PEER REVIEW HISTORY

ARTICLE DETAILS

TITLE (PROVISIONAL)	A school-based, multi-faceted health promotion programme to prevent obesity among children: protocol of a cluster-randomized controlled trial (the DECIDE-Children study)
AUTHORS	Liu, Zheng; Wu, Yangfeng; Niu, Wen-Yi; Feng, Xiangxian; Lin, Yi; Gao, Aiyu; Zhang, Fang; Fang, Hai; GAO, Pei; Li, Hui-Juan; Wang, Haijun

VERSION 1 – REVIEW

REVIEWER	Liselotte Schäfer Elinder Karolinska Institutet, Sweden
REVIEW RETURNED	31-Jan-2019

GENERAL COMMENTS	This protocol describes the study protocol for an ambitious school and family 5-component intervention to prevent obesity in children in three regions in China. The intervention started in September 2018 and will end in June 2019 with the final follow-up in June 2020. No baseline data or other results are presented. Although the protocol describes the intervention and the study relatively well, there are several elements which need further clarification. In addition, the language needs proofreading. This study is being carried out in China. Most readers of the journal will not be familiar with the Chinese school system, which therefore should be described in more detail in the introduction. What is the usual size of a school class and what does “usual care” (control condition) mean in Chinese schools? Do schools have in-house school health care? School doctors are mentioned, what is their role in routine practice? Another question relates to the choice of regions in China. How were the regions chosen? It is mentioned that the regions have “diversely geographical characteristics”. In what way is this relevant for the intervention? Was child obesity high in these regions and schools? How many regions and schools were invited to participate and opted out? This information should also be added to Figure 1. Authors say that the intervention was developed systematically as explained in reference 19. However, I could not locate this reference and I wonder if it is in

	Chinese. I would therefore suggest that the authors briefly explain the formative process in the introduction of the study protocol. The same is true for reference 14, please explain briefly. Figure 2 claims to be a theoretical framework for the intervention. But the social ecological model is a multilevel model, not a theory. The smartphone app should be described in more detail. How are parents incentivized to use it? Was this evaluated in the formative phase of the trial? Does the app build on a theory of behaviour change? Please explain in more detail how the app is believed to "promote the professional-teacher-parent interaction". Who will provide the "individualized feedback"? In the discussion it is mentioned that "all intervention components were integrated into the regular academic schedule". However, it is also mentioned that activities outside school are taking place. Please clarify. How did the researchers manage to get one extra hour of physical activity into the daily schedule? The study is ongoing and I wonder about potential negative consequences of the frequent weighting of the children once a month by research staff. In addition to that children weigh themselves once a week in the classroom. Could this lead to negative effects like stigmatization? Are the authors monitoring potential negative effects? What about children with underweight? Are they getting any help or advice? The process evaluation seems to be comprehensive. It involves field observations, user logs on the app and questionnaires. I think it would be informative to include interviews as well with participants. Is this planned? How will the control schools be monitored for "treatment as usual"? The health economic evaluation includes costs for the research staff. This is not normally included since this is part of the study, not the intervention itself. Please explain why it is included. Specific comments: p. 5 l. 46-51: The literature referred to here concerns adults, not children. Use e.g. Martin J, Chater A, Lorencatto F. Effective behaviour change techniques in the prevention and management of childhood obesity. Int J Obes (Lond). 2013;37(10):1287-94. p.7 l. 17: If possible, give a reference to the overall DECIDE project. P.7 l.20: I would not call obesity an example of cerebrovascular disease. p.8 l. 28: Clarify that one or two classes were recruited from each school. p. 8 l. 46-60: When it comes to recruitment of students, authors mention 6 reasons for exclusion. Please clarify who made the decision to exclude students and based on which specific criteria, e.g. losing weight by vomiting. p.9 l. 12-38: Refer to Table 1 in this section. p.10 l. 54: Please mention when exactly the control group will receive the health education materials. p.14 l. 15: Please give the mean BMI on which the sample size calculation is based.

	p. 15 l. 6: For coming meta-analyses it would be good to report not only group differences in outcomes but also pre and post values for the intervention and control group. Figure 1: The 21-month follow-up should be in June 2020 (not January 2020). Table 1: Table 1 should be in exact agreement with the outcomes stated in the trial registration. The behavioural and other measures are not specified.

REVIEWER	Megan Hammersley University of Wollongong, Australia
REVIEW RETURNED	13-Jun-2019

GENERAL COMMENTS	Thank you for the opportunity to review this manuscript on a multi-component intervention focussed on childhood obesity in a school-based setting. Overall I would suggest making the tense consistent throughout eg 'will' rather than 'were' etc There are a number of items in the reporting checklist that were marked as n/a that I would suggest should be addressed in the manuscript, such as data management, protocol amendments, confidentiality and data access. Abstract P2, line 12 – suggest changing 'intervention' to 'interventions' P2, line 20, suggest deleting 'the' from 'to prevent among the 4th' P2, line 35 – sometimes 'professionals' are referred to and sometimes 'research staff". I would suggest changing all to 'research staff' or 'researcher' P2, line 41 – suggest deleting 'one academic year' as it is already mentioned above. P2, line 41 – suggest changing 'Data of other' to 'Data on other' P2, line 43 – Suggest adding 'potential' before 'mediators' P2, line 61 – suggest changing sentence so it is clear that data is collected at baseline ie " Data will be collected at baseline and 4, 9 and 21 month follow-up'. Strengths and limitations of this study Point 1. I would suggest clarifying what the actual strength of the smartphone application is. Introduction There is no research question or hypothesis at the end of the introduction. I would also suggest that there needs to be a clearer explanation of the gap in the literature leading up to the research question/hypothesis. There also seems to be a focus on smartphone apps later in the introduction. I would suggest that the focus should be broader as the intervention is framed as a multi-component intervention. Why have you taken a multi-component approach, what is the evidence for this? Are school-based interventions that include more components more successful? Similarly are those that include researchers, students, parents and teachers more successful? and what is the gap in the literature? P5, line 6 – I would suggest rewording the first sentence, it currently doesn't read well. P5, line 15 – Suggest changing to "with the annual rate of increase in obesity during 2010-2014..' P5, line 20 – Suggest changing 'showed' to 'show'

	P5, line 43 – While this is technically true, obesity is very complex so I think this should be recognised. I would suggest changing to something like “Childhood obesity is multi-factorial, but at the most basic level, in most cases it results from an imbalance of energy intake and energy expenditure…’ P5, line 465 – suggest changing ‘supports’ to ‘indicates’ P5, line 61 – is this just in regard to research in adults, is so it is important to note this P5, line 61-63 – I am not sure that ‘technique’ is the appropriate word to use here, perhaps ‘tool’ is better (ie monitoring is the technique, the diary is the tool) P6, line 6 – Suggest changing to ‘Smartphone applications (apps) have been particularly promising due to individualized…’ Methods and Analysis Study design I would suggest that the study design be described in more detail ie parallel group cluster RCT P7, line 4 – I would suggest changing to ‘This study is known as the ….’ And ‘The primary purpose of the DECIDE project is to provide a comprehensive… P7, line 4 and line 9 – Is it Cardiovascular or Cerebrovascular? Neither of these are mentioned in the title, abstract or introduction – the focus is on obesity. I would suggest that the relevance of the study to cardiovascular/cerebrovascular disease be included/discussed in the title, abstract, introduction and discussion Page 7, line 25 – I would suggest changing ‘be lasting’ to ‘continue’ P 7, line 27 – you state that 8 schools were from 3 regions of China. Where were the other schools from? Recruitment Overall I would suggest that there needs to be some information on how and when the schools were recruited and who recruited them. How long was the recruitment period? What strategy was used to approach the schools? (face-to-face, email, phone, another method?) Was it a convenience sample? How many schools were approached? Or did all 24 who were approached agree to participate? Were any incentives provided to the school or students? Page 7, line 63 – I would suggest adding ‘of students’ after ‘with age’ Page 7, line 69 – I would suggest changing to ‘..years old), as they are old enough to understand health education knowledge and at a stage of their schooling where they will remain in …’ Page 7, line 9 and 30 – I am a bit confused about the information in these two lines as they appear to be conflicting. The inclusion criteria was that there would be no less than 50 students from grade 4 recruited. However in line 30 it states that ‘if the number of eligible students in each class was predicted to be less than 40, one class was selected’. Wouldn’t this mean that they wouldn’t meet the inclusion criteria? Could you please clarify this? Page 7, line 20 – I would suggest changing ‘programme’ to ‘programmes’ Page 7, line 66 – I would suggest using the technical term here ‘pectus carinatum’ instead of chicken breasts

	Baseline and follow-up data collection P9, line 59 – suggest changing to 'be blinded to group allocation..' P10, line 9 – suggest changing to ..previous studies, and the piloted. They were found to be feasible…' Randomization Procedures P10, lines 30-45 - The description of selection of the schools is not clear to me, particularly the sentence ' all of eight schools were selected from urban Changzai (only one administrative district). Could you please clarify this section. Could you please describe the type of randomization used (simple vs restricted) and the ratio. Intervention Description P10, lines 50-59 - Suggest changing to 'The twelve schools in the intervention group will participate in the multi-component intervention. Schools in the control group will carry on their usual activities. After the study is completed, participants in the control group will receive the health education materials that were delivered to the intervention group' Theoretical Framework of the Intervention P11, line 17 – Suggest changing 'which are likely to influence' to 'with the intent to influence' I would suggest providing some more detail regarding the how the components of the study align with the theory. The app is briefly described, but I don't find the link to theory very strong. Description of the intervention components I would suggest providing some more detail regarding the interventions in this section. P12, line 17 – Suggest changing 'details' to 'detail' P12, line 38 – Are the observations for quality improvement or monitoring? If they are for quality improvement, what steps will be taken to improve fidelity if it is found that participants are not completing activities as intended? Discussion I would suggest that there should be more explanation provided on what this study will add to the evidence base. For Table 2 and Figure 2 – where it is stated 'activities towards students/parents etc', I would suggest changing 'towards' to 'for' Table 1 I would suggest changing the wording of the each of the methods to 'measured to the nearest 0.1cm at least twice' (ie remove 'for') Table 2 I would suggest changing 'snack' to 'snacks' and 'beverage' to 'beverages' I would also suggest that 'information' rather than 'knowledge' is being provided to the parents through the app. The footnote at the bottom of the table currently doesn't read well 'which are eaten out of three meals per day'. Perhaps change to 'which are eaten at times other than at main meals'. In regard to the smartphone app, what feedback are the parents provided with? In regard to the weight management and assessment and feedback points (3&4) of the app section, do you mean 'weight status' rather than nutritional status'? Could more

	information be provided on the 'synthetic and individualized assessment and feedback' provided by the app. In regard to the reinforcement of students' physical activity I would suggest that instead of stating that teachers 'should' or 'will' that they will be 'instructed' or 'advised' to. In regard to health education activities, I would suggest changing 'health education activities towards parents' to 'health education activities for parents'. I would also suggest clarifying when activities are held. Eg 'In the first semester, two activities are conducted. In the second semester, one activity is conducted, with a second activity conducted if required. Under 3. Health education activities towards students – should 2) Forms be Forums? Overall I would suggest some further detail on what is involved in the activities conducted. Figure 1 In the 'intervention group' box, I would suggest changing 'activities towards students' to 'student-focussed activities' etc In the 'control group' box, I would suggest changing 'usual care' to 'usual practice'

VERSION 1 – AUTHOR RESPONSE

Comments from the Reviewer 1:

Comment 1: Although the protocol describes the intervention and the study relatively well, there are several elements which need further clarification. In addition, the language needs proofreading.

Response: Thanks so much for your valuable comments and suggestions. We have revised the manuscript accordingly below. Additionally, we have proofread the language.

Comment 2: This study is being carried out in China. Most readers of the journal will not be familiar with the Chinese school system, which therefore should be described in more detail in the introduction. What is the usual size of a school class and what does "usual care" (control condition) mean in Chinese schools? Do schools have? School doctors are mentioned, what is their role in routine practice?

Response: We described the Chinese school system in more detail in the introduction. The usual size of a class is less than 45, but varies in different schools, ranging from 30 to 60. We revised “usual care” to “usual practice” as the latter is better. The usual practice in primary schools in China means that schools protect and promote health of students according to Chinese Regulations on School Health issued by Ministry of Education in 1990, including student health surveillance, health education for students, improvement of school health environment and conditions, prevention and control of infectious diseases and common diseases of students. Schools with more than or equal to 600 students should have the school doctor and in-house school health care, while schools with less than 600 students should have the full-time or part-time health care teachers. However, a survey in 3589 primary schools (with more than or equal to 600 students) in 16 provinces reported only 22.8% schools had school doctors [1]. School doctors routinely carry out the usual health care in schools as described above, while health care teachers could do a part of school health care work.

Reference:

[1]Yao H, Zhu G, Zhang X, et al. Current situation and analysis of school physicians in primary and secondary schools in 16 provinces in China. Chinese Journal of School Health, 2018, 39(10):1455-8. [In Chinese]

As this literature is written in Chinese, we have also attached the English abstract below.

·重要论著·

中国 16 省中小学校校医配备现状分析

姚海舟[1]，朱广荣[1]，张芯[2]，王海雪[1]，张冰[1]，马军[1]，温萌萌[1]，刘晓静[3]，林艺[3]，周艳[4]，杨俊芬[4]，庞淑兰[5]，冯晓萍[6]

1.北京大学公共卫生学院/北京大学儿童青少年卫生研究所，北京 100191；2.教育部体育卫生与艺术教育司；
3.乌鲁木齐市中小学卫生保健所；4.郑州市中小学卫生保健站；5.华北理工大学公共卫生学院；6.唐山市教育局

【摘要】 目的 分析中国中小学校校医配备现状，为加强中小学校校医队伍建设提供参考。方法 采用分层整群抽样方法，按照中国三大经济地带划分，分层选择调研省份，每个调研省份选择 1～2 个调研点，调研点内整群抽取全部中小学校进行问卷调查。共调查 16 个省、自治区、直辖市 26 个调研点的 10 027 所学校，选择学校规模大于 600 人或寄宿制学校共 6 466 所进行分析。结果 校医配备率为 33.1%（2 140/6 466），校医配备生医比为 2 814.6∶1，满足 600∶1 的学校占 5.0%（321/6 466）。多因素 Logistic 回归分析结果显示，经济地带、城乡、学段、学校规模、是否为寄宿学校均是校医配备的重要影响因素（P 值均<0.05）；在控制其他变量的情况下，东部学校配备校医概率是中部学校的 3.30 倍（95%CI=2.86～3.81）；西部学校是中部学校的 1.66 倍（95%CI=1.40～1.96）；随着学段的提高，校医配备概率亦提高，初中是小学的 2.06 倍（95%CI=1.79～2.36），高中是小学的 7.93 倍（95%CI=6.36～9.89）；寄宿制学校是非寄宿制学校的 1.34 倍（95%CI=1.11～1.61）；规模≥600 人学校是规模<600 人学校的 1.72 倍（95%CI=1.40～2.12）；城市学校是农村学校的 2.79 倍（95%CI=2.39～3.25）。结论 目前中国中小学校校医配备整体不足，不同经济发展地区和不同学段区别明显。中西部地区农村小学和小规模寄宿制学校的校医配备缺口较大。需要深入探索适宜政策，重视学校卫生立法，加强校医队伍建设。

【关键词】 医务人员；学生保健服务；回归分析
【中图分类号】 G 637.8 R 192 【文献标识码】 A 【文章编号】 1000-9817（2018）10-1455-04

Current situation and analysis of school physicians in primary and secondary schools in 16 provinces in China/*YAO Haizhou** , *ZHU Guangrong*, *ZHANG Xin*, *WANG Haixue*, *ZHANG Bing*, *MA Jun*, *WEN Mengmeng*, *LIU Xiaojing*, *LIN Yi*, *ZHOU Yan*, *YANG Junfen*, *PANG Shulan*, *FENG Xiaoping*.* *Institute of Child and Adolescent Health, School of Public Health, Peking University, Beijing* (100191), *China*

【Abstract】 Objective To analyze the status of school physicians in primary and secondary schools in China, and to provide possible reference for strengthening the school physician team in primary and secondary schools in China. **Methods** Investigated provinces were selected by stratified cluster sampling method according to China three major economic zones, 1 or 2 research centers were selected from each province above, all schools were surveyed in each research center. A total of 16 provinces, autonomous regions, and municipalities, 26 survey points and 10 027 primary and secondary schools were selected, and 6 466 schools which had a school size of more than 600 people or boarding schools were selected for analysis. **Results** For all schools, 33.1%(2 140/6 466) schools had at least one school physician, an average of 2 814.6 students shared 1 school physician and 5.0%(321/6 466) schools with qualified number of school physicians. Multivariate logistic regression analysis showed that the equip rate of school physicians was affected by the economic zone, school type, school boarding system, school size, urban and rural factors(P<0.05). Compared with schools in the middle region, schools in the eastern region (OR=3.30, 95%CI=2.86–3.81) and west region (OR=1.66, 95%CI=1.40–1.96) with a higher probability in school physician equipment. Compared with primary schools, middle schools (OR=2.06, 95%CI=1.79–2.36) and high schools (OR=7.93, 95%CI=6.36–9.89) with a higher probability in school physician equipment; Boarding schools had a higher probability in school physician equipment than non-boarding schools(OR=1.34, 95%CI=1.11–1.61); Schools with students higher=600 had a higher probability in school physician equipment than schools with students <600(OR=1.72, 95%CI=1.40–2.12); Compared with rural schools, schools in urban areas (OR=2.79, 95%CI=2.39–3.25) had a higher probability in school physician equipment. **Conclusion** School physicians in primary and secondary schools in China are not enough; there are significant differences between different economic development zones and different school types. The gaps in rural primary schools and small-sized boarding schools in the central and western regions are particularly serious. It is necessary to explore appropriate policies and strengthen the construction of school physician team.

【Key words】 Medical staff; Student health services; Regression analysis

Please see:

Page 6, Line 94-106: "*In primary schools in China, there are six grades in total, with age of students ranging from 6 to 11 years. The usual size of a class is less than 45, but varies in different schools, ranging from 30 to 60. There are two school policies issued by Chinese*

government that are particularly relevant to prevention and management of childhood obesity. First, schools should have the school doctor or health care teachers who provide in-house school health care. Their routine practices include student health surveillance, health education for students, prevention and control of common diseases of students. Second, schools should implement 'One-Hour Physical Activity On Campus Every School Day'. That is, the total time of physical activity (i.e. physical education classes, class-break exercise and extracurricular activities) per school day should be no less than one hour. However, implementation of these policies in school system is varying in different regions in China [14]."

Comment 3: Another question relates to the choice of regions in China. How were the regions chosen? It is mentioned that the regions have "diversely geographical characteristics". In what way is this relevant for the intervention? Was child obesity high in these regions and schools? How many regions and schools were invited to participate and opted out? This information should also be added to Figure 1.

Response: We have clarified the choice of regions in this revised manuscript. Chinese government has classified the provinces into eastern (the more than average developed area), central (the average developed area) and western (the less than average developed area) based on their economic development status. As the prevalence of childhood obesity is associated with regional socioeconomic development [2], it is necessary to study the effectiveness of a school-based, multi-faceted health promotion program in eastern, central and western provinces with different economical levels. So we will intentionally choose one city for each economical level (eastern, central or western). We have replaced "diversely geographical characteristics" by the descriptions above as the latter is better.

Three regions were invited to participate and none of them opted out. A total of twenty-seven schools were invited to participate and three of them opted out because two schools did not agree with randomization and another school was not cooperative and less likely to comply with the study protocol. This information has also been added to Figure 1 in this revised manuscript.

Reference:

[2] Dong Y, Jan C, Ma Y, et al. Economic development and the nutritional status of Chinese school-aged children and adolescents from 1995 to 2014: an analysis of five successive national surveys. Lancet Diabetes Endocrinol, 2019, 7(4): 288-99.

Please see:

(1) Page 8 in Manuscript, Line 135-140: *"To accommodate with the social and economic variations within the country and increase the scalability of our interventions, we will intentionally select study schools from three different regions of China, the more than average developed area in the east (Beijing), the average developed area in the central (Shanxi) and the less than average developed area in the west (Xinjiang)."*

(2) Figure 1 Study flow chart of the DECIDE-children.

Comment 4: Authors say that the intervention was developed systematically as explained in reference 19. However, I could not locate this reference and I wonder if it is in Chinese. I would therefore suggest that the authors briefly explain the formative process in the introduction of the study protocol. The same is true for reference 14, please explain briefly.

Response: The reference 19 and 14 are in Chinese. I attached the abstracts of these two references below. According to your suggestion, we further added a brief description about the information of these two references in the introduction section and Methods section.

中华流行病学杂志 2003 年 10月第 24 卷第 10 期 Chin J Epidemiol, October 2003, Vol. 24, No. 10

小学生 7 天体力活动问卷信度和效度的评价

刘爱玲 马冠生 张倩 马文静

【摘要】 **目的** 评价小学生 7 天体力活动问卷的效度和信度。**方法** 采用专题小组讨论、观察、专家咨询等方法设计问卷。随机选取北京市城区 4 所小学的 4～6 年级小学生 92 名作为调查对象。采用重复实验评价问卷的信度，专家评价和 Caltrac 测量仪分别评价问卷的表面效度、内容效度和准则效度。**结果** 问卷重复实验的结果之间的一致性较高，Kappa 值在46.3%～78.9%之间，男生斯皮尔曼相关系数 r 值在0.66～0.87之间，女生的 r 值在0.57～0.82之间，P 值均＜0.01。问卷表面效度和内容效度较高，问卷结果与 Caltrac 测量仪结果之间在男女生中差异均无显著性，而且两种测量方法在男生中存在显著的正相关关系（r=0.46、0.38）。**结论** 7 天体力活动问卷能可靠地测量北京市城区4～6 年级小学生的体力活动水平，能有效地测量4～6 年级小学男生的体力活动水平。

【关键词】 体力活动问卷；信度；效度；儿童

Reliability and validity of a 7-day physical activity questionnaire for elementary students *LIU Ai-ling**, *MA Guan-sheng*, *ZHANG Qian*, *MA Wen-jing*. **Department of School Nutrition, Institute of Nutrition and Food Safety, Chinese Center for Disease Control and Prevention, Beijing* 100050, China

【**Abstract**】 **Objective** To evaluate the use of a 7-day physical activity questionnaire in epidemiologic studies on 4-6th grades children. **Methods** Focus group discussion, observation and expert consultation were used to develop 7-day physical activity questionnaire. The reliability and validity of questionnaire were determined in a sample of 92 children in 4-6th grades who were randomly selected from four schools in urban Beijing. A two-week test-retest reliability was determined. The questionnaire was validated against experts' evaluation and Caltrac motion sensor. **Results** For different measures of activity, the agreement was good between the test and retest. Kappa values ranged from 0.46 to 0.79, and the Spearman correlations ranged from 0.66 to 0.87 in boys and 0.57 to 0.82 in girls, with significante difference (P< 0.01). The face validity and content validity were good by experts' evaluation. There was no significant difference between questionnaire results and Caltrac motion sensor for both boys and girls, and the questionnaire correlated significantly (r= 0.46, 0.38 for different measures of activity) with Caltrac motion sensor for boys. **Conclusion** These data provided evidence that the 7-day physical activity questionnaire yield a reliable estimate of past week physical activity for 4-6-grade children and provided valid estimation of past week physical activity for boys.

【**Key words**】 Physical activity questionnaire; Reliability; Validity; Children

·疾病控制·

基于学校儿童肥胖综合干预的效果评价

林力孜[1]，李晨雄[1]，高爱钰[2]，张芳[3]，张弦[4]，李京晶[5]，冯强[1]，金楚瑶[1]，刘峥[1]，王海俊[1]

1.北京大学公共卫生学院妇幼卫生系，北京 100191；2.北京市东城区中小学卫生保健所；
3.北京市门头沟区中小学卫生保健所；4.北京市东城区金台书院小学；5.北京市门头沟区育园小学

【摘要】 目的 了解采用结合移动健康技术辅助饮食及身体活动的综合干预对学校儿童人群进行干预的效果，为有效开展儿童超重肥胖干预提供依据。方法 选取北京市城区和郊区各 1 所学校共 58 名四年级学生进行 3 个月的综合性肥胖干预，干预期间采用微信服务号的形式加强家长互动。在干预前后分别进行身高、体重、腰围、臀围、血压及体成分等身体测量，并调查肥胖相关的饮食及身体活动行为的达标情况。结果 干预前后儿童的体质量指数 Z 评分、腰臀比及舒张压差值分别为−0.13，−0.02 和−2.47 mmHg，均有统计学意义（t 值分别为−4.24，−2.07，2.15，P 值均<0.05）。超重肥胖率和中心肥胖率均下降（39.60%和 34.48%，36.21%和 32.76%），但差异均无统计学意义（P 值均>0.05）。干预前后肥胖相关的行为达标率除过量饮食外均得到提高，且差异均有统计学意义（χ^2 值分别为 3.85，4.00，8.26，7.54，9.85，P 值均<0.05）。结论 采取移动健康技术辅助的饮食和身体活动的综合性干预措施对儿童肥胖相关指标的改善有较好效果。

【关键词】 肥胖症；干预性研究；儿童；运动活动；超重

【中图分类号】 R 153.2 R 723.14 【文献标识码】 A 【文章编号】 1000-9817（2018）10-1505-04

Effect of a comprehensive school-based intervention on childhood obesity/*LIN Lizi**, *LI Chenxiong*, *GAO Aiyu*, *ZHANG Fang*, *ZHANG Xuan*, *LI Jingjing*, *FENG Qiang*, *JIN Chuyao*, *LIU Zheng*, *WANG Haijun*.* *Department of Maternal and Child Health*, *School of Public Health*, *Peking University*, *Beijing*(100191), *China*

【**Abstract**】 **Objective** To assess the effectiveness of a comprehensive school-based intervention combining diet and physical activity components with a mobile health technology on childhood obesity. **Methods** Fifty-eight four-grade students were recruited from an urban and a rural school in Beijing and participated in the 3-months comprehensive intervention. WeChat platform was used to promote communication with students' parents during the intervention period. All students underwent measurements of height, weight, waist circumference, hip circumference, blood pressure, body fat percentage, and obesity-related diet and physical activity behaviors at baseline and three months after the intervention. **Results** After the intervention, the body mass index Z-score, waist-to-hip ratio and diastolic pressure declined by 0.13 kg/m^2, 0.02 and 2.47 mmHg statistically(P<0.05). Healthy eating and physical activity behaviors improved significantly(P<0.05) except for overeating. **Conclusion** A comprehensive school-based intervention combining diet and physical activity components with a mobile health technology showed moderate effect on improving obesity-related outcomes in children.

【**Key words**】 Obesity; Intervention studies; Child; Motor activity; Overweight

Please see:

(1) Page 6-7 in Manuscript, Line 108-118: "*To fill in the research gaps and in accordance with school system in China, we underwent four stages to develop the intervention: (1) we systematically reviewed previous literature to identify intervention elements related to intervention effectiveness; (2) we conducted focus group discussions and interviews with key informants (children, parents, teachers, school principals, local health and education officials) to further revise and refine the intervention approaches; (3) to test feasibility of the proposed intervention, we also undertook a three-month, before-after, pilot study at two primary schools*

*in Beijing (one in the urban area and the other in the rural area) among 58 Grade 4 students (mean age: 9.38±0.49 years)[15]; (4) we further discussed the proposed intervention with multiple experts. Based on all the work mentioned, we finally developed the intervention elements used for this study.***"**

(2) Page 34 in Manuscript, "Students' duration of moderate-to-vigorous physical activity" in Table 3: "*Questions were designed based on a validated 7-day physical activity questionnaire (PAQ; kappa values for test-retest results: 0.46~0.79 (different measures of activity); face validity and content validity were good by experts' evaluation; correlations between PAQ and Caltrac motion sensor ranging from 0.38 to 0.46 (different measures of activity) for boys) [22].***"**

Comment 5: Figure 2 claims to be a theoretical framework for the intervention. But the social ecological model is a multilevel model, not a theory.

Response: Thanks for this suggestion. In one of the earliest references [3], we found that both social ecological theory and social ecological model were interchangeably used. For example, "Social ecological theory, which integrates and extends behavioral change and environmentally focused models of health promotion, was used as a basis for deriving several practical guidelines for organizing and evaluating community health promotion programs." [3] Having said this, we have changed this term as you suggested.

Reference:

[3] Stokols D. Translating social ecological theory into guidelines for community health promotion. Am J Health Promot, 1996, 10(4):282-98.

Please see:

Page 11 in Manuscript, Line 200-204: "*We used Social Ecological Model to identify intervention elements in this multi-faceted health promotion programme [18]. As shown in Figure 2, the programme will target the influencing factors of childhood obesity at both individual (student-focused activities) and environmental levels (providing a supportive family and school environment), with the intent to influence knowledge, attitude and behaviors of school children.*"

Comment 6: The smartphone app should be described in more detail. How are parents incentivized to use it? Was this evaluated in the formative phase of the trial? Does the app build on a theory of behaviour change? Please explain in more detail how the app is believed to "promote the professional-teacher-parent interaction". Who will provide the "individualized feedback"?

Response: We agree and have described the smartphone app in more detail. We will not directly incentivize the parents to use the app. In the first health education session for parents, project staff will introduce the using method and functions of the app to parents. Project staff will also emphasize the functions of the app, including health education information, monitoring weight status and behaviour change of the children, etc, all of which could help the children keep healthy weight. This is how we will encourage the parents to use the app, which has been evaluated in the formative phase of the trial.

The app was built on a theory of behavior change. According to a taxonomy of behavior change techniques (BCT) applied in the prevention and management of childhood obesity [4], the specific BCTs used in this intervention will include:

1) Providing information on consequences of behavior

The app will regularly send health education messages (related to consequences of unhealthy behaviors, e.g., drinking sugar-sweetened beverages) to the parents.

2) Goal setting

The app will set the behavioral goals to achieve healthy weight: not eating excessively; not drinking sugar-sweetened beverage; eating less high-energy food; less sedentary behaviors; doing more physical activity.

3) Prompting self-monitoring of behavior

Parents and their children will be educated to regularly monitor the behaviours of children according to the behavioral goals mentioned above. Parents and their children will be asked to record these behaviors together in the app.

4) Providing feedback on performance

Based on the BMI status of children, which will be regularly input into computer management system of the app, as well as the behaviors recorded by the users, the app will automatically provide the individualized feedback. Logic of the individualized feedback was developed by project staff and has been described in Table 2 in this revised manuscript.

Therefore, the app is believed to assist in implementing this intervention. Its major functions will include information diffusion, behavior monitoring, weight management, assessment and feedback (Figure 2). After serious consideration, we have replaced the previous words “promote the professional-teacher-parent interaction” by the words above.

Reference:

[4] Martin J, Chater A, Lorencatto F. Effective behavior change techniques in the prevention and management of childhood obesity. Int J Obes, 2013, 37:1287-94.

Please see:

(1) Page 11 in Manuscript, Line 214-218:

“*The smartphone app: Project staff, school teachers and parents will be suggested to install the app--“Eat Wisely, Move Happily”. The app, developed based on behavior change techniques [19], will be assisted in implementation of the intervention, including information diffusion, behavior monitoring, weight management, assessment and feedback.“*

(2) Page 30-31, Table 1 (4. A smartphone app assisted in implementation of the intervention) in Manuscript:

“1) Information diffusion (the behavior change technique (BCT) used: providing information on consequences of behavior)

The smartphone app will provide information to parents, class teachers and project staff in accordance with health education activities.

2) Behavior monitoring (the BCT used: prompting self-monitoring of behavior)

Parents together with their children will be asked to weekly record diet and physical activity behaviors of students in the app, and then they will receive individualized feedback related to these behaviors (described in Table 2).

3) Weight management (the BCT used: prompting self-monitoring)

According to monthly monitoring of students' weight and height (described above), parents, school teachers and project staff will view the recent weight status (categorized according to the BMI percentile criteria [24]), changes compared with previous records of the students as well as the individualized feedback related to weight management.

4) Assessment and feedback (the BCT used: providing feedback on performance)

The smartphone app will also provide a synthetic and individualized assessment that will combine changes of behaviors and weight status of students. Four kinds of feedback are provided in Table 2."

(3) Page 32 in Manuscript, Table 2 The four kinds of regular evaluation messages feedback to all stakeholders by the smartphone mobile app on the basis of data from regular monitoring of children's weight, height and behaviors

Comment 7: In the discussion it is mentioned that "all intervention components were integrated into the regular academic schedule". However, it is also mentioned that activities outside school are taking place. Please clarify. How did the researchers manage to get one extra hour of physical activity into the daily schedule?

Response: We feel very sorry for this imprecise description. Activities outside school will not be integrated into the regular academic schedule. To clarify we have replaced the description of “all intervention components” by “most of the intervention components”. By most of the intervention components we mean school policies, regular monitoring of students’ weight and height, reinforcement of students’ physical activity within school, health education activities for students.

We have also clarified the intervention component for improvement of physical activity within school. The aim of this component is to improve the implementation of the Chinese national requirement for ‘One-Hour Physical Activity On Campus Every School Day’ in intervention schools. If intervention schools have met this requirement, no extra physical activity activities will be added within the intervention schools; if not, extra physical activities (i.e. physical education classes, class-break exercise or extracurricular physical activities) will be additionally added to the schedule of these intervention schools. Monitoring of implementation of these extra physical activities will be continuous within the intervention period for these intervention schools.

Please see:

(1) Page 19 in Manuscript, Line 380-384: “*most of the intervention components (school polices, regular monitoring of students’ weight and height, reinforcement of students’ physical activity within school, health education activities for students) will be integrated into the regular academic schedule of each intervention school.* **”**

(2)Page 28 in Manuscript, Table 1 (Reinforcement of student' physical activity within school): *"Students will be organized by physical education teachers to do physical activity within school for at least one hour per school day (including physical education classes, class-break exercise, extracurricular activities), achieving moderate-to-vigorous intensity. The aim of this component will be to improve the implementation of the Chinese national requirement for 'One-Hour Physical Activity On Campus Every School Day'. If schools have met this requirement, no extra physical activities will be added within school; if not, extra physical activities (i.e. physical education classes, class-break exercise or extracurricular activities) will be additionally added to the school schedule."*

Comment 8: The study is ongoing and I wonder about potential negative consequences of the frequent weighting of the children once a month by research staff. In addition to that children weigh themselves once a week in the classroom. Could this lead to negative effects like stigmatization? Are the authors monitoring potential negative effects? What about children with underweight? Are they getting any help or advice?

Response: We agree that monitoring body weight might lead to potential negative consequences such as stigmatization, particularly for those with obesity. To avoid any potential negative effects, we will not implement any activities specifically targeting children who are obese. Rather, we will provide health education to all children in intervention schools. Key messages of health education for all children will include the benefits of healthy weight, measurement and assessment of weight, as well as skills to achieve a healthy weight (not eating excessively; not drinking sugar-sweetened beverage; eating less high-energy food; less sedentary behaviors; doing more physical activity). The aim of measuring weight and

height for all children is to let them know the change of their BMI and distance to the healthy weight. We will not only encourage normal-weight children to keep appropriate increase of weight along with increase of age, but also those who are underweight, overweight or obese to make efforts to get close to healthy weight.

The school teachers and project staff will pay attention to the feelings of all students during the process of intervention. If a child do not want to continue attending the intervention, he/she could quit at any time according to the ethic principles. Additionally, we will use questionnaires for students and their parents to investigate the degree of satisfaction with each components of the intervention at the end of the intervention, which will help to analyze the potential negative effects.

Key messages of health education will also apply for children with underweight in terms of the benefits of healthy weight, as well as keeping healthy lifestyle related to diet and physical activity. If they have any questions about diet and physical activity, school teachers or project staff will provide further advice.

Comment 9: The process evaluation seems to be comprehensive. It involves field observations, user logs on the app and questionnaires. I think it would be informative to include interviews as well with participants. Is this planned? How will the control schools be monitored for “treatment as usual”?

Response: Yes, we planned to conduct interviews with participants (6~8 students in each school) in the follow-up investigations in both intervention and control schools.

The control schools will be monitored for “treatment as usual” in three ways. First, we will use student and parent questionnaires to collect students’ behaviors and family environment in both intervention and control schools. Second, we will use school questionnaires to investigate school policies related to obesity prevention and management in both intervention and control schools. Third, we will conduct interviews (as described above) to investigate whether intervention and control schools comply with the study protocol.

Please see:

(1) Page 16 in Manuscript, Line 309: “*The control schools will also be monitored for “treatment as usual”.*

(2) Page 16 in Manuscript, Line 321-327: *“**(3) student and parent questionnaires (Table 3) on students’ behaviors and family environment in both intervention and control schools; (4) school questionnaires on school policies related to obesity prevention and management in both intervention and control schools; (5) interviews with participants (6~8 students per school) conducted in follow-up investigations in both intervention and control schools.”***

Comment 10: The health economic evaluation includes costs for the research staff. This is not normally included since this is part of the study, not the intervention itself. Please explain why it is included.

Response: Sorry for the misunderstanding due to our incorrect wording. We clarify that only time of project staff spent in implementing the intervention will be included in the health economic evaluation, because this is also the cost that will happen when the intervention is

implemented in other populations in the future. We have changed the wording and used "project staff" instead of "researchers".

Please see:

Page 17 in Manuscript, Line 331-334: "*Intervention costs include times (project staff, school staff, and students' primary caregivers (parents in most cases)) for all the intervention activities and material expenses. Only time of project staff spent in implementing the intervention will be included.***"**

Comment 11: The literature referred to here concerns adults, not children. Use e.g.

Martin J, Chater A, Lorencatto F. Effective behaviour change techniques in the prevention and management of childhood obesity. Int J Obes (Lond). 2013;37(10):1287-94.

Response: Many thanks for this suggestion. We have referred to this literature in the revised manuscript.

Please see:

Page 11 in Manuscript, Line 215-218: "*The app, developed based on behavior change techniques [19], will be assisted in implementation of the intervention, including information diffusion, behavior monitoring, weight management, assessment and feedback.*

*[19] Martin J, Chater A, Lorencatto F. Effective behaviour change techniques in the prevention and management of childhood obesity. Int J Obes (Lond). 2013;37(10):1287-94.***"**

Comment 12: If possible, give a reference to the overall DECIDE project.

Response: We feel sorry that we do not have a published reference to the overall DECIDE project. However, we have described the aim of the overall DECIDE project, as well as the relationship between the overall DECIDE project and the DECIDE-children study.

Please see: Page 7 in Manuscript, Line 120-126:

"To develop effective lifestyle interventions for prevention and control of cardiovascular disease in China, the Diet, ExerCIse and CarDiovascular hEalth (DECIDE) project was initiated in 2016. As one of five independent DECIDE studies, the DECIDE-Children study is to develop a school-based, multi-faceted childhood obesity prevention programme targeting on school children aged 8-10 years in China and rigorously test its effect in preventing excessive weight gain in Chinese primary school settings."

Comment 13: I would not call obesity an example of cerebrovascular disease.

Response: Sorry for this mistake. We have now clarified that the aim of the overall project is to prevent and control cardiovascular disease in China, while this study is to develop a school-based, multi-faceted childhood obesity prevention programme.

Please see: Page 7 in Manuscript, Line 120-126:

"To develop effective lifestyle interventions for prevention and control of cardiovascular disease in China, the Diet, ExerCIse and CarDiovascular hEalth (DECIDE) project was initiated in 2016. As one of five independent DECIDE studies, the DECIDE-Children study is to develop a school-based, multi-faceted childhood obesity prevention programme targeting

on school children aged 8-10 years in China and rigorously test its effect in preventing excessive weight gain in Chinese primary school settings."

Comment 14: Clarify that one or two classes were recruited from each school.

Response: We have clarifed this information as below.

Please see:

Page 9 in Manuscript, Line 165-170: *"For schools participating the program, the size of a class varies from less than 30 to approximately 60 children a class. To meet the sample size requirement, we will recruit two classes of the school if the number of students in each class is less than 50 and one class otherwise. If the number of classes in one school is more than needed, the school principal will recommend which classes to be selected."*

Comment 15: When it comes to recruitment of students, authors mention 6 reasons for exclusion. Please clarify who made the decision to exclude students and based on which specific criteria, e.g. losing weight by vomiting.

Response: The project staff will make the decision to exclude students based on one of the 6 conditions reported by parents, such as losing weight by vomiting. We clarified this information as below.

Please see:

Page 10 in Manuscript, Line 181-184: "*Then parents with informed consent will be required to fill in a self-administrative questionnaire about health status of their children. The project*

*staff will collect the questionnaires and if find one or more of the following conditions reported by parents, their children will be excluded:……..***"**

Comment 16: Refer to Table 1 in this section.

Response: Thanks for this suggestion and we have revised it. As the manuscript has been revised and restructured, the previous Table 1 has now been renumbered asTable 3.

Please see:

Page 13 in Manuscript, Line 244: "*Table 3 describes what, when and how the study outcomes will be evaluated.***"**

Comment 17: Please mention when exactly the control group will receive the health education materials.

Response: We have clarified this information as below.

Please see:

Page 12 in Manuscript, Line 239-242: "*Participants in the control group will receive the health education materials that will have been delivered to those in the intervention group as soon as the 21-month follow-up investigation be completed in June 2020.***"**

Comment 18: Please give the mean BMI on which the sample size calculation is based.

Response: Thanks for this suggestion. In addition to other parameters, the sample size calculation is based on the mean **difference** between arms in change of BMI, rather than on the mean BMI [5,6]. We assumed the difference between two groups in change of BMI (effect

size) would be 0.50 kg/m^2, a standard deviation (SD) of BMI would be 1.40 kg/m^2, an intra-cluster correlation coefficient would be 0.05 and the rate of attrition would be 10% for sample size calculation in our study. We aimed to recruit a total of 1,200 students from 24 schools with an average cluster size of 50 students per school. This sample size will provide 88% power with a=0.05 to detect a mean difference of 0.50 kg/m^2 in change of BMI between groups after the one-school-year intervention.

References:

[5] Donner, A. and Klar, N. 1996. 'Statistical Considerations in the Design and Analysis of Community Intervention Trials.' The Journal of Clinical Epidemiology, Vol. 49, No. 4, 1996, pages 435-439.

[6] Donner, A. and Klar, N. 2000. Design and Analysis of Cluster Randomization Trials in Health Research. Arnold. London.

Please see Page 14 in Manuscript, Line 277-283:

"*We assumed the difference between two groups in change of BMI (effect size) would be 0.50 kg/m^2, a standard deviation (SD) of BMI would be 1.40 kg/m^2, an intra-cluster correlation coefficient would be 0.05 and the rate of attrition would be 10% for sample size calculation in our study. We aimed to recruit a total of 1,200 students from 24 schools with an average cluster size of 50 students per school. This sample size will provide 88% power with a=0.05 to detect a mean difference of 0.50 kg/m^2 in change of BMI between groups after the one-school-year intervention.*"

Comment 19: For coming meta-analyses it would be good to report not only group differences in outcomes but also pre and post values for the intervention and control group.

Response: Thanks for this suggestion. We have added the reporting of pre and post values for the intervention and control group.

Please see:

Page 15 in Manuscript, Line 296-300: "*For continuous outcomes, we will report pre-, post-intervention means for intervention and control groups, respectively, and model-adjusted mean differences between groups. For binary outcomes, we will report pre, post-intervention percentages for intervention and control groups, respectively, and adjusted odds ratio (OR) between groups."*

Comment 20: Figure 1: The 21-month follow-up should be in June 2020 (not January 2020).

Response: We feel very sorry for this mistake, and we have corrected it in this revised manuscript.

Please see:

Figure 1 in Manuscript.

Comment 21: Table 1: Table 1 should be in exact agreement with the outcomes stated in the trial registration. The behavioural and other measures are not specified.

Response: We have now added the behavioural and other measures as stated in the trial registration. As the manuscript has been revised and restructured, the previous Table 1 has now been renumbered as Table 3.

Please see: Page 34&35 in Manuscript, Table 3

Comments from the Reviewer 2:

Comment 1: Overall I would suggest making the tense consistent throughout eg 'will' rather than 'were' etc. There are a number of items in the reporting checklist that were marked as n/a that I would suggest should be addressed in the manuscript, such as data management, protocol amendments, confidentiality and data access.

Response: Thanks so much for your suggestions. We have made the tense consistent throughout by using 'will' in this revised manuscript. To clary the trial status, we have further added a section as described below.

We have also addressed data management, protocol amendments, confidentiality and data access in this revised manuscript.

Please see:

(1) Page 17 in Manuscript, Line 303-309:

Trial status: *"The trial started and completed recruitment of schools and children in September 2018. Baseline measures commenced in late September 2018 and completed by the end of September in 2018. The one-school-year intervention started at the end of September in 2018 and completed in June 2019. The 4-month follow-up measurements started and completed in January 2019. The 9-month follow-up measurements started and completed in June 2019. The 21-month follow-up measurements will start and complete in June 2020."*

(2) Page 3 in Manuscript, Line 46-49:

Data management and confidentiality: "*All data collected will be entered into electronic database with personal identification information de-identified. The database will be accessed only by designated staff with password.*"

(3) Page 2-3 in Manuscript, Line 44-45:

Protocol amendments: "*Any amendments to the study protocol will be submitted for IRB approval prior to implementation.*"

(4) Page 3 in Manuscript, Line 48-52:

Data access: *"The database will be accessed only by designated staff with password. …On completion of the trial, and after publication of these results, data would be available on request by contacting the corresponding author of this protocol."*

Comment 2:

P2, line 12 – suggest changing 'intervention' to 'interventions'

P2, line 20, suggest deleting 'the' from 'to prevent among the 4th'

P2, line 35 – sometimes 'professionals' are referred to and sometimes 'research staff". I would suggest changing all to 'research staff' or 'researcher'

P2, line 41 – suggest deleting 'one academic year' as it is already mentioned above.

P2, line 41 – suggest changing 'Data of other' to 'Data on other'

P2, line 43 – Suggest adding 'potential' before 'mediators'

P2, line 61 – suggest changing sentence so it is clear that data is collected at baseline ie " Data will be collected at baseline and 4, 9 and 21 month follow-up'.

Response: Thanks so much for these helpful suggestions. We have reworded the sentences in the revised manuscript. We have used 'project staff' consistently throughout the manuscript, instead of 'professional' or 'research staff'

Comment 3: I would suggest clarifying what the actual strength of the smartphone application is.

Response: We agree that this should be clarified. The app is built on a theory of behavior change. According to a taxonomy of behavior change techniques (BCT) applied in the prevention and management of childhood obesity [4], the specific BCTs used in this intervention will include:

<u>1) providing information on consequences of behavior;</u>

The app will regularly send health education messages (related to consequences of unhealthy behaviors, e.g., drinking sugar-sweetened beverages) to the parents.

<u>2) goal setting;</u>

The app will set the behavioral goals to achieve a healthy weight: not eating excessively; not drinking sugar-sweetened beverage; eating less high-energy food; less sedentary behaviors; doing more physical activity.

3) prompting self-monitoring of behavior;

Parents and their children will be educated to monitor the behaviours of children regularly according to the behavioural goals mentioned above. They will be asked to record these behaviours together in the app.

4) providing feedback on performance.

Based on the BMI status of children, which will be regularly input into computer management system of the app, as well as the behaviours recorded by the users, the app will automatically provide the individualized feedback. Logic of the individualized feedback was developed by project staff and has been described in Table 2 in this revised manuscript.

Therefore, the app is believed to assist in implementing this intervention. Its major functions will include information diffusion, behavior monitoring, weight management, assessment and feedback (Figure 2).

Reference:

[4] Martin J, Chater A, Lorencatto F. Effective behavior change techniques in the prevention and management of childhood obesity. Int J Obes, 2013, 37:1287-94.

Please see:

(1) Page 11 in Manuscript, Line 214-218:

"The smartphone app*: Project staff, school teachers and parents will be suggested to install the app--"Eat Wisely, Move Happily". The app, developed based on behavior change techniques [19], will be assisted in implementation of the intervention, including information diffusion, behavior monitoring, weight management, assessment and feedback."*

(2) Page 30-31, Table 1 (4. A smartphone app assisted in implementation of the intervention) in Manuscript:

"1) Information diffusion (the behavior change technique (BCT) used: providing information on consequences of behavior)

The smartphone app will provide information to parents, class teachers and project staff in accordance with health education activities.

2) Behavior monitoring (the BCT used: prompting self-monitoring of behavior)

Parents together with their children will be asked to weekly record diet and physical activity behaviors of students in the app, and then they will receive individualized feedback related to these behaviors (described in Table 2).

3) Weight management (the BCT used: prompting self-monitoring)

According to monthly monitoring of students' weight and height (described above), parents, school teachers and project staff will view the recent weight status (categorized according to the BMI percentile criteria [24]), changes compared with previous records of the students as well as the individualized feedback related to weight management.

4) Assessment and feedback (the BCT used: providing feedback on performance)

The smartphone app will also provide a synthetic and individualized assessment that will combine changes of behaviors and weight status of students. Four kinds of feedback are provided in Table 2."

(3) Page 32 in Manuscript, Table 2 The four kinds of regular evaluation messages feedback to all stakeholders by the smartphone mobile app on the basis of data from regular monitoring of children's weight, height and behaviors

Comment 4: There is no research question or hypothesis at the end of the introduction. I would also suggest that there needs to be a clearer explanation of the gap in the literature leading up to the research question/hypothesis. There also seems to be a focus on smartphone apps later in the introduction. I would suggest that the focus should be broader as the intervention is framed as a multi-component intervention. Why have you taken a multi-component approach, what is the evidence for this? Are school-based interventions that include more components more successful? Similarly are

those that include researchers, students, parents and teachers more successful? and what is the gap in the literature?

Response: Thanks so much for these suggestions. We have specifically clarified the research question at the end of the introduction.

Please see:

Page 7 in Manuscript, Line 122-130: "*the DECIDE-Children study is to develop a school-based, multi-faceted childhood obesity prevention programme targeting on school children aged 8-10 years in three different regions of China and rigorously test its effect in preventing excessive weight gain in Chinese primary school settings. The research objectives of the DECIDE-Children were: (1) to assess the effectiveness of the intervention compared with usual practice in preventing childhood overweight and obesity; (2) to determine sustainability of the intervention in preventing overweight and obesity; (3) to undertake process evaluation and health economic evaluation of the intervention.***"**

We have also more clearly elaborated the gap in the literature, the evidence for taking a multi-component approach and involving a family component.

Please see:

Page 5-6, Line 78-93 in Manuscript: "*Children spend half of their waking hours and consume at least one-third of their daily calories at school, and thus school-based interventions are promising in preventing childhood obesity [7]. Particularly, multi-faceted interventions combining diet, physical activity and a family component have shown the greatest effectiveness [7, 8]. However, there is a paucity of rigorously developed and evaluated prevention interventions for Chinese children [8, 9]. Moreover, not all school-based interventions were effective in preventing excessive weight gain of children [10, 11]. On one hand, it is crucial to increase our understanding of how and why these interventions work or do not work [12]. To achieve this, a thorough process evaluation of the intervention implementation is necessary. On the other hand, socioeconomic development is associated with patterns of childhood obesity [13] and may also affect the effectiveness of a childhood obesity intervention. Yet previous studies have been largely conducted in a single region, which limits the generalizability of study findings to other populations. Another weakness is that most studies*

*examined outcomes only at the end of the intervention. Thus, it remains unclear whether healthy behaviors and weight continue beyond the period of the intervention.***"**

Comment 5:

P5, line 6 – I would suggest rewording the first sentence, it currently doesn't read well.

P5, line 15 – Suggest changing to "with the annual rate of increase in obesity during 2010-2014..'

P5, line 20 – Suggest changing 'showed' to 'show'

P5, line 43 – While this is technically true, obesity is very complex so I think this should be recognised. I would suggest changing to something like "Childhood obesity is multi-factorial, but at the most basic level, in most cases it results from an imbalance of energy intake and energy expenditure…'

P5, line 465 – suggest changing 'supports' to 'indicates'

P5, line 61 – is this just in regard to research in adults, is so it is important to note this

P5, line 61-63 – I am not sure that 'technique' is the appropriate word to use here, perhaps 'tool' is better (ie monitoring is the technique, the diary is the tool)

P6, line 6 – Suggest changing to 'Smartphone applications (apps) have been particularly promising due to individualized…'

Response: Thanks for these suggestions and we have reworded these sentences accordingly.

Comment 6: I would suggest that the study design be described in more detail ie parallel group cluster RCT.

Response: We have elaborated more on the study design.

Please see:

Page 8 in manuscript, Line 135-154: "*DECIDE-Children is a cluster-randomized, parallel-group controlled trial. To accommodate with the social and economic variations within the country and increase the scalability of our interventions, we will intentionally select study schools from three different regions of China, the more than average developed area in the east (Beijing), the average developed area in the central (Shanxi) and the less than average developed area in the west (Xinjiang) in convenience with previous partnerships in research. A total of 24 primary schools (clusters) equally distributed among three regions will be selected. In Beijing, 4 schools will be*

*selected from Dongcheng district (located in the central city) and 4 from Mentougou district (located in a suburban rural area). In Xinjiang, all 8 schools will be selected in Urumchi, the capital city of the autonomous region; and half of the schools will be selected from Shayiba district (an urban district) and half from Shuimogou district (a rural district). In Shanxi, all 8 schools will be selected from only one urban district of Changzhi, a small to mediam size city in the province. The reason for excluding rural schools in Changzhi is that most of these schools were boarding schools. Thus, a total of 24 primary schools from five sites in three regions will be selected and randomized into two groups, one on the obesity prevention intervention and the other on usual practice. The intervention will be implemented for one school year from late September 2018 to June 2019, and the study will continue with a one-year follow-up investigation in June 2020. Figure 1 shows the study flow.***"***

Comment 7: P7, line 4 – I would suggest changing to 'This study is known as the ….' And 'The primary purpose of the DECIDE project is to provide a comprehensive…

Response: We have reworded these sentences.

Please see:

Page 7 in Manuscript, Line 120-123: *"To develop effective lifestyle interventions for prevention and control of cardiovascular disease in China, the Diet, ExerCIse and CarDiovascular hEalth (DECIDE) project was initiated in 2016. As one of five independent DECIDE studies, the DECIDE-Children study is to develop……."*

Comment 8: Is it Cardiovascular or Cerebrovascular? Neither of these are mentioned in the title, abstract or introduction – the focus is on obesity. I would suggest that the relevance of the study to cardiovascular/cerebrovascular disease be included/discussed in the title, abstract, introduction and discussion

Response: We feel very sorry for this mistake. It should be cardiovascular, not cerebrovascular.

The focus of this intervention study (DECIDE-children) is to prevent and reduce childhood obesity, which is an independent risk factor for cardiovascular diseases in adulthood. Accordingly, effective strategies to curb and reduce childhood obesity prevalence would bear great long-term potential to

prevent cardiovascular diseases in adulthood. We have included the relevance of the study to cardiovascular disease in the abstract, introduction and discussion.

Please see:

(1) Page 2 in Manuscript, Line 24-26: "*Obesity is an increasingly serious public health concern globally. Effective and sustainable childhood obesity prevention strategies would have potential to help and may have impact on its lifelong health."*

(2) Page 5 in Manuscript, Line 71-73: "*Childhood obesity is not only associated with adverse consequences on physical and mental health of children in the short term [3, 4], but also increases risk of developing cardiovascular diseases in the long term [5, 6].***"**

(3) Page 18 in Manuscript, Line 362-364: *"**Non-communicable diseases, especially cardiovascular diseases, have been the public health burden among the whole population. Preventing childhood obesity in early life could have the greatest long-term potential to curb this epidemic burden.****"***

Comment 9: Page 7, line 25 – I would suggest changing 'be lasting' to 'continue'
Response: We have reworded this sentence.

Please see:

Page 8 in Manuscript, Line 152-153: *"**the study will continue with a one-year follow-up investigation in June 2020****".***

Comment 10: P 7, line 27 – you state that 8 schools were from 3 regions of China. Where were the other schools from?

Response: We feel very sorry for these ambiguous words. A total of 24 primary schools (clusters) will be selected. To cover 3 different regions of China, 8 schools will be selected from Beijing, 8 schools will be selected from Changzh, and 8 schools will be selected from Urumchi. We have made clarifications in this revised manuscript.

Please see:

Page 7 in Manuscript, Line 140-151: "*A total of 24 primary schools (clusters) equally distributed among three regions will be selected. In Beijing, 4 schools will be selected from Dongcheng district*

(located in the central city) and 4 from Mentougou district (located in a suburban rural area). In Xinjiang, all 8 schools will be selected in Urumchi, the capital city of the autonomous region; and half of the schools will be selected from Shayiba district (an urban district) and half from Shuimogou district (a rural district). In Shanxi, all 8 schools will be selected from only one urban district of Changzhi, a small to mediam size city in the province. The reason for excluding rural schools in Changzhi is that most of these schools were boarding schools. Thus, a total of 24 primary schools from five sites in three regions will be selected and randomized into two groups, one on the obesity prevention intervention and the other on usual practice."

Comment 11: Overall I would suggest that there needs to be some information on how and when the schools were recruited and who recruited them. How long was the recruitment period? What strategy was used to approach the schools? (face-to-face, email, phone, another method?) Was it a convenience sample? How many schools were approached? Or did all 24 who were approached agree to participate? Were any incentives provided to the school or students?

Response: We agree with these helpful suggestions. The project staff first contacted the local education authority to gain their opinion, support, approval and basic information of the schools, and they approached the schools by a phone call or a visit. The project staff clarified for the school principals that to be eligible, the school should agree to be allocated to either intervention or control groups with the randomization procedure, and schools in both intervention and control groups should comply with the study protocol. The project staff approached a total of 27 potentially eligible schools. Among these schools, 3 of them did not agree with the randomization or compliance with the study protocol and opted out. The project staff did not provide any incentives to the school or students.

Please see:

(1) Page 9-10 in Manuscript, Line 171-177: *"Three steps will be undertaken for the recruitment of schools. First, project staff will contact the local education authority to gain their opinion, support, approval and basic information of the schools (type of schools, number of students and teachers). Second, project staff will approach the schools by a phone call or a visit to understand the eligibility of the potential schools for participation. Third, the final list of eligible schools and classes will be made by the principal investigator and schools will be invited by local research partners.**"***

(2) Figure 1 in Manuscript

Comment 12: Page 7, line 63 – I would suggest adding 'of students' after 'with age'

Response: We have added this in the revised manuscript.

Please see:

Page 6 in Manuscript, Line 95-96: ***"****In primary schools in China, there are six grades in total, with age* ***of students*** *ranging from 6 to 11 years."*

Comment 13: Page 7, line 69 – I would suggest changing to '..years old), as they are old enough to understand health education knowledge and at a stage of their schooling where they will remain in …'

Response: We have added this in the revised manuscript.

Please see:

Page 9 in Manuscript, Line 157-158: ***"****The present study will be carried out in Grade 4 students (8 to 10* ***years old****), as they are old enough to…."*

Comment 14: Page 7, line 9 and 30 – I am a bit confused about the information in these two lines as they appear to be conflicting. The inclusion criteria was that there would be no less than 50 students from grade 4 recruited. However in line 30 it states that 'if the number of eligible students in each class was predicted to be less than 40, one class was selected'. Wouldn't this mean that they wouldn't meet the inclusion criteria? Could you please clarify this?

Response: We feel very sorry for this mistake. We have clarified this in the revised manuscript.

Please see:

Page 9 in Manuscript, Line 165-170: ***"****For schools participating the program, the size of a class varies from less than 30 to approximately 60 children a class. To meet the sample size requirement, we will recruit two classes of the school if the number of students in each class is less than 50 and one class otherwise. If the number of classes in one school is more than needed, the school principal will recommend which classes to be selected."*

Comment 15:

Page 7, line 20 – I would suggest changing ‘programme’ to ‘programmes’

Page 7, line 66 – I would suggest using the technical term here ‘pectus carinatum’ instead of chicken breasts

P9, line 59 – suggest changing to ‘be blinded to group allocation..’

P10, line 9 – suggest changing to ..previous studies, and the piloted. They were found to be feasible…’

Response: Thanks so much for these suggestions. We agree with them and the words have been revised accordingly.

Comment 16: The description of selection of the schools is not clear to me, particularly the sentence ‘ all of eight schools were selected from urban Changzai (only one administrative district). Could you please clarify this section.

Response: We feel very sorry for these confusing words. In Shanxi, all 8 schools will be selected from only one urban district of Changzhi. The reason for excluding rural schools in Changzhi is that most of these schools were boarding schools. This section has been clarified in the revised manuscript.

Please see:

Page 8 in Manuscript, Line 140-151: “*A total of 24 primary schools (clusters) equally distributed among three regions will be selected. In Beijing, 4 schools will be selected from Dongcheng district (located in the central city) and 4 from Mentougou district (located in a suburban rural area). In Xinjiang, all 8 schools will be selected in Urumchi, the capital city of the autonomous region; and half of the schools will be selected from Shayiba district (an urban district) and half from Shuimogou district (a rural district). In Shanxi, all 8 schools will be selected from only one urban district of Changzhi, a small to mediam size city in the province. The reason for excluding rural schools in Changzhi is that most of these schools were boarding schools. Thus, a total of 24 primary schools*

from five sites in three regions will be selected and randomized into two groups, one on the obesity prevention intervention and the other on usual practice."

Comment 17: Could you please describe the type of randomization used (simple vs restricted) and the ratio.

Response: The random sequence of allocation of schools (clusters) to intervention or control will be stratified by the study sites. Schools in the same study site will be randomly allocated in 1:1 ratio to either the intervention or control group using a computer-generated random number system (the simple random sampling method). We have elaborated the randomization procedures.

Please see:

Page 10 in Manuscript, Line 192-198: *"**The random sequence of allocation of schools (clusters) to intervention or control will be stratified by the study sites. Schools in the same study site will be randomly allocated in 1:1 ratio to either the intervention or control group using a computer-generated random number system (the simple random sampling method). Randomization will be performed by an independent person at the central coordinating center at Peking University Clinical Research Institute. The randomization will take place only after the baseline assessments complete to ensure the allocation concealment.****"***

Comment 18: P10, lines 50-59 - Suggest changing to 'The twelve schools in the intervention group will participate in the multi-component intervention. Schools in the control group will carry on their usual activities. After the study is completed, participants in the control group will receive the health education materials that were delivered to the intervention group'

Response: We agree with these suggestions. To clarify we have specifically added a section to describe the control group in this revised manuscript.

Please see:

Page 12 in Manuscript, Line 237-242: *"**The twelve schools in the control group will not carry out any interventions delivered by the study and will continue usual practice according to their own teaching curriculum during the study period (from September 2018 to June 2020). Participants in the control***

*group will receive the health education materials that will have been delivered to those in the intervention group as soon as the 21-month follow-up investigation be completed in June 2020.***"**

Comment 19: Suggest changing 'which are likely to influence' to 'with the intent to influence' I would suggest providing some more detail regarding the how the components of the study align with the theory. The app is briefly described, but I don't find the link to theory very strong.

Response： Thanks so much for these suggestions.

(1) We have reworded the sentence and changed 'which are likely to influence' to 'with the intent to influence'.

(2) We have also provided more details in terms of how the components of the study align with the theory. We used Social Ecological Model to identify intervention elements in this multi-faceted health promotion programme. The programme will target the influencing factors of childhood obesity at both individual (student-focused activities) and environmental levels (providing a supportive environment at family- and school-levels).

(3) We additionally provided more details of the app in this revised manuscript. The app is built on a theory of behavior change.

Please see:

(1) Page 11 in Manuscript, Line 200-204: "*We used Social Ecological Model to identify intervention elements in this multi-faceted health promotion programme [18]. As shown in Figure 2, the programme will target the influencing factors of childhood obesity at both individual (student-focused activities) and environmental levels (providing a supportive family and school environment), with the intent to influence knowledge, attitude and behaviors of school children.***"**

(2) Page 11 in Manuscript, Line 214-218: "*Project staff, school teachers and parents will be suggested to install the app--"Eat Wisely, Move Happily". The app, developed based on behavior change techniques [19], will be assisted in implementation of the intervention, including information diffusion, behavior monitoring, weight management, assessment and feedback.***"**

(3) Page 30-31, Table 1 (4. A smartphone app assisted in implementation of the intervention) in Manuscript:

"1) Information diffusion (the behavior change technique (BCT) used: providing information on consequences of behavior)

The smartphone app will provide information to parents, class teachers and project staff in accordance with health education activities.

2) Behavior monitoring (the BCT used: prompting self-monitoring of behavior)

Parents together with their children will be asked to weekly record diet and physical activity behaviors of students in the app, and then they will receive individualized feedback related to these behaviors (described in Table 2).

3) Weight management (the BCT used: prompting self-monitoring)

According to monthly monitoring of students' weight and height (described above), parents, school teachers and project staff will view the recent weight status (categorized according to the BMI percentile criteria [24]), changes compared with previous records of the students as well as the individualized feedback related to weight management.

4) Assessment and feedback (the BCT used: providing feedback on performance)

The smartphone app will also provide a synthetic and individualized assessment that will combine changes of behaviors and weight status of students. Four kinds of feedback are provided in Table 2."

(4) Page 32 in Manuscript, Table 2 The four kinds of regular evaluation messages feedback to all stakeholders by the smartphone mobile app on the basis of data from regular monitoring of children's weight, height and behaviors

Comment 20: I would suggest providing some more detail regarding the interventions in this section.

P12, line 17 – Suggest changing 'details' to 'detail'

P12, line 38 – Are the observations for quality improvement or monitoring? If they are for quality improvement, what steps will be taken to improve fidelity if it is found that participants are not completing activities as intended?

Response: Thanks so much for these suggestions.

(1) We have elaborated more regarding the interventions in the text as well as in Table 1&2.

(2) “Details” has been reworded as “detail”.

(3) The observations are for quality improvement. To improve fidelity, if it is found that schools are not complying with the study protocol, project staff will timely communicate with school team members and continue with follow-up supervision.

Please see:

(1) Page 11 in Manuscript, Line 206-208:

“*The intervention components are described in Table 1 and 2.*

Student-focused activities*: These will include health education activities for students, reinforcement of students’ physical activity within school and regular monitoring of students’ weight and height.*

Activities towards parents*: These will include health education activities for parents, supervision and encouragement of children to increase physical activity outside school.*

Activities towards schools*: These will include school policies related to obesity prevention and health education activities for teachers.*

The smartphone app*: Project staff, school teachers and parents will be suggested to install the app--“Eat Wisely, Move Happily”. The app, developed based on behavior change techniques [19], will be assisted in implementation of the intervention, including information diffusion, behavior monitoring, weight management, assessment and feedback.* **”**

(2) Page 27-32 in Manuscript, Table 1&2

(3) Page 12 in Manuscript, Line 233-235: ***"****To improve fidelity, if it is found that schools are not complying with the study protocol, project staff will timely communicate with school team members and continue with follow-up supervision.****"***

Comment 21: I would suggest that there should be more explanation provided on what this study will add to the evidence base.

Response: Thanks for this suggestion. Although several childhood obesity intervention studies have been conducted in China, research gaps existed in terms of methodological flaws, process measures, scalability and sustainability of the intervention. Based on a theory-driven and systematic development during its formative phase (e.g., systematic review, qualitative interviews, panel discussions and a piloted study), the DECIDE-Children study provides one of the first examples of rigorous development and evaluation of a childhood obesity prevention programme implemented in eastern, central and western regions of China.

Please see:

Page 18-19 in Manuscript, Line 364-371: *"Although several childhood obesity intervention studies have been conducted in China, research gaps existed in terms of methodological flaws, process measures, scalability and sustainability of the intervention. Based on a theory-driven and systematic development during its formative phase (e.g., systematic review [8], qualitative interviews, panel discussions and a piloted study [15]), the DECIDE-Children study provides one of the first examples of rigorous development and evaluation of a childhood obesity prevention programme implemented in eastern, central and western regions of China."*

Comment 22:

For Table 2 and Figure 2 – where it is stated 'activities towards students/parents etc', I would suggest changing 'towards' to 'for'

Table 1

I would suggest changing the wording of the each of the methods to 'measured to the nearest 0.1cm at least twice' (ie remove 'for')

Table 2

I would suggest changing ‘snack’ to ‘snacks’ and ‘beverage’ to ‘beverages’

I would also suggest that ‘information’ rather than ‘knowledge’ is being provided to the parents through the app.

The footnote at the bottom of the table currently doesn’t read well ‘which are eaten out of three meals per day’. Perhaps change to ‘which are eaten at times other than at main meals’.

Response: Thanks for these suggestions. We have revised the corresponding descriptions accordingly.

Comment 23: In regard to the smartphone app, what feedback are the parents provided with? In regard to the weight management and assessment and feedback points (3&4) of the app section, do you mean ‘weight status’ rather than nutritional status’? Could more information be provided on the ‘synthetic and individualized assessment and feedback’ provided by the app.

Response: Thanks for these suggestions.

(1) We have further elaborated the four types of feedback that will be provided to the parents in Table 2.

(2) In regard to weight management and assessment and feedback points, we do mean ‘weight status’ rather than ‘nutritional status’, and we have reworded it accordingly.

(3) In regard to assessment, the smartphone app will provide a synthetic and individualized assessment that combines changes of behaviors (recorded by parents and children) and weight status (regular monitoring data) of students. This information has also be elaborated in Table 2.

Please see:

(1) Page 34 in Manuscript: “*The smartphone app will also provide a synthetic and individualized assessment that will combine changes of behaviors and weight status of students.***”**

(2) Page 32 (Table 2) in Manuscript.

Comment 24:

In regard to the reinforcement of students' physical activity I would suggest that instead of stating that teachers 'should' or 'will' that they will be 'instructed' or 'advised' to.

In regard to health education activities, I would suggest changing 'health education activities towards parents' to 'health education activities for parents'.

I would also suggest clarifying when activities are held. Eg 'In the first semester, two activities are conducted. In the second semester, one activity is conducted, with a second activity conducted if required.

Under 3. Health education activities towards students – should 2) Forms be Forums?

Overall I would suggest some further detail on what is involved in the activities conducted.

Response: Thanks for these suggestions.

(1) We have reworded 'should' or 'will' to 'instructed' or 'advised'. We have also reworded 'health education activities towards parents' to 'health education activities for parents'.

(2) We agree with the suggestion and have further clarified when activities will be held. At least one activity is held in the beginning of each semester. One more activity is required in the middle of the first semester. Another activity is also held in the middle of the second semester if necessary (such as fidelity is unsatisfactory).

(3) Under 3. Health education activities for students, we have clarified it as 'different kinds of activities', including seven health education lectures and three theme class meetings. For health education lectures, the focus is on information diffusion. For theme class meetings, the focus is on consolidation of the key messages learned in health education lectures through interactive and interesting group work (e.g., "Let me guess").

Please see:

Page 27-28 "Health education activities for students" (Table 1) in Manuscript.

Comment 25:

Figure 1

In the ‘intervention group’ box, I would suggest changing ‘activities towards students’ to ‘student-focussed activities’ etc

In the ‘control group’ box, I would suggest changing ‘usual care’ to ‘usual practice’

Response: Many thanks for these suggestions. We have reworded it accordingly.

Please see:

Figure 1 in the manuscript.

VERSION 2 – REVIEW

REVIEWER	Liselotte Schäfer Elinder Karolinska Institutet, Sweden
REVIEW RETURNED	12-Aug-2019

GENERAL COMMENTS	The authors have done a great job to answer my questions to the first version, which has improved the manuscript considerably. But a couple of questions remain to be answered. The language also has improved with some remaining corrections to be made. Major points 1. Throughout the manuscript I would be more specific concerning the role of the app. I suggest exchanging “assist in implementation of the intervention” with “assist in providing information and monitoring and providing feedback on behavior and body weight”. 2. To be precise, as far as I understand it this study will not provide information on scalability as argued by the authors, but rather on sustainability of effects on diet, PA and BMI. This is also mentioned in l.85-86 and in l.121-122. In l.129-130 I would therefore remove “and increase the scalability of our intervention”. 3. In order to assess scalability, meaning the possibility to implement this intervention on a wide scale in China, authors would have to interview school leaders and decision-makers towards the end of the intervention regarding barriers and facilitators in each region. This is not mentioned in the manuscript. 4. In order to see whether effects are the same or different in the three regions, a stratified analysis of effects would have to be made. I did not see that mentioned anywhere. If you are planning to do that it should be mentioned in l.295-297. 5. L. 76-77: Authors should give arguments why they think that DECIDE will be more effective than previous interventions in China, either in the introduction or in the discussion. 6. For readers, especially outside of China, it would be of interest to learn how socio-economic status affects the prevalence of

	obesity (l.81). Is it like in Western countries where low SES is associated with high obesity? 7. l.302: I think it is still not clear how the process evaluation will be conducted in control schools. What will be assessed and by who? 8. L.312-320: Likewise it is not really clear to me who does what in the process evaluation in intervention schools. Table 3 (p.35-36) is somewhat confusing since there are no lines between the different measures. Also, I question whether children should and are able to answer the questions related to "stage of change related to weight reduction", but I assume that this has been cleared with the ethics committee. 9. Figure 2 has been improved. I would suggest the following legend:" The Social ecological model as applied to the DECIDE intervention" Language 1. L. 26: remove "its" 2. L. 31: remove "the" 3. L.62: change to "fast growing economy" 4. L. 90: write "the Chinese.." 5. L.98 and l.101: write "the school system" 6. L.116: write "study aims to develop.." 7. L.117: write "targeting school children.." 8. L. 137 and 138: Replace "half of the schools" by "four of the schools" 9. L. 141 and l. 155-156: You could add that parents and difficult to reach in boarding schools, if this was the reason for excluding them. 10. L.161: replace "If the number of classes in one school is more than needed" by " If there are more classes in one school than needed" 11. L. 169: write "invited to participate by" 12. L. 174: write "about the health status" 13. L. 175: write "if parents report one of the following conditions, their children will be excluded" 14. L. 179: I think the term "physically incomplete" is not correct, suggest delete 15. L.181: write "having lost weight" 16. L.213 and 215: write "project staff involved in" 17. L.230: clarify "the twelve schools in the control group will not carry out any of the DECIDE intervention components" 18. L.240: write "one school semester and half way through the intervention" 19. L. 261: remove "in" 20. L.263: write "BMI z-score" 21. L.324: write "Intervention costs include hours spent by project staff…" 22. L. 335: Write "intervention approach" 23. L.346-348: write "was completed" 24. L.348: write "measurements will start and will be completed" 25. L.355: write: "into an electronic database with de-identified information" 26. L. 376: write "determine the sustainability of the effects of the intervention"

REVIEWER	Megan Hammersley University of Wollongong, Australia
REVIEW RETURNED	16-Aug-2019

GENERAL COMMENTS	Thank you for addressing all of the feedback provided. I feel that all comments have been responded to appropriately.

VERSION 2 – AUTHOR RESPONSE

Reviewer: 1
Major points
1. Throughout the manuscript I would be more specific concerning the role of the app. I suggest exchanging “assist in implementation of the intervention” with “assist in providing information and monitoring and providing feedback on behavior and body weight”.
Our reply: Thanks so much for this suggestion. We agree with it and has revised the corresponding words in Abstract, Strengths and limitations of this study, Intervention, and Discussion in this revised manuscript.
Please see:
(1) Page 2, Line 37-39 in Manuscript (referred to the manuscript with the track changes): “A smartphone application will be used to assist in providing information on, monitoring and providing feedback on the behaviours and body weight of the students.”
(2) Page 4, Line 56-59 in Manuscript: “We will employ a smartphone application to assist in providing information on, monitoring and providing feedback on the behaviours and body weight of the students.”
(3) Page 12, Line 238-241 in Manuscript: “The app, which was developed based on behaviour change techniques, will be aid in information diffusion, behaviour monitoring, weight management, assessment and feedback.”
(4) Page 21, Line 432-435 in Manuscript: “a smartphone app is employed to assist in providing information on, monitoring and providing feedback on the behaviours and body weight of the children.”

2. To be precise, as far as I understand it this study will not provide information on scalability as argued by the authors, but rather on sustainability of effects on diet, PA and BMI. This is also mentioned in l.85-86 and in l.121-122. In l.129-130 I would therefore remove “and increase the scalability of our intervention”.
3. In order to assess scalability, meaning the possibility to implement this intervention on a wide scale in China, authors would have to interview school leaders and decision-makers towards the end of the intervention regarding barriers and facilitators in each region. This is not mentioned in the manuscript.
Our reply: We agree with this suggestion. Increasing the scalability of our intervention would be a focus of our future study, and so we have removed the corresponding words (“increase the scalability of our intervention”) in the revised manuscript.
Please see:
(1) Page 4, Line 53-55 in Manuscript: “This study will rigorously evaluate the effectiveness of a childhood obesity prevention programme in eastern, central and western regions…”
(2) Page 8, Line 147-149 in Manuscript: “To accommodate the social and economic variations within the country, we will intentionally select schools from…”
(3) Page 20, Line 415-418 in Manuscript: “Although several childhood obesity intervention studies have been conducted in China, research gaps exist in terms of methodological flaws, process measures, and sustainability of the intervention.”

4. In order to see whether effects are the same or different in the three regions, a stratified analysis of effects would have to be made. I did not see that mentioned anywhere. If you are planning to do that it should be mentioned in l.295-297.
Our reply: We agree with this suggestion and have added a stratified analysis of effects by three regions in this revised manuscript.

Please see:
Page 17, Line 335-337 in Manuscript: “We will also examine whether the differences in the outcomes between the control and intervention groups vary by the three regions (Beijing, Shanxi, Xinjiang), the sex of children, socioeconomic status…..”

5. L. 76-77: Authors should give arguments why they think that DECIDE will be more effective than previous interventions in China, either in the introduction or in the discussion.
Our reply: We agree with this suggestion and has elaborated on why the DECIDE-Children study will be more effective than previous interventions in China, in both the introduction and the discussion.
Please see:
(1) Page 5-6, Line 87-90 in Manuscript: “Moreover, not all school-based interventions have been effective in preventing excessive weight gain in children. One potential interpretation of this finding is that adherence to the intervention components was not guaranteed [11].”
(2) Page 21, Line 424-427 in Manuscript: “Our DECIDE-Children study can overcome poor adherence to the intervention components, which is a weakness of most previous studies, due to our favourable collaboration with local education authorities as well as the rigorous quality control of implementing the intervention.”

6. For readers, especially outside of China, it would be of interest to learn how socio-economic status affects the prevalence of obesity (l.81). Is it like in Western countries where low SES is associated with high obesity?
Our reply: It is indeed of interest to learn how socioeconomic status affects the prevalence of obesity. Until now, social disparities in the pattern of obesity have been differing between China and Western countries. In China, socioeconomic development has been positively associated with overweight and obesity prevalence in children (Lancet Diabetes Endocrinol 2019;7(4):288-299). We have further added a brief interpretation for this point in this revised manuscript.
Please see:
Page 6, Line 95-97 in Manuscript: “Social disparities in the pattern of obesity differ between China and Western countries. In China, socioeconomic development has been positively associated with overweight and obesity prevalence in children.”

Reference:
Dong Y, Jan C, Ma Y, et al. Economic development and the nutritional status of Chinese school-aged children and adolescents from 1995 to 2014: an analysis of five successive national surveys. Lancet Diabetes Endocrinol, 2019, 7: 288-299.

7. l.302: I think it is still not clear how the process evaluation will be conducted in control schools. What will be assessed and by who?
Our reply: The process in control schools will be assessed in two ways. First, the trained investigators will fill in school questionnaires after face-to-face interviews with school principals, doctors/health care teachers and physical education teachers. Second, interviews with participants (6~8 students per school) will be conducted in follow-up investigations in control schools.
Please see:
(1) Page 18, Line 362-367 in Manuscript: “The intervention process data collection procedure will include … (3) school policies related to obesity prevention and management, which will be be collected by the questionnaires (Table 3) in both the intervention and the control groups; (4) interviews with participants (6~8 students per school) which will be conducted in both the intervention and the control groups.”
(2) Page 35-37 in Manuscript: Table 3

8. L.312-320: Likewise it is not really clear to me who does what in the process evaluation in intervention schools. Table 3 (p.35-36) is somewhat confusing since there are no lines between the

different measures. Also, I question whether children should and are able to answer the questions related to “stage of change related to weight reduction”, but I assume that this has been cleared with the ethics committee.
Our reply: Thanks for this comment and we have further clarified the description of the process evaluation methods.
Concerning “stage of change related to weight reduction” (SOC), it does have been cleared with the ethics committee. We will use two items for the assessment of SOC. First, we will ask "Have you taken action to reduce your weight during the last three months?" Yes/no choices will be provided. In addition, we will ask "Do you currently intend to reduce your weight?" Five choices ranging from "completely do not intend" to "intend to very much" will be provided. Assessment of SOC is important, as we can observe whether SOC is related to the effects of intervention, given that SOC demonstrates the readiness to change diet and physical activity behaviors (Appetite 87(2015) 229-235). Furthermore, assessment of SOC has been demonstrated to be feasible among children of this age (Appetite 87(2015) 229-235).
Please see:
(1) Page 18, Line 356-367 in Manuscript: “The intervention process data collection procedure will include (1) direct regular field observation and records which will be collected for the quality control of the intervention (e.g., quality and quantity of the intervention sessions and number of students attending the lectures) and will be recorded by the trained project staff; (2) the user logs (e.g., frequency and duration) which will be collected by the smartphone app; (3) school policies related to obesity prevention and management, which will be collected by the questionnaires (Table 3) in both the intervention and the control groups; and (4) interviews with participants (6~8 students per school) which will be conducted in both the intervention and the control groups.”
(2) Page 37 in Manuscript: Table 3: “We will use two items for the assessment. First, we will ask "Have you taken action to reduce your weight during the last three months?" Yes/no choices will be provided. In addition, we will ask "Do you currently intend to reduce your weight?" Five choices ranging from "completely do not intend" to "intend to very much" will be provided.”
Reference: da Silva DF, Bianchini JA, Lopera CA, et al. Impact of readiness to change behavior on the effects of a multidisciplinary intervention in obese Brazilian children and adolescents. Appetite. 2015;87:22935.

9. Figure 2 has been improved. I would suggest the following legend:” The Social ecological model as applied to the DECIDE intervention”
Our reply: We agree with this suggestion and has revised the legend in Figure 2 as “The Social Ecological Model as applied to the DECIDE-Children study”.

Language
1. L. 26: remove “its”
2. L. 31: remove “the”
3. L.62: change to “fast growing economy”
4. L. 90: write “the Chinese..”
5. L.98 and l.101: write “the school system”
6. L.116: write “study aims to develop..”
7. L.117: write “targeting school children..”
8. L. 137 and 138: Replace “half of the schools” by “four of the schools”
9. L. 141 and l. 155-156: You could add that parents and difficult to reach in boarding schools, if this was the reason for excluding them.
10. L.161: replace “If the number of classes in one school is more than needed” by “ If there are more classes in one school than needed”
11. L. 169: write “invited to participate by”
12. L. 174: write “about the health status”

13. L. 175: write “if parents report one of the following conditions, their children will be excluded”
14. L. 179: I think the term “physically incomplete” is not correct, suggest delete
15. L.181: write “having lost weight”
16. L.213 and 215: write “project staff involved in”
17. L.230: clarify “the twelve schools in the control group will not carry out any of the DECIDE intervention components”
18. L.240: write “one school semester and half way through the intervention”
19. L. 261: remove “in”
20. L.263: write “BMI z-score”
21. L.324: write “Intervention costs include hours spent by project staff…”
22. L. 335: Write “intervention approach”
23. L.346-348: write “was completed”
24. L.348: write “measurements will start and will be completed”
25. L.355: write: “into an electronic database with de-identified information”
26. L. 376: write “determine the sustainability of the effects of the intervention”

Our response: Thanks so much for these helpful suggestions. We have corrected the errors or rephrased the sentenced accordingly. We have further asked for the help of a professional copyediting service to improve the quality of the English throughout this manuscript.

Reviewer: 2

Reviewer Name: Megan Hammersley
Institution and Country: University of Wollongong, Australia
Please state any competing interests or state ‘None declared’: None declared

Please leave your comments for the authors below
Thank you for addressing all of the feedback provided. I feel that all comments have been responded to appropriately.

VERSION 3 – REVIEW

REVIEWER	Liselotte Schäfer Elinder Karolinska Institutet, Sweden
REVIEW RETURNED	21-Sep-2019

GENERAL COMMENTS	The manuscript is now acceptable, but I have a few final comments for the authors to consider for clarification: l.36 (abstract): Write "the intervention will last for one school year (9 months) and consist of...."' l. 202-203: remove "self-administrative" l.306-307: It should be explained what the "other outcomes" are l.356: exchange "intervention" with "implementation" l.399: remove "will start and"

VERSION 3 – AUTHOR RESPONSE

Reviewer: 1
The manuscript is now acceptable, but I have a few final comments for the authors to consider for clarification:
l.36 (abstract): Write "the intervention will last for one school year (9 months) and consist of...."'
l. 202-203: remove "self-administrative"

l.306-307: It should be explained what the "other outcomes" are
l.356: exchange "intervention" with "implementation"
l.399: remove "will start and"
Our response: Thanks for these comments. We have revised the manuscript accordingly.
Please see:
(1) Page 2, Line 34-36: “The intervention will last for one school year (9 months) and consist of activities towards students, parents and school environment.”
(2) Page 10, Line 185-187: “the parents who provide informed consent will be required to complete a questionnaire about the health status of their children.”
(3) Page 15, Line 284-289: “behavioural outcomes (including students’ duration of moderate-to-vigorous physical activity, students’ eating behaviour and students’ sedentary behaviour) and other outcomes (including students’ knowledge related to energy balance, school policies for the prevention and management of childhood obesity and stage of readiness for behaviour change related to weight reduction)”
(4) Page 17, Line 332: “The implementation process data collection procedure will include….”
(4) Page 18, Line 369-370: “The 21-month follow-up measurements will be completed in June 2020.”