

# Preschoolers in the Playground: a pilot cluster randomised controlled trial of a physical activity intervention for children aged 18 months to 4 years

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**Declared competing interests of authors:** none

Published May 2015

DOI: 10.3310/phr03050

## Scientific summary

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Public Health Research 2015; Vol. 3: No. 5

DOI: 10.3310/phr03050

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# Scientific summary

## Background

The preschool years are considered critical for establishing healthy lifestyle behaviours such as physical activity. Levels of physical activity track through childhood into adulthood; thus, establishing habitual physical activity early in life is vital. Physical activity declines markedly during childhood and this decline potentially begins in the early years; promoting physical activity in the preschool years is therefore critical to slowing the rate of age-related physical activity decline. The UK Chief Medical Officer's (CMO) report highlighted that new interventions to promote movement in the early years (0–5 years) are required and suggested that there should be investment in community-level programmes in settings such as school playgrounds. We have developed and pilot tested such an intervention, Preschoolers in the Playground (PiP), in the city of Bradford, an area of ethnic diversity and social deprivation in West Yorkshire, UK. The PiP intervention is grounded in behavioural theory (social cognitive theory, the predominant behaviour change theory used in successful childhood obesity prevention interventions). It is informed by existing literature which suggests that outdoor play is associated with a lower risk of overweight and that parent involvement is important for physical activity intervention success in the early years. The intervention has been developed in accordance with CMO guidance for physical activity in the early years. It has also been informed by qualitative data collected from focus groups with parents of preschool children. The intervention was delivered in primary school playgrounds. Six 30-minute PiP sessions per week were available for 30 weeks and families were encouraged to come to three a week. The initiation phase (10 weeks) was facilitated by a member of school staff. The maintenance phase (20 weeks) was unsupervised.

## Objectives

The study aimed to undertake a pilot cluster randomised controlled trial (RCT) of the PiP intervention and to assess the feasibility of a full-scale cluster RCT. The specific objectives were to determine:

1. the feasibility and acceptability of the recruitment strategy for schools and families and whether or not there was a difference in recruitment rate between ethnic groups
2. follow-up and attrition rates during the trial and whether or not there was a difference between trial arms and ethnic groups
3. the acceptability of the trial procedures
4. the feasibility of collecting the outcome measures and whether or not there was a difference between trial arms and ethnic groups
5. the influence of financial incentives on trial participation
6. attendance to, and acceptability of, the intervention, whether or not there was a difference between ethnic groups and whether or not attendance varied by season
7. the fidelity of programme implementation
8. the capability and capacity of schools to deliver and incorporate the intervention within existing services
9. the effect of participation in the intervention on health outcomes and whether or not there were any differences between ethnic groups
10. estimates of effect size, typical cluster sizes and intraclass correlation coefficients (ICCs) to enable an accurate sample size calculation for a full trial
11. a preliminary assessment of the potential cost-effectiveness of PiP and an estimate of the value of further research
12. whether or not links can be established between short-term outcomes and long-term quality of life, potentially including across sectors
13. whether or not it is appropriate to apply for further funding for a full-scale RCT.

## Methods

The study was a two-armed pilot cluster RCT with economic and qualitative evaluations. The two arms consisted of the PiP intervention and usual practice (control). Recruitment, randomisation and implementation of the intervention or control took place in three waves. Wave 1 commenced in autumn 2012, wave 2 in winter 2013 and wave 3 in summer 2013. The recruitment target was 10 schools and 150 children aged from 18 months to 4 years. Schools were allocated on a 1 : 1 basis. Block randomisation was used for the first four schools and minimisation for the subsequent six schools.

### *Quantitative and health economic data collection and analysis*

Data relating to recruitment, attrition and follow-up were captured on a central database system. Parents and children were invited to attend a measurement session at baseline and at 10 and 52 weeks' follow-up where the following health outcome data were collected: physical activity via triaxial accelerometry (Actigraph GT3X+, Actigraph Pensacola, FL, USA), anthropometry [height, body mass, body mass index (BMI), waist and upper arm circumference], health-related quality of life (HRQoL) for the child [Pediatric Quality of Life Inventory (PedsQL)] and parent [European Quality of Life-5 Dimensions (EQ-5D)], parent well-being [Comprehensive Quality of Life Scale – Adult (ComQol-A5)], parent general self-efficacy and child's injuries and health service use. The feasibility of collecting the outcome measures was assessed by examining completion rates. Summaries were produced overall, by trial arm, by ethnicity and over time. Summary statistics were calculated in Stata version 12 (StataCorp LP, College Station, TX, USA) following the intention-to-treat principle for each of physical activity, anthropometry, parent well-being and general self-efficacy. A linear regression model compared the PiP intervention arm and the control arm weighted by the number of participants followed up in each cluster and adjusted for baseline average moderate to vigorous physical activity (MVPA) per day for each cluster. A sample size calculation was undertaken. A cost-effectiveness analysis was conducted for the HRQoL of children, assessed using the PedsQL, and of parents, assessed using the EQ-5D.

The fidelity of the implementation of the PiP intervention was assessed in line with guidance from the National Institutes for Health (NIH) Behavior Change Consortium; summary statistics were produced for the fidelity scores relating to five key intervention factors. Attendance at PiP intervention sessions was recorded at each session by the PiP facilitator.

### *Qualitative data collection and analysis*

Qualitative interviews with parents, PiP facilitators and head teachers were conducted to assess the acceptability of the trial procedures. Views on recruitment, randomisation, the influence of financial incentives on trial participation, the acceptability of the intervention and the capability and capacity of the schools to deliver the intervention were also explored and analysed using a thematic analysis.

## Results

### *Recruitment and follow-up rates*

In total, 37% of schools and 48% of parents approached agreed to take part. One of the main reasons why head teachers agreed for their school to take part was because the PiP intervention offered a new way to engage with families. Parents reported that taking part was a good way to introduce their child to the school environment.

Levels of retention at 10 and 52 weeks' follow-up were good (82.3% and 83.5% respectively). There were no differences in follow-up rates at any time point between trial arms and rates were higher for South Asian children than for white children. The consensus from parents and head teachers was that financial incentives were important for trial participation.

### ***Acceptability of the trial procedures and feasibility of collecting outcome data***

Parents reported that in general the trial procedures (study information, measurement sessions and accelerometers) were acceptable. However, the ComQol-A5 was not acceptable. Parents felt uncomfortable answering personal questions about themselves and found the questionnaire long and repetitive.

At baseline 69% of children provided valid accelerometer data (meeting the wear time of 6 hours on any 3 days). Only 39% of participants provided valid data at both baseline and 52 weeks' follow-up. Completion of height and weight measurements decreased over time, with 88% of children completing both measurements at baseline and only 65% completing both measures at 52 weeks. This resulted in 57% of children having BMI data available for both time points. A similar pattern was observed for waist and upper arm circumference, with only 45% and 41% of children providing data, respectively, at both baseline and 52 weeks. The completion rates for the outcomes related to the economic evaluation were sufficient (77% and 76% for the EQ-5D and 100% and 75% for the PedsQL at baseline and 52 weeks respectively).

### ***Attendance to, and acceptability of, the intervention***

Overall, 65% of children attended one or more sessions during the initiation phase. The number of children attending at least one session was lowest during the winter initiation phase (40%, wave 2); this doubled during the summer initiation phase (> 80%, wave 3). Among those children who attended at least one session, the average number of sessions attended was 9.1 [standard deviation (SD) 9.6 sessions], with a median of three sessions. During the maintenance phase, 16% of children attended any sessions. Attendance was low across all waves (0% in wave 1 and 29% in wave 3 attending any sessions). Among those children who attended at least one session, the average number of sessions attended was 5.2 (SD 3.4 sessions), with a median of 4.5 sessions. Attendance was higher among South Asian children than among white children. Among those children who attended at least one session, the average number of sessions attended for white children was 10.7 (SD 12.1 sessions), with a median of three sessions attended (minimum–maximum 1–33 sessions), and for South Asian children was 11.3 (SD 11.8 sessions), with a median of 4.5 sessions attended (minimum–maximum 1–35 sessions).

The initiation phase of the intervention was acceptable to parents, facilitators, and head teachers and they all reported perceived benefits. The poor attendance during the maintenance phase was attributed to changes in family routines and circumstances and the lack of visibility of the intervention without a facilitator. One head teacher indicated that, with the maintenance phase, the intervention was too long and parents attending the school do not engage in long-term programmes.

### ***Fidelity of the intervention and capacity of schools to deliver the intervention***

The fidelity of intervention implementation was good (81% adherence). Schools had the capacity and capability to incorporate the delivery of the intervention into existing workloads. One head teacher commented that the intervention would not be sustainable without additional funding to support the facilitator.

### ***Health outcomes***

The primary outcome for a full trial would be levels of MVPA. The mean number of minutes spent in MVPA per day was lower in the intervention group than in the control group at both 10 [61.8 (SD 25.2) vs. 62.1 (SD 22.9)] and 52 [72.6 (SD 30.4) vs. 74.3 (SD 25.5)] weeks. South Asian children showed very small improvements in MVPA following the intervention whereas white children did not. A sample size for a full trial was calculated to be 38 schools and 600 children.

### Cost-effectiveness

The incremental cost per quality-adjusted life-year (QALY) generated from the PiP intervention compared with usual practice was £19,588. At current threshold values of a QALY, the PiP intervention is bordering on cost-effective, although there is significant uncertainty surrounding this estimate. An exploratory subgroup analysis demonstrated that the PiP intervention is likely to be cost-effective in the South Asian participants (incremental cost-effectiveness ratio of £9346 per QALY in the base case and £10,329 per QALY in the complete-case analysis) but not in the white participants.

### Conclusions

The findings from the PiP pilot trial can help to modify the PiP intervention, inform a full-scale trial of the intervention and also provide advice for researchers planning to conduct public health interventions with schools and deprived and ethnically diverse populations.

### Proposed changes to the intervention

1. Deliver the intervention during the summer term only.
2. Deliver the intervention for 10 weeks only (the initiation phase).
3. Encourage families to come to at least two and ideally three sessions per week.
4. Send text reminders about session days and times each week with information about the free take-home play equipment for that week.
5. Agree the timings of the sessions with schools before recruiting families.
6. Facilitators to become familiar with the families recruited before the start of the intervention.
7. Engage early with schools so that all staff members are aware of the intervention and can support the families taking part to attend.
8. Display visible promotional materials in schools, in children's centres and at local groups to remind families and early years workers about the intervention.
9. Provide refreshments and social time at the end of sessions for parents as an incentive to attend.
10. Produce the intervention information on physical activity on a website and use videos to increase the likelihood that the information is received and understood.
11. Sustain the behaviour change by providing information, prompts and reminders about physical activity and physical activity opportunities available in the local area.
12. Recontact families with a newsletter/video link during the summer holidays after the 10-week initiation phase and once a term for the subsequent year with relevant and local activities available to them.

### Recommendations for a full trial and for other researchers

1. Include qualitative interviews, assessments of fidelity, attendance reports and a health economic evaluation when designing evaluations of preschool physical activity interventions.
2. Build in sufficient time and resources to research plans to ensure successful follow-up of, and extra support for, hard-to-reach participants.
3. With very young children consider the impact of multiple measures over time on research fatigue and minimise measurements when it is possible to do so.
4. The ComQol-A5 questionnaire was not acceptable to parents because of the sensitive questions about their mental health and income. It would not be used in a full trial of the PiP intervention.
5. Ensure that study materials are appealing to participants by using colours and pictures and ensure that they can be easily understood.
6. Ask participants to provide as many different forms of contact details as possible.
7. Incentives for research appear to be important in deprived communities; consider the type of incentive that is appropriate and useful to the participant population.

8. Consider the motivation for schools and families to take part in a study (in the PiP trial this was mainly to become familiar with the school and for social and learning benefits) and describe these potential benefits in the study information; be aware that these may not match up with the intended primary outcome of the study (in this case increasing physical activity).
9. Ensure that participants can identify with the research staff who are conducting recruitment, for example the researchers can translate study materials into relevant language for participants and are not 'too academic'.

### **Follow-on research**

In autumn 2014 we undertook additional research to evaluate the effectiveness of strategies to improve adherence to the accelerometer protocol. Sixty-seven preschool children were recruited from four schools. The new sample was similar to the population in the pilot trial. The following strategies were employed:

1. Nursery staff were made aware of which children should be wearing accelerometers and offered support to parents and children.
2. Parents received a daily reminder by telephone or text message to put the accelerometer on their child.
3. Accelerometers were checked to see whether or not valid wear time had been met when they were collected from families.
4. The monitor was left for longer with the family if wear-time criteria had not been met.
5. A desirable incentive (a goodie bag of toys) was offered rather than a voucher.
6. All monitors were checked before each measurement time point to ensure that malfunctioning monitors were not distributed.

The newly employed strategies increased the percentage of children with valid accelerometry data at both baseline and the 10-week follow-up, from 39% in the pilot trial to 60% in the improvement study. These new strategies could be used in a full-scale trial of the PiP intervention and by other researchers using accelerometers with preschool children.

### **Trial registration**

This trial is registered as ISRCTN54165860.

### **Funding**

Funding for this study was provided by the Public Health Research programme of the National Institute for Health Research.

# Public Health Research

ISSN 2050-4381 (Print)

ISSN 2050-439X (Online)

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## This report

The research reported in this issue of the journal was funded by the PHR programme as project number 11/3001/16. The contractual start date was in September 2012. The final report began editorial review in August 2014 and was accepted for publication in December 2014. The authors have been wholly responsible for all data collection, analysis and interpretation, and for writing up their work. The PHR editors and production house have tried to ensure the accuracy of the authors' report and would like to thank the reviewers for their constructive comments on the final report document. However, they do not accept liability for damages or losses arising from material published in this report.

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