 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).	We have now included as a supplementary material (Appendix 1) a brief description of the preschool education in Guangzhou, which we hope to give readers outside China improved contextual background of the study.	Appendix 1	
The Introduction would also benefit from another careful read with an eye toward basic grammar, etc. There are numerous easy-to-fix typographical errors.	We have carefully read through the manuscript and have corrected the grammatical and typographical errors.	Throughout the manuscript	
What is known about the differences, if any, between the eligible kindergartens that participated and the eligible kindergartens that did not participate in the research? What are the demographic characteristics of the families for each of the participating schools (that is, not in the aggregate, as shown in Table 2)?	We have prepared supplementary tables to show the characteristics of the kindergartens that have or have not participated in the study (Supplementary Table 1, referred in Page 11, Line 3-6): <i>"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."</i>	Supplementary Table 1 Page 11, Line 3-6 Supplementary Table 2 Page 11, Line 12-13	

<p>1 2 3 4 5 6</p>	<p>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): <i>“Table 2 and Supplementary Table 2 summarize the baseline characteristics of the intervention and control groups, and for each participating preschool, respectively.”</i></p>		
<p>7 8 9 10 11 12 13 14 15 16 17</p>	<p>Component 1: Were any pre-intervention data gathered about the school nutrition environment? Without information about typical meal plans and patterns (similar to the USDA’s National School Lunch program and the Child and Adult Care Food Program), it is difficult to know what needed to be changed/improved.</p> <p>We conducted dietary surveys before and during the intervention (6 months into the trial) to measure the nutrient content of the meals provided by the preschools (breakfast and lunch). Further information is given in Appendix 2 (referred in Page 7, Line 17-20) and Supplementary Table 3(referred in Page 7,Line 20-22). <i>“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 staffs were trained to use the dietary software to develop balanced menus specifically for preschool children, in line with the prevailing nutritional guidelines (Appendix 2). Overall, the nutrient content of modified menus was largely consistent with the Chinese Nutrition Society guidance for preschool children (Supplementary Table 3).”</i></p>	<p>Appendix 2 Page 7, Line 17-20 Supplementary Table 3 Page 7, Line 20-22</p>	
<p>18 19 20 21 22</p>	<p>Component 2: The last sentence of this paragraph is unclear; specifically, what is meant by “less than 10 minutes during break”?</p> <p>We have revised the statement to clarify the meaning. It now reads (Page 8, Line 5-6): <i>“The curriculum also introduced daily, short (<10 min) activities and dance sessions after lunch to increase children’s physical activity levels.”</i></p>	<p>Page 8, Lines 5-6</p>	
<p>23 24 25 26 27</p>	<p>Component 3: Can the authors include attendance data for the parent lectures?</p> <p>We have revised our tables so that a new Table 5 now includes the attendance data for the parent lectures: <i>“This was reflected by a high awareness at 92%, but a lower attendance rate at 69%.”</i></p>	<p>Table 5</p>	
<p>28 29 30 31 32 33 34 35 36 37 38 39 40 41</p>	<p>The secondary outcomes described on pp 8-9 are very interesting; are there plans for dissemination? If so, please include a citation for interested parties to learn more. The limited information included in this manuscript does not provide a sufficient understanding of this aspect of the evaluation.</p> <p>The original Table 1 has included aspects of the evaluation and the findings. We agree with the reviewer that the information initially presented was limited and we have since inserted a new Table 5 documenting secondary outcomes, providing comprehensive information for interested parties and presented a summary of findings in Table 5 as follows (Page 12,Line 22; Page 13, Line 1-5): <i>“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.”</i></p>	<p>Table 5 Page 12, Line 22 Page 13, Line 1-5</p>	
<p>42 43 44</p>	<p>This is my primary concern with the study. The authors’ analytic approach</p> <p>We have considered using multilevel models, but as (i) the intraclass correlation coefficient (ICC) for our outcomes, which is an indirect measure of the extent of</p>	<p>Page9,Line 21-22 Page 10,Line 1-14</p>	

1 does not account for the clustered nature
 2 of the data (i.e., at the school level). Use
 3 of multilevel models would acknowledge
 4 the non-random similarity of children
 5 attending the same schools and produce
 6 better estimates of standard errors.
 7

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 SURVEYLOGISTIC
 /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 PROC SURVEYREG procedures to assess
 the intervention effect, after adjustment for the potential confounders
 aforementioned. The SAS Survey Procedures (PROC SURVEYLOGISTIC/ PROC
 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

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

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