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

Protocol

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1. Background

1.1 Physical activity and the pre-school years

The pre-school years are considered a critical period for establishing healthy lifestyle behaviours such as physical activity (PA). [1] The benefits of engaging in regular PA in the pre-school years are many, with one of the most significant being the promotion of healthy weight during childhood.[2] In pre-school children the prevalence of overweight and obesity has doubled in recent decades [3] and in the mid 2000's over a third of pre-school children in the UK and US were overweight and obese. [4] Despite the widespread belief that the prevalence of childhood obesity is still escalating, contemporary high quality studies suggest a slowing in the rate of rise in some countries including the UK. [5] Whilst this appears promising, levels still remain high and are heterogeneous within countries. For example, in England childhood obesity is higher in urban areas, in children from deprived backgrounds and in certain ethnic minority groups including Black and Asian populations. [6] Although the cause of obesity has not been fully identified it is probable that reduced PA and increased sedentary behaviour are important contributing factors. [,7,8] Lower time spent in MVPA during the early years has been shown to be associated with higher fat mass (+0.75 kg for girls and +0.61 kg for boys in the lowest compared to highest quartile).[2] Additionally reduced MVPA at age 5 increases fat mass at age 8 and 11 years old; for every 10 minutes/day of MVPA at age 5, fat mass has been reported to decrease by 0.2kg at age 8 and 11 years. [2] Furthermore, levels of MVPA have been inversely associated with measures of central adiposity in children aged 3-8 years old. [9]

Observational and experimental studies have shown that regular PA has other important health and social implications for pre-school children. Physical activity is valuable for developing motor skills, enhancing bone and muscle development and for learning social skills. [10] Furthermore, regular PA in this age group may also have beneficial effects upon cardiovascular disease risk factors including more favourable blood pressure and blood lipids.[11,12] Levels of PA in childhood track into adulthood,[13,14] thus establishing habitual PA early life may be key to the remaining active throughout the lifespan. The benefits of PA in adulthood are numerous, well established and include; reduced risk of cardiovascular disease, diabetes, some cancers, and depression and improved bone health and well-being. [15,16]

Despite the well-known and multiple health benefits associated with PA throughout the lifespan, there are high levels of inactivity in the UK across all age groups. A study in England measured PA objectively using accelerometry and reported only 6% of men and 4% of women meet the government recommendations for PA. [17] Proxy-reports of pre-school children's PA also show low levels of engagement in this age group.[18] UK children aged 3-4 years old children spend on average 120-150 minutes per day in PA, [19] 30-60 minutes less than the recommendations[15]. Indeed, the true position is likely to be worse as proxy reports often over-estimate[18]. Recent studies in the UK using accelerometers to measure PA and sedentary behaviour in preschool children (aged 3-5 years) have shown that they spend high amounts of time sedentary (77-88% of the monitoring period) and very low amounts of time in moderate to vigorous intensity PA (only 2-5% of the monitoring period).[20,21]

1.2 UK physical activity policy for pre-school children

The importance of engaging pre-school children in daily PA was brought to the forefront in July 2011 with the publication of UKs' first PA guidelines for the under 5's in the Chief Medical Officer's (CMO) report "start active, stay active". [15] The report recommends 180 minutes of PA (light, moderate and vigorous intensity) each day, and states that the amount of PA is more important than the intensity. Physical activity should be spread throughout the day and include active play (activities that involve movements of all the major muscle groups), and the development of locomotor, stability and object-control skills.

These guidelines are an important step in reversing the trend for low PA levels among pre-school children; however, guidelines themselves do not change behaviour. The CMO report states that a "concerted and committed action to create environments and conditions that make it easier for people to be more active" is needed.[15] The guidelines highlight the need for activities to promote movement in the early years and, recognise that local communities can have a strong influence on people's behaviour. The report suggests investment in community level programmes in settings such as school playgrounds.

1.3. Components of successful interventions.

A) Theoretical underpinning

The utility of basing health promotion interventions upon sound theoretical frameworks is well expounded.[22] A systematic review [23] conducted by co-applicants on the current proposal reports that the predominant behaviour change theory used in successful childhood obesity prevention interventions is Bandura's Social Cognitive Theory (SCT).[24,25] This theory describes behaviour change as an interaction between *personal*, *behavioural* and *environmental* factors. Skills, self-efficacy, and outcome expectancies are the primary *personal* concepts within SCT for understanding behaviour change. Modelling, rewarding/reinforcement (from parents, carers) are the *behavioural* variables, and availability (e.g. provision of space for PA) is the primary *environmental* variable within SCT for understanding behaviour change. The review also reported that providing information on behaviour-health links appeared to be an important component in childhood obesity prevention/PA interventions.

B) An outdoor setting

Observational studies have shown that time outdoors correlate with PA levels in school-aged children.[26,27] Time outdoors has also been associated with higher objectively measured PA [28,29] and with lower prevalence of overweight.[28] One daily routine of parents with school aged children is the "school run" which occurs on every week day, 39 weeks a year regardless of weather. Capitalising on this to provide an outdoor space (school playground) for pre-school children to play safely and with supervision, may be an effective PA intervention. Indeed, in school aged children, playground interventions have increased PA.[21,31] Greater provision of equipment [30,31] and greater play space per child [29] has increased levels of moderate-vigorous PA in school aged children. Interventions in pre-school playgrounds supervised by pre-school teachers however have had mixed success. Adding portable play equipment in a US pre-school playground increased physical activity levels in 3-to-5 year olds[32]. In contrast, in Belgium, no change in PA levels of 4 and 5 year olds was reported after providing playground markings, or play equipment or both in the pre-school playground. [33] The authors concluded that creating an activity friendly environment may not be sufficient to promote PA in pre-schoolers and regular infusions of different equipment with more guidance and encouragement from adults to play in an active way is needed. Currently there is no evidence regarding pre-school playground interventions from the UK.

C) Parental involvement

The idea that adult encouragement is required to increase active play is further supported by findings from a systematic review of pre-school obesity prevention interventions.[34] Twelve interventions conducted in a variety of settings (pre-school/childcare, home, group, primary care and mixed settings) included a PA component. Home-based interventions appeared to be the most successful at increasing PA despite the small sample sizes of studies and poor adherence to the interventions. This is perhaps due to parental involvement in the interventions, which has been suggested to be vital for facilitating behaviour change during the early years.[23]

1.4 Risks and benefits of a physical activity intervention

Regular PA can impact upon a plethora of health outcomes (described in section 1.1); however, an unintended consequence of PA is risk of injury. A high percentage of childhood injuries occur during PA.[36, 36] The risk of injury resulting from PA has not been quantified in younger pre-school children, however in a study of children aged 4-12 years fewer than two injuries requiring professional medical treatment occurred for every 10 000 hours of exposure to PA.[37] Thus the overall harm of PA can be considered quite low compared to the multiple benefits to be gained.[37] A further risk of a PA intervention in a school playground is to the schools. There is a potential risk of liability for injuries sustained by children when using the playground belonging to the school. This risk has been studied through an examination of legal rules [38]; it was reported that although schools can be subject to liability in certain cases arising out of recreational use of their facilities, there are important government defences. It was concluded that the liability risks are unlikely to justify the denial of recreation access to school playgrounds to children who are at risk of obesity.[38]

1.5 Health Inequalities

Physical activity is lower in low-income households and in minority ethnic groups. [6] The high levels of deprivation and multi-ethnic nature of Bradford's population make it an ideal setting for this public health

research. Bradford is the 6th largest metropolitan borough in England with a population of ~ 500,000 and includes some of the most deprived areas in the UK. The national child measurement programme for 2010-11 reports that 22% of children in reception and 35% percent in Year 6 in Bradford are overweight or obese. [6] Additionally, the city has very low levels of participation in school sport. [39]

Half of all of babies born in Bradford are of South Asian origin [40] and 60% of these are born into the poorest 20% of the population of England and Wales based on the index of multiple deprivation (IMD).[3] Furthermore, South Asian adults [41] and children [42] have substantially lower levels of PA than White Europeans. These low levels of PA may contribute to the increased risk of coronary heart disease and diabetes seen in South Asians living in the UK. [41]

Social deprivation places children at risk for both short- and long-term deficits in health, relationships, social integration and economic success. Early childhood problems often translate into lifelong inequalities in health and wellbeing, and the pre-school period is seen as a key period for intervention. The Marmot Review of health inequalities [43] concluded that 'giving every child the best start in life' was their 'highest priority recommendation'. Research on physical inactivity and overweight in early childhood in relation to later obesity and sedentary lifestyles has been extensive, and recent decades have seen the development of a large number of interventions that aim to improve child PA, reviewed above. Whilst some interventions have been shown to be effective, there is still a need for randomised controlled trials of interventions for pre-school children with a strong theoretical base, clear model of change, that target known barriers to participation and engagement. Interventions aimed at reducing health inequalities can inadvertently exacerbate disparities, when they are differentially effective for those from different socioeconomic positions. Physical activity interventions for young children most critically need to be effective in reaching, engaging and retaining those families most in need of increasing their PA levels. Successful early interventions have a high potential return in terms of health, social and economic benefits for children throughout their lives.

1.6 Preparatory work for the PiP intervention

We have conducted preliminary research to assess barriers and facilitators for regular engagement in PA for White and Pakistani toddlers living in Bradford. Six focus groups with a total of 17 White and Pakistani mothers and caregivers (English and Urdu speaking) explored typical PA in toddlers and their barriers to and facilitators for PA .[44] Mothers reported that their children were innately active and enjoyed playing outside. Lack of time was a major barrier to PA. Mothers' minimised the amount of 'journeys' they took and were put off organised activity sessions finding it inconvenient to leave the house with young children. Other barriers to outdoor physical activity included feeling that their neighbourhood was an unsafe place to play outdoors and needing help from another adult to take the children to the park. Additionally the season, weather, and having to take public transport to parks were also identified as barriers. Some key facilitators for PA were having someone to help during activities and having activities available locally. There was little variation in barriers and facilitators between ethnicities.

The "preschoolers in the playground; PiP" intervention is described in section 6; we have consulted widely with schools and the Bradford local authority about the acceptability of PiP and all have been very supportive of the proposed intervention and study. We have chosen to trial PiP in Bradford due to the aforementioned health inequalities within the city. Additionally, the introduction of the Born in Bradford (BiB) cohort study in 2007 (www.borninbradford.nhs.uk) has geared the city up to be involved in research studies. We feel that hosting the intervention in Bradford will enhance the uptake of the study since the BiB study is widely known and well accepted across the city. We do not think however, that the link with BiB will affect the intervention participation rates. Participants have not been involved in other intervention trials within BiB. Thus if the pilot trial proves successful and a subsequent full RCT is also successful, we feel that it could be implemented across the country with similar participation rates.

The genesis of PiP came from:

- Existing literature described in this background section
- Preliminary qualitative data collected from focus groups described above

- Epidemiological data which show that 60% of children in the BiB cohort (children are 0 – 3 years old) have siblings of a primary school age and that children in the BiB cohort are representative of children in Bradford.

Using the school setting for PiP has clear advantages and overcomes some of the barriers reported in the focus groups as follows:

- PiP will be available to hard to reach families, who often do not attend other community based children's activities, such as those held at children's centres
- PiP will be available locally and will fit into the families routines
- The playground is an enclosed space which can be easily supervised
- Parents and children will be accessible for recruitment to the trial and the intervention

2. Research objectives

The aim of the study is to undertake a pilot cluster RCT of an outdoor playground based PA intervention "Pre-schoolers in the Playground" (PiP; see section 6 for description of the intervention) to assess the feasibility of a full scale cluster RCT of the PiP intervention. The pilot trial will determine:

1. Feasibility of the recruitment strategy of schools and of families and identify if there is a difference in recruitment between South Asian and White families
2. Follow-up and attrition rates (in particular if there is a difference between control and intervention, and South Asian and White families)
3. Fidelity of programme implementation and delivery by parent involvement workers
4. Influence of financial incentives on trial and intervention participation
5. Acceptability of randomisation, intervention and measurement tools and measurement time-points to families
6. Feasibility of using accelerometry for the primary outcome measure
7. Capability and capacity of schools to deliver and incorporate the intervention within existing services
8. Estimates of effect size, typical cluster sizes and ICCs to enable an accurate sample size calculation for a full RCT
9. The effect of participation in the intervention upon public health outcomes at 10, 30 and 52 weeks, including: minutes of MVPA/day, percentage of children meeting PA recommendations and percentage of children overweight and obese and any difference in health outcomes between ethnic groups (South Asian and White)
10. What data are required for economic analysis and if they can be collected reliably
11. Whether links can be established between short term outcomes and long term quality of life, potentially including across sectors.
12. Preliminary assessment of the potential cost-effectiveness of PiP and potentially an estimate of the value of further research (including the likely value of conducting the full trial)
13. Whether it is appropriate to apply for further funding for a full scale RCT

3. Research design, Recruitment and Randomisation

The study design is a two-armed pilot cluster randomised controlled trial with economic and qualitative evaluations. The two arms are: PiP intervention and usual practice (control). The intervention will be delivered in 3 waves. Wave 1 will commence in the autumn 2012 term and include two PiP intervention schools and two control schools. Wave 2 will commence in the spring 2013 term and include one PiP intervention school and one control school. Wave 3 will commence in the summer 2013 term and will include two PiP intervention schools and two control schools. During this wave, two of the recruited schools will have linked children's centres/nurseries. One of these will be randomised to the intervention arm and the other the control arm. The purpose of this is to examine the feasibility of conducting the PiP intervention in children's centre playgrounds.

This staggered approach mimics the approach that would be required for a fully powered RCT and will allow the examination of seasonal variations in the effectiveness of the intervention.

The setting is Bradford and sampling will cover a representative geographical spread of schools in Bradford and include both White and South Asian families.

3.1 School recruitment
Ten schools will be recruited from the 155 Primary schools in Bradford between September and March 2013. We have secured funding to run training sessions with school staff, including head teachers to translate the current findings from the BiB cohort study into practice. We will use this scheduled training to inform schools about the PiP study and invite them to put their school forward to participate in the pilot study. Schools that are located in the two highest quintiles of index of multiple deprivation for Bradford, located across the city of Bradford (Bradford South, West, East and Shipley) will be selected. Four schools with predominantly South Asian pupils (>50%) and four with predominantly White pupils (<50%) will be randomly selected. It is important to have a mix of South Asian and White schools in order to identify whether there is a difference between the two arms in terms of participation in the trial and intervention (objectives 1 and 2), and whether there are difference in health outcomes of the trial (objective 9). We estimate using the English Indices of Deprivation 2010 for Bradford District (4), that >80% of schools in Bradford will fall into the highest quintile of IMD and therefore the findings of the pilot study will be generalizable to a full trial.

The selected primary schools that decide to take part in the trial will be asked to sign an agreement with the research team, to ensure they understand their role and responsibilities in the trial and to ensure on-going support. In each participating school we will invite school governors, teaching staff, other staff and parents to a presentation informing them about the study. Additionally in schools randomised to the PiP intervention we will inform attendees about the format of the intervention. We will work closely with teaching staff to ensure minimal disruption from the intervention at each school.

3.2 Participant recruitment
Families will be recruited prior to the schools being randomised (randomisation is described in section 3.4). Recruitment will occur through sending letters home with school-going children in participating schools and through face-to-face conversations with families in schools/children's centres.

In order to publicise the study, community research administrators (two research assistants/school) will be available to talk to parents in the playground. The siblings of school-going children from participating schools, who are aged 18 months to 4 years old, will be invited along with their parent/carer to take part in the study. Families who attend children's centres/nurseries will also be invited to take part in the study.

For children to be eligible for wave 1 they must have been born between 01/09/2008 and 01/04/2011, for wave 2 between 01/09/2009 and 07/07/2011 and for wave 3 between 01/09/2009 and 06/11/2011. This will ensure that the children are available to complete 3 terms worth of the intervention before they begin in reception class. The lower age range has been chosen to capture very young children who are at an age where they are likely to be able to walk and the upper limit has been to capture children before they begin primary school education. Children who are disabled will be included in the trial. Families will be excluded if the parent is unable to provide informed consent.

Parents will be given written information about the study when they are invited to participate; this will include the known risks of physical activity as outlined in section 1.4. Any injuries sustained by the children during the intervention period will be the responsibility or the parent/carer; this will be made clear in the information sheet and also on the consent form for the study. The invitation to participate will also include a reply slip with a stamped envelope addressed to the research team. To express interest in participating in the study, parents will return the reply slip or give verbal agreement to be subsequently be contacted via telephone by a community research administrator to discuss their participation in the trial. If the family agrees to participate an appointment will be arranged for the parent to provide written informed consent for themselves and their child and for the baseline measurements. In schools randomised to the PiP intervention, families who are excluded from the study or do not wish to participate in the study will still be allowed to access the PiP intervention. To account for the linguistic diversity among the study population, all project materials including information sheets and consent forms will be prepared in English and Urdu (translations will be prepared in collaboration with BiB staff, according to standard BiB procedures). [38]

3.3 Incentives for participation

As a thank you for participating in the pilot trial, all schools will receive a donation of £200 towards play equipment which will be given at the beginning of the trial. We do not foresee that this will confound the control arm since the pre-school children do not attend school and will not have access to the equipment.

All families will also receive a £10 voucher as a thank you for attending each study measurement session. Due to the significant time commitment of the measurement sessions (~ 1 hour) and using the accelerometers for 6 days, we feel that it is appropriate to give families a voucher as a thank you for committing to the measurements in the study. We feel that if this is not given families may opt into participating in the intervention and opt out of the measurement sessions. The vouchers will be given at measurement sessions and not during the PiP sessions. The specifics of the voucher will be decided by the parent panel and will be health related (e.g. leisure facility voucher). They will be given at the baseline 10, 30 and 52 weeks assessment and worth £40 (£10 per visit) an additional £10 will be given to those families who agree to participate in the qualitative interviews.

3.4 Randomisation and blinding

Randomisation will be carried out by York Trials Unit Randomisation Service using a secure computer system. Once baseline data have been collected, participating schools will be randomly allocated to one of the two arms: PiP intervention and control on an equal basis (i.e. 4 schools in each arm). We believe that ethnicity may be an important predictor of physical activity [41] and thus to avoid chance imbalance in ethnicity, schools will be stratified and blocked by ethnicity (>50% South Asian pupils or >50% White pupils).

We have chosen not to stratify schools by index of multiple deprivation (IMD) because Bradford is particularly skewed towards a high IMD. We believe that this is a particular strength of conducting the study in Bradford and will be fundamental in addressing the issue of health inequalities.

Blinding of the trial co-ordinator, schools, participants, and parent involvement workers will not be possible. The community research administrators who will be assessing outcome measures will be blinded to each schools allocation as will the statistician performing the data analyses.

4. Control arm – usual practice

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

5. Sample size

Our pilot study will recruit at least 150 children from 10 schools (15 children at each school); Thus 5 schools with a total of 75 children in the PiP intervention arm and 5 schools with a total of 75 children in the control arm. At least 4 clusters per arm are recommended for a cluster RCT [45] and our sample size exceeds recommendations for pilot trials. [46] Therefore our sample will be sufficiently large to provide clear estimates of recruitment and follow up.

6. Planned intervention

The PiP intervention aims to increase levels of PA and reduce levels of obesity in pre-school children by changing the culture of school playgrounds. The PiP programme is grounded in theory (based on the social cognitive theory; SCT, of behaviour change) [24,25], and is in line with the CMO guidance for PA in the under 5's [13]; it is informed by existing literature [23,33,34] and by focus groups from our target population in Bradford [44]. Primary schools playgrounds will be made available to parents with children aged 18 months to 4 years during the "school run." PiP thus fits into the daily routine of families with school aged siblings and this was highlighted as important in our focus groups. [44] The children will have the opportunity to use the outdoor space to run freely and play with the school's existing, age appropriate, play facilities such as playgrounds, climbing frames and equipment (hoops, balls, etc). Play equipment worth approximately £15/child will also be given to children so that families can re-create the games that they learn during the

PiP sessions at home. This will take place in three schools to examine the impact of this additional behaviour change technique.

There will be two phases to the intervention; Initiation phase and Maintenance phase. In the Initiation phase, sessions will be led by parent involvement workers employed by schools each week for 10 weeks (one school term). In the maintenance phase participating parents will facilitate the 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. Parents will be encouraged to attend three of the six sessions. (See Appendix 1, Figure 1). We feel this will allow some flexibility for parents, which was highlighted as important in focus groups. Each PiP session will last for 30 minutes, research suggests that pre-school children require at least an additional 30 minutes of PA per day to meet PA recommendations. [14] Furthermore, there is some research which suggests as little as an extra ten minutes per day of MVPA significantly reduces fat mass.[2] Given the sporadic nature of PA in these very young children, and that around a 70% of total physical activity in 4-6 year olds has been classified as MVPA [47], it is likely that during a 30 minutes session, the children will spend between 10-20 minutes in MVPA.

6.1 Initiation phase

A parental involvement worker will lead sessions in the initiation phase; their role will be to:

- Encourage the children to be physically active (this strategy is based on the SCT of behaviour change, [24,25])
- Support the parents in giving positive reinforcement to their children's PA (this strategy is based on the SCT behaviour change, [24,25] and evidence that parent involvement is important for children's behaviour change [23])
- Offer added supervision at the sessions (focus group work showed that parents feel they need extra supervision to facilitate outdoor PA in pre-school children, [44])
- Deliver two 5 minute structured parent and child play sessions using the existing outdoor play equipment (one at the beginning and one at the end of the session). Examples of how to modify physical activities and games to suit the needs of different age/ability levels will be given. For example if a throwing game is being played, children <3years will throw the ball and then chase the ball to retrieve it. Children aged ≥ 3 years will throw the ball at a target and then retrieve it. Of course each child is different and skill rather than age should be the determining factor as to game each child plays. These structured sessions will support the children's observational learning and the development of locomotor, stability and object control skill, as well as promoting child and parent self-efficacy. They will also encourage physical play between parent and child outside of the intervention setting (e.g at local parks); this is a recommendation from the CMO report.[15]
- Encourage families to seek other PA on the non-intervention days
- Ensure regular infusions of different play equipment during sessions (recommendation for pre-school playground interventions [33])
- Provide information (verbally) and give leaflets especially designed for PiP on the link between PA and health, guidelines for PA and sedentary behaviour in under 5's and ideas for active play (is a recommendation for pre-school obesity interventions[23]).
- Provide play equipment for families to take away and use at home (2 schools only).

6.2 Maintenance phase

During the Maintenance phase playgrounds will remain available six times a week to parents and pre-school children for 30 minutes at the beginning of school and before the end of school. For the purposes of the pilot trial, a parent involvement worker will take a register of attendees at the beginning of the sessions but will not give formal supervision during the session.

The intervention will be low-cost and potentially sustainable within existing resources. The playground facilities and play equipment will be provided for free by schools. We aim to incorporate the initial added supervision in the initiation phase into the existing roles and responsibilities of parental involvement workers. Families who do not wish to take part in the trial will still be allowed to access the playground facilities in schools randomised to PiP and therefore the intervention is not exclusive in PiP schools.

7. Data collection

A central database will capture all data collected throughout the pilot trial to highlight issues with fidelity, attendance and attrition. Standardised forms and electronic methods will be used to collect data from participants, parent involvement workers and head teachers. Baseline and follow-up data will be collected by community research administrators in measurement sessions held in school halls or nearby community centres. The measurement sessions will be conducted in a child friendly way with toys and play equipment available to entertain children. Additionally some data will be collected via telephone interview. A combination of qualitative data and quantitative measures will be used to address the research objectives relating to the feasibility of conducting a definitive trial in the future. These measures are described below.

7.1 Recruitment (objective 1, section 2)

Materials and methods will be developed to promote the trial. The number or enquiries resulting from the recruitment process will be recorded for South Asian and White families and the subsequent consent rate will be determined for South Asian and White families. During recruitment parents will receive a letter of invitation for the study. The letter will contain a short questionnaire with a list of reasons for entering or declining entry to the study. Parents will be asked to indicate why they have chosen to enter or decline entry to the trial and then return the questionnaire in a pre-paid envelope. This will help with the development of further promotion materials and determine whether declines are related to the intervention, the trial itself or the outcome measures.

7.2 Attendance and attrition (objective 2, section 2)

The following will be collected:

- Attendance rates at PiP sessions (completed by parental involvement worker)
- Who attends the session with the child (parent, grandparent, carer etc)
- Attendance to measurement sessions, frequency and time taken to complete data collection (at baseline, 10, 30 and 52 weeks)
- Attrition (to both PiP and measurement sessions)

7.3 Fidelity of implementation (objective 3, section 2)

Three sessions at each school (2 in the initiation and 1 in maintenance phase) will be observed by the trial co-ordinator to assess fidelity to the delivery of the programme. A standardised form will be used for each observation.

7.4 Acceptability of randomisation, the PiP intervention/control, and measurement tools, and influence of incentives (objective 4, 5 & 6, section 2)

A purposive sample of 20 parents/carers will be recruited to the qualitative component of the study. Selection will be on the basis of role (e.g. mother, father, grandparent, and carer), ethnicity and attender or drop-out. We will select 15 parents from the intervention arm and 5 from the control arm. This maximum variation sampling approach [48] will ensure a wide range of views are collected. Parents will be interviewed after completing their 10 week data collection. Semi-structured interviews will explore the acceptability of PiP (intervention only) and their experience of taking part in the trial e.g. randomisation, data collection measurement tools and incentives (intervention and control). All interviews will be conducted using a topic guide to ensure consistency, although the format will be flexible in order to allow participants to generate naturalistic data on what they see as important. They will be audio-recorded digitally and transcribed verbatim. A draft interview topic guide for parents (Appendix 2) is given in section 16. These interviews will be piloted and may be slightly modified.

We will also test the feasibility of using accelerometry for the primary outcome measure by examining the number of participants who meet the criteria for inclusion in data analysis (≥ 4 days of monitoring and ≥ 8 hours; see section 7.7).

7.5 Capability and capacity for delivery (objective 7, section 2)

At 10 weeks, data will be collected from the parent involvement workers who have delivered the intervention to explore the feasibility of the delivery and help refine the nature and content of intervention. Qualitative interviews will be conducted with parent involvement workers who have completed one

complete intervention programme from beginning to end. Interviews will all be recorded. At 30 weeks (after the maintenance phase) we will conduct telephone interviews with head teachers at schools in the intervention arm (n=4) to explore their views on acceptability of the intervention within the school setting in particular the impact of PiP upon the school day. All interviews will be conducted using a topic guide to ensure consistency, although the format will be flexible in order to allow participants to generate naturalistic data on what they see as important. They will be audio-recorded digitally and transcribed verbatim. A description of each school's playground environment including size, availability of equipment/facilities/markings will be recorded along with the schools local environment (e.g. proximity to other outdoor play space). A draft interview topic guide for parent involvement workers (Appendix 3) and head teachers (Appendix 4) is given in section 16.

7.6 Data to inform sample size calculation (objective 8, section 2)

An important aspect of the pilot study is to collect data to estimate the sample size required for a full RCT. The pilot RCT will provide data on the variability of outcome measures; estimates of effect sizes between control and intervention, and estimates of ICCs which are currently unavailable from other studies. It will also provide a more accurate estimate of the follow-up rate.

7.7 Health outcomes (objective 9)

The following outcomes will be assessed at baseline, 10 weeks, 30 weeks and 52 weeks (1 year) for the child: daily time spent in physical activity, body mass index (BMI) waist and arm circumferences, health related quality of life; and for the parent: health related quality of life, self-efficacy and wellbeing.

At baseline; ethnicity, postcode (IMD), child's name, date of birth and any known mental or physical health condition of the child and parent will also be collected. At 10 and 30 weeks parents will report any injuries their child has sustained during the intervention/control period.

7.7.1 Primary outcome

The primary outcome will be minutes of moderate-to-vigorous physical activity (MVPA)/day at 52 weeks (1 year) assessed via accelerometry. Moderate-to-vigorous PA is an important for maintaining a healthy weight throughout childhood and is an important public health outcome. Results from longitudinal analysis indicate that for each ten minutes of MVPA/day at age 5, fat mass at age 8 and 11 years is reduced by 0.2kg.[2] Accelerometers are currently considered to be the most promising tool for measuring habitual physical activity in free-living children aged 0 to 5 years. [18] They allow the detection of short spurts of activity, characteristic of pre-school children and they enable the objective quantification of frequency, intensity and duration of PA during waking hours over several days.

The children will wear a triaxial, GT3X plus Actigraph monitor on a belt around their waist during waking hours for six days including one weekend day. [49] Parents will also be provided with a diary to record the times that the accelerometer is put on and taken off their child. Physical activity will be measured using vector magnitude counts from the GT3X Actigraph. All data with ≥ 4 days of monitoring and ≥ 8 hours on each of these days will be included in the analyses.[50]

Time in MVPA will be defined as ≥253 counts per 15 second epoch [51]. Time when the accelerometer is not worn will be defined as >60 minutes with zero activity counts, allowing for interruption of up to two consecutive minutes with counts ≤100. [52] Total time spent in MVPA will be calculated for each day and then averaged across all of the child's valid days to give mean daily time spent in MVPA. We have conducted a feasibility study of using Actigraph accelerometers in children aged 1 to 3 years old and early results show that this is acceptable to both children and parents.[53,54]

7.7.2 Secondary outcomes:

- Minutes of total PA (light-to-vigorous; ≥146 counts per 15 second epoch) per day and minutes spent in total PA/hour accelerometer worn; Minutes spent in MVPA/hour worn, minutes spent sedentary/day, minutes spent sedentary/hour worn (sedentary will be defined as <146 counts per 15 second epoch.[51]). Minutes spent in light activity/day, minutes spent in light activity/hour worn (defined as 146 to 252 counts per 15 second epoch). Additionally the percentage of children

meeting physical activity guidelines of 180 minutes/day (including light, moderate and vigorous PA) will be calculated.

- Height and weight will be used to calculate BMI and the percentage of children overweight/obese in each arm (intervention or control) will be reported.
- Waist and upper-arm circumferences will be measured as markers of central adiposity
- Child's health related quality of life will be assessed using the PedsQL (for 2-4 year olds) and parent's health related quality of life will be assessed using the EQ5D; these measures will be used in the Health economic analysis (see section 7.8).
- Parental well-being will be assessed using the Comprehensive Quality of Life Scale- Adult (ComQol-A5 [55]) and parental self-efficacy will be assessed using the General Self Efficacy Scale. [56]
- Number and type of injuries sustained during the intervention/control period and the consequence of the injury (i.e. medical attention from GP, or hospital visit) and service use (health and social care) will be reported by parents and recorded at each assessment point.

7.8. Health economics *(objectives 10, 11, 12 section 2).*

We will explore the possibility of using routine databases to capture relevant resource use and we will back this up with participant questionnaires. The latter will also be used to capture quality of life measures. If the data can be collected reliably, an exploratory evaluation will assess whether the addition of the PiP intervention is likely to be cost-effective in the pilot trial. It is acknowledged that the benefits of PiP may be generated over a longer time frame than captured by the trial. We will thus conduct a "within-trial" analysis and, if possible, an analysis of the costs and benefits associated with the intervention modelled over a more appropriate time horizon. A key part of the economic analysis will be to identify potential sources of data to populate a longer term economic model.

7.8.1Within trial analysis

The health economist will be blinded to the allocation of schools during the analysis of the data. Analysis will present the outcome measures described in section 7.7. In addition, the delivery costs and the resource use associated with the intervention (for example, health service usage including GP visits, A&E attendances) will be estimated. The trial assesses a large number of primary and secondary outcomes. Hence, for a complete picture of the trials results, all the costs and outcomes will be presented in a descriptive and disaggregated way.

7.8.2 Extrapolation to longer term

A review of the literature will be conducted to establish whether it is possible to make links between short term outcomes measured in the trial and longer term quality of life, and therefore populate the model.

7.8.3 Generating cost data and presentation of results

Resource use (health and social care services) will be recorded as above. Unit costs estimated from the published literature and government sources will be presented. These unit costs will then be applied to the relevant resource use. Each total cost item will then be summed to generate a total cost per trial participant. For this exploratory analysis, where it is considered appropriate, cost and QALY data will be synthesised to generate an Incremental Cost-Effectiveness Ratio (ICER) where the additional cost of the intervention is formally compared with the additional benefit. Probabilistic sensitivity analyses will be conducted to characterise the uncertainty around the adoption decision (depicted using Cost-Effectiveness Acceptability Curves) and to assess the potential and value of further research in this area.

8. Criteria for success of the Pilot trial (objective 13 section 2)

The pilot trial will be deemed successful and lead to the development of a proposal for a fully powered RCT appropriate if:

- No more than 40 schools were approached to recruit 10 schools to the study and at least 15 preschool children at each school were recruited.
- There is at least 70% retention to the intervention at 10 weeks (this figure is based on results from previous physical activity interventions in this age group which have reported intervention retention rates at 6 months of 70 – 75% [34])

The criteria for success will provide the basis for interpreting the results of the pilot and determine whether it is appropriate to proceed to a full trial. Depending upon the study results, one of the following outcomes will occur:

a) Stop – the main study is not feasible
b) Continue, but modify the protocol (feasible with modifications)
c) Continue without modifications, but monitor closely (feasible with close monitoring)
d) Continue without modification (feasible as it is)

These interpretations are based on methodology for pilot studies described by Thabane et al., 2010

9. Analysis

The statistician will be blinded to the allocation of schools during the analysis of the data.

For both arms the numbers of schools and children approached, randomly assigned, receiving PiP or control, completing the study protocol, and providing outcome data will be summarised. The number of children withdrawing from the intervention and/or the trial, and where available the reasons for withdrawal, will be summarised by arm. For each data collection point the number of non-attenders will be calculated for each arm and attendance rates compared.

While the main aim of this study is to establish practicality, feasibility, recruitment rates and samples size in order to inform a full-scale trial, and although it is unlikely that the small sample size will result in effectiveness being established, we will none the less test the primary outcome to mimic practice in a full-scale trial. We must emphasise that results from this analysis will be treated as preliminary and interpreted with caution. [57,58] As the number of clusters is low, we will utilise cluster summary statistics rather than multi-level modelling. [59,60] The analysis will be carried out using school as the unit of analysis and the mean MVPA/day for the individuals in the school as the outcome variable. A weighted linear regression model will be used to compare the treatment arms weighted by the number of participants followed up in each cluster and adjusted for the baseline average MVPA/day for each cluster. We will assess whether playground environment and local environment have a significant impact upon intervention uptake, attendance and changes in levels of physical activity. If they are found to be significant we will consider stratifying schools according to their environment in the full trial.

The qualitative interview data (from parents, parent involvement workers and head teachers; see section 7.4 and 7.5) will be analysed using the constant comparison method through thematic coding of the data.[61] Coding will take place using a combination of a prior themes and emergent themes. Negative cases will actively be sought throughout the analysis and emerging ideas and themes modified in response.[62] ATLAS-ti software will aid data handling.

10. Ethical arrangements

Ethical approval will be sought prior to the pilot RCT commencing. An ethics application will be prepared jointly between the research team and senior managers at the local authority, and submitted to the Bradford Research NHS Ethics Committee. Primary Schools that decide to take part in the trial will be asked to sign an agreement with the research team, to ensure they understand their role and responsibilities in the trial and to ensure on-going support. The recruitment of schools and families is described in section 3.1 and 3.2. The intervention is a low risk programme of child play and PA and we do not anticipate ethical concerns in its implementation. Parents or carers will be responsible for any accidents. Parents will confirm that they understand that this is their responsibility when they sign the study consent form. School first aiders will treat cuts and scrapes. Activity data collection with accelerometers is potentially the most invasive aspect of the study. We have extensive local experience with such data collection and have identified no significant ethical issues.[53, 54]

11. Research Governance

The trial will be sponsored by Bradford Institute for Health Research and will be fully compliant with the Research Governance Framework for Health and Social Care.[63] Systems are in place to ensure that new

applications for research and on-going studies comply with the applicable legislation and good practice guidance. For example, there is a system to ensure each project has secured a study sponsor prior to the research commencing, that the study has adequate funding in place for the life of the study and that management arrangements are put and kept in place to ensure compliance with regulatory requirements and the Trust's own policies and procedures including information governance and incident reporting. Regular GCP training sessions are run by trained NIHR GCP Facilitators based in the Bradford Institute for Health Research.

In order to protect the trial participants the following provisions will be made/upheld; the trial has been designed to minimise the burden of participants and any foreseeable risk in relation to the intervention involved; the explicit wishes of the participant will be respected including the right to withdraw from the trial at any time; the interest of the participant will prevail over those of science and society; provision will be made for indemnity by the investigator and sponsor.

We have spoken to two schools and Bradford Teaching Hospitals Trust (BTHT) Legal Service about the issue of Insurance. Our understanding is that BTHT (the study sponsor) will cover the Insurance for the research i.e. the data collection, data management etc. The schools' public liability insurance will cover any accidents that occur on school premises for which blame might be apportioned to them. This will be clarified with schools before they agree to participate in the study.

We will set up a Study Steering Committee (SSC) to oversee and guide the research. Independent experts will be invited to join this group. They will include Professor Greet Cardon, expert in pre-school physical activity interventions, a representative from Play England, and other experts in clinical trials and public health interventions. We will also invite observers from NIHR PHR to the meetings. Due to the low risk nature of this trial, we request not to set up an independent Data Monitoring and Ethics Committee (DMEC), but instead to include a monitoring role within the remit of the SSC, to review of all serious adverse events which are thought to be intervention related and unexpected. The committee's terms of reference and meetings minutes will be sent to NIHR regularly.

York Trials Unit is a partner in this research. It is a fully accredited clinical trials unit providing management advice and support in addition to strong academic credentials to clinical trials across a range of clinical areas. Quality assurance is a key element in ensuring the efficacy of all York Trials Unit trials.

12. Project timetable and future plans

The duration of the project will be 22 months and the study will begin in June 2012. A Gantt chart of the project time table is shown in the Appendix 5, Figure 2. Recruitment of 10 schools will occur between September 2012 and March 2013.The study will be frequently reviewed at steering group meetings and parent panel meetings (see Gantt chart, Appendix Figure 2).

If the pilot trial meets the criteria for success (detailed in section 8) a funding application will be written requesting funds for a fully powered cluster RCT of the PiP intervention. As part of the full RCT the study will link with the national child measurement programme (using links established by BiB), all the children will have their height and weight measured and BMI calculated in reception and year 6 at school. These data will serve as long-term follow up for the children participating in the study.

If the full RCT finds PiP to be effective it will be rolled out to schools. This integration into local practice will be led by Shirley Brierley, the public health consultant who is a co-applicant on this application. In addition, because of the ethnic segregation which exists within schools in Bradford we feel that PiP will be transferable to other deprived areas of the country with both predominantly white communities and also South Asian communities (e.g. Leicester, Birmingham, Bedford and the London boroughs of Newham, Harrow and Brent).

13. Members of the Public

We have extensive experience in patient and public involvement in research, including a current £2 million NIHR programme grant investigating new approaches to involving patients in their care. We have found

that patient and public panels provide a much more effective approach towards co-production of research. We hope to build on this experience with parental involvement in this trial. The parent panel will meet five times during the project. Their role will be:

- To feedback on decisions and key issue identified in the study
- To review research plans and protocols as they progress
- To provide a parent's perspective on research plans and progress
- To provide advice on progress and recommend how public involvement can be strengthened
- To review results and implications for families
- To recommend how best to implement findings into practice

14. Involvement of school practitioners

After consultation with the Education Bradford and the Children's Services at Bradford Metropolitan Council we have decided to strengthen schools involvement through local area partnerships (LAPs). There are nine LAPs (Bradford East (3), Bradford South (2) Bradford West (3) and Shipley (1)) covering all primary schools in our sampling frame. Head teachers represent each school and attend meetings every half term. During this pilot study we will work in close partnership with these teachers to ensure that the intervention is adapted to the local context and acceptable to local schools. Three of the chairs of these LAPs will join the trial steering group to provide feedback from each locality (Bradford South Bradford East, Bradford West, (including Shipley) to the steering group and promote a strong practitioner voice in the development and implementation of the trial.

15. References

(1) Reilly JJ. Physical activity, sedentary behaviour and energy balance in the preschool child: opportunities for early obesity prevention. *Proc Nutr Soc* 2008;67:317-25.
(2) Janz KF, Kwon S. Letuchy EM et al. Sustained effect of early physical activity on body fat mass in older children. Am J Prev Med. 2009;37(1):35-40
(3) Ogden CL, Carroll MD, Curtin LR,et al. Prevalence of overweight and obesity in the United States, 1999-2004. *JAMA.* 2006;295(13):1549-1555.
(4) Wang, Y. and T. Lobstein, Worldwide trends in childhood overweight and obesity. International *Journal of Pediatric Obesity* 2006;1(1):11-25.
(5) Olds T, Maher C, Zumin S et al. Evidence that the prevalence of childhood overweight is plateauing: data from nine countries. Int J pediatr Obes, 2011;6:342-360.
(6) The NHS Information Centre for Health and Social Care. National Child Measurement Programme 2010/2011. Available from:http://www.ic.nhs.uk/webfiles/publications/003_Health_Lifestyles/ncmp%202010-11/NCMP_2010_11_Report.pdf
(7) Epstein LH, Paluch RA, Gordy CC, et al. Decreasing sedentary behaviors in treating pediatric obesity. *Arch Pediatr Adolesc Med.* 2000;154(3):220-226.
(8) Department of Health *At least five a week:* Evidence on the impact of physical activity and its relationship to health. A report from the Chief Medical Officer (2004). www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_4080994
(9) Martinez-Gomez D, Eisenmann JC, Tucker J et al. Associations between moderate-to-vigorous physical activity and central body fat in 3–8-year-old children. Int J of Pediatr Ob. 2011;(6):611-614
(10) Gortmaker SL, Peterson K, Wiecha J, et al. Reducing obesity via a school-based interdisciplinaryintervention among youth: Planet Health. *Arch Pediatr Adolesc Med.* 1999;153(4):409-418.
(11) Shea S, Basch CE, Gutin B, et al. The rate of increase in blood pressure in children 5 years of age is related to changes in aerobic fitness and body mass index. *Pediatrics.* 1994 Oct;94(4 Pt 1):465-70.
(12) Sääkslahti A, Numminen P, Varstala V,et al. Physical activity as a preventive measure for coronary heart disease risk factors in early childhood. *Scand J Med Sci Sports*.2004;14:143-9.
(13) Shankaran S, Bann C, Das A, et al. Risk for obesity in adolescence starts in early childhood. J Perinatol. 2011
(14) Herman KM, Craig CL, Gauvin L, et al. Tracking of obesity and physical activity from childhood to adulthood: the Physical Activity Longitudinal Study. *Int J Pediatr Obes.* 2009;4:281-8.

(15) Department of Health, Physical Activity, Health Improvement and Protection. Start Active, Stay Active: A report on physical activity from the four home countries' Chief Medical Officers. Jul 2011.http://www.dh.gov.uk/prod_consum_dh/groups/dh_digitalassets/documents/digitalasset/dh_128210.pdf

(16) Allender S, Foster C, Scarborough P et al. The burden of physical activity-related ill health in the UK. *Journal of Epidemiology and Community Health 2007* 61: 344–348.

(17) NHS Information Centre for Health and Social Care *Health Survey for England 2008: Physical Activity and Fitness.* London: NHS Information Centre for Health and Social Care 2009.

(18) Oliver M, Schofield GM, Kolt GS. Physical activity in preschoolers: understanding prevalence and measurement issues. *Sports Med*. 2007;37(12):1045-70.

(19) Reilly JJ, Okely AD, Almond L et al. *Making the Case for UK Physical Activity Guidelines for Early Years: Recommendations and draft summary statements based on the current evidence.* Working paper 2009.

(20) O'Dwyer MV. Physical activity in non-overweight and overweight UK preschool children: Preliminary findings and methods of the Active Play Project. Science and Sports 2011;Epub: doi:10.1016/j.scispo.2011.01.006.

(21) Reilly JJ. Total energy expenditure and physical activity in young Scottish children: mixed longitudinal study. *Lancet* 2004;363:211-2.

(22) Nutbeam D. The challenges to provide evidence in health promotion, *Health Promotion International* 1999;14:99-101

(23) Nixon CA, Moore HJ, Douthwaite W, Gibson EL, Vogele C, Kreichauf S, Wildgruber A, Manios Y and Summerbell CD on behalf of the ToyBox-study group. Identifying behavioural models and behaviour change strategies underpinning successful pre-school and school-based obesity prevention interventions aimed at four to six year olds: a systematic review. *Obesity Reviews* (in press)

(24) Bandura A. Social Learning Theory. New York: General Learning Press; 1977.

(25) Bandura A. Self-efficacy: the exercise of control. New York: Freeman; 1997.

(26) Sallis JF, Prochaska JJ, Taylor WC. A review of correlates of physical activity of children and adolescents. *Med Sci Sports Exerc.* 2000;32:963–975.

(27) Ferreira I, Horst K Van der, Wendel-Vos W,et al.. Environmental correlates of physical activity in youth - a review and update. *Obes Rev.* 2006;8:129–154.

(28) Cleland V, Crawford D, Baur LA, et al. A prospective examination of children's time spent outdoors, objectively measured physical activity and overweight. *Int J Obes.* 2008;32:1685–93.

(29) Cooper AR, Page AS, Wheeler BW, et al. Patterns of GPS measured time outdoors after school and objective physical activity in English children: the PEACH project. *Int J Behav Nutr Phys Act*. 2010 Apr 22;7:31.

(30) Ridgers ND, Fairclough SJ, Stratton G. Variables associated with children's physical activity levels during recess: the A-CLASS project. *Int J Behav Nutr Phys Act*. 2010;12;7:74.

(31) Taylor RW, Farmer VL, Cameron SL,et al. School playgrounds and physical activity policies as predictors of school and home time activity. *Int J Behav Nutr Phys Act.* 2011;27;8:38.

(32) Hannon JC, Brown BB. Increasing preschoolers' physical activity intensities: an activity-friendly preschool playground intervention. *Prev Med.* 2008;46(6):532-6.

(33) Cardon G, Labarque V, Smits D,et al.. Promoting physical activity at the pre-school playground: the effects of providing markings and play equipment. *Prev Med*. 2009 Apr;48(4):335-40.

(34) Hesketh KD, Campbell KJ. Interventions to prevent obesity in 0-5 year olds: an updated systematic review of the literature. *Obesity*.2010;18 Suppl 1:S27-35.

(35) Finch C, Valuri G, Ozanne Smith J. Sport and active recreation injuries in Australia: evidence from emergency department presentations. *Br J Sports Med*.1998;32 :220– 225

(36) Nolan T, Penny M. Epidemiology of non-intentional injuries in an Australian urban region: results from injury surveillance. *J Paediatr Child Health.*1992;28 :27– 35

(37) Spinks AB, McClure RJ, Bain C, et al. Quantifying the association between physical activity and injury in primary school-aged children. *Pediatrics.* 2006;118(1):e43-50.

(38) Baker T, Masud H. Liability risks for after-hours use of public school property to reduce obesity: a 50-state survey. *J Sch Health*. 2010;80(10):508-13.

(39) Health Profile Bradford. Department of Health 2011http://www.apho.org.uk/default.aspx?QN=HP_METADATA&AreaID=50328
(40) Born in Bradford Collaborative Group. Born in Bradford, a cohort study of babies born in Bradford and their parents: protocol for recruitment phase. *BMC Public Health* 2008; 8:327
(41) Fischbacher CM. How physically active are South Asians in the United Kingdom? A literature review. *J Public Health* 2004;26:250-8.
(42) Owen CG. Ethnic and gender differences in physical activity levels among 9-10-year-old children of white European, South Asian and African-Caribbean origin: the Child Heart Health Study in England (CHASE Study). *Int J Epidemiol* 2009;38:1082-93.
(43) The Marmot review. Fair Society, Healthy Lives: A Strategic Review of Health Inequalities in England Post-2010 *http://www.marmotreview.org/AssetLibrary/pdfs/Reports/FairSocietyHealthyLives.pdf*
(44) Costa S, Clemes S, Barber S, et al. Barriers and facilitators for the regular practice of physical activity in white and pakistani toddlers. 16th Annual ECSS-Congress 2011 http://www.ecss2006.com/asp/CONGRESS/ScPro1AbstractText.asp?MyAbstractID=1238
(45) Murray DM (1998). Design and analysis of group-randomized trials. Oxford: Oxford University Press.
(46) Julious SA. Sample size of 12 per group rule of thumb for a pilot study. Pharmaceutical Statistics 2005;4:287-291
(47) Vale S, Santos R, Soares-Miranda L, et al. Objectively Measured Physical Activity and Body Mass Index in Preschool Children *Int J Pediatr.* 2010
(48) Patton MQ, Qualitative evaluation and Research Methods (2nd ed.). Newbury Park, CA: Sage; 1990.
(49) Van Cauwenberghe E, Gubbels J, De Bourdeaudhuij I et al.Feasibility and validity of accelerometer measurements to assess physical activity in toddlers. *Int J Behav Nutr Phys Act.* 2011;26;8(1):67.
(50) Fitzgibbon ML, Stolley MR, Schiffer LA et al. Hip-Hop to Health Jr. Obesity Prevention Effectiveness Trial: postintervention results. Obesity 2011;19(5):994-1003
(51) Cliff DP. Methodological considerations in using accelerometers to assess habitual physical activity in children aged 0-5 years. *J Sci Med Sport* 2009;12:557-67.
(52) Troiano RP, Berrigan D, Dodd KW et al. Physical activity in the United States measured by accelerometer. *Med Sci Sports Exerc* 2008;40:181–188.
(53) Costa, S, Barber, S, Akhtar, S et al. Feasibility of using activity monitors in surveillance studies with 2 to 3 year old white and pakistani children. ICAMPAM, Glasgow 2011.
(54) Moore HJ, McLure SA, Ells LJ, et al. An evaluation of a creative dance programme in preschool children: quantitative findings from a 10 week pilot controlled trial. ISBNPA Minneapolis, 2010.
(55) Cummins, R.A. The Comprehensive Quality of Life Scale: Development and evaluation. Proceedings. Health Outcomes and Quality of Life Measurement Conference. Australian Institute of Health and Welfare; 1995:18-24 http://www.deakin.edu.au/research/acqol/instruments/comqol-scale/
(56) Schwarzer, R, Jerusalem, M. Generalized Self-Efficacy scale. In J. Weinman, S. Wright, & M. Johnston, Measures in health psychology: A user's portfolio. Causal and control beliefs, 1995;35-37.
(57) Lancaster GA, Dodd S and Williamson PR Design and analysis of pilot studies: recommendations for good practice. Journal of Evaluation in Clinical Practice, 10, 2, 307–312
(58) Arain M, Campbell MJ , Cooper CL and Lancaster GA What is a pilot or feasibility study? A review of current practice and editorial policy. BMC Medical Research Methodology 2010,
(59) Bland JM, Kerry SM. Trials randomised in clusters. British Medical Journal. 1997; 315: 600
(60) Kerry SM, Bland JM. Analysis of a trial randomised in clusters. British Medical Journal. 1998; 316: 54
(61) Silverman D. Interpreting Qualitative Data: Methods for Analyzing Talk, Text and Interaction: 3rd Ed. London: Sage; 2006.
(62) Mays, N. & Pope, C. Rigour and qualitative methods. *BMJ* 1995;311:109-112.
(63) Department of health. Research governance for health and social care.2005. http://www.dh.gov.uk/prod_consum_dh/groups/dh_digitalassets/@dh/@en/documents/digitalasset/dh_4122427.pdf

16. Appendix

APPENDIX 1.

Figure 1: PiP pilot RCT flow diagram

"Pre-schoolers in the Playground" – a pilot cluster randomised controlled trial of a physical activity intervention for children aged 18 months – 4 years old.

Recruit 10 schools

↓

Recruit families (15 children per school)
Recruitment rates assessed

↓

Baseline measurement of health outcomes
Child: physical activity (accelerometry) BMI, anthropometry, quality of life, demographics.
Parent: quality of life, self efficacy, well-being .

↓

Schools stratified by ethnicity (>50% South Asian pupils or >50% White pupils) and randomised to PiP or control

4 PiP schools

PIP Initiation phase
(10 weeks)
6 X 30 min/week, led by parental involvement workers
Attendance at sessions recorded
Fidelity of intervention assessed

4 control schools

control period
(10 weeks)

↓

10 week follow-up measurements of health outcomes
Attendance and attrition rates
Acceptability of intervention and study
Parent Involvement worker interviews at PiP schools assessing capability and capacity for PiP

PiP Maintenance phase
(20 weeks)
6 X 30 min/week, no formal supervision
Fidelity of intervention assessed

control period
(20 weeks)

↓

30 week follow-up measurements of health outcomes.
Head teacher interviews at PiP schools assessing capability and capacity for PiP

↓

52 week (1 year) follow-up measurements of health outcomes

APPENDIX 2

Draft interview topic guide for parents/carers

Introductions

Talk through Participant Information Sheet for the interview, provide opportunity for questions about the interview, re-confirm the parent/carer's consent to take part.

Experience of taking part in the PiP pilot trial

Recruitment and randomisation

Can you tell me how did you first hear about the PiP study?
Prompt: Letter sent home from school, spoke to community research administrator in playground

What was your initial reaction to receiving the invitation to take part in the PiP study?
Prompt: What were your reasons for deciding to take part?

What did you think about the way that you were recruited to the PiP study?
Prompt: Send a reply slip back, phoned by the community research administrator, what did you like/dislike about this process? How could we improve this?

What do/did you like/dislike about the written information about the study *(look through invitation letter, information sheet, consent form and reply slip with parent)*
Prompt: English or Urdu version, How could we improve these?

What did you think about being randomised to one of the 2 groups in the study?
Prompt: What do you understand randomisation to mean? How did you feel about being in the intervention/control group? Why was that?

Data collection (including accelerometry) and measurement time points

We asked you and your child to attend 4 measurement sessions over a year, how did you find these?
Prompt: How many times did you manage to come along? If you missed any, what would have helped you to attend? (time/place) What did you like/dislike about these sessions? How might we improve these measurement sessions for parents and children?

What did you think about the questionnaire that we asked you to fill in? *(look through questionnaire)*
Prompt: How might we make it easier for parents to fill in these questionnaires i.e. complete at the appointment/complete at home/send back/ complete over the phone

How did you find recording your child's levels of physical activity over 6 days using a diary and the accelerometer that we gave you?
Prompt: What went well? What went less well? How can we make this easier for parents?

Incentives

Can I ask how important were the incentives in encouraging you to take part in the PiP study? Will they encourage you to finish the study?
Prompt: Why is that? How might it differ for you if you were in the other group (intervention versus control)

What types (e.g. vouchers, cash) of incentives do you think are appropriate for parents?

What level (£) of incentives do you think are appropriate for parents?

Experience of taking part in playground intervention (intervention group only)

What did you think of the PiP playground sessions?
Prompt: What did you like about them? What did you dislike? What did your child do in the sessions? What were the benefits to your child? How can we improve the sessions?

How did the sessions change over time?
Prompt: Parental involvement worker led sessions in term 1, no formal supervision in term 2. Which approach did you prefer? Why is that?

Approximately how many sessions a week did your child attend?
Prompts: Were these before or after school? If you didn't manage to attend what would have helped you to do so?

How might we encourage more parents and children to come along to the sessions?

End interview

Finally, is there anything else you want to tell us about the PiP Study?

Thank participant and let them know that they will receive a summary of the findings of the PiP study in due course.

APPENDIX 3

Draft interview topic guide for parent involvement workers

Introductions

Talk through Participant Information Sheet for the interview, provide opportunity for questions about the interview, re-confirm the parent involvement worker's consent to take part.

Experience of leading the PiP playground sessions

What has been your experience of leading the PiP playground session?
Prompt: How have you found doing it? Have you had sufficient training and support? How can we improve this?

Can you tell me what a typical 30 minutes PiP playground session looked like?
Prompt: Roughly how many children and parents were there? How did you go about organising the sessions? What types of activities did you include? What worked well / less well?

How about the 5 minute structured parent and child play sessions, what did they include?
Prompt: How did they go? How did you modify the activities for different children? What worked well / less well?

What type of equipment was available for the sessions?
Prompt: Did the parents and children use it? What other equipment would you suggest we make available?

How did you go about working with the parents encourage their children and to find other opportunities for activity for their child?
Prompt: How did that go? What worked well / less well?

How did you use the PiP leaflets with parents?

Prompt: How did that go? What worked well / less well?

How do you think we could improve the PiP playground sessions?

End interview

Finally, is there anything else you want to tell us about the PiP playground sessions or the wider research study?

Thank participant and let them know that they will receive a summary of the findings of the PiP study in due course.

APPENDIX 4
Draft interview topic guide for head teachers
(telephone interview)

Introductions

Talk through Participant Information Sheet for the interview, provide opportunity for questions about the interview, re-confirm the head teacher's consent to take part.

Experience of the playground intervention
Can you tell me what has been your experience of hosting the PiP playground sessions in your school?
Prompt: From the perspective of the school, how has it gone? What has gone well / less well?

Have the sessions impacted on the school day? How?
Prompt: What changes (if any) would you recommend we made?

In the first term, the playground sessions were led by a parent involvement worker, after that the sessions were not formally supervised, did that make any difference to the school? *Prompt:* How? Which did you prefer? Why is that?

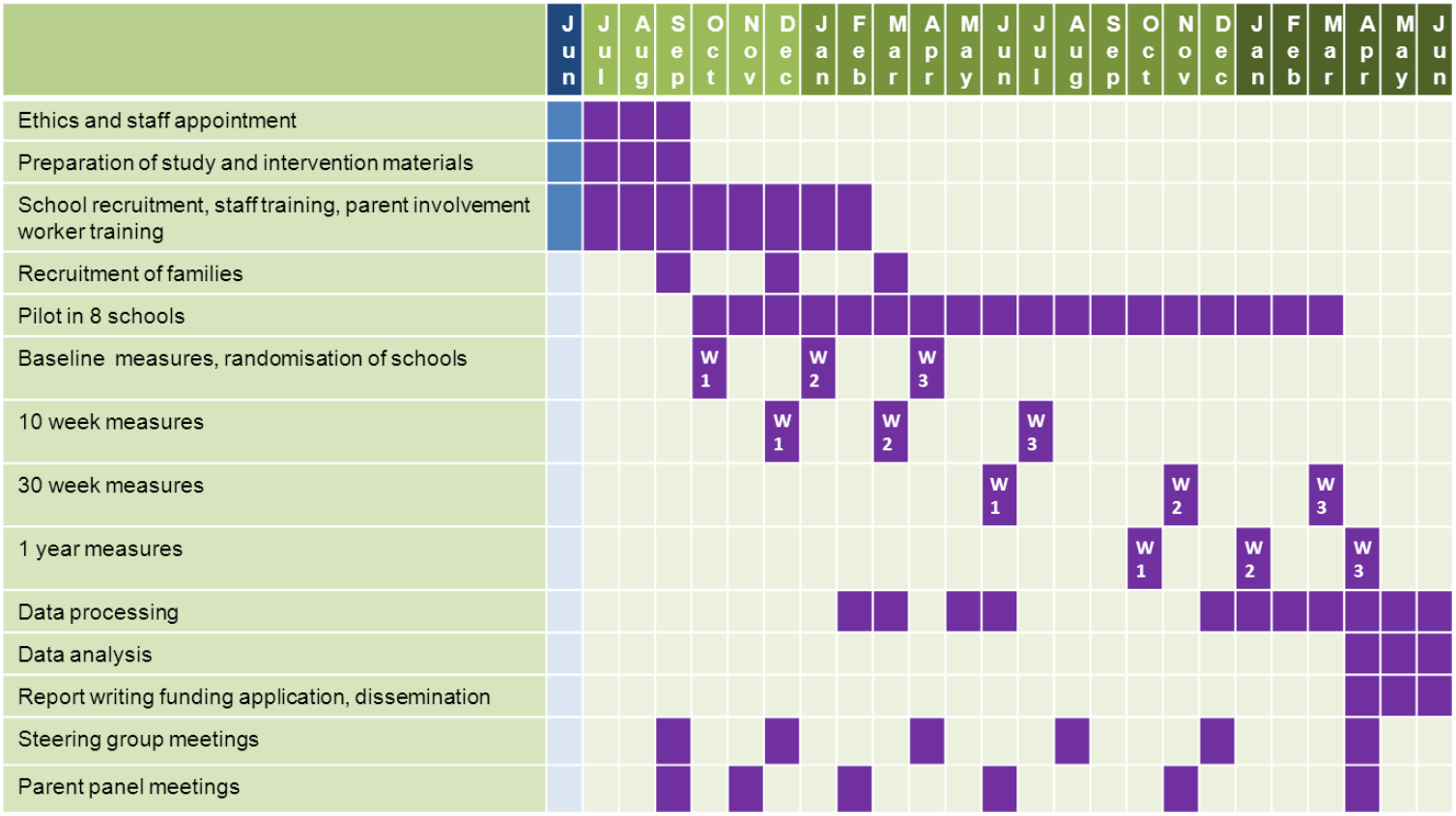
Do you have any advice for us about encouraging other schools to take part?
Prompt: What are your thoughts on the benefits to schools of hosting the PiP playground sessions? What about the disadvantages? What types (e.g. vouchers, cash) of incentives do you think are appropriate for schools? What level (£) of incentives do you think are appropriate?

End interview
Finally, is there anything else you want to tell us about the PiP playground sessions or the wider research study?

Thank participant and let them know that they will receive a summary of the findings of the PiP study in due course.

APPENDIX 5

Figure 2: Gantt chart of PiP pilot cluster randomised controlled trial



W1, wave 1; W2, wave 2 and W3, wave 3.
NB: the intervention will not be available during school holidays. Therefore data will be collected after the 10th and 30th week of the intervention and not the 10th or 30th week after the beginning of the intervention. 52 week data (1 year follow-up) will be collected 52 weeks after the beginning of the intervention.