

# 'Pre-schoolers in the Playground' (PiP) - physical activity for children aged 18 months to 4 years old

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| <b>Submission date</b><br>04/09/2012   | <b>Recruitment status</b><br>No longer recruiting              | <input type="checkbox"/> Prospectively registered<br><input checked="" type="checkbox"/> Protocol |
| <b>Registration date</b><br>05/10/2012 | <b>Overall study status</b><br>Completed                       | <input type="checkbox"/> Statistical analysis plan<br><input checked="" type="checkbox"/> Results |
| <b>Last Edited</b><br>30/01/2020       | <b>Condition category</b><br>Nutritional, Metabolic, Endocrine | <input type="checkbox"/> Individual participant data  |

## Plain English summary of protocol

### Background and study aims

The pre-school years is a critical period for establishing healthy lifestyle behaviours such as physical activity (PA). There are many benefits of taking part in regular PA for pre-school children, e.g. maintaining a healthy weight. Tackling childhood obesity is a national public health priority. Although the rate of rise in childhood obesity is slowing, levels in England remain high in urban areas, in those from deprived backgrounds and in ethnic minority groups such as South Asians. Regular PA also has many other important health and social benefits for pre-school children; it is valuable for developing motor skills, enhancing bone and muscle development and for learning social skills. Despite the well-known health benefits of PA there are high levels of physical inactivity across the UK in all age groups, including the pre-school years. Only a few PA programmes for pre-school children have been tested to see how effective they are and the results of these studies are mixed. In a report published in July 2011 the UK's Chief Medical Officer highlighted that we need new programmes that promote movement in the early years (0-5 years old) in the UK. The 'pre-schoolers in the playground' (PiP) programme aims to increase PA levels in children aged 18 months - 4 years old. PiP will open up school playgrounds for pre-school siblings to use with their parent/carer. The 'school run' occurs on every week day for 39 weeks a year, regardless of weather. Capitalising on this daily routine to provide a safe, organised, supervised area for pre-school children to enjoy active play outdoors may increase PA and over time, reduce adiposity. Additionally, involving parents in their community settings has the potential to bond them together and improve their well-being.

### Who can participate?

Children aged 18 months to 4 years of age

### What does the study involve?

Eight schools will be selected from locations across deprived areas of Bradford. Four of the schools will have mostly South Asian pupils and the 4 schools will have mostly Caucasian (white) pupils. Families will be invited to take part in the study, before the schools are randomly allocated to one of the two groups. Four schools will be allocated to the PiP programme and 4 to a group where the usual practice (the control). All participants taking part in the study will have

to complete a questionnaire at the start of the study and at 10 weeks, 30 weeks and 52 weeks during the study

Where is the study run from?

Bradford Teaching Hospitals NHS Foundation Trust - Born in Bradford Project

What are the possible benefits and risks of participating?

There may be no benefit to taking part in the trial; however, parents will be given a £10 voucher towards play equipment following each completed measurement session. The disadvantages to taking part in the trial may include injuries to the child whilst engaging in play and for the adults participating, the time taken to complete the data collection.

When is the study starting and how long is it expected to run for?

The PiP trial is expected to be completed two years from the start of the first wave in September 2012. The second wave of recruitment will take place in January 2013 and the third and final wave in April 2013.

Who is funding the study?

National Institute for Health Research (NIHR) - Public Health Research Programme (UK).

Who is the main contact?

Dr Sally Barber

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## Contact information

### Type(s)

Scientific

### Contact name

Prof John Wright

### Contact details

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## Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

## Secondary identifying numbers

N/A

# Study information

## Scientific Title

'Pre-schoolers in the Playground' (PiP) - a pilot cluster randomised controlled trial of a physical activity intervention for children aged 18 months to 4 years old

## Acronym

PiP

## Study objectives

Preschoolers in the Playground (PiP) aims to assess the feasibility of opening primary school playgrounds to preschool children aged 18 months to 4 years of age, in order to increase physical activity levels over a sustained period of time leading to a healthier lifestyle and reduced risk of childhood obesity.

## Ethics approval required

Old ethics approval format

## Ethics approval(s)

NRES Committee Yorkshire and The Humber, 30/07/2012 ref: 12/YH/0334

## Study design

Two-armed pilot cluster randomised controlled trial

## Primary study design

Interventional

## Secondary study design

Cluster randomised trial

## Study setting(s)

School

## Study type(s)

Quality of life

## Participant information sheet

Not available in web format, please use the contact details below to request a patient information sheet

## Health condition(s) or problem(s) studied

Childhood obesity

## Interventions

The intervention will include the introduction of organised and supported physical activity sessions in playgrounds, followed by access to the playgrounds and play equipment unsupported up to 52 weeks from the start.

**Intervention Type**

Other

**Phase**

Not Applicable

**Primary outcome measure**

1. Increased levels of physical activity in preschoolers
2. Improved wellbeing and self efficacy for adults attending the intervention with the preschoolers

**Secondary outcome measures**

1. Child health related quality of life (PedsQL) as well as anthropometric measurements from the children
2. Parent health-related quality of life (EQ5D)
3. Self-efficacy (GSES)
4. Wellbeing (ComQol-A5)

**Overall study start date**

07/09/2012

**Completion date**

30/09/2014

**Eligibility****Key inclusion criteria**

Children aged 18 months to 4 years of age not in school

**Participant type(s)**

Patient

**Age group**

Child

**Lower age limit**

18 Months

**Upper age limit**

4 Years

**Sex**

Both

**Target number of participants**

120

**Total final enrolment**

164

**Key exclusion criteria**

1. Children aged less than 18 months of age and those children aged 4 years and over
2. Enrolled into school

**Date of first enrolment**

07/09/2012

**Date of final enrolment**

30/09/2014

## **Locations**

**Countries of recruitment**

England

United Kingdom

**Study participating centre**

**Bradford Teaching Hospitals NHS Foundation Trust**

Bradford

United Kingdom

BD9 6RJ

## **Sponsor information**

**Organisation**

Bradford Teaching Hospitals NHS Foundation Trust (UK)

**Sponsor details**

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**Sponsor type**

Hospital/treatment centre

**Website**

<http://www.bradfordresearch.nhs.uk>

**ROR**

<https://ror.org/05gekvn04>

## Funder(s)

**Funder type**

Government

**Funder Name**

NIHR - Public Health Research Programme (UK)

## Results and Publications

**Publication and dissemination plan**

Not provided at time of registration

**Intention to publish date****Individual participant data (IPD) sharing plan****IPD sharing plan summary**

Not provided at time of registration

**Study outputs**

| Output type                      | Details  | Date created | Date added | Peer reviewed? | Patient-facing? |
|----------------------------------|----------|--------------|------------|----------------|-----------------|
| <a href="#">Protocol article</a> | protocol | 09/10/2013   |            | Yes            | No              |
| <a href="#">Results article</a>  | results  | 01/05/2015   |            | Yes            | No              |
| <a href="#">Results article</a>  | results  | 01/12/2016   |            | Yes            | No              |
| <a href="#">Results article</a>  | results  | 28/01/2020   | 30/01/2020 | Yes            | No              |