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School-based behaviour change intervention to increase physical activity levels among children: a feasibility cluster non-randomised controlled trial in Yangzhou, China

Haiquan Wang ,[1,2] Holly Blake,[3,4] Kaushik Chattopadhyay [1,2]

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For numbered affiliations see end of article.

Correspondence to
Mr Haiquan Wang;
Haiquan.Wang@nottingham.ac.uk

ABSTRACT

Objectives Children in China have low levels of physical activity. We developed a school-based behaviour change intervention to increase their physical activity levels. The study aimed to determine the feasibility of undertaking a cluster randomised controlled trial (RCT) in the future. This future cluster RCT will evaluate the effectiveness of the intervention.

Design Feasibility cluster non-RCT design.

Setting Two public schools (one intervention and one control) in Yangzhou, China.

Participants Children aged 10–12 years and their parents.

Intervention The 16-week school-based behaviour change intervention to increase physical activity levels consisted of three components (a) health education (physical education), (b) family involvement and (c) school environment support.

Outcomes measures We estimated important parameters that are needed to design the future cluster RCT, such as SD of the primary outcome (ie, 7-day steps in children), intracluster correlation coefficient (ICC), recruitment of child–parent dyads, follow-up of children, completion of and time needed for data collection among children and intervention attendance.

Results Sixty-four children and their parents participated in the study (32 per study group). The SD of the primary outcome was 34 519 steps. The ICC was 0.03. The recruitment and follow-up rates were 100%. The completion of data collection was 100% (except for the 7-day steps at baseline—one child lost the step log in the intervention group and two children lost their pedometer in the control group). The time needed to complete the self-reported questionnaire by children was around 15 min per study group, and the measurement of their anthropometric parameters took around 40 min per study group. The intervention attendance was 100%.

Conclusions Based on the promising recruitment, follow-up, completion of and time needed for data collection and intervention attendance, it would be feasible to undertake the future cluster RCT in China.

Trial registration number ChiCTR1900026865.

STRENGTHS AND LIMITATIONS OF THIS STUDY

- ⇒ The study provided the estimates of many important parameters needed to design the future cluster randomised controlled trial.
- ⇒ The study indicated an improvement in children's self-efficacy, enjoyment and social support for physical activity through a physical activity intervention.
- ⇒ It was difficult to blind participants and those delivering the intervention in this study, and, so, the study was not blinded and was open, which could have introduced information bias and performance bias.
- ⇒ The anthropometric parameters at postintervention were not directly measured by the study team due to the COVID-19 pandemic and related social distancing rules.

INTRODUCTION

The Chinese physical activity guideline recommends that children aged 5–17 years should engage in at least 60 min of moderate-to-vigorous physical activity (MVPA) per day and reduce their sedentary time.[1] Physical activity improves children's overall health and can contribute to their social well-being.[2] It can boost their learning abilities, including improvement in concentration power, memory, intellectual development and academic performance.[2–4] However, around 84% of children in China do not meet the recommended physical activity levels, and this proportion is higher compared with that in many high-income Asian, European and American countries.[5] The problem is more common among girls as there is a huge socio-cultural pressure in the conservative Chinese society, and they are not allowed to do physical activities.[5] MVPA starts to decline at around 10–12 years of age.[6–9] For example, approximately 25% of children spend over 30 min on MVPA per day in primary school (for children aged 7–12 years), whereas it is only 15% and

10% in junior middle schools (for children aged 13–15 years) and junior high schools (for children aged 16–18 years), respectively.[6] In other words, it can be beneficial to target health behaviours (including physical activity) at this transition period as children approach adolescence.[10]

Yangzhou is an eastern city in China, located in the Jiangsu Province. Over half of the school-aged children are physically inactive in the Jiangsu Province, and their health and fitness are below the national average.[11] In this province, physical activity, health and fitness levels are the worst in Yangzhou city.[12] In Yangzhou, less than 50% of children do physical activities for an hour per day, and the situation is even worse during the weekends when it comes down to only 14%.[12]

Targeting schools to promote children's physical activity appears to be promising. Children spend the majority of their waking hours in school, and, therefore, schools represent an ideal environment to reach them.[13] Schools can provide access to children from different socioeconomic backgrounds and help institutionalise the physical activity interventions into other settings, such as communities.[13] For instance, 5 to 45 min of MVPA per day can be achieved through school-based physical activity interventions.[14] School-based physical activity interventions are relatively easy to implement and reasonably easy to evaluate.[15–17]

The promotion of physical activity requires an understanding of the underlying influences on this behaviour.[18] However, in China, previous physical activity interventions for children lacked a theoretical basis for targeting the potential drivers of this behaviour.[19–21] We have addressed this issue, and our Joanna Briggs Institute qualitative systematic review on barriers and facilitators to physical activity among ethnic Chinese children has synthesised four broad themes, namely, personal, sociocultural, environmental and policy-related and program-related factors.[22 23] Based on these findings, we have developed a school-based behaviour change intervention to increase physical activity levels among children (aged 10–12 years) in China.[24]

From the evaluation point of view, the principal research question to be addressed by the cluster randomised controlled trial (RCT) in the future is whether the intervention is effective in increasing physical activity levels among children in China. The primary outcome of the future cluster RCT will be the difference in mean 7-day steps between the two study groups (ie, intervention and control). The chances of successful completion of a costly cluster RCT will improve if the feasibility of its key elements is checked before it starts. Thus, we determined the feasibility of undertaking the cluster RCT in the future and estimated important parameters that are needed to design this cluster RCT.

METHODS

Study design

This feasibility study was a cluster non-RCT. Cluster design (rather than individual allocation) was required to minimise contamination between intervention and control group participants due to the nature of the intervention.

Study setting, participants and duration

In China, the majority of children attend public schools.[25] This study was conducted in two public schools in Yangzhou. The intervention was provided in one public school. Another public school in the city, matched on the basis of similar socioeconomic background of attending students, class size and curriculum structure, acted as the control. The distance between the two schools is around 15 km, which minimised contamination. In these two schools, children aged 10–12 years (ie, from one class) with verbal assent and their parents with verbal consent were eligible, that is, child–parent dyads. The study information sheet and opt-out consent form were provided to parents through their children. Those who did not return the opt-out consent form signed by their parents were included in the study. Those with medical conditions or physical injuries that prevented them to engage in outdoor physical activities were excluded (as reported by their parents or teachers). The study duration was from May 2020 to October 2020.

Sample size

A formal sample size calculation is not usually required for a feasibility study.[26] Sim and Lewis have recommended recruiting at least 50 participants.[27] Thus, we recruited a total of 64 children and their parents (32 per study group).

Intervention

A structured school-based behaviour change intervention was provided over 16 weeks to increase physical activity levels among children (aged 10–12 years). The intervention development paper will be published elsewhere.[24] Briefly, this behaviour change intervention is based on the Behaviour Change Wheel and Theoretical Domains Framework.[28 29] It has three components: (a) health education (physical education), (b) family involvement and (c) school environment support. Health education for children was delivered face-to-face, using presentation slides and printed materials including a physical activity diary. Family involvement was promoted through an online session and a physical activity booklet. Under school environmental support, sport equipment (eg, jumping rope, shuttlecock), a pedometer and a physical activity poster were provided to children. The content, structure and theoretical basis of each intervention component are detailed in online supplemental file 1.

Control

No intervention was delivered in the control group, and children were requested to continue their usual physical activities.

Wang H, et al. BMJ Open 2021;11:e052659. doi:10.1136/bmjopen-2021-052659

Table 1 Data collection

	Assessment details*	Baseline	At 16 weeks (postintervention)
Socio-demographics		√	√
Measurement of anthropometric parameters in children			
Height	TZG (stadiometer)	√	√
Weight	RGT-140 (weighing scale)	√	√
Body mass index	Weight divided by the square of height (unit)	√	√
Waist circumference	Lufkin W606PM (measuring tape)	√	√
Physical activity	(a) Children's Leisure Activities Study Survey[48]; time recall: past 1 week, (b) Yamax SW-200 pedometer: 7-day steps	√	√
Self-efficacy (to assess confidence in children's ability to do physical activities)	0–40 rating scale; time-recall: at the time of questionnaire completion[49]	√	√
Enjoyment (to assess children's perceived enjoyment when doing physical activities)†	0–35 rating scale; time-recall: at the time of questionnaire completion[49]	√	√
Social support (to assess children's perceived support from parents and friends when doing physical activities)	0–50 rating scale; time-recall: at the time of questionnaire completion[49]	√	√

*A standard operating procedure was developed for this purpose.
†Enjoyment scales are negatively worded and thus, higher scores indicate lower physical activity enjoyment.

Study parameters and data collection

- SD of the primary outcome (ie, 7-day steps in children) and intracluster correlation coefficient (ICC) were estimated and used to calculate the sample size of the future cluster RCT.
- Recruitment of child–parent dyads—number of them approached to participate, gave assent (children) and consent (parents), screened for eligibility and found eligible and recruited.
- Follow-up of children—number of them followed-up at 16 weeks (postintervention).
- Data collection completion among children—number of them completed the self-reported questionnaire, on whom anthropometric parameters were measured and provided the recording of 7-day steps at baseline and 16 weeks (postintervention) (see table 1).
- Time needed for data collection among children—time needed to complete the self-reported questionnaire by them and measure their anthropometric parameters at baseline and 16 weeks (postintervention).
- Intervention attendance—number of children and parents attended their respective group sessions.

Adverse events

The plan was to collect information on any adverse event (including death) occurring in children as a result of participation in the study and to involve two physical activity experts to determine the relationship between the intervention and adverse event.

Withdrawal

Children and their parents were made aware (through the information sheet) that their participation was entirely voluntary, and they could withdraw from the study at any time.

Data analysis

Data were summarised using summary measures of mean or median and spread (for continuous data) and numbers and percentages (for categorical data). This was a feasibility study and so was not adequately powered to detect a difference in outcomes between the two study groups. However, we calculated the initial estimates of effects to guide the design of the future cluster RCT. All primary analyses were based on the intention-to-treat principle and were unadjusted. Missing data were imputed using multiple imputations. Between the study groups, baseline and postintervention continuous data were compared using an independent t-test (for normally distributed data) or Mann-Whitney U-test (for skewed data). Categorical data were compared using the χ^2 test. Within a study group, the change in an outcome from baseline to postintervention was compared using a paired t-test. As the study was not randomised, the adjustment was subsequently done for children's sex and the respective baseline value using multiple linear regression (in case of continuous data). The results were considered statistically significant when p values were less than or equal to 0.05. Statistical analysis was performed using Stata V.15 (StataCorp, Texas).

Patient and public involvement

Six lay people in China (intended user community) were involved when the intervention was developed.

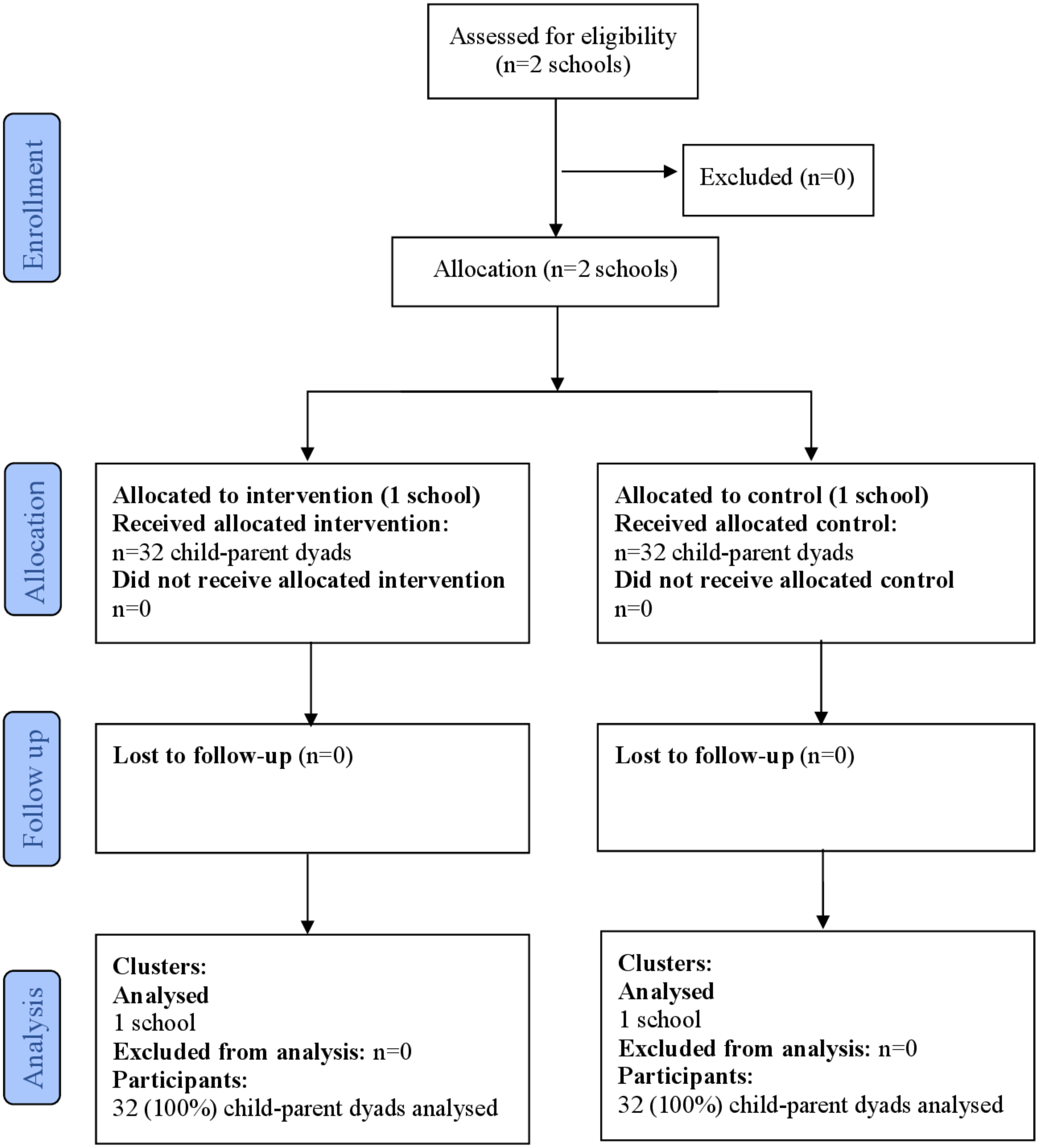

Figure 1 Flow diagram of study.

Specifically, the group included one boy and a girl aged 10–12 years, parents of each child (one father and one mother) and two physical education teachers (one man and one woman). The intervention materials were shared with them for feedback, that is, children reviewed the materials for the children, parents reviewed the materials for the children and parents and teachers reviewed all the materials. Apart from this, there was no other patient and public involvement in the study.

RESULTS

The results are reported in accordance with the relevant extension of the Consolidated Standards of Reporting

Table 2 Estimation of parameters needed for designing the future cluster RCT

	Total	Intervention	Control
Recruitment of child–parent dyads n (%)			
Child–parent dyads approached to participate	64 (100%)	32 (100%)	32 (100%)
Children gave assent	64 (100%)	32 (100%)	32 (100%)
Children's parents gave consent	64 (100%)	32 (100%)	32 (100%)
Child-parent dyads screened for eligibility	64 (100%)	32 (100%)	32 (100%)
Child-parent dyads found eligible and recruited	64 (100%)	32 (100%)	32 (100%)
Follow-up of children at 16 weeks (postintervention) n (%)	64 (100%)	32 (100%)	32 (100%)
Data collection completion among children n (%)			
(a) Children completed the self-reported questionnaire			
Baseline	64 (100%)	32 (100%)	32 (100%)
16 weeks (postintervention)	64 (100%)	32 (100%)	32 (100%)
(b) Anthropometric parameters were measured in children			
Baseline	64 (100%)	32 (100%)	32 (100%)
16 weeks (postintervention)	64 (100%)	32 (100%)	32 (100%)
(c) Children provided the recording of 7 day steps			
Baseline	61 (95.3%)	31 (96.9%)	30 (93.8%)
16 weeks (postintervention)	64 (100%)	32 (100%)	32 (100%)
Time needed for data collection among children (mean minutes)			
(a) Time needed to complete the self-reported questionnaire by children			
Baseline	30	15	15
16 weeks (postintervention)	30	15	15
(b) Time needed to measure anthropometric measurements in children			
Baseline	80	40	40
16 weeks (postintervention)	80	40	40
Intervention attendance n (%)			
(a) Group sessions for children			
Group session 1	32 (100%)	32 (100%)	n/a
Group session 2	32 (100%)	32 (100%)	n/a
Group session 3	32 (100%)	32 (100%)	n/a
Group session 4	32 (100%)	32 (100%)	n/a
(b) Group session for parents	32 (100%)	32 (100%)	n/a

RCT, randomised controlled trial.

Trials statement and checklist (for pilot and feasibility trials) and flow diagram (for cluster trials; adapted).[30–32] The study flow diagram is shown in figure 1. Sixty-four children and their parents participated in the study (32 per study group).

Estimation of parameters needed for designing the future cluster RCT

Table 2 reports the estimation of parameters needed for designing the future cluster RCT.

Sample size calculation for the future cluster RCT

The SD of the primary outcome (ie, 7-day steps) was 34 519 and ICC was 0.03 (previous Chinese studies have found similar smaller estimates).[33–35] Using these estimates, a power of 80%, a significance level of 5%, an average class size of 32 children and assuming a 20% loss to follow-up at 16 weeks (postintervention), a sample size of 2000 participants recruited from 50 schools (ie, 1000 participants in 25 intervention schools and 1000 participants in 25 control schools) will be sufficient to determine a minimum clinically important difference of 7000 steps in the mean 7-day steps between the two study groups.[36 37]

Feasibility of undertaking the future cluster RCT

The recruitment and follow-up rates were 100%. The completion of data collection was 100% (except for the 7-day steps at baseline—one child lost the step log in the intervention group and two children lost their

Table 3 Baseline characteristics of participants

	Intervention (n=32)	Control (n=32)	P value
Children's age (years)*	11.3±0.7	11.3±0.6	0.302
Children's sex n (%)			
Female	11 (34.4%)	17 (53.1%)	0.131
Male	21 (65.6%)	15 (46.9%)	
Parents' education n (%)			
Father			
None	0	1 (3.1%)	0.001
High school diploma or equivalent (0–12 years)	17 (53.1%)	29 (90.6%)	
University or equivalent (>12 years)	15 (46.9%)	2 (6.3%)	
Mother			
None	0	1 (3.1%)	0.002
High school diploma or equivalent (0–12 years)	22 (68.6%)	31 (96.9%)	
University or equivalent (>12 years)	10 (31.4%)	0	
Parents' employment n (%)			
Father			
Employed	31 (96.9%)	32 (100%)	0.313
Unemployed	1 (3.1%)	0	
Mother			
Employed	29 (90.6%)	32 (100%)	0.076
Unemployed	3 (9.4%)	0	
Physical activity			
MVPA (minutes/week)*	508.8 (231.5, 752.0)	201 (87.0, 293.0)	<0.001
Seven-day steps*	54 989.0 (35430.0, 64805.0)	67 447.0 (43667.0, 90950.0)	0.036
Height (cm)*	138.6±7.2	137.1±7.1	0.378
Weight (kg)*	38.0±8.8	36.2±6.2	0.360
BMI (kg/m^2)*	19.7±4.1	19.3±3.1	0.652
Waist circumference (cm)*	69.2±10.7	65.5±6.4	0.101
Self-efficacy*	33.0 (27.5, 37.5)	26.0 (22.0, 30.0)	0.001
Enjoyment*	8.0 (7.0, 10.5)	8.0 (7.0, 16.5)	0.730
Social support*			
Parents	32.0 (26.5, 35)	25.5 (17.0, 29.5)	0.018
Friends	26.0 (14.0, 34.0)	22.5 (15.0, 31.0)	0.455

*Values are n (%), mean±SD or median (IQR).
BMI, body mass index; MVPA, moderate-to-vigorous physical activity.

pedometer in the control group). The time needed to complete the self-reported questionnaire by children was around 15 min per study group, and the measurement of their anthropometric parameters took around 40 min per study group. The intervention attendance was 100%.

Baseline characteristics of participants

The baseline characteristics of participants are presented in table 3. At baseline, both the study groups had similar characteristics except for parents' education, self-reported physical activity level, 7-day steps, self-efficacy and perceived social support from parents.

Initial estimates of effects

Tables 4 and 5 report the unadjusted and adjusted study outcomes, respectively. Compared with the control group, the 7-day steps were significantly lower in the intervention group (mean difference: −27742.3; 95% CI −49112.6 to −6372.0) but had a higher self-efficacy (mean difference: 6.3; 95% CI 3.1 to 9.5). In the intervention group, body mass index (BMI) significantly reduced from the baseline to 16 weeks (mean difference: −1.9; 95% CI −2.3 to −1.4) and self-efficacy significantly increased during this period (mean difference: 4.6; 95% CI 2.4 to 6.8). After adjustment, similar results were found except for the BMI.

Table 4 Unadjusted study outcomes

	Intervention				Control				At 16 weeks (postintervention) comparison	
	Baseline	**At 16 weeks (post intervention)**	**Mean difference* (95% CI)**	**Within-group p value**	**Baseline**	**At 16 weeks (post intervention)**	**Mean difference* (95% CI)**	**Within-group p value**	**Mean difference† (95% CI)**	**Between-group p value**
Physical activity										
MVPA (min/week)‡	508.8 (231.5, 752.0)	348.0 (187.5, 519.0)	−188.3 (−378.9 to 2.4)	0.053	201.0 (87.0, 293.0)	271.0 (159.0, 352.5)	99.9 (−62.4 to 262.3)	0.219	80.1 (−106.9 to 267.2)	0.171
Seven-day steps‡	54 989.0 (35430.0, 64805.0)	49 096.0 (38084.0, 61005.5)	−3295.0 (−19757.6 to 13167.7)	0.686	67 447.0 (43667.0, 90950.0)	76 923.0 (45487.0, 101723.5)	11 739.8 (−5232.5 to 28712.1)	0.168	−27742.3 (−49112.6 to −6372.0)	0.006
Seven-day steps‡	56966.5±36 941.0	53671.5±32 960.5			69674.0±31 201.9	81413.8±50 703.9				
Weight (kg)‡	38.0±8.8	38.5±8.6	0.5 (−0.2 to 1.3)	0.177	36.2±6.2	37.2±6.8	1.0 (0.1 to 1.9)	0.041	1.3 (−2.6 to 5.2)	0.504
BMI (kg/m^2)‡	19.7±4.1	17.8±3.8	−1.9 (−2.3 to 1.4)	<0.001	19.3±3.1	17.5±2.4	−1.8 (−2.5 to −1.2)	<0.001	0.4 (−1.2 to 2.0)	0.616
Waist circumference (cm)‡	69.2±10.7	68.2±9.2	−1.0 (−3.1 to 1.0)	0.315	65.5±6.4	65.9±8.5	0.3 (−1.2 to 1.9)	0.645	2.3 (−2.1 to 6.7)	0.304
Self-efficacy‡	33.0 (27.5, 37.5)	37.0 (34.0, 40.0)	4.6 (2.4 to 6.8)	<0.001	26.0 (22.0, 30.0)	29.0 (24.0, 36.0)	3.4 (1.1 to 5.8)	0.006	6.3 (3.1 to 9.5)	<0.001
Enjoyment‡	8.0 (7.0, 10.5)	7.0 (7.0, 8.5)	−1.0 (−2.9 to 0.8)	0.261	8.0 (7.0, 16.5)	8.5 (7.0, 14.0)	−0.3 (−2.5 to 2.0)	0.800	−1.8 (−4.4 to 0.8)	0.090
Social support (from parents)‡	32.0 (26.5, 35.0)	30.0 (20.0, 38.5)	0.4 (−4.2 to 4.9)	0.868	25.5 (17.0, 29.5)	27.0 (17.0, 34.0)	1.4 (−1.6 to 4.5)	0.355	3.6 (−1.5 to 8.7)	0.195
Social support (from friends)‡	26.0 (14.0, 34.0)	28.5 (17.0, 37.5)	2.8 (−1.2 to 6.7)	0.161	22.5 (15.0, 31.0)	25.5 (17.0, 32.5)	1.7 (−2.3 to 5.7)	0.385	2.7 (−2.7 to 8.0)	0.310

*At 16-week (postintervention)−baseline.
†Intervention−control at 16 weeks (postintervention).
‡Values are median (IQR) or mean±SD.
BMI, body mass index; MVPA, moderate-to-vigorous physical activity.

Table 5 Adjusted study outcomes

	Intervention		Control		At 16 weeks (postintervention) comparison	
	Regression coefficient (95% CI)*	**P value**	**Regression coefficient (95% CI)***	**P value**	**Regression coefficient (95% CI)†**	**P value**
Physical activity						
MVPA (min/week)‡	−188.3 (−430.6 to 54.1)	0.125	99.9 (−65.4 to 265.3)	0.232	−33.9 (−229.6 to 161.7)	0.730
Seven-day steps‡	−3295.0 (−20908.1 to 14318.1)	0.710	11 739.8 (−9475.8 to 32955.3)	0.273	−25216.8 (−46387.1 to −4046.4)	0.020
Weight (kg)‡	0.5 (−3.8 to 4.9)	0.816	1.0 (−2.1 to 4.0)	0.538	−0.6 (−1.8 to 0.5)	0.276
BMI (kg/m^2)‡	−1.9 (−3.8 to 0.1)	0.065	−1.8 (−3.1 to −0.5)	0.006	−0.1 (−0.7 to 0.6)	0.839
Waist circumference (cm)*	−1.0 (−5.8 to 3.7)	0.663	0.3 (−2.9 to 3.6)	0.832	−1.1 (−3.5 to 1.4)	0.383
Self-efficacy‡	4.6 (1.4 to 7.8)	0.006	3.4 (0.2 to 6.7)	0.037	4.3 (1.3 to 7.3)	0.005
Enjoyment‡	−1.0 (−3.4 to 1.4)	0.395	−0.3 (−3.0 to 2.5)	0.839	−1.6 (−4.1 to 0.8)	0.193
Social support (from parents)‡	0.4 (−4.7 to 5.5)	0.884	1.4 (−2.8 to 5.6)	0.504	2.1 (−3.0 to 7.2)	0.418
Social support (from friends)‡	2.8 (−2.7 to 8.3)	0.314	1.7 (−3.3 to 6.8)	0.497	1.6 (−3.3 to 6.5)	0.527

*Multiple linear regression adjusted for children's sex (At 16-weeks (postintervention)–baseline).
†Multiple linear regression adjusted for children's sex and the respective baseline value (intervention–control at 16 weeks (postintervention)).
‡Values are median (IQR) or mean±SD.
BMI, body mass index; MVPA, moderate-to-vigorous physical activity.

Adverse events

No adverse event was reported during the study.

Withdrawal

No one withdrew from the study.

DISCUSSION

In our study, the feasibility of undertaking the future cluster RCT was found to be promising even though the study was conducted during the COVID-19 pandemic. The recruitment, follow-up, completion of and time needed for data collection and intervention attendance were promising. In our study, the recruitment rate was high (100%), similar to cluster RCTs conducted in China where the intervention targeted the physical activity levels of children in school settings (91.2% and 96.5%).[33 38] This indicates that schools are one of the best places to recruit child–parent dyads in China. Globally, similar school-based studies have reported lower recruitment rates. For example, the recruitment rates were 87.1% and 67.2% in studies conducted in the UK and Finland, respectively.[39 40] Similarly, the follow-up rate was high (100%) in our study, similar to the studies conducted in China (96.4% and 93.7%), UK (97%) and Finland (86.5%).[33 38–40] The completion of data collection was 100% (except for the 7-day steps at baseline—one child lost the step log in the intervention group and two children lost their pedometer in the control group). In the future cluster RCT, we will use different strategies to minimise such losses, such as sending reminders and giving rewards.[40] The intervention attendance was high (100%) in our study, compared with children's attendance in studies conducted in the UK (53%) and Finland (70.4%).[39 40]

Although the 7-day steps did not increase in the intervention group compared with the control, the improvements were observed in children's BMI and self-efficacy, which could enhance children's motivation to take part in future physical activities.[41–43] This decrease in BMI among children may be partly due to puberty, that is, growth in terms of height.[44 45] It should be noted that this feasibility study was not adequately powered to detect a difference in outcomes between the two study groups, and the effectiveness of the intervention will be determined in the future cluster RCT. In the future cluster RCT, a leaflet containing information on physical activity will be provided to the participants in the control group.

If our school-based behaviour change intervention is found to be effective in the future cluster RCT, it could be scaled up in China and integrated into the health education curriculum through the involvement and engagement of key stakeholders. The intervention will increase the physical activity levels among children and their self-efficacy for physical activity participation. The long-term positive health, social and economic impact will be enormous. The promotion of one healthy behaviour can bring positive changes in another behaviour, for example, diet. The support needed from family and school to promote physical activity will improve. The schools and teachers (responsible for promoting physical activity) will get an evidence-based intervention to increase children's physical activity levels.

To the best of our knowledge, this was the first feasibility study of a physical activity intervention in Yangzhou. Although the baseline characteristics of the intervention and control group participants in this study were exceedingly different due to the non-randomised study design, the non-randomised study design has provided the estimates of many important parameters needed to design the future cluster RCT. A qualitative study (using semi-structured interviews) was also conducted with a sample of children and their parents and teachers to explore their experiences in taking part in this intervention and study, which will be published separately. Decisions over whether to modify the intervention and study will mainly be informed by the qualitative data. The sample size was modest, although reasonable to address the aim of this feasibility study and was comparable with other feasibility studies of physical activity interventions targeting children.[40 46] This study was not blinded and was open, and this could have introduced information bias and performance bias. Although it was difficult to blind participants and those delivering the intervention in this case, the plan is to blind the outcome assessors and data analysts in the future cluster RCT. In the future cluster RCT, there will be 25 schools (clusters) per study arm, and we will use multilevel models in the analysis that will address the clustered nature of the data.[47] The follow-up was short in this study. We intend to do long-term (≥1 year) follow-ups in the future cluster RCT. Due to the COVID-19 pandemic and related social distancing rules, the anthropometric parameters at postintervention were not directly measured by the study team. Instructions were provided by the study team over a video call, and anthropometric parameters were measured synchronously by the parents.

CONCLUSIONS

Based on the promising recruitment, follow-up, completion of and time needed for data collection and intervention attendance, it would be feasible to undertake the future cluster RCT in China.

Author affiliations

[1]Division of Epidemiology and Public Health, School of Medicine, University of Nottingham, Nottingham, UK
[2]The Nottingham Centre for Evidence-Based Healthcare: A Joanna Briggs Institute Centre of Excellence, University of Nottingham, Nottingham, UK
[3]School of Health Sciences, University of Nottingham, Nottingham, UK
[4]NIHR Nottingham Biomedical Research Centre, University of Nottingham, Nottingham, UK

Twitter Holly Blake @hollyblakenotts

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ORCID iDs
Haiquan Wang http://orcid.org/0000-0003-2874-766X
Kaushik Chattopadhyay http://orcid.org/0000-0002-3235-8168

REFERENCES

1 Zhang Y, Zhang Y, Ma S, *et al*. Physical activity guide for children and adolescents in China. *Chin J Evid Based Pediatr* 2017;12:401–9.
2 Strong WB, Malina RM, Blimkie CJR, *et al*. Evidence based physical activity for school-age youth. *J Pediatr* 2005;146:732–7.
3 Te Velde SJ, Lankhorst K, Zwinkels M, *et al*. Associations of sport participation with self-perception, exercise self-efficacy and quality of life among children and adolescents with a physical disability or chronic disease-a cross-sectional study. *Sports Med Open* 2018;4:38–48.
4 Wu XY, Han LH, Zhang JH, *et al*. The influence of physical activity, sedentary behavior on health-related quality of life among the general population of children and adolescents: a systematic review. *PLoS One* 2017;12:e0187668.
5 Guthold R, Stevens GA, Riley LM, *et al*. Global trends in insufficient physical activity among adolescents: a pooled analysis of 298 population-based surveys with 1·6 million participants. *Lancet Child Adolesc Health* 2020;4:23–35.
6 Zhang R, LI H. Associated factors of physical exercise participation among primary and middle school students in Jiangsu. *Chinese Journal of School Health* 2017;12:1793–5.
7 Zhu Z, Tang Y, Zhuang J, *et al*. Physical activity, screen viewing time, and overweight/obesity among Chinese children and adolescents: an update from the 2017 physical activity and fitness in China-the youth study. *BMC Public Health* 2019;19:197–204.
8 World Health Organization. Spotlight on adolescent health and well-being: findings from the 2017/2018 health behaviour in school-aged children (HBSC) survey in Europe and Canada, 2020. Available: http://www.hbsc.org/publications/international/
9 Scottish Office Department of Health. The Scottish health survey 2019, 2020. Available: https://www.gov.scot/publications/scottish-health-survey-2019-volume-1-main-report/pages/3/
10 He L, Lin L. The tendency of the physical activity level among school-aged urban children in China. *Chinese Journal of School Health* 2016;37:663–40.
11 Lu S, Li Z. Analysis of the influence of ecological factors on physical activity behaviour of urban adolescents in China: a case study of Jiangsu. *Sports* 2016;145:6–7.
12 Li L. *Investigation and analysis of sunshine sports in secondary schools in Yangzhou [Master thesis]*. Yangzhou: University of Yangzhou, 2011.
13 Chen Y, Ma L, Ma Y, *et al*. A national school-based health lifestyles interventions among Chinese children and adolescents against obesity: rationale, design and methodology of a randomized controlled trial in China. *BMC Public Health* 2015;15:210–9.
14 Dobbins M, DeCorby K, Robeson PH. School-Based physical activity programs for promoting physical activity and fitness in children and adolescents aged 6-18. *Cochrane Database Syst Rev* 2013;2:CD007651.
15 Owen KB, Parker PD, Van Zanden B, *et al*. Physical activity and school engagement in youth: a systematic review and meta-analysis. *Educ Psychol* 2016;51:129–45.
16 Watson A, Timperio A, Brown H, *et al*. Effect of classroom-based physical activity interventions on academic and physical activity outcomes: a systematic review and meta-analysis. *Int J Behav Nutr Phys Act* 2017;14:114–37.
17 Hills AP, Dengel DR, Lubans DR. Supporting public health priorities: recommendations for physical education and physical activity promotion in schools. *Prog Cardiovasc Dis* 2015;57:368–74.
18 Craig P, Dieppe P, Macintyre S, *et al*. Developing and evaluating complex interventions: the new medical Research Council guidance. *Int J Nurs Stud* 2013;50:587–92.
19 Feng L, Wei D-M, Lin S-T, *et al*. Systematic review and meta-analysis of school-based obesity interventions in mainland China. *PLoS One* 2017;12:e0184704.
20 Li Y-P, Hu X-Q, Schouten EG, *et al*. Report on childhood obesity in China (8): effects and sustainability of physical activity intervention on body composition of Chinese youth. *Biomed Environ Sci* 2010;23:180–7.
21 Liu A, Hu X, Ma G, *et al*. Evaluation of a classroom-based physical activity promoting programme. *Obes Rev* 2008;9 Suppl 1:130–4.
22 Wang H, Blake H, Chattopadhyay K. Barriers and facilitators to physical activity among ethnic Chinese children in school, home and community settings: a qualitative systematic review. *JBI Evid Synth* 2020;18:2445–11.
23 Wang H, Blake H, Chattopadhyay K. Barriers and facilitators to physical activity among ethnic Chinese children: a systematic review protocol. *JBI Database System Rev Implement Rep* 2019;17:1–8.
24 Wang H, Blake H, Chattopadhyay K. Development of a school-based intervention to increase physical activity levels among Chinese children: a systematic iterative process based on behavior change wheel and theoretical domains framework. *Front Public Health* 2021;9:610245.
25 Meng X. An analysis of the course, mode and prospect of the development of private schools in China. *Journal of Jianghan University* 2004;21:97–100.
26 Thabane L, Ma J, Chu R, *et al*. A tutorial on pilot studies: the what, why and how. *BMC Med Res Methodol* 2010;10:1.
27 Sim J, Lewis M. The size of a pilot study for a clinical trial should be calculated in relation to considerations of precision and efficiency. *J Clin Epidemiol* 2012;65:301–8.
28 Michie S, Atkins L, West R. *The behaviour change wheel: a guide to designing interventions*. Great Britain: Silverback Publishing, 2014.
29 Cane J, O'Connor D, Michie S. Validation of the theoretical domains framework for use in behaviour change and implementation research. *Implement Sci* 2012;7:37–53.
30 Eldridge SM, Chan CL, Campbell MJ, *et al*. Consort 2010 statement: extension to randomised pilot and feasibility trials. *BMJ* 2016;355:i5239.
31 Thabane L, Hopewell S, Lancaster GA. Methods and processes for development of a consort extension for reporting pilot randomised controlled trials. *Pilot Feasibility Stud* 2016;2:25.eCollection 2016.
32 Campbell MK, Piaggio G, Elbourne DR, *et al*. Consort 2010 statement: extension to cluster randomised trials. *BMJ* 2012;345:e5661.
33 Li B, Pallan M, Liu WJ, *et al*. The CHIRPY DRAGON intervention in preventing obesity in Chinese primary-school--aged children: A cluster-randomised controlled trial. *PLoS Med* 2019;16:e1002971.
34 Xu F, Ware RS, Tse LA, *et al*. A school-based comprehensive lifestyle intervention among Chinese kids against obesity (CLICK-Obesity): rationale, design and methodology of a randomized controlled trial in Nanjing City, China. *BMC Public Health* 2012;12:316.
35 Li B, Adab P, Cheng KK. Family and neighborhood correlates of overweight and obesogenic behaviors among Chinese children. *Int J Behav Med* 2014;21:700–9.
36 Duncan S, McPhee JC, Schluter PJ, *et al*. Efficacy of a compulsory homework programme for increasing physical activity and healthy eating in children: the healthy homework pilot study. *Int J Behav Nutr Phys Act* 2011;8:127–10.

37 Duncan S, Stewart T, McPhee J, *et al*. Efficacy of a compulsory homework programme for increasing physical activity and improving nutrition in children: a cluster randomised controlled trial. *Int J Behav Nutr Phys Act* 2019;16:1–12.
38 Xu F, Ware RS, Leslie E, *et al*. Effectiveness of a randomized controlled lifestyle intervention to prevent obesity among Chinese primary school students: CLICK-Obesity study. *PLoS One* 2015;10:e0141421.
39 Jago R, Sebire SJ, Davies B, *et al*. Randomised feasibility trial of a teaching assistant led extracurricular physical activity intervention for 9 to 11 year olds: action 3:30. *Int J Behav Nutr Phys Act* 2014;11:114.
40 Hankonen N, Heino MTJ, Hynynen S-T, *et al*. Randomised controlled feasibility study of a school-based multi-level intervention to increase physical activity and decrease sedentary behaviour among vocational school students. *Int J Behav Nutr Phys Act* 2017;14:37–50.
41 Salmon J, Brown H, Hume C. Effects of strategies to promote children's physical activity on potential mediators. *Int J Obes* 2009;33:S66–73.
42 Dishman RK, Motl RW, Saunders R, *et al*. Enjoyment mediates effects of a school-based physical-activity intervention. *Med Sci Sports Exerc* 2005;37:478–87.
43 Mendonça G, Cheng LA, Mélo EN, *et al*. Physical activity and social support in adolescents: a systematic review. *Health Educ Res* 2014;29:822–39.
44 Vanderwall C, Randall Clark R, Eickhoff J, *et al*. Bmi is a poor predictor of adiposity in young overweight and obese children. *BMC Pediatr* 2017;17:135.
45 Himes JH. Challenges of accurately measuring and using BMI and other indicators of obesity in children. *Pediatrics* 2009;124 Suppl 1:s3–22.
46 Quirk H, Glazebrook C, Blake H. A physical activity intervention for children with type 1 diabetes- steps to active kids with diabetes (STAK-D): a feasibility study. *BMC Pediatr* 2018;18:37–48.
47 Kirkwood BR, Sterne JA. *Essential medical statistics*. 2nd edition. New Jersey: Blackwell publishing, 2003: 355–70.
48 Li H, Chen P, Zhuang J. Revision and reliability validity assessment of Children's leisure activities study survey. *Chinese Journal of School Health* 2011;32:268–70.
49 Liang Y, Lau PWC, Huang WYJ, *et al*. Validity and reliability of questionnaires measuring physical activity self-efficacy, enjoyment, social support among Hong Kong Chinese children. *Prev Med Rep* 2014;1:48–52.