

THE UNIVERSITY *of* York

Participant Information Sheet

Study title: PiP (Pre-schoolers in the Playground)

We would like to invite you to take part in this research study. Before you decide if you would like to take part, you need to understand why the research is being done and what it would involve for you. Please take time to read the following information carefully. Talk to others about the study if you wish, such as members of your family or friends.

Please ask us if there is anything that is not clear or if you would like more information. Take time to decide whether or not you wish to take part.

Why is the study necessary and what does it involve?

Why is the study necessary?

This small study will find out how practical it is to provide a play programme for pre-school children in primary school playgrounds. We want to find out if the programme increases levels of physical activity in pre-school children and how acceptable the programme is to families and schools.

Why have I been approached?

You have been invited to take part in this study because you have a child that is aged between 18 months and 4 years of age who has a brother or sister at one of the schools taking part in the PiP study. The pre-school years are an important time when children establish healthy lifestyle behaviours like physical activity. There are many benefits of taking part in regular physical activity for pre-school children. One of the most significant is maintaining a healthy weight.

If I decide to take part in this research, what will it involve?

A research assistant will ask you some simple questions to make sure your child is eligible to take part in the study. She will explain the study and you can ask her any questions you have about the study. At this point if you decide you are not interested in taking part we will not contact you again. If you decide you would like to take part a member of our research team will contact you to arrange an appointment for you and your child at your school or a nearby community centre.

At your appointment you will again be able to ask the research team any other questions that you may have. You will then be asked to sign a consent form. You will be asked to complete some questions about your own and your child's wellbeing, and your own self-confidence. Your child will be asked to wear an activity monitor on a belt, similar to a pedometer, for 6 days, to assess their physical activity level. They will also have their height, weight, waist and upper arm circumference measured. The appointment will take approximately 30-45

minutes. The session will be fun for your child and toys will be provided for them to play with.

Then your school will be allocated to either the PiP programme group or the control group (where you do not do anything different with your child than you usually do). You will have a 50/50 chance of being in either group a bit like tossing a coin.

You will be asked to attend 3 more appointments (10 weeks, 30 weeks and 52 weeks later) which should last about 30 minutes where you and your child will repeat the questionnaires and measurements. After you have attended your appointment at 10 weeks you may also be asked to take part in a short conversation over the telephone with a researcher who will ask you what you thought about the PiP programme and about taking part in this research study. We would ask for your permission to record this conversation and for us to type up the recording of the conversation into a transcript.

PiP programme group

The school playground will be made available for parents to use with their younger children after dropping older children off to their classrooms in a morning, or before picking them up in the afternoon. The children will have the opportunity to use the outdoor space to run freely and to play with the school's age appropriate play facilities such as playgrounds, climbing frames and equipment (hoops, balls, etc.).

There will be two phases to the intervention: 1 The Initiation phase and 2 The Maintenance phase. The Initiation phase will be 10 weeks long (one school term) and 30 minute sessions will be led by Parent Involvement Workers. In the Maintenance phase participating parents will facilitate the 30 minute sessions themselves and this will last for 20 weeks (two further school terms). In each phase, Six PiP sessions will be available per week, three in the morning and three in the afternoon.

Control group

Families in the control group will not have access to a playground programme and will continue with their daily routines as normal.

Do I have to take part?

No. It is up to you whether you would like to take part in the study. If you do decide to take part you can contact the school Parental Involvement Worker or call us on 01274 364474. After this, we will invite you to an appointment and you will be asked to sign a consent form to show you have agreed. You are free to withdraw at any time, without giving a reason.

What are the possible benefits of taking part?

There may be no direct benefits to anyone taking part in this study. The study is being undertaken to find out whether or not this programme is beneficial to families. All those taking part in the study will be helping to answer this question. The results of the study may benefit other young families in the future. All parents who bring their children to the measurements sessions will be given £10 in vouchers toward play equipment at each measurement session. Participants who take part in the interviews with researchers will also be given £10 in vouchers toward play equipment.

What are the possible disadvantages and risks of taking part?

For families allocated to the PiP programme, as with any physical activity, there is a risk of injury to children. However you will always be with your child and supervising their play, therefore injury risk should be minimised.

PART TWO: MORE INFORMATION ABOUT THE CONDUCT OF THE RESEARCH

Will information about my child taking part in this study be kept confidential?

All the information we collect will be entered onto a computer using an ID number so your child will not be identifiable to anyone outside the PiP study. The records will be held securely for up to 3 years and accessed only by the researchers involved in the study at Bradford Teaching Hospitals Foundation Trust (BTHFT) and our partner organisations the University of York and Durham University.

What happens if we don't want to carry on taking part?

It is entirely up to you and your child if you wish to discontinue taking part. If you decide that you do not wish to continue being involved, that is also up to you, but you would still have the option to continue with the assessments.

What if there is a problem?

If you have a concern about any aspect of this study, you should ask to speak with the researchers who will do their best to answer your questions. In the first instance you should contact the Dr Sally Barber the PiP Trial Manager (telephone [REDACTED]). If you remain unhappy and wish to complain formally, you can do this through the NHS Complaints Procedure. Details can be obtained from Bradford Teaching Hospitals NHS Foundation Trust [REDACTED].

What will happen to the results of the research?

We will write a report at the end of the study and send a copy to you. We also anticipate that the results of the study will be published in a medical journal and presented at medical meetings, and are happy to send you copies of this if you wish. The results will be analysed and reported in an anonymous form so that there can be no identification of individuals

Who is organising and funding the research?

The research has been organised by Professor John Wright who is Director of Bradford Institute for Health Research. He is helped by the Born in Bradford team of researchers and partner organisations the University of York and Durham University. The research is funded by the National Institute for Health Research which is a government department who fund health research. The researchers are doing this research as part of their jobs and do not receive any extra payment for doing it.

Who has reviewed the study?

The National Institute for Health Public Health Research Programme Panel have reviewed this study and recommended that the research is important and good enough to be funded. It has also been reviewed by the Bradford Research Ethics Committee and been given ethical approval.

Who can I contact for more details?

- The Trial Coordinator, Ms Shaheen Akhtar is happy to discuss the research over with you again, either at home or over the phone. You can reach her on [REDACTED] or on her mobile [REDACTED].