Scientific title:	**Action 3:30: A cluster randomised feasibility study of a teaching assistant led, extracurricular physical activity intervention for 8 to 10 year olds**
Lay title:	**Action 3:30 R (Revised)**
Study logo:	
Protocol date:	21 / 09 / 2017
Protocol version:	Version: 1.1
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Trial registration number:	ISRCTN34001941
Project website:	http://www.bristol.ac.uk/sps/action330/
Funding & grant number:	This project is funded by the National Institute for Health Research Public Health Research (NIHR-PHR) Programme (Project number 15/55/09)

Sponsor: This project is sponsored by the University of Bristol (Ref 2695)

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Protocol contributors

The study design was developed by the applicants who all made important contributions to the study design and will play key roles in the study conduct.

- Prof Jago takes overall responsibility for the study and all aspects of the protocol with the support of the Trial Manager (to be appointed).
- Dr Metcalfe will lead on all trial and statistical issues.
- Prof Powell will lead on the health economic analysis.
- Dr Sebire will lead on all psychosocial and process evaluation components.
- Darren Gillett will contribute to the intervention and school components.
- Byron Tibbitts will manage the project

Declaration of interests

The Action 3:30 intervention was developed by the applicants. There are no other conflicts of interest to declare.

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2. Background

2.1. Existing research

2.1a) General background: Physical activity has been shown to reduce the adult risk of heart disease, stroke, type 2 diabetes mellitus, some cancers and obesity, and is associated with higher levels of mental well-being [1]. Physical activity during childhood has been shown to moderately track into adulthood [2] and is associated with lower levels of a number of risk factors including insulin, glucose, blood pressure and body composition [3]. Physical activity is also associated with improved emotional well-being and self-esteem among young people [4]. Data from the UK Millennium cohort study shows that only 51% of seven year olds met the recommendation of an hour of moderate-to-vigorous intensity physical activity (MVPA) per day [5]. Physical activity levels decline with age, with the end of primary school being a key period of decline [6]. Primary school is the key time for developing motor co-ordination and sport-related skills, and building children's confidence and interest in physical activity. Making the most of these "skill hungry" years is essential for the development of positive physical activity attitudes. As such, finding ways to foster physical skills and positive attitudes during primary school will help children engage in the many activities on offer at secondary school, and on to adulthood.

2.1b) Physical activity interventions: Schools provide opportunities to implement public health interventions to large numbers of children [7]. Systematically reviewed evidence has indicated that the effectiveness of school-based physical activity interventions delivered during the curriculum is limited [8]. The review concluded that where there was an effect it was mainly in studies with poor methodological quality [8]. Identified limitations included short duration of follow-up, inadequate adjustment for potential confounders, lack of adjustment for children clustered in schools, and the use of self-report measures of physical activity [8]. A 2012 review of physical activity interventions for children and adolescents, which included an objective assessment of physical activity reported an average improvement of four minutes of MVPA per day in intervention compared to control participants [9]. Of the 30 studies included in the review only 16 were deemed to be of high methodological quality. Contributory factors to low quality scores included high attrition, lack of intention-to-treat analyses, and not adjusting for the clustered nature of the data.

2.1c) Developing interventions that are ready for implementation – **The RE-AIM Framework**. There is absence of child physical activity programmes that are ready to be implemented by local public health teams [10]. The **RE-AIM** framework (Reach, Effectiveness, Adoption, Implementation, Maintenance) was developed to translate research into practice [11]. RE-AIM strikes a balance between public health-focussed interventions that have good internal validity (as examined in effectiveness trials) and good external validity (can be nationally implemented) [11]. There are numerous physical activity interventions that have shown promise at pilot/feasibility stage but have either failed to achieve an impact in a definitive trial [9] or if an impact was achieved in a trial this was not sustained during implementation [12]. As such, it is important to design physical activity interventions with future implementation in mind. A feasibility study can be used to identify changes to the study/intervention design that can enhance the external validity of the definitive trial evaluation. One way to achieve this is to identify whether all elements of the RE-AIM framework can be assessed and then use the information to guide changes to the design [10].

2.1d) What change in physical activity would be meaningful and could be achieved by Action 3:30? Meta-analysis evidence of global accelerometer-assessed physical activity has shown that a 10-minute increase in MVPA is associated with smaller waist circumference and fasting insulin levels among youth [13]. Furthermore, a systematic review has shown that physical activity levels decline by 7% annually during adolescence [14]. Thus, increasing or maintaining physical activity during primary school is critical for maintaining health as children move into secondary school. In terms of the proposed study, analysis of the original Action 3:30 baseline data (see below) indicates that

across both intervention arms, increasing baseline levels of weekday MVPA by 10 minutes would increase the proportion of participants meeting the Chief Medical Officer's recommendation of an hour of MVPA per day from 40.3% to 61.2%. This potential increase in physical activity was obtained from two extra-curricular sessions per week. Two sessions per week has been selected following extensive discussions with schools who feel that more than two sessions per week would be difficult to accommodate. Thus, the intervention dose of two sessions per week is pragmatic, maximises the potential increase in MVPA, and can be accommodated in the school calendar.

2.1e) Rationale for extra-curricular interventions: Physical activity during the primary school curriculum is limited to 2 hours of physical education (PE) per week. As a result, the school curriculum provides little opportunities for children to meet physical activity guidelines or develop their physical skills. One solution is to develop additional, non-curriculum based activities after school. This time period is children's discretionary physical activity time [15] and children who are inactive after school are less likely to meet physical activity guidelines [15]. On a practical level, after-school clubs are common in schools and many children already move from curriculum time to extra-curricular supervised programmes for additional academic support, music, art-based activities and competitive sports. Organised after-school programmes that focus on increasing physical activity opportunities for a broad range of children could provide an effective means of engaging inactive children in physical activity. Provision is likely to continue and be enhanced by the announcement in the 2016 Budget that the primary school PE premium (which often funds after-school programmes) will be doubled to £320 million from September 2017 [16]. Current extra-curricular provision is dominated by fee-paying provision from external practitioners, such as football coaches [17]. In the current economic climate, more cost-effective means of delivering these programmes, such as the use of existing school staff, are required.

Teaching Assistants (TA) help teachers support children with a variety of tasks. The number of TAs has significantly increased in the UK since 2000 and TAs now comprise around a third of the workforce in UK schools [18]. Many TAs would welcome an opportunity to deliver after-school activities but lack the skills and confidence to do so. Head-teachers are keen to allow TAs to deliver after-school activities because: a) it is consistent with the Extended Schools and NICE guidance; b) commercial activity session providers are expensive [17]; and c) it shows that the school is developing the skills of its workforce. Training TAs is an intervention approach which, if shown to be effective, could be rolled out nationwide and would be relatively easy to sustain within existing school systems. We recognise, however, that school budgets are coming under pressure and, as such, an aim of this study it is assess the potential sustainability of this approach and identify the potential routes for commissioning and dissemination of the intervention. An after-school physical activity intervention delivered by TAs could be a cost-effective, sustainable intervention for delivery in primary schools.

2.1f) Psychological theory of behaviour change: Interventions based on psychological theory have been more successful than those that have not, and can provide key advances for intervention design as they facilitate the identification of key mediators of behaviour change [19]. Self-determination theory (SDT) [20] may be particularly appropriate for understanding children's physical activity. SDT focuses on motivation for behaviour and contends that being motivated for autonomous reasons (i.e., because PA is fun or provides valued benefits) leads to more positive cognitive, affective and behavioural outcomes than being motivated by controlled reasons. Evidence from the physical education and sport psychology literature indicates that autonomous motivation is associated with positive outcomes in children and adolescents, such as self-reported exercise behaviour [21]. Our own research provides evidence in primary school children that intrinsic motivation is positively associated with objectively-assessed physical activity [22]. Autonomous motivation and psychological well-being are facilitated when three innate needs are satisfied; (a) autonomy (i.e., being the origin of one's behaviour), (b) competence (i.e., feeling effective in one's environment) and (c) relatedness (i.e., feeling a mutual sense of connectedness with others). Thus, programmes that help primary school children feel more physically competent and confident in

front of their peers, which show that their efforts are key to their success, and engender being part of a supportive team, will increase children's motivation to try harder and stay involved in PA. Our research supports cross-sectional associations between psychological need satisfaction and autonomous motivation amongst UK primary school age children [22].

An additional feature of SDT, which makes it particularly appropriate for Action 3:30, is that it suggests that motivational quality is determined in part by the motivational climate created by the leader [23]. For example, teachers can enhance autonomous motivation by: (a) being autonomy-supportive (e.g. engaging children in decision-making), (b) providing structure (e.g., clear expectations and guidelines), and (c) being interpersonally involved (e.g., showing empathy with pupils). Leaders who use these empowering strategies have positive effects on pupils' motivation, behavioural engagement, and psychological well-being [23]. Our research has shown that TAs can be trained in how to provide curricular content using a delivery style that fosters optimal motivation and development [24]. TAs will also require training in the safe management of the physical activity environment and activities using a style that fosters children's motivation [25].

2.1g) Brief summary of previous work conducted to develop Action 3:30: We recently completed an evaluation of an afterschool intervention, **Action 3:30** [26]. The study was conducted in 20 schools and participants were Year 5 and 6 pupils (9 to 11 year olds). Ten schools were randomly allocated to the Action 3:30 intervention and 10 schools to the control arm (normal practice). The intervention consisted of training TAs to deliver physical activity sessions in the period immediately after-school. Two TAs from each intervention school received a five-day training programme that focussed on delivering physical activity sessions after-school. The intervention was based on SDT and the TAs were trained to facilitate sessions that covered a range of physical activities, including games, pair work, and individual challenges. TAs were also trained in how to use a need-supportive style that acknowledged pupils' feelings and preferences, conveyed a sense of choice and provided support for children's autonomy, competence and relatedness [27]. The focus of the intervention was promoting children's perceptions of physical activity autonomy, belonging and competence. Among a range of techniques to promote autonomy, TAs were encouraged to provide choices within the activities, such as leading warm-ups, adapting games (e.g., rule changes, group sizes, equipment) and there were child-led sessions in which children chose the activities. TAs supported competence by setting progressive activities targeting quick successes balanced with providing optimal challenge and praise for attempts as well as outcomes. Relatedness was supported through empathic TA-child interactions, TAs showing interest in children's lives outside the intervention and encouraging team-work.

Once trained, the TAs were asked to deliver two, 60-minute Action 3:30 after-school clubs per week, for 20 weeks. Detailed session plans were provided for all sessions. Every two weeks the pupils were provided with an information sheet that included activity ideas based on the content of the last four sessions which they could practise outside the club. Intervention schools were reimbursed for TAs' time to attend training and deliver the sessions.

Measures: Session delivery and session attendance was calculated. Weekday MVPA was assessed by accelerometer at baseline (T0), during the last few weeks of the intervention (T1), and four months after the intervention ended (T2). Costs of delivering the intervention were estimated.

Process evaluation: Children's enjoyment of sessions was assessed fortnightly. Reasons for non-attendance were recorded at the end of the intervention. Post-intervention interviews were held with participating TAs and school contacts, and focus groups were conducted with intervention children. Interviews and focus groups examined how recruitment and session attendance might be improved and established elements of the programme that could be improved.

Main results: Five intervention schools ran 40 sessions, three ran 39, one ran 38 and one 29 sessions. Mean attendance was 53%. The adjusted difference in weekday MVPA at T1 was 4.3

minutes (95% CI = -2.6 to 11.3) with higher MVPA in the intervention arm. Sex-stratified analyses indicated that intervention boys obtained 8.6 more minutes of weekday MVPA than the control group boys (95% CI = 2.8 to 14.5) at T1 with no effect for girls (0.15 minutes, 95% CI = -9.7 to 10.0). The indicative average cost of the intervention was £2,425 per school or £81 per participating child during in the first year, and £1,461 per school or £49 per child thereafter [26].

Process evaluation results: Multiple positive aspects were identified, including high session variety, the opportunity for teamwork, the child-led sessions, the engaging leader style and perceived positive impacts on skill and self-esteem levels of children [28]. We also identified ways to enhance the motivational experience of girls [24]. TAs and key contacts felt that recruitment could be improved by providing 'taster' sessions during PE lessons and clarifying the days that the clubs would run at the point of recruitment. The program could be improved to enhance interest for girls, and by including training for managing disruptive behaviour and making some activities more 'age appropriate'. TAs also told us that they found some materials hard to interpret and they would find the resource more useful if video recordings of model content were provided and if resources signposted supportive content available on third party websites.

Summary of lessons learnt from original Action 3:30 study: The original evaluation showed that Action 3:30 is an intervention that is liked by schools, children and TAs and holds promise as a scalable physical activity approach. The effect on mean levels of MVPA among boys (8.6 more minutes per day than the control group) is among the best effects that have been shown for physical activity interventions [9]. However, more work is needed to improve the content for girls, recruit less active participants, improve attendance, and increase the TAs' ability to manage disruptive behaviour. Schools reported that usually after-school programmes have re-enrolment points every term and to maximise external validity it would be advantageous to let new children join the sessions once they have heard positive feedback from their friends. Each of these issues has been addressed in a revised intervention which is outlined in more detail in section 7. The goal of this study is to test, via a feasibility study, if addressing these issues results in a public health intervention that shows sufficient promise and potential for population health impact, to warrant evaluation via a larger, cluster randomised controlled trial.

2.2. Risks and benefits

Benefits: Recent data from the Millennium Cohort study has shown that large proportions of 7-8 year old children do not meet the Chief Medical Officers recommendation of an hour of MVPA per day [5]. There are major public health and economic gains to society from public health interventions that increase physical activity at a population level. Local Health and Wellbeing Strategic Needs Assessments, from which future health services and school-based preventive intervention strategies will be commissioned, need to be evidence-based to ensure effectiveness and cost effectiveness. If the proposed intervention is shown to be feasible and later both effective and cost-effective it could be disseminated nationwide. Potential participant benefits include increased PA and the development of self-esteem. In addition, TAs will gain from skill development.

Risk: The main potential risk of this study is that a pupil may develop a sports injury. This level of risk is consistent with a standard physical education class and can therefore be classed as minimal. As such, the benefits outweigh the risks associated with the study.

2.3. Rationale for current study: The evaluation of the original Action 3:30 programme showed that training TAs to deliver physical activity programmes in the after-school period holds promise. However, there is a need to evaluate the revised programme and particularly whether the revised content yields increases in the physical activity of both boys and girls and results in higher attendance levels. There is also a need to examine the potential utility of new approaches to recruiting low active children, adopting a rolling-recruitment approach and whether it is possible to use the RE-AIM framework to assess the implementation potential of the intervention.

3. Research objectives: There are six objectives, underpinned by seven research questions.

Objective 1: Optimise the intervention to increase activity in boys and girls.

1. How can the intervention materials be optimised to increase activity in boys and girls?

Objective 2: Identify effective means of recruiting low-active children.

2. How can recruitment be optimised to recruit low-active children?

a) Is it feasible to collect self-reported activity data from Year 4/5 using "opt-out" consent?
b) Is it feasible to collect accelerometer data from all Year 4/5 using an "opt-out" consent procedure at T0 and T1 in a sub-group of pupils in four schools?
c) Does an "enhanced recruitment approach" facilitate recruiting low-active children?
d) Is it feasible and acceptable for schools and pupils to provide opportunities for enrolment at the mid-point of the intervention?

Objective 3: Assess intervention fidelity.

3. To what extent was Action 3:30 delivered as intended?

a) What proportion of the Action 3:30 sessions were delivered?
b) What was the mean attendance and were there differences by gender?
c) To what extent was the intervention delivery consistent with the underpinning theory?

Objective 4: Estimate the effect of allocation to the Action 3:30 intervention on weekday MVPA of participants and related physical activity behaviours.

4. What is the difference in the means of the accelerometer-assessed MVPA of boys and girls in the intervention and control groups in the last few weeks of the intervention (Time 1)?

a) Is there any evidence that intervention participants' school travel mode or organised club attendance changes as a result of attending Action 3:30?

Objective 5: Collect the information needed to assess the feasibility of conducting a definitive trial and assess the implementation potential of the intervention.

5. What are the levels of data provision for secondary outcomes?

a) Is it feasible to collect information on how costs of implementation are influenced by school infrastructure and staff leadership/participation and overall extra-curricular club provision/cost in schools?
b) Is there any evidence of contamination between intervention and control schools?
c) Identify factors that need to be addressed to minimise health inequalities.

6. What would the sample size for a definitive trial be?

7. Is it feasible to collect all data on all dimensions of the RE-AIM framework to estimate the potential population impact of Action 3:30 in a definitive trial?

Objective 6: Assess whether 5 progression criteria for conducting a definitive trial are met.

a. 1/4 of schools that are approached agree to join the study
b. 1/4 of eligible Year 4/5 pupils express an interest in the study by returning consent forms.
c. At least 40% of participants expressing an interest in the study are girls.
d. At least 50% of the participants in the intervention arm attend 50% of the sessions
e. At time 1, at least a small benefit for weekday MVPA is observed for each of boys & girls, comparing intervention to control schools, and the upper bound of the 95% CI for each difference exceeds a 10-minute benefit for the intervention group.

4. Research design: The proposed research contains two related components: a) intervention optimisation; and b) a cluster randomised feasibility study.

Component A: intervention optimisation: Details of the intervention components, how they were changed after the original Action 3:30 study, how they map onto SDT, how they link to behaviour change techniques and session content is outlined in Section 7. To ensure that the intervention is optimised for boys and girls and that all changes maximise interest and appeal for both sexes we will conduct two iterative steps of formative research to identify any final changes before the intervention commences. In step one, we will run a sample session of intervention content for Year 5 students in the summer of Year 1 (months 1-2). These students will not be eligible to be enrolled in the study because by the time that the intervention commences they will be in Year 6. This session will be delivered by Bristol City Council staff during a PE lesson. After the sample session we will run one focus group with boys (n = 6-8) and one with girls (n = 6-8). During the session pupils will be asked to comment on enjoyment of the session, their perception of the extent to which boys and girls interacted together and ways in which the session could be improved both in terms of activity content and TA instruction. We will make necessary changes to session content and repeat the process in a second school. Lessons learnt from the focus groups will be incorporated into all 30 session plans prior to the intervention starting in month eight.

Component B: Cluster randomised feasibility study.

Setting: Eligible schools will be state funded primary schools in North Somerset and South Gloucestershire. (As it is now several years since the earlier work was completed, schools who took part in the earlier work are eligible to join the study). To ensure that the sample represents local diversity we will ensure that half of the schools are above the local authority median for free school meals (as an indicator of socioeconomic status of the pupils' families). Twelve schools will take part in the study, eight from South Gloucestershire and four from North Somerset, as it is a smaller local authority area.

Recruitment of schools: All schools meeting the inclusion criteria will be invited to participate via a letter. Non-responding schools will be followed up by email and phone if necessary. Study entry will be on a first come first served basis. Two reserve schools (one per Local Authority) will be recruited to allow for withdrawal of schools prior to baseline data collection. To ensure that Action 3:30 does not just replace current after-school provision we will ask all schools to agree to continue with current delivery if allocated to the intervention arm.

Recruitment of pupils: Recruitment of pupils will happen in three stages:

Stage 1: Prior to the main study commencing we will conduct a brief survey of the physical activity levels of pupils using Physical Activity Questionnaire for Older Children (PAQ-C) scale [29] in **eight** schools. These data will be collected via an opt-out consent procedure in which we will inform parents that we are collecting information on the physical activity levels of all pupils. Data will be collected during a normal class. These data will provide information about the physical activity levels and after-school club attendance of all Year 4 and 5 pupils in the school and will facilitate a comparison of the levels of activity among the pupils who take part in the study and the overall sample of pupils in the school. In **four** further schools, we will attempt to collect baseline (T0) and T1 accelerometer and PAQ-C data via an opt-out consent procedure.

Stage 2: Stage 2 will be an active consent procedure. As this study is a feasibility study, we will use two different enhanced recruitment strategies. Half of the schools will be randomly assigned to receive Recruitment Strategy A and the other half will receive Recruitment Strategy B. Both approaches will include more components than those used in our previous assessment of Action 3:30. A goal of this project is to examine which of the two new approaches is most effective. Details for each strategy are outlined below.

Recruitment Strategy A
For *Recruitment Strategy A,* project staff will conduct a briefing for Year 4 and 5 students in which they are provided with information about the Action 3:30 clubs, assessments and the randomisation process. Students will be provided with a parental recruitment pack (information sheet and consent form). In addition, a project staff member will have individual meetings with class teachers. In these meetings, the team member will outline the aims of project and ask the class teacher to encourage the children who are less active and / or less engaged in extra-curricular activities to consider participating in Action 3:30.

Recruitment Strategy B
Recruitment Strategy B will include all of the elements of Recruitment Strategy A, but we will also deliver taster sessions during PE classes that focus on fun and enjoyment and recruiting low-active children. All Year 4 and 5 pupils in the six schools that are allocated to *Recruitment Strategy B* will receive an exemplar Action 3:30 session, which is non-competitive and focusses on fun during a PE lesson. The session will be taught by a member of the sport coaching team from Bristol City Council. The session will be specifically designed to encourage less active children and children who do not participate in regular physical activity to join the new Action 3:30 clubs. At the end of the session pupils will receive the same briefing and forms as per the standard recruitment campaign.

Reasons for non-consent: As this is a feasibility study, we want to assess if there are ways in which the recruitment process could be improved before proceeding to a definitive trial. Understanding why parents do not sign their children up at the stage 2 process is therefore critical. We will ask all parents of children who do not consent to join the study at stage 2 to complete a brief questionnaire to measure why they did not consent to participate. The information will be requested at the point of consent as a reason for non-consent and will be provided anonymously via the schools. We will perform basic descriptive analyses of these questionnaires to identify the main reasons for why children do not join the study. We will then use the information to guide two parent PPI sessions. One session will be conducted with parents that received recruitment strategy A with the other conducted with parents in a school that and one school that received recruitment strategy B. The sessions school will be used to understand in more detail how to overcome the issues that were raised in the surveys. We will then repeat the process with Year 4 and 5 pupils in the same schools to understand how recruitment could be improved. The information gained from these sessions will be used to inform recruitment approaches for a definitive trial.

Stage 3: Data from the original study and our recent experience evaluating an extra-curricular dance programme has highlighted that normally schools provide an opportunity for pupils who did not register an interest at the start of an after-school programme to join at a later date [26, 28, 30]. We recognise that in a tightly controlled trial setting allowing pupils to join a study after baseline data have been collected adversely affects internal validity. However, we think that in order for a study to be able to be implemented, it also needs to have high external validity [11]. We therefore propose to assess the feasibility of conducting a second enrolment in each intervention school and examine whether the pupils who are recruited from such a method differ to those recruited initially in stage 2. In each intervention school, we will assess the levels of attendance after session 12 to identify the potential space available in each school. We will then send all Year 4 and 5 pupils who are not currently enrolled in the programme an invitation to join. Participants who express an interest will be required to provide informed parental consent and complete the baseline demographic assessments outlined in section 9.1 and will complete the T1 assessments.

Allocation: School is the unit of allocation. Twelve primary schools will be randomly allocated after baseline data collection is complete in equal number to intervention (Action 3:30) or control arms. Allocation will be performed by a member of the Bristol Randomised Trials Collaboration who will be blinded to the identity of the schools and otherwise not involved in the study. Allocation will be stratified by local authority, and standard or enhanced recruitment method.

Data collection procedures: Pupil assessments: To mimic the processes that would be used in a definitive trial, all measures will be collected at baseline - prior to randomisation (T0) and during the last 6 intervention sessions (T1). Data will be collected in schools by the Project Manager, Fieldworker and casual Fieldworkers. At each time point pupils will wear an ActiGraph accelerometer to assess physical activity. Height and weight will be assessed to calculate body mass index. Pupils will also complete a questionnaire assessing demographics and psychosocial variables (possible mediators). To maximise data completeness and eliminate data entry errors all questionnaires will be completed on tablet devices.

Process evaluation: The process evaluation will focus on addressing the five elements of the RE-AIM framework and any specific changes that are needed to the study design or intervention. Specifically: **Reach** will be assessed via the engagement and participation of children and school; **Effectiveness** will be assessed via evidence of change in primary outcome; **Adoption** will be assessed by willingness of schools to initiate the intervention and participation of staff; **Implementation** will be assessed by the delivery (often influenced by school infrastructure; and **Maintenance**, will be assessed in relation to the potential to sustain the outcome of the intervention in a real world context.

Economic assessment: The economic assessment will also be based on RE-AIM and will assess the potential for change in health related quality of life (**Effectiveness)** the ability to assess costs variation in delivery among school settings **(Implementation)** and the potential to sustain the outcome of the intervention from a cost perspective (**Maintenance**). Details of the process and economic assessment are presented in section 9 with the analysis outlined in section 12.

Methods to protect against bias: The following steps will be used to reduce the risk of bias in a definitive trial. In this study we will examine whether these steps are feasible and acceptable:

(1) Confounding: Allocation to study arms will be performed after recruitment, consent and baseline data collection is completed by a statistician in the Bristol Randomised Trials Collaboration (a UKCRC registered Clinical Trials Unit) who is otherwise not involved in the study.
(2) Contamination: While relocation of pupils between schools allocated to different study arms is possible, we anticipate that this would be minimal and therefore have little impact. We will qualitatively assess if contamination has occurred in the interviews with TAs, school contacts and academy chain leads that will be conducted at the end of the project.
(3) Detection Bias: This is likely to be negligible as accelerometer assessed MVPA is objective.
(4) Measurement bias: Given the nature of the intervention it is not possible to blind participants to its aim. To reduce self-report biases for the main outcome (MVPA) in this study and a definitive trial we will measure physical activity using accelerometers which do not provide behavioural feedback. Every effort will be made to obtain data from all participants who do not withdraw consent.

5. Study population

Setting: The research will be conducted in 12 primary schools in the South Gloucestershire and North Somerset local authority areas. We aim to recruit 8 schools from the South Gloucestershire area (suburban, rural with areas of high ethnic diversity) and 4 schools from North Somerset (rural, high deprivation). In light of the significant adaptations to the training and session content that would be required, Special Educational Needs schools will be excluded.

Participants: The target population for this study is Year 4 and 5 pupils. We aim to recruit at least 1/4 of the Year 4 and 5 pupils in each school but for logistical reasons we will set a maximum limit of 30 children per school that can be enrolled. Both boys and girls will be eligible to participate. We will aim to recruit children who have low levels of physical activity and are not participating in organised team sports. These low-active children will be targeted via our recruitment campaign (see above). Children will be informed that if they join the Action 3:30 study and are assigned to

the intervention group that they will be expected to attend two sessions per week. (This will be more difficult for children who attend sport activities and will help to recruit low active children.)

Exclusion criteria: All Year 4 and 5 pupils who provide parental informed consent and who are physically able to participate in regularly scheduled physical education classes will be eligible. Children who cannot engage in physical education lessons will be excluded.

6. Socioeconomic position and inequalities: This study aims to address pre-existing disparities in physical activity provision by providing a free after-school physical activity programme. Low levels of physical activity is a public health issue that affects **all** socio-economic groups. We will therefore recruit schools from across socioeconomic groups. As part of the end of study qualitative research we will conduct, we will ask all school contacts and academy chain leads whether economic factors would affect future uptake of the intervention and how those issues could be addressed.

7. Planned interventions: The Action 3:30 intervention consists of four components:

1) Two TAs from each intervention school attend a 25-hour (5-day) training programme focussing on delivering a physical activity programme after-school. Action 3:30 is based on SDT and as such the programme will focus on promoting children's perceptions of autonomy, belonging and competence in relation to physical activity. Amongst a range of techniques to promote autonomy, TAs will be encouraged to provide choice within the activities, such as leading warm-ups and adapting games and in regards to the speed at which activities progress. There will be child-led sessions in which children choose the activities. TAs will be trained to support competence by setting progressive activities targeting quick success balanced by optimal challenge. They will give specific praise for attempts as well as outcomes. Relatedness will be supported through empathetic TA-child interactions.

The 5-day training programme will be delivered by Darren Gillet, Coach Development Manager at Bristol City Council.

2) Once trained, TAs will deliver Action 3:30 twice a week for 15 weeks. Each session will last 60 minutes. Thirty detailed session plans have been produced and TAs will be asked to deliver sessions in the prescribed order. The session plans include a range of activities and games and emphasise participation and enjoyment. For 22 sessions there is a video recording of model delivery, on 19 session plans there are links to additional online resources, and on all 30 there are reminders for the TAs on how to embed the core principles of SDT within the session.

3) All intervention schools will receive £200 of equipment to deliver the sessions.

4) All pupils will be provided with 10 home activity cards that will be distributed after every three sessions. The cards provide advice on how children can practice activities that have been taught during the sessions with family and friends. The cards reinforce session content.

How the intervention has changed since the original: Table 1 (below) outlines the issues that were raised in the original study and the changes that we have made to the intervention content.

Table 1: Issues raised and changes made to Action 3:30 intervention

Issue raised	**Change that has been made**
Need to make sessions more appealing for girls	All session plans were reviewed by three independent physical activity experts to identify how to increase appeal to girls. All sessions were re-written to include more activities that appeal to girls: less traditional team sports and more small-sided games and personal goal setting. Sessions were further refined based on local advisory group input and feedback from 8 TAs who took part in PPI work to inform this study. Key changes included activities in which girls can work in girl only groups initially to build confidence, exposure to a variety of activities to find those that are enjoyed, and increasing options in sessions for all children to choose activities or modify activities.
Content would be better pitched at younger children	Target group changed to Year 4 and 5 (from Year 5 and 6)
Prioritising the Action 3:30 club	TAs felt that ensuring school leadership were aware of the sessions and school commitments was essential for success and that trying to schedule Action 3:30 to avoid clashes with other activities that might be important for Year 4/5 pupils was key. We have embedded these principles in our revised school / study agreement that is signed at school recruitment. We will develop school specific contingency plans of what will happen if the usual school space is unavailable due to a performance in the school hall etc. These plans will be agreed with TAs and the school leadership and a process to notify the TAs of a need for contingencies put in place.
It would help to see exemplar sessions being delivered	Model sessions have been video recorded and professionally edited. There are 22 sessions that have online video recordings attached to them.
Signpost additional resources	We have added “skills links” to all session plans which are links to third party websites that highlight content that could aid delivery of sessions.
Teaching Assistants need more help in managing disruptive behaviour	We developed a ‘Managing disruptive behaviour’ training session. The session has been reviewed by 8 TAs who commented on applicability to them and how it could be improved. The TAs liked our “warning sign system” to flag a session that could be susceptible to disruption and suggested adding other warning signs such as bad weather, supply teacher during the day, and non-uniform days. TAs suggested forming closer links with classroom based teachers so that the TAs were aware of arguments or disruption during the school day. We will incorporate this suggestion by ensuring that TAs know the Year 4/5 teachers and have a process for receiving feedback on Action 3:30 pupils on club days. TAs suggested that sanctions for disruptive behaviour had to be consistent with school policy and follow a process of warnings that were used in school. To address this issue we will identify the school policies within each school and ensure that all TAs are aware of these policies and their use. To gain attention in noisy groups all TAs use consistent signals, such as standing with their hand raised and counting backwards from 3-2-1. If this signal were standardised and adopted in all sessions it would be easy to use in difficult situations. We will add this signal and time to practise its use to the TA training.
Enhance embedding of motivation content in sessions	We have added a 'star' symbol to each session plan that details where and how TAs can build 'want to' motivation (related to nurturing autonomy, belonging and competence). We added 'Motivation Memos' which direct the TAs to a resource which helps them implement efficient motivational techniques.

How the intervention maps onto the underpinning theory of SDT and behaviour change techniques: As shown in the logic model (*page 25*), the key hypothesised mediators of behaviour change for Action 3:30 are changes in participant physical activity-based perceptions of autonomy, relatedness, competence, enjoyment (during the sessions and overall) and motivation. These mediators are the targets of the TA's delivery of the 30 session plans and participation in the study. We therefore hypothesise that the Action 3:30 intervention will change pupil behaviour (at least in part) through the following behaviour change techniques (BCTs) [31]; Feedback on behaviour, social support (TA-pupil, pupil-pupil), instructions on performing behaviour, behavioural practice and rehearsal, setting graded tasks, demonstrating the behaviours, providing information on health and emotional consequences of PA, social rewards (positive verbal reinforcement), restructuring the physical environment and adding objects (new equipment) to the environment.

Control group provision: Participants in the control schools (6/12) will receive 2 small activity related reimbursements (£5 in total) in recognition of the time given for each data collection (T0 and T1), **but no intervention will be provided**. (Pupils in the intervention arm will also receive the same reimbursements). All control schools will receive a £300 donation in recognition of the time spent by school staff in accommodating data collection.

Funding of intervention costs: The intervention costs are estimated at £16,000. We have secured £10,000 from South Gloucestershire Council and £6000 from North Somerset Council.

8. Give a brief explanation of the methods proposed: The study is a cluster randomised feasibility study. The study will be mixed-methods, with quantitative assessments of physical activity and psychosocial variables as well as a quantitative assessment of intervention costs. All measures will be collected at baseline (prior to randomisation - T0) and during the last 6 intervention sessions (T1)**.** In addition there will be a process evaluation of the intervention delivery and fidelity and post-study qualitative assessment with participants, TAs, school contacts and school administrators. Section 9 outlines all of the measures and Section 12 details the proposed analyses that will be conducted. Section 9 also includes the study progression criteria.

9. Proposed outcome measures: Assessments are being conducted in seven areas, which are outlined below, along with the progression criteria for a full-trial.

9.1: Participant characteristics: At recruitment, parents will be asked to report child date of birth, gender, and home post-code (which will be used to estimate the index of multiple deprivation for the primary residence). Participant (child) height and weight will be assessed at each data collection to the nearest 0.1 cm and 0.1 Kg and BMI SDS calculated to describe the participants.

9.2: Self-reported physical activity, club attendance and parental time: As noted above, during the first phase of recruitment we will ask all Year 4 and 5 pupils in the twelve schools to complete the PAQ-C scale [29], which provides an estimate of levels of physical activity. We will also ask Year 4 and 5 pupils to complete a questionnaire, which assesses the number and type of after-school physical activity clubs [30] that they attend at school and elsewhere. We are interested in parental time to support children's physical activity after-school. We will ask pupils how they generally travel home after school, whether parents/guardians are involved and whether the mode of travel changes for attendance at Action 3.30. (See section 9.5 costs) We will repeat this measure for children enrolled in the study (intervention or control group at T1).

9.3: Physical activity: Accelerometer-determined minutes of MVPA per day is the likely primary outcome in a definitive trial. We will assess physical activity using ActiGraph accelerometers which record bodily acceleration and have been extensively used and validated amongst young people [32]. Participants will be asked to wear an accelerometer for seven days at T0 and T1. Periods of ≥ 60 minutes of zero counts will be recorded as "non-wear time" and removed. Participants will be included in analyses if they provide ≥ 3 valid days (i.e., 500 minutes of data between 6am and

11pm). Mean minutes of daily MVPA will be estimated using the Evenson cut-point [32]. We will also estimate participants' sedentary time from accelerometer data based on a cut-point of less than 100 counts per minute. Furthermore, as our previous studies have suggested that attending extra-curricular programmes could affect mode of travel home from school [33] we will ask participants to complete a school travel questionnaire at each assessment. Data on school travel mode will be collected via the parental questionnaire from all children in all 12 schools who opt in at T0 and T1 .

9.4: Self-reported psychosocial questionnaires: We will ask children to self-report activity-based perceptions of autonomy, relatedness, competence and enjoyment at each time point using established scales that we have developed and used with this age group successfully [22]. The potential for the intervention to increase self-esteem will also be assessed [34].

9.5: Economic measures: Outcome**:** We will pilot the use of KIDSCREEN-10 [35] and the Child Health Utility 9D (CHU9D) [36] as potential health-related quality of life outcome measures.
Costs**:** We will ask all twelve schools at T0 to complete a retrospective school survey in which the number, cost and funding source of all extra-curricular clubs is reported. The project team will use time sheets and expense sheets to collect resource use data and actual costs incurred to plan, prepare and deliver Action 3.30. Parental time to collect children after-school by travel mode will be estimated from pupil self-reported data. We will consider whether this information is sufficient to estimate parental time in a full trial and how we might estimate resource use and prices separately for the various travel modes involving parents. We will develop, if feasible, a set of assumptions and inferences that might be applied in a full trial. We will then repeat the process at T1 to assess provision while Action 3:30 is running in both intervention and control schools.

9.6: Process evaluation: We will conduct a process evaluation to provide insight into the extent to which the intervention was delivered as planned and facilitate the RE-AIM evaluation of the intervention. Each element is outlined below along with how it is aligned with RE-AIM.

REACH: We will record the number of schools approached and the proportion recruited.
TAs will record attendance at each session. The dose of the intervention (number of planned sessions delivered) will be recorded by TAs in each school.

EFFECTIVENESS: Qualitative methods will be used to understand factors that affected effectiveness at each site (see section 9.7 for details).

ADOPTION: We will record the number and proportion of schools and TAs who state that they will continue to deliver some version of Action 3:30 once the intervention period has ended.

IMPLEMENTATION: Intervention fidelity will be assessed by asking the TAs to complete a log-book in which they will assess whether they delivered the planned core components of each session *fully*, *partially* or *not at all*. In addition, a member of the project team will observe three randomly-selected sessions in each school. During these sessions the observer will assess whether they delivered the planned core components of each session either *fully*, *partially* or *not at all.* At the end of these sessions, we will ask all participants to complete a brief perceived enjoyment questionnaire. We will also ask all TAs to report their self-efficacy to deliver PA sessions (including behavioural management) using existing validated, self-reported questionnaires [37] [38] before and after the training and at three occasions during the intervention. During one of these visits a fieldworker will also assess the school-level physical activity provisions to provide information on the physical activity context in the school using validated school physical activity environment scale [39]. We will assess the school physical activity policy context by soliciting information from a school contact in relation to policies regarding physical activity and physical activity throughout the curriculum and use of relevant government resource such as the "sports premium funding". The fieldworker will collect these data during a process evaluation visit [40].

MAINTENANCE: It is not possible to assess maintenance in this study but the data from the study will be used to inform the assessment of maintenance in a definitive trial.

9.7: Post-study qualitative assessments: The post-study qualitative assessments are designed to inform how the intervention and trial design could be improved and also contribute to the RE-AIM evaluation of the feasibility study. Details of each component are outlined below.

We will conduct 12 focus groups, 2 per intervention school, one with 6 boys and another with 6 girls per school. We will also interview all intervention TAs (n = 12) and key contacts (n = 6). All focus groups and interviews will examine factors that might have affected recruitment and attendance (**REACH**), delivery, enjoyment (**EFFECTIVENESS**), and anything that could be improved. In the TA interviews we will assess how effective the 'managing disruptive behaviour training' was and if it could be improved. Key contact interviews will ascertain if there was evidence of contamination in control schools and any factors that affected contamination (such a proximity to intervention schools). To assess long-term sustainability of the programme we will use the Key Contact interviews to ask if schools would continue to run Action 3:30 when the study has ended, what factors would affect that decision, and how the cost of Action 3:30 compared to existing programmes. We will also assess how well the second enrolment was received in the intervention schools including the feasibility of this and any issues that this process created. Finally, we will examine whether provision or uptake is likely to be affected by any ethnic or socio-economic factors and how issues that arise could be addressed (**IMPLEMENTATION**).

We will conduct interviews with the key contact (n=4) and class teachers (n=4) in the four schools that took part in the accelerometer "opt-out" consent process at T0 and T1 (for intervention schools, we will add additional questions to the end of the interview outlined in the previous paragraph). These interviews will focus on a) school burden and how it could be mitigated; b) any logistical issues that can be addressed (**ADOPTION** and **IMPLEMENTATION**); and c) whether the opt-out consent process would have an impact on participation in a future trial.

We will conduct interviews with academy chain leads, local public health commissioners and directors of public health non-profit organisations, such as DECIPHher Impact (http://www.decipher-impact.com/), Bristol Community Health ((http://briscomhealth.org.uk/) and Bristol health partners (http://www.bristolhealthpartners.org.uk) (n=8) who have all successfully translated public health interventions. These interviews will focus on the sustainability and potential future commissioning of the intervention. Specifically, the interviews will assess the potential for dissemination of Action 3:30 and any changes that could be made prior to a full-trial to increase external validity and facilitate further dissemination (**ADOPTION** and **IMPLEMENTATION**).

Progression criteria: The primary outcome in a definitive trial would be weekday MVPA at T1. Moreover, in light of our original study we would want to be sure that the intervention has the potential to positively affect the physical activity of both boys and girls. Therefore a key progression criteria will be whether the intervention shows evidence of promise for both boys' and girls' MVPA. Furthermore, to ensure that the Action 3:30 study would have the potential to have high external validity and be translatable once the study ends we also want to ensure that the study is attractive to children and schools. As such the five progression criteria for our study are:

a. 1/4 of schools that are approached agree to join the study
b. 1/4 of eligible Year 4/5 pupils express an interest in the study by returning consent forms.
c. At least 40% of participants expressing an interest in the study are girls.
d. At least 50% of the participants in the intervention arm attend 50% of the sessions
e. At time 1, at least a small benefit for weekday MVPA is observed for each of boys & girls, comparing intervention to control schools, and the upper bound of the 95% CI for each difference exceeds a 10-minute benefit for the intervention group.

10. Assessment and follow up

10.1. Assessment of efficacy: It is envisaged that in a definitive trial that the primary comparison will be while the programme is still running (T1). We note that this is different than the conventional study designs that places the last assessment as the indicator of long-term behaviour change. We believe, however, that for this particular intervention the T1 data provides information that is more relevant for assessing the public health and population level impact of the intervention. The essence of this programme is provision of new activities that are delivered in a fun and enjoyable way by existing school staff and as such the entire premise of this programme is that it is a cost-effective and sustainable intervention that schools could provide indefinitely to promote longer term physical activity. If the programme is removed, the key opportunity to be active that is provided by the intervention would cease. Moreover, if the programme were effective, the public health guidance would be to implement the programme in schools and encourage less active children to attend. As such, the T1 data would be the key evidence of intervention effect and would be the information used by policy makers and schools to commission Action 3:30 programmes in UK schools and it is this evidence that we seek to provide the **T1 assessment will be the primary comparison.**

10.2. Assessment of harms: Based on the original study, in which no adverse events were reported, we consider Action 3:30 to be low risk with high potential benefits. It is likely that some children may report minor injuries (e.g., bumps and falls) but such instances are in keeping with school activities and will be recorded in accordance with normal school procedure. We will ask the school to notify us of any more serious instances, such as hospital admissions or adverse events, which are perceived to be study-related. Adverse events will be reported to the Principle Investigator who will report to the co-applicants and chair of the ethics committee. Adverse events will also be a standing item on all Trial Management and Trial Steering Committee meetings.

11. Proposed sample size

The proposed sample size is up to 30 children per school. The maximum sample size is therefore 360 children (30 x 12 schools). This study aims to demonstrate the feasibility of recruitment, and provide early evidence of the intervention's potential for increasing activity in both girls and boys. Twelve schools will estimate the recruitment rate with sufficient precision for planning the definitive trial; under the assumption that the 12 schools will have a total of around 900 pupils in years 4 and 5, a true 25% recruitment rate (225 pupils) will be estimated with approximate 95% confidence interval of 22 to 28%. Further, assuming 112 boys and 112 girls, equally split between intervention and control schools, a true difference between groups in mean weekday MVPA of 10 minutes will be estimated for boys and girls separately with 95% confidence interval of approximately 2.5 to 17.5 minutes, assuming a t-distribution for the sampling error, and a standard deviation of 20 minutes [previous study results suggest this SD].

12. Data analysis

Statistical analysis: The statistical analyses from this study will focus on the characteristics of the sample, levels of data provision, process evaluation, evidence of promise for the intervention, the collection of cost data and estimating the sample size for a future definitive trial.

Participant characteristics: Initial analysis will examine the characteristics of the sample including if we were able to recruit low-active children and if there were differences between participants recruited via the standard versus enhanced recruitment method schools. These comparisons will explore whether there were differences in the characteristics of children who joined the study at the second enrolment compared to those who joined at baseline. We will use descriptive methods to describe the participants and how they compare to the overall sample of eligible pupils in the school. A CONSORT flow-chart will include the numbers of children eligible to participate, who agree to attend the after-school clubs at each of the two recruitment points, who attend sessions and who provide follow-up information. A CONSORT flowchart will give separate recruitment figures for schools trialling Recruitment Strategies A and B (please see page 26 for an uncompleted version of the flowchart). The proportion of eligible students recruited will be

presented with a 95% confidence interval. For eight schools, the characteristics of children signing up versus those not signing up to the programme, such as physical activity from PAQ-C scale, year group (Year 3 or 4 during the recruitment phase Year 4 or 5 during intervention period) and gender, will be compared using descriptive statistics. For the other four schools we will also compare the T0 levels of weekday MVPA of those who sign-up and those who do not.

Data provision, intervention effect: Data provision rates for accelerometer (missing, invalid, valid) and questionnaire data (missing vs. not missing) will be recorded at both measurements. We will examine whether attending Action 3:30 affected the PA levels of children attending the intervention compared to the control group. We will also examine the physical activity profile of children who did not attend to assess whether their baseline physical activity levels were different to children who attended. Change in mean activity over the intervention period will be presented with 95% confidence intervals for intervention and control schools separately, and further divided to present the findings for girls and boys separately within the two study arms. Mean change in activity in those children recruited to the intervention once it is underway will be presented separately. All analyses will be completed after T1 data have been collected and there will be no interim analyses.

Once the main analysis has been completed we will conduct a secondary analysis in which we will pilot the use of a complier average casual effect (CACE) analysis [41] for the four schools that used the "accelerometer out-out" consent procedure. This model will examine the effect of receiving Action 3:30 on MVPA (original recruits and late joiners) when compared to the control arm. This analysis, which will facilitate the use of the data from all children who were eligible to join the study in the intervention and control schools will provide an indication of the overall benefits of the study for all participants who were exposed to Action 3:30 as part of the original sample and late joiners. *A detailed statistical analysis plan (SAP) will be produced and shared with the independent Trial Steering Committee (TSC) prior to any analysis.*

Blinding: The primary analysis will be conducted by a statistician in the Bristol Randomised Trials Collaboration who will be blinded to allocation for the primary analysis. The statistician will then be un-blinded to conduct the CACE analysis. In light of the nature of the project it will not be possible to blind the Trial Manager or Fieldworkers as they will be collecting both the outcome and process evaluation data.

Process evaluation: Session attendance will be graphically presented, by school and overall. Mean attendance per session and by gender will also be calculated. The same process will be adopted for session enjoyment. The extent to which sessions were delivered according to the session plans (TA reported and observations) will be presented graphically. Interviews with TAs, and boys' and girls' focus groups will be analysed to identify codes and themes which pertain to the successes or challenges in session delivery and receipt and identifying refinements with a particular focus on differences in the experiences of girls and boys. Session observation notes will be analysed qualitatively and used to triangulate the TA and participant findings and provide a qualitative indication of fidelity to the underpinning theory.

Economic assessment: Action 3:30 costs will be categorised as research costs, non-recurrent development costs, one-off training costs and recurrent programme delivery costs. Costs will be estimated treating resource use and prices separately, to examine the feasibility and appropriateness of the costing methods that would be needed to estimate variation in the cost of implementation at the school level in a definitive trial. Mean changes and variation in KIDSCREEN and CHU9D scales and health related quality of life scores will be estimated at the school level. The surveys conducted at T0 and T1 will also be used to assess if there were any changes to after-school physical activity provision (number of clubs, funds allocated) between the two time points and if this differed between intervention and control arms. These descriptive analyses are intended to assess whether the provision of Action 3:30 clubs increased the intended after-school physical activity provision in the schools.

Sample size: Potential sample sizes for a future definitive trial will be estimated using the derived ICC for MVPA from this study and published ICCs from comparable studies and based on different combinations of key parameters (type I and type II error).

Qualitative analysis: Digital recordings of all interviews and focus groups will be transcribed. Thematic analysis techniques, utilising QSR N-Vivo 8, will be employed to produce initial codes categorising the content of each transcript. The initial codes will be iteratively refined to produce emergent themes. We will examine divergence and similarities across interviews and compare the experiences of the intervention across pupils, TAs, all key contacts and academy chain leads / potential commissioners. We will examine factors that might have affected recruitment, delivery, behaviour management, attendance, enjoyment, anything that could be improved, potential contamination, and any inequalities that might affect future delivery. The academy chain leads / potential commissioner interview analysis will focus on changes that could be made prior to a full-trial to ensure that the intervention delivery in the trial mimics the most likely dissemination approach. Finally, the interviews conducted with class teachers and key contacts in the four schools that piloted the "opt-out" accelerometer protocol will be analysed to identify the burden on the schools, likely impact of the process on school recruitment to a future trial and any practical suggestions that could be implemented to improve the data collection process in the schools.

RE-AIM evaluation: Potential for population impact in real world settings is something that commissioners/sponsors value in making resource allocation decisions. We will use all data collected in this study **to operationalise the dimensions of RE-AIM to estimate the potential population impact of Action 3:30 in a definitive trial**. Table 2 provides an overview of all the information that we will collect in relation to the RE-AIM assessment of Action 3:30. At the end of the feasibility study the table will be populated and any gaps that would need to be assessed in a definitive trial identified. In addition, costs will be examined from the perspective of implementing Action 3:30 in schools and combined with other evidence from the process evaluation to understand potential for population impact.

Table 2: Action 3:30 Feasibility Study - RE-AIM Framework & implications for a definitive trial

RE-AIM dimension	Outcomes	Possible to measure? Yes / no	What measure / tool?	Ready for use in a definitive trial? Yes / no
Reach	**Engagement and participation** School response rate Participant response rate			
	Participant characteristics compared to non-participants Date of birth, gender, PAQ-C			
	Exclusion criteria # parental consent, children who cannot engage in physical activity lessons			
Effectiveness	Measure of primary outcome: • Weekday MVPA minutes			
	Measure of secondary outcomes: • Mean KIDSCREEN-10 scores • After school travel mode • Self-reported self-esteem			
	Use of qualitative methods to understand effectiveness			

Adoption – Setting	Percentage of school settings that continue delivery once formal intervention has ended			
	Use of qualitative methods to understand adoption at setting level			
Adoption Staff	• Percentage of teaching assistants (TAs) invited that participate and complete delivery Action 3.30			
	• Use of qualitative methods to understand TA participation			
Implementation	• Delivery (Manual Fidelity)			
	• Cost of delivery (resource use and prices)			
	• Consistency of implementation and (cost) across schools			
	Use of qualitative methods to understand implementation			
Maintenance	Definitive trial needed to assess this domain			

13. Ethical arrangements & data confidentiality: This study has received ethical approval from the School for Policy Studies Ethics and Research Committee at the University of Bristol (ref SPSREC16-17.B2). Parents of children who agree to take part in the study will be asked to provide written informed consent for their child's participation. Adult participants (TAs and school contacts) will provide written informed consent.

Questionnaire data will be downloaded from tablet devices to study databases, stored anonymously using numerical identification codes and then deleted from the tablet. Interviews and focus groups will be recorded using encrypted digital devices. Audio files will be sent to a University of Bristol authorised transcription service using a secure file transfer link, transcribed and then anonymised by the study team. All data will be stored on password protected university networked computers. A separate database of participant names and unique identification numbers will be stored securely and in a separate location to the study data. In reporting the results of the process evaluation, care will be taken to avoid the identification of participants through quotations. All participants will be made aware of the limits of confidentiality and that the research team will break confidentiality according to a protocol approved by the School for Policy Studies Research Ethics Committee should they feel that a child is at risk of harm.

14. Research Governance: We will instigate 4 groups to govern and guide the study. We will form a **Trial Management Group (TMG)** which will be chaired by Prof Jago and include all applicants, the Trial Manager and study staff. The TMG will meet every month to discuss key issues with meeting frequency increased if necessary. In addition Prof Jago will meet with the Trial Manager at least every 2 weeks to address day-to-day issues. We will invite a representative of the **Local Advisory Group (LAG)** to attend and provide input at a TMG meeting at least every 4 months.

LAG membership will be drawn from the two local authority areas in which we will be working and include TAs, Headteachers, parents and Local Authority physical activity staff. The LAG will meet five times. During the recruitment and optimisation phase the LAG will meet twice to guide on recruitment, training, session delivery and data collection. The LAG will meet twice during the intervention to advise on school related / intervention issues. At the end of the project, the LAG will be asked to provide feedback in terms of interpretation of findings and progression to a full-trial.

A **Children's Advisory Group (CAG)** will be formed from children in four intervention schools. We will recruit 2 boys and 2 girls enrolled in the study in each intervention school, one high active and one low from each gender. The committees will provide feedback on how the programme is perceived and any logistical issues. Each of the four separate groups will meet twice during the intervention period. **Information from the CAG will be shared with the LAG and TMG**.

We will form a **Trial Steering Committee (TSC)**. The TSC will include an independent chair plus two independent members and senior members of the study team. We will also invite a representative of the LAG to join the TSC and ensure that the views of the LAG and CAG are represented. The TSC will meet at least three times during the project and provide independent scientific scrutiny of the project, guidance on progression to a definitive trial, and support to the project team. (Please note that we have not planned to have a data monitoring and ethics committee (**DMEC**) as it seems unlikely that such a committee is needed for this project). We will, however, ask the TSC at the first meeting if they feel that such a group is necessary and, if needed, we will instigate such a committee and seek additional PHR resource). *We will specifically seek input from the TSC on the whether the data collected from this study suggests that the additional data provided by employing an "opt-out" accelerometer data collection process warrants the additional research costs and school burden. The input from the TSC on this issue will be used to help decide on the final design of a definitive trial if the progression criteria have been met.*

Sponsorship & Trial registration: The University of Bristol has agreed to act as the sponsor for this study. We will register the trial with the International Standard Randomised Controlled Trial Number Register prior to starting and will submit the trial protocol for publication.

15. Project timetable and milestones: The project will commence on 01/04/17 for 18 months. Specific milestones and date are shown below in bold with an asterix.

Date completed	**Task**
	Pre-study
Oct-Dec 2016	Interviews with parents of low-active Year 4 children participating in the B-PROACT1V project.
Jan 2017	Enhanced recruitment methods finalised
Jan 2017	Ethics submission and staff recruited
	Main study
April 2017	**Project starts***
	School and pupil recruitment starts
April 2017	**TSC Meeting 1***
	Trial registered
May 2017	**T0 data collection begins*** 1st Intervention optimisation focus groups with year 4 pupils LAG / CAG Meetings
June 2017	**Protocol paper submitted***
July 2017	**T0 data collection completed*** 2nd Intervention optimisation focus groups with year 4 pupils **Randomisation and schools notified of allocation*** LAG / CAG Meetings
August 2017	Final changes to intervention
Sept 2017	TSC Meeting 2
Oct 2017	**TA Training complete, Intervention starts***
Oct – Feb 18	Process evaluation conducted
Oct – Feb 18	LAG / CAG Meetings
Feb 2018	**T1 Assessment***
March 2018	Qualitative and Quantitative analysis begin
July 2018	Quantitative and quantitative analysis complete

July 2018	Quantitative and quantitative analysis complete
August 2018	Papers submitted
August 2018	**TSC meeting 3 including review of progression criteria***
Sept 2018	**Project end, trial report submitted***

16. Expertise: This project brings together a team who have all of the skills and experience necessary to deliver the proposed research. With the exception of Dr Metcalfe (who has replaced Dr Alan Montgomery as lead methodologist and statistician) this is the same team that delivered the original Action 3:30 study and we have excellent working relationships. Team members are:

Russell Jago is Professor of Paediatric Physical Activity and Public Health at the University of Bristol. He has expertise in leading the design and evaluation of feasibility and full-physical activity based RCTs with children, optimising recruitment and retention and measuring physical activity.

Darren Gillet is Sport, Play and Coaching Manager at Bristol City Council. Mr Gillet developed the Action 3:30 intervention in partnership with the academic team. He will advise on all school and Teaching Assistant related issues.

Chris Metcalfe is Reader in Medical Statistics & Co-Director of the Bristol Randomised Trials Collaboration (BRTC) a UKCRC accredited clinical trials unit. Dr Metcalfe has extensive experience as the lead methodologist on a number of RCTs. Dr Metcalfe will lead all statistical analyses, BRTC input to the study and will manage the Statistics Research Assistant.

Jane Powell is Professor of Public Health Economics at the University of the West of England. Prof Powell has extensive experience of conducting cost-effectiveness analyses and modelling of complex interventions in randomised and non-randomised trials. Prof Powell will lead the economic analyses of the study. Ms Emma Bird, who is an experienced Health Economist will support Prof Powell in conducting the economic analysis of the project.

Simon Sebire is Senior Lecturer in Physical Activity & Public Health at the University of Bristol. He has experience in designing, implementing and evaluating complex feasibility trials within schools, integrating behavioural theories into interventions, and qualitative process evaluation. Dr Sebire will lead the process evaluation project.

The study is adopted by the Centre for the Development and Evaluation of Complex Interventions for Public Health Improvement (DECIPHer) - a UKCRC Public Health Research Centre of Excellence. The project team is also working with the Bristol Randomised Trials Collaboration.

17. Partner Collaboration: This project builds on our existing collaborations with local schools and education authorities. As noted above we will ask local teachers, TAs and physical education specialists to join our Local Advisory Group and we have a well-established track record of working in partnership with these groups. The intervention is also a partnership with Bristol City Council (represented by Darren Gillet) as well as both South Gloucestershire Council and North Somerset Council who have agreed to **fund the intervention costs for the proposed research (please see attached letters of support)**. In addition, these collaborators have also agreed to facilitate the recruitment of schools within their respective areas and a team member from both Bristol and North Somerset will join the Local Advisory Group.

The study is affiliated to the Bristol Randomised Trials Collaboration (BRTC) a UKCRC accredited trials unit based in the School of Social and Community Medicine for which Dr Metcalfe is a co Director. The study is adopted by the UKCRC DECIPHer (Development and Evaluation of Complex Interventions for Public Health Improvement) Centre, which is based jointly at Universities of Bristol, Cardiff and Swansea and is directed by Professor Rona Campbell who is based in the

School of Social and Community Medicine at the University of Bristol. Professor Jago leads physical activity, diet and obesity work in DECIPHer. We will also draw on the experience of our DECIPHer colleagues to facilitate dissemination to academic and non-academic audiences.

18. Dissemination plan

We will produce a separate publication plan, which will outline the planned outputs, data access policy and publication timelines. The dissemination plan will be shared with the Trial Steering Committee.

Project summary

The original Action 3:30 study showed that this intervention has the potential to improve the physical activity of children. However, in the original study the intervention was more effective for boys than girls and recruitment strategies required improvement. We also identified that it would be important to identify whether it possible to increase external validity by allowing a second enrolment of pupils. The goal of this study is to systematically test, via a feasibility study, if addressing these issues results in a public health intervention that shows sufficient promise to warrant evaluation via a larger, cluster randomised controlled trial. We have shaped this study to focus on the implementation potential of Action 3:30 and ensuring that we can design a study and intervention that if effective can be implemented nationally and have used the RE-AIM framework to guide this work. **It is envisaged that if a definitive trial provided evidence of a benefit for participants, that Action 3:30 is a public health programme that could easily be scaled-up for dissemination. Acton 3:30 therefore has the potential to have a national impact on children's physical activity, but the first step in that process, is to assess the feasibility of conducting a trial of the revised intervention.**

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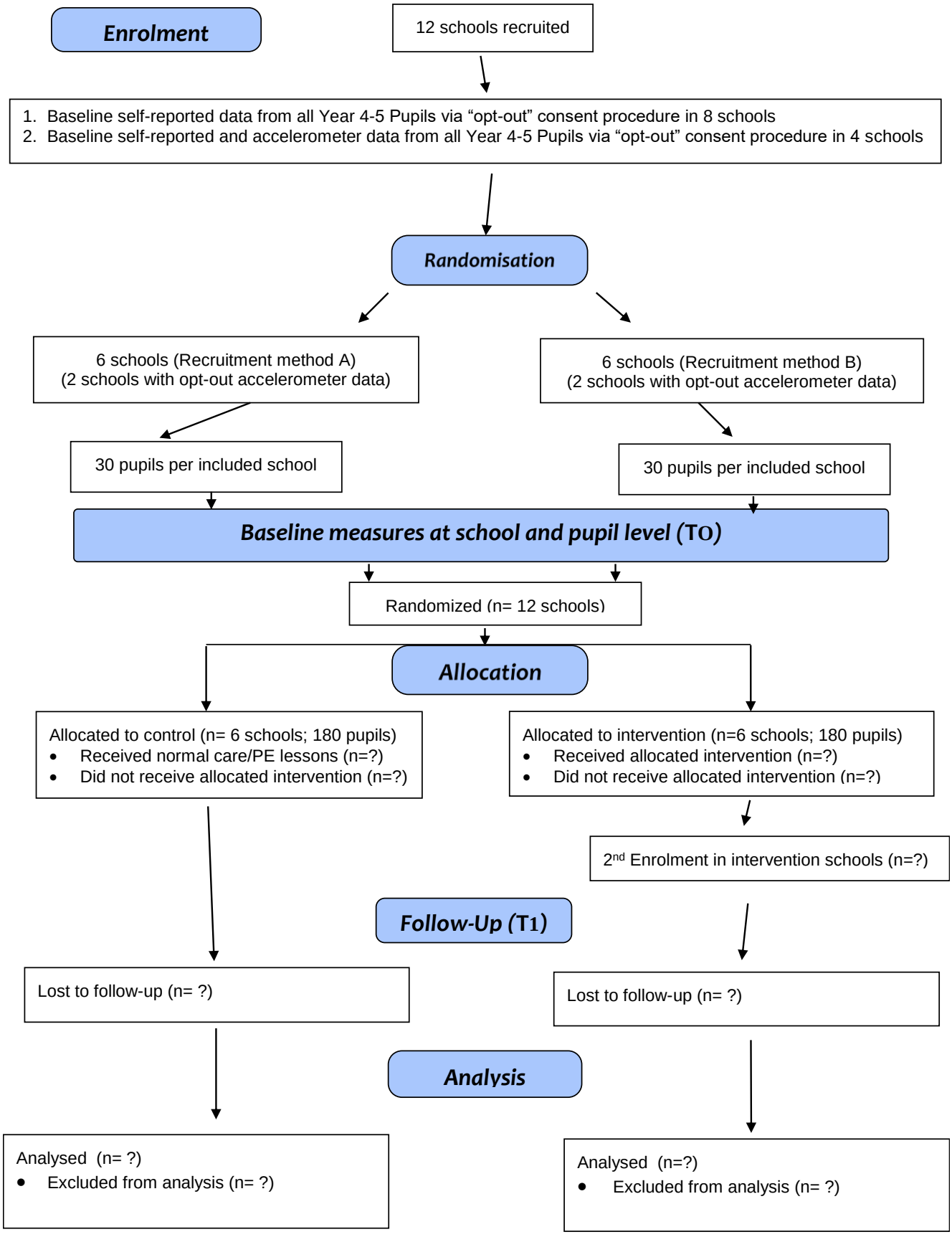
This protocol refers to independent research commissioned by the National Institute of Health Research (NIHR). Any views and opinions expressed therein are those of the authors and do not necessarily reflect those of the NHS, the NIHR, the PHR programme or the Department of Health.

CONSORT FLOWCHART



Action 3:30 - Logic Model