1. **Project title:** Development and feasibility cluster randomised controlled trial evaluation of a Peer-Led physical Activity Intervention for Adolescent girls (PLAN-A)

2. Background

2.1 Existing Research

Girls' physical activity and the transition to secondary school: Among adults physical activity (PA) is associated with reduced risk of heart disease, stroke, type 2 diabetes and all-cause mortality.[1] Among children and adolescents PA is associated with lower levels of cholesterol and blood lipids, favourable blood pressure and body composition.[2] These risk factors are more prevalent in children of lower socioeconomic position.[3] There is also some evidence that PA is associated with young people's well-being, self-esteem[4] and academic performance.[5] Physical activity tracks moderately from early to late adolescence and into adulthood.[6,7] Despite the benefits, PA levels decline during childhood (7% per year)[8] and girls are less active than boys.[9] The age-related decline in PA, particularly from early adolescence, is steeper for girls than for boys and only 10% of girls in the Health Behaviour in School-age Children study aged 11-15 participated in 60 minutes of moderate-to-vigorous PA (MVPA) per day.[10] In England, when measured objectively, 96% of girls aged 11-15 performed less than 30 MVPA per day and none met Government recommendations.[11] **Thus, there is a specific need to increase the PA of 12-13 year old girls.**

Systematic reviews suggest that psychological correlates of girls' PA participation include enjoyment, perceived competence, self-efficacy and physical self-perceptions.[12] Qualitative research suggests that changes to friendship groups, peer support, changes in perceived competence, competing priorities, self-presentational concerns and "sporty" gender stereotypes experienced during the transition from primary to secondary school may contribute to the observed decline in girls' PA.[13-15] A recent systematic review showed that PA interventions aimed at young girls produce small but significant positive effects.[16] Importantly, larger effects were observed for interventions that targeted girls only, rather than girls and boys, and used educational and multi-component designs. The overall small effect of PA interventions involving younger girls suggests that it may be possible to increase girls' PA, but new and more effective interventions are needed. **There is thus a need to develop and test PA interventions targeting adolescent girls.**

Promoting young people's health in schools is a public health priority[17] and school-based interventions can reach many girls over a sustained period. However, a recent Cochrane review of school PA interventions showed that none were conducted in the UK involving adolescents and the non-UK interventions did not increase adolescents' PA.[18] Current school-based interventions have focussed on "top-down approaches of providing education and short-term structured PA" [18] and there is a need for alternative designs. One way to approach this is to develop interventions which capitalise on naturally-occurring determinants and sustainable health promotion mechanisms (i.e., peer groups and their influence on PA) to promote long-term PA.

Peers & physical activity: Peers play a central role in adolescents' PA.[19] A recent systematic review identified six categories of peer influence (peer support, presence of peers during PA, peer norms, friendship quality, peer affiliation and peer victimisation)[19] and found evidence for consistent positive associations between peer support, presence, norms and quality and PA/determinants of PA. The importance of peers in young people's PA is further supported by recent social network research which has shown that adolescents choose friends who are similarly active and they may moderate their PA behaviour over time to be more like that of their friends.[20] Both systematic reviews support the potential of peer-led interventions to increase adolescents' PA. One review[19] highlighted the **need to develop interventions, especially amongst girls, to increase PA which capitalise on existing peer processes in schools by promoting peer support and enhancing peer communication skills**. **This study will develop such an intervention.**

Peer-led health interventions: Peer-led interventions have targeted a range of health behaviours amongst young people including smoking, asthma, alcohol consumption, drug use, PA and sedentary behaviour.[21-23] A review of 12 peer-led health interventions[24] identified that the majority were delivered in secondary education and trained peer-leaders to educate their peers through

information provision and skill development. Seven were effective in changing a behavioural outcome, three changed psychological mediators and two were unclear in their effect.

A recent systematic review examined the effect of peer-led PA interventions.[23] Of the ten interventions identified, only two targeted young people (1 small special population & 1 poorly reported study) and none were conducted in the UK. Overall, consistent positive effects of the interventions on PA behaviour were identified, suggesting that such interventions are viable. A number of limitations to existing research of peer-led PA interventions were identified; (1) there are no high quality controlled trials conducted amongst adolescents, (2) interventions are largely atheoretical and (3) peer-peer education is limited to formal delivery methods (e.g., leading educational classes, co-participation & giving advice) which are time limited and intensive.

An alternative peer-led approach is to train peer-supporters to informally diffuse health promotion messages to their peers. This approach is based on Diffusion of Innovations Theory (DOI)[25] which conceptualises how ideas, beliefs or behaviours are informally communicated through members of a social system (see section 2.2) and was adopted in the ASSIST (A Stop Smoking in Schools Trial) study (Prof Campbell Principal Investigator).[21] This intervention involves training a proportion of pupils within a school year group, identified by their peers as influential, to informally diffuse messages about being smoke-free for 10 weeks. The effectiveness of the ASSIST intervention was examined in a cluster RCT comprising 10730 pupils aged 12-13 within 59 schools in England and Wales. Pupils who received the intervention had lower odds of being a smoker compared to pupils in the control condition immediately after the intervention (OR = 0.75, 95% CI = 0.55 to 1.01) and at one (OR = 0.77, 95% CI = 0.59 to 0.99) and two (OR = 0.85, 95% CI = 0.72 to 1.01) year follow up.[21] The findings suggest that **informal school-based peer-led interventions can be effective in changing health behaviours. However, no studies have yet specifically focussed on peer-led PA interventions that utilise DOI Theory.[25] The proposed study will address this gap.**

2.2 Theoretical background

Interventions which target theoretical mechanisms of behaviour change are likely to be more effective than those that do not.[26] However, few peer-led PA interventions incorporate theoretical principles.[23] The present study combines two complementary theories: DOI Theory[25] and Self-determination Theory (SDT).[27] As a cornerstone of the study, DOI provides a framework for harnessing the influential capacities of *change agents* (e.g., Year 8 girls identified as opinion leaders by their peers) who can informally diffuse messages about being active amongst their peers and in turn influence shifts in beliefs/attitudes and adoption of new behaviours. SDT concerns the personal and social conditions needed to foster high quality and sustainable motivation and has been applied extensively to understand motivation for PA amongst children and adolescents[15,28,29] and guide PA interventions[30], including a peer-led PA intervention for older adults.[31] SDT contends that autonomous motivation for PA (based on authentic choices, inherent satisfaction or personal value) is associated with positive behavioural, affective and cognitive outcomes, whereas controlled motivation (based on guilt or compliance with others' demands) undermines these outcomes. Autonomous motivation is supported by the degree to which the social environment satisfies, and individuals perceive the satisfaction of, three psychological needs- autonomy, competence and social belonging.

Research amongst children, adolescents and adults has identified positive associations between autonomous versus controlled motivation and PA[29,32 33] positive affect, challenge-seeking[33] and quality of life.[34] Further, autonomous motivation is positively associated with psychological need satisfaction.[29,35] SDT is well suited to a peer-peer intervention model because peers can create a social climate that can either undermine or facilitate girls' interest in PA[23] and other determinants including health and affiliation motives, perceptions of competence, connectedness and social support, and realistic choices and options of how to be physically active.[13,15]

Within the proposed intervention, SDT will be used in a layered manner informing both the delivery and the content of the peer-supporter training. ***Delivery***: peer-supporter educators will be trained in how to facilitate the training in an autonomy-supportive way to increase autonomy (e.g., empowerment to support peers and provide choice), competence (e.g., confidence in how to be an

effective peer supporter) and belonging (e.g., supportive network of peer supporters). *Peer training content*: this will be designed to encourage peer supporters to recognise and promote autonomous rather than controlled motivation for PA (focussing on health, challenge-seeking & social affiliation reasons rather than appearance & peer pressure), support peers' needs for autonomy, competence and belonging and use autonomy-supportive language when diffusing PA messages (e.g., *"I'm going to walk to school will you come with me"* vs. "*you need to do more activity so you don't get fat*"). **Combining complementary theoretical approaches will allow the intervention to target psychosocial ingredients that are candidate mediators of any intervention effect.**

2.3 Pilot and formative work:
This project builds on the successful ASSIST intervention[21] and information gained from the Activity and Healthy Eating in Adolescents (AHEAD) study (PI: R Campbell, completed 2009) which tested the acceptability and feasibility of a peer-led intervention, using the ASSIST model to target healthy eating and PA amongst 928 Year 8 boys and girls (79 peer supporters) from six schools.[36 37] Results showed that it was feasible to adapt ASSIST to focus on healthy eating and PA and that the intervention was acceptable. However the intervention did not show evidence of promise in changing either behaviour. The authors concluded that focussing on both healthy eating and PA was too demanding and complex for trainers to deliver and for peer-supporters to understand and diffuse. There was limited discussion of PA and the mixed gender training prevented exploration of barriers to PA faced by girls. The intervention was also expensive with large costs attributed to the equipment and resources needed for the healthy eating component. We will build on the successes of AHEAD (recruiting peer-supporters, engaging them in training) and address its limitations **by developing a more cost effective new intervention which targets simpler but more comprehensive messages, specifically targetting adolescent girls' PA.**

In 2013 one of our MSc students undertook research focussed on the views and attitudes towards PA in a sample of 13-14 year old girls who self-identified as being disinclined towards PA (41% of 110 girls). Interviews with 15 girls revealed themes related to the development and maintenance of their disinclination: (1) the importance of the transition to secondary school, (2) peer groups and changes in peers, (3) an "inactive identity", (4) low perceptions of competence and (5) PA among competing priorities. These results, and importantly the direct quotes from the girls, will be used to inform the topics that the peer-education intervention will target and provide "real life" examples for participants to reflect upon and try to resolve within the peer-supporter training.

We have also conducted formative research with adolescent girls and a teacher to inform the development of this application: a focus group of six adolescent girls aged 14-17 from the DECIPHer (Centre for the Development and Evaluation of Complex Interventions for Public Health Improvement) ALPHA group was conducted to explore the design of the intervention. A female PE teacher from a local secondary school was also interviewed. Table 1 shows the question topics, summarised findings and the implications for the intervention design.

Table 1: Findings and implications of adolescent and teacher public involvement.

Question topic	Findings	Implications for PLAN-A design
Peer-education concept	● Concept is clear. Friends are powerful in setting trends. PA is very peer driven ♦ Peer-mentoring used already in academic support ♦ Supportive of 10-week intervention duration	• Concept will make sense to Yr 8 girls • Schools open to peer-mentoring
How to encourage peer-supporters to participate	• Sell the benefits (e.g., build peer-supporters' CV) • Provide certificates • Use videos of Yr 8s from the pilot in recruitment • Refer to long-term benefits ♦ Sign of Kudos as nominated by peers	• Explore other "benefits" in Phase 1 focus groups • Make video messages of peer supporters from pilot intervention
Peer-supporter training content and logistics	• Non-school location & young female training staff • Consensus for girls only intervention • Focus on health and not appearance • Provide route map to local PA opportunities	• Trainer and location • Explore use of health messages • What information is needed about local PA opportunities?

	♦ Focus on PA primary-secondary transition issues ♦ Balance theory and practice – team building, fun.	
PA terminology and how PA fits into the life of adolescent girls	• Avoid complex terms, just talk normally • Relate activity to Yr 8 everyday life • Identify times for incidental PA (Active travel) • Explore a day in the life of a Yr 8 for PA	• Simplify terms • Design activities to relate to Yr 8 lives • Peer-education on incidental PA
Diffusing messages amongst peers	• Peer supporting & compromise not pressure • Frame messages in Yr 8 terms "what are you doing tonight?" to encourage PA	• Focus training on peers supporting not "instructing" and negotiation skills
Using social media	• Support for Twitter, Instagram ("Active selfies"), Facebook page for peer-supporters. • Research team-peer and peer-peer idea sharing • Social media valued more than SMS ♦ Social media supported	• Integrate social media • Facilitate photo sharing • Use social media to support peer-supporters during the intervention

Note: ● = adolescent findings; ♦ = Teacher findings.

2.4 Risks & benefits

Benefits: PA levels of adolescent girls are low[10] and there are major public health and economic gains to society from preventative interventions that reduce the economic burden associated with low PA and high levels of obesity. Local Health and Wellbeing Boards need robust scientific evidence on which to commission future health services and school-based preventative strategies need to be evidence-based. If the proposed intervention is shown to be feasible and later effective, the intervention could be disseminated widely. Potential participant benefits include increased PA, improved health and self-esteem. Peer supporters may further benefit from engaging in non-curricular activities and developing their communication and leadership skills.

Risks: We do not envisage many risks associated with study involvement. There is the potential that peer-leaders may not be well accepted and teased for this role. However, as the peer-supporters are nominated by their peers and their role is informal, the opportunity for teasing is minimised. This view was supported in the teacher interview. Although the peer-education will seek to minimise negative outcomes, we will examine whether the intervention had any unintended consequences (e.g., disrupting peer groups, creating cliques, de-motivating via increased social comparisons of PA level) through the proposed qualitative process evaluation.

2.5 Rationale for the current study

PA during childhood is associated with positive physical and psychological health. PA levels decline during childhood and girls are less active than boys. By early adolescence, few girls are sufficiently active and interventions are needed which address the particular barriers associated with girls' non-participation. The provision of structured PA opportunities is likely to appeal to and reach a limited group and such opportunities are transient which threatens the longevity of behaviour change. Interventions embedded within girls' everyday lives represent an alternative and peers offer a powerful, natural and sustainable intervention opportunity which has received little attention. Peers are central to the lives of adolescent girls, and have a strong influence on behavioural decision making. There is therefore great potential in interventions which harness the power of peer processes within schools to increase girls' PA.

The MRC framework for the development of complex interventions highlights that they are likely to be most effective if designed via an iterative process that is based on prior knowledge and which progressively builds the evidence base.[38] The current project therefore includes formative research (Phase 1) to refine an existing intervention which focuses on a new target behaviour. Specifically, we will refine an existing health-based peer-education intervention package to support girls aged 12-13 years to maintain or increase their PA and that of their peers. We will then conduct a feasibility trial of the PLAN-A intervention (Phase 2).

3. Research objectives:

Phase 1: the formative research objectives are:

1) To adapt and refine the ASSIST intervention to develop a peer-supporter training programme which focuses on promoting PA amongst Year 8 girls.

2) To develop an intervention logic model to refine in the feasibility trial.

Phase 2: the feasibility trial research objectives are:

3) To estimate the recruitment rate of peer supporters and attendance at peer-supporter training.
4) To examine the acceptability of the intervention to schools, pupils, peer-supporter trainers and parents to identify what refinements are necessary.
5) To estimate questionnaire and accelerometer data provision rates, examine data quality and explore the implications of missing accelerometer data in terms of how this data might be imputed in a definitive trial.
6) To examine the proportion of participants who consent to and provide the necessary data to allow linkage to their academic achievement record through schools and the local education authority and to health records.
7) To estimate the potential effect of the intervention on daily accelerometer-derived MVPA and secondary activity-related and psychological variables immediately after the intervention and at 6-month follow up.
8) To estimate the school-related intra-class correlation (ICC) for daily MVPA, combining data from this project with our data from other local secondary schools.
9) To explore through qualitative process evaluation the acceptability of the intervention and the influence of school context on intervention implementation.
10) To identify and test the feasibility of collecting the data needed to cost the intervention and conduct a cost-effectiveness analysis.

4) Research design

The study is organised into two phases; Phase 1 (8 months) comprises public involvement, intervention refinement and piloting. Phase 2 (22 months) comprises a feasibility cluster randomised controlled trial (RCT) and assessment of how the intervention could be improved.

Phase 1: (8 months) will consist of two elements. In Part A we will develop the peer-led intervention and in Part B we will conduct a pilot study in one school. Details are below:

1. Developing peer-education programme: Building on the findings from the public involvement (Section 2.3) we will adapt the ASSIST intervention model to develop a two-day (+1 "booster training day") peer-supporter training programme that will educate girls about PA and develop their skills in communication, negotiation and peer-supporting. We will adapt successful activities from the ASSIST peer-supporter training to the PA context, and add new content specifically targeting PA issues identified by adolescent girls.[13,15] We will then conduct further public involvement with adolescent girls in Year 8 to seek feedback and ideas on refinements and incorporate their changes into the training. Two semi-structured focus groups will be conducted iteratively with Year 8 girls (N = 6-8 per group) from the pilot school. We will present participants with proposed peer-supporter recruitment approaches and materials, training activities/materials and terminology and seek their views on acceptability and refinements. We will also seek the participants' views on how to avoid bullying/distress in the peer-nomination and support processes and their views on dealing with this should it occur. We will also develop the three-day training programme and manual for the peer-supporter educators. This training will cover the aims of the intervention, key messages about adolescent girls' PA, teaching style, and practical guidance on facilitation. Following refinements we will seek the girls' views again to ensure the intervention reflects current opinion.

2. Pilot intervention: We will conduct a pilot of the peer nomination, recruitment process and peer-supporter training among Year 8 girls recruited from one pilot study school in order to rehearse all components and diagnose/resolve any problems in these elements before the feasibility trial. The recruited school will be above the median of the Pupil Premium Indicator (an indicator of socioeconomic position of the children in schools). The pilot intervention will follow the protocol of the main feasibility intervention (see Section 7). We will conduct peer-nomination and recruit at least 15% of the female Year 8 cohort to be peer-supporters. We will train the peer-supporter educators and conduct the peer-supporter training. At the end of the final day of peer-supporter training, two semi-structured focus groups with the peer-supporters (N ≈ 15) will identify

areas for improvement in peer-nomination, peer-supporter training, peer-educator delivery, resources and content. We will ask peer-supporters to return to school and diffuse physical activity messages. We will conduct a focus group with the peer supporters to gather feedback on their experiences to inform the Phase 2 intervention. Semi-structured interviews with two peer-supporter educators will examine their views on the peer-educator and peer-supporter training. Focus groups and interviews will be analysed thematically and results triangulated to inform refinements to the intervention.

Phase 2: (22 months) the acceptability and feasibility of the refined intervention will be examined via a cluster RCT. This phase will address research objectives 3-10.

Setting: Eligible settings will be secondary schools in Wiltshire and South Gloucestershire which are above the median of the local Pupil Premium Indicator (i.e., more deprived). Special educational schools will be excluded. 14 schools in Wiltshire and 8 in South Gloucestershire are above the median PPI. Six schools will participate in the feasibility trial, three from each area.

Recruitment of schools: All schools which meet the inclusion criteria stated above will be invited to participate via a letter to the Head/Deputy Head Teacher including study information. Non-responding schools will be followed up by email and phoned if necessary. Schools wishing to participate will be contacted and provided with further information. Schools will be asked to express an interest in participating in the study (i.e., a simple response to a study invitation letter, phone call and/or email). If more than eight schools volunteer to participate, schools will be selected at random to enter the study. Two reserve schools (one per arm) will be recruited to allow for withdrawal of schools prior to baseline data collection.

Allocation: School is the unit of allocation. Six schools will be randomly allocated after baseline data collection has been completed; four intervention and two control schools. Allocation will be performed by a member of the Bristol Randomised Trials Collaboration (BRTC: a UKCRC-registered Clinical Trials Unit) who will be blind to the school identity and otherwise not involved in the study. Allocation of intervention schools will be stratified by school size (large vs. small: threshold to be determined after recruitment of schools) and geographical area. Control school allocation will be stratified by geographical area only.

Recruitment of pupils: A presentation will be made to all girls in Year 8 to inform them about the trial, including the nature of the intervention and control conditions and the chance of the school being in either condition. All girls will be invited to take part and given study information for themselves and their parents. Pupils nominated and selected to be peer-supporters will also be asked to agree to the role and assent to take part in the training and qualitative process evaluation.

Data Collection Procedures

Pupil measurements: Data will be collected at three time points; baseline (T0), immediately after the 10 week intervention (T1) and 12 months post-baseline (T2, 5-6 months post-intervention). Data will be collected in schools by the Project Manager supported by Fieldworkers. At each time point, pupils will wear an ActiGraph accelerometer for seven days to estimate levels of PA and sedentary time. Pupils will also complete a questionnaire assessing demographics, psychosocial outcomes (e.g., self-esteem) and potential effect mediators (e.g. peer support/perceptions of autonomy). To maximise data completeness and reduce data transcription errors questionnaires will be completed on tablet devices. We have used this approach in our recent Action 3:30 (MRC)[39] and Active7 (NIHR)[40] projects where we have achieved >94% data provision for all self-reported variables. (see Section 9 for details on all measures.)

Data linkage: Data linkage involves connecting participant-level study data with individual data held in non-study databases. It is good practice to obtain consent and assent to linkage to examine longer-term social and health outcomes. We will establish the feasibility of collecting parental consent and pupil assent, school and local authority permission and the pupil-level data required to link study data to broader pupil data held on school and local authority databases (e.g., academic achievement) and also to health records. Parental consent will occur in two separate steps, (1) opt-

out consent for the research study and (2) opt-out consent for the data linkage component of the research. Pupil assent will be obtained to collect identifiers (name, gender, address and date of birth) necessary for data linkage. Unique pupil identifier numbers will be requested from schools for all assenting pupils. This approach worked very well in a previous study.[3] We will conduct a number of case-studies (i.e. quality of identifiers) to examine the feasibility of linking data at school and local authority level for educational data and also to link to the NHS Personal Demographic Spine. Collecting these data will inform the potential use of data linkage in a future definitive trial as a cost-effective means of examining long-term broader social and health effects of the intervention.

Process evaluation and context: A detailed process evaluation of the feasibility RCT will examine acceptability of the intervention and methods, delivery, implementation, mechanisms of impact and the influence of school context[41] using qualitative and quantitative approaches among peer-supporters, non-peer supporter pupils, training deliverers and school contacts. Data collection and analysis will be undertaken by the qualitative Research Assistant using the following methods:

Informant	Method	Data
Peer-supporters	Questionnaire (N ≈ 77 in 4 schools)	Quantitative ratings of training, intervention, perceptions of influence
	Focus groups (1 per school, n ≈ 30)	Perceptions of training and intervention
Non-peer supporter pupils	T1 questionnaire	Items assessing perceived contact/conversations with peer-supporters
	Focus groups (1 per school, n ≈ 30)	Perceptions of receiving peer-support, research methods
Parents of pupils	Semi-structured interviews (n = 24)	Views on acceptability of training, intervention, influence of family context and study child's activity and attitudes.
Peer-supporter educators	Semi-structured interviews (n = 4) Observe training	Perceptions of peer-educator training and 2-day peer-supporter training; success, challenge, refinements. Observation notes of the training.
School contact	Semi-structured interviews (n = 8)	Peer nomination, training, intervention, difficulties and successes. Acceptability of research methods.
Context. School level data: size, pupil premium, school contact questionnaires assessing PA provisions, school policies, PA in the curriculum (PSHE) and school staff attitudes towards PA at T0.		

Economic costs: Data will be collected to allow the intervention costs to be estimated and to examine the feasibility and appropriateness of the methods and tools that would be needed to calculate cost-effectiveness alongside a definitive trial. The Project Manager will record cost categories such as intervention resources, venue costs, peer-educator time, expenses and travel and peer-supporter time. We will pilot the EQ-5D-Y[42] measure of quality of life.

Proposed duration and follow up: Following peer-supporter training, the intervention will last for 10 weeks. Baseline data collection (T0) will occur before randomisation to study arms at the beginning of Year 8. Follow up assessment will be immediately post-intervention (T1: the end of Year 8) and 12 months post-baseline (T2: the start of Year 9, 5-6 months post intervention).

Methods to protect against bias

We propose to use the following steps to reduce the risk of bias in a definitive trial. In the proposed research we will examine whether these steps are feasible and acceptable:

(1) Allocation: allocation to trial arms will be performed after recruitment, consent and baseline data collection is completed by a statistician in the BRTC not otherwise involved in the study.
(2) Contamination: whilst relocation of pupils between schools allocated to different trial arms is possible, we anticipate that this would be minimal and therefore have little impact.
(3) Blinding of participants: 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 a full trial, we will measure PA using accelerometers which do not provide any behavioural feedback.

(4) Incomplete outcome data: every effort will be made to obtain data from all participants who do not withdraw consent.
(5) Selective outcome reporting: a comprehensive statistical and health economic analysis plan will be developed for the feasibility trial before analysts are un-blinded. This will provide a parsimonious list of primary, secondary and subgroup analyses for use in the feasibility trial and the protocol of the definitive trial.

Criteria for progressing to a full trial:

Study Component	Proposed assessment & progression criteria
Feasibility	
Can we recruit peer-supporter educators?	• N of expressions of interest & target N (4) trained
Is it feasible to implement the PLAN-A intervention in secondary schools?	• Recruitment rate of peer-supporters (at least 15% female year group) • Focus groups with peer-supporters and non-peer supporters
Is it feasible to collect the consent and data needed for data linkage? (these will be monitored but they are not absolute criteria as data linkage is for longer term secondary outcomes in a definitive trial)	• 70% of parents providing consent to data linkage • 80% of unique pupil identifier numbers recorded • Qualitative feedback on data linkage case studies
Acceptability of the intervention	
Were the training and materials for the peer-educators and peer supporters acceptable?	• Interviews: peer-supporter educators & parents • Focus groups with peer-supporters
Was the intervention acceptable to schools?	• Interviews with school contact
Acceptability of the trial design	
Were trial design and methods acceptable?	• Recruitment of target N of schools (8) • 70% accelerometer and 85% questionnaire data provision (30% loss to follow up at T1 and T2 on full trial primary outcome - Accelerometer MVPA) • Interviews with control school contacts.
Evidence of promise	
Does the intervention show evidence of promise to positively influence the proposed primary outcome in a definitive trial?	• 95% confidence intervals around the point estimate of the difference in means between trial arms on daily minutes in MVPA to include approximately 10 minute difference.
Indications of affordability and cost-effectiveness for local authorities	• Estimation of the mean and range of intervention cost per school and cost per increase in MVPA.

5) Study population

The target population is girls aged 12-13 (Year 8) attending schools above the median of the PPI in Wiltshire and South Gloucestershire. There are 45 secondary schools in these areas, with 22 above the local PPI median. All female Year 8 pupils in intervention schools will be targeted in the intervention. A subgroup (≥15%) of the Year 8 girls in each intervention school will be trained as peer-supporters. *Inclusion criteria:* Participants will be required to provide parental consent and child assent. *Exclusion criteria:* Pupils who do not provide parental consent or child assent.

6) Socioeconomic position and inequalities

The study aims to reduce the disparity in PA levels amongst boys and girls. Boys are more active than girls[9] and girls face a distinct set of personal, social and physical barriers to maintaining PA in adolescence.[13] Our formative focus group with the DECIPHer ALPHA group similarly identified the gendered nature of PA and support for an intervention which focussed only on girls. We will recruit schools for the feasibility trial which are above the median on the Pupil Premium Indicator to examine the feasibility and acceptability of the intervention in schools with pupils who are of lower socioeconomic position. We will measure multiple dimensions of socio-economic position as listed in the PROGRESS-Plus[43] framework which are appropriate for the study population (adolescent girls) (e.g., IMD as a measure of place of residence, participant ethnicity, parent education, parent

occupation and parent income). In addition to parent-report factors we will ask adolescents to self-report whether they receive free school meals and complete the four-item Family Affluence Scale.[44] To ensure that we are not reinforcing health inequalities, in a definitive trial we would perform subgroup analysis based on an indicator of SES to estimate whether the intervention is differentially effective in subgroups of socioeconomic position. Although the small size of the trial would prevent us being fully powered to detect effectiveness in subgroups, this analysis will provide an estimate. These findings would be reported according to the Cochrane PROGRESS-Plus framework.

7) Planned interventions

Intervention: The intervention builds on the ASSIST model, a school-based peer-led intervention which has shown effectiveness in reducing smoking among UK adolescents.[21] The ASSIST design - (1) peer-nomination, (2) peer-supporter training and (3) a 10-week informal health message peer-diffusion - will be followed. The peer-supporter training will target PA.

1) **Peer-nomination:** peer-supporters will be identified by peer nomination in which consenting Year 8 girls will identify, by questionnaire, the female peers who they perceive to be influential. The highest scoring 18% (those with most nominations) will be invited to be peer-supporters, with the aim of ensuring that ≥15% take on this role as outlined in DOI theory.[25]
2) **Peer-supporter training:** peer-supporters will attend a two-day course to develop the skills, knowledge and confidence to promote PA amongst their peers. Training will be held off-site and led by external peer-supporter educators who will have attended a 3-day training programme. The peer-supporter training will be informed by Phase 1 findings, will be interactive and address issues central to girls' PA including: PA benefits, active choices, developing an active identity, being active with friends, sedentary behaviour, communicating with confidence, empathy and supporting motivation. The content will be grounded in SDT to build the girls' perceived autonomy, competence and sense of social support for being a peer-supporter and in their PA and to keep these concepts in mind when having informal conversations with their peers.
3) **10-week intervention:** peer-supporters will informally promote messages about increasing PA amongst their peers for 10 weeks. At the mid-point of the intervention peer-supporters will attend an off-site top-up session to revisit core messages, share successes and collaboratively resolve problems. Our PPI work to date suggests that incorporating social media (e.g., peer-peer support, sharing active photos, ideas and the research team sending tips) is important and we will explore this further in Phase 1. Participants in intervention schools will receive a high-street voucher in recognition of the time given to each data collection (T0 £5, T1 & T2 £10). We will incorporate participants' suggestions from Phase 1 qualitative work of how to minimise and deal with any bullying or distress that arises within the intervention period.
4) **Who will deliver the intervention?** The intervention will be delivered by Year 8 girls themselves, who will be trained as outlined above. Peer-supporter training will be delivered by four individuals who (a) are educated to graduate level in a subject such as PA, health promotion and/or public health and (b) have experience of teaching/working with groups of young people. Such individuals are representative of personnel employed in Healthy Lifestyles teams in Local Authorities to deliver health promotion programmes thus enhancing the scalability of the project should it be disseminated. Each peer training day will be facilitated by two peer-supporter educators who will attend 3 days of training and be provided with a manual for the peer-supporter training curriculum, resources, activities and learning outcomes. Peer-supporter educators will be reimbursed at an hourly rate to attend the training and deliver the peer-supporter training. The applicant team are experienced in writing and delivering training for intervention deliverers (i.e., MRC-funded Action 3:30[45], ASSIST[21], the MRC-NPRI funded Bristol Girl's Dance Project feasibility trial[46], NIHR-funded Active 7 trial[40] & Active for Life Year 5[47]).

Control group provision: Two schools will be randomly assigned to the control arm after baseline (T0) data collection and will not receive any form of intervention. Year 8 pupils in control schools will participate in data collection at T0, T1 and T2. Control schools will receive £500 donation at the end of the project in recognition of the time devoted to accommodating the study. Participants in control schools will receive a high-street voucher in recognition of the time given to each data collection (T0 £5, T1 & T2 £10).

Funding of intervention costs: The intervention provision costs are estimated to be £19,000 (£3,800 per school: 1 pilot school & 4 feasibility RCT intervention schools). £11,400 of the intervention costs will be paid by Wiltshire Council and £7,600 will be funded by South Gloucestershire Council (see Letters of Support appended to application form).

8) Explanation of methods proposed

School recruitment: The ASSIST project reported initial interest in the project from 57% of the schools approached. There are 22 secondary schools in Wiltshire and South Gloucestershire above the local pupil premium median. Based on the ASSIST school recruitment rate and our extensive experience with recruiting schools, we are confident that we can recruit the 8 schools required (incl. 2 reserves). We will include a questionnaire for school contacts to indicate reasons for not wishing to participate.

Peer-supporter recruitment: Previous work using the proposed peer nomination technique with Year 8 pupils (ASSIST & AHEAD) has successfully met the 15% peer-supporter recruitment targets (ASSIST 16%, AHEAD 17%). We are confident that we can therefore recruit 15% of girls from each intervention school Year 8 group.

Accelerometers: The project team has extensive experience of measuring young people's PA using accelerometers. In projects involving a self-selecting group of Year 7 girls (e.g., Active 7) we have achieved a baseline compliance rate of (94%) providing "valid" accelerometer data (i.e., ≥3 days of 500 minutes). We acknowledge that measuring the PA of a whole year group of girls may result in a lower compliance rate and greater loss to follow-up. In the AHEAD project, 80% of girls provided valid accelerometer data at baseline (i.e., ≥3 days of 600 minutes). At the second follow-up 60% of girls met this criterion and 85% provided at least 1 day. The lessons learned regarding accelerometer data collection in AHEAD[36] will be used alongside our recent experience of working with adolescent girls to optimise data provision rates (e.g., engaging school admin support, sending messages via ParentMail and using return boxes). As this is a feasibility trial a main outcome will be data provision rates. We also propose to explore the implications for data completeness of imputing missing accelerometer data (to achieve the valid day threshold). We will adopt the Multiple Imputation by Chained Equation (MICE) approach to deal with missing values. This will involve exploring the pattern of missing values including whether the pattern is monotone or arbitrary, whether there are a lot of missing values for certain variables or a group of participants. We will create a series of imputed datasets by running an imputed model based on chosen variables (including auxiliary variables) such as child gender and socio-economic status and combine the parameter estimates from each imputed dataset. We have previously found that these variables are associated with accelerometer data provision in controlled trials.[48] We will also examine the feasibility of wrist-worn devices in one intervention and one control school by asking participants to wear both a waist-worn and wrist-worn ActiGraph in the baseline data collection. We will explore the differences in wear time compliance rates as well as the agreement between the data derived from the two devices, with the waist-worn data interpreted as the criterion measure.

Questionnaires: in our experience the proposed questionnaire data collection technique (using tablet devices) has resulted in high data provision rates (100% Active 7 project Baseline; Action 3:30 ≥ 94% at 3 time points) and the mean completion rate across three time points in AHEAD was 95%. We are confident that we can replicate this. In the process evaluation of the feasibility trial we will explore participants' views on longer term follow-up and maintaining study involvement.

9) Proposed outcome measures:

Primary outcomes: For the purposes of the feasibility study the primary outcomes are:

i. **Recruitment and retention of peer-supporters and non-peer supporter Year 8 girls.** Consent rates of pupils to participate in the study will be recorded alongside the conversion rate of peer-supporter nominees becoming trained peer-supporters. Retention of participants will be determined (provided vs. did not provide data) at T1 and T2.

ii. **Data provision rates.** Data provision rates for accelerometer (missing, invalid, valid) and questionnaire data (missing vs. not missing) will be recorded at T0, T1 and T2. Accelerometer-determined minutes of MVPA is likely to be the primary outcome in a definitive trial. As we will measure PA in a whole year group, rather than a sub-sample involved in a structured PA intervention, and based on AHEAD findings we anticipate a level of missing data. To maximise power in the analysis of a definitive trial, it may therefore be advantageous to impute missing accelerometer data. We propose to estimate questionnaire and accelerometer data provision rates, examine data quality and explore the implications of missing accelerometer data in terms of how this data might be imputed in the larger trial.

iii. **Acceptability of the training and intervention to peer-supporters, pupils, parents, peer-educators and schools.** This will be assessed via qualitative process evaluation (See section 4).

iv. **Feasibility of collecting the data needed to conduct data linkage to long-term outcomes.** We will examine pupils' views on data linkage qualitatively in process evaluation (e.g., when to ask for consent). The rate of consent to perform either, or both, education and health data linkage will be recorded.

v. **Collection of data needed to conduct a cost-effectiveness analysis of the intervention.** Resource use categories will include intervention materials, venue costs, trainer and pupil time, expenses, travel and administration costs. These data will be used to assess the feasibility and appropriateness of the methods and tools that would be needed for an economic evaluation from a public sector perspective alongside a definitive trial. Resource use data will be collected prospectively during each stage (i.e. training the trainers, peer nomination, peer supporter recruitment, peer-supporter training, booster sessions) using expense claim forms and data collection forms completed by the Project Manager and Research Assistant. We will also measure data provision and completeness rates for a measure of quality of life (EQ-5D-Y).

Secondary outcomes: The following outcomes will focus upon establishing evidence of promise and inform the selection of the primary outcome in a definitive trial:

i. **Physical activity.** Accelerometer-determined minutes of MVPA per day is the likely primary outcome in a definitive trial. We will assess PA using ActiGraph accelerometers which are small devices that record bodily acceleration and have been used and validated amongst young people.[49] Participants will be asked to wear an accelerometer for seven days at T0, T1 and T2. Periods of ≥ 60 minutes of zero counts will be recorded as "non-wear" and removed. Participants will be included in analysis 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[50] cut-point which is the most accurate threshold for adolescents.[51] We will also estimate participants' sedentary time based on a cut-point of less than 100 cpm.[50]
ii. **School-travel mode.** As school travel mode is likely to be a key way for peer-supporters to encourage an increase in PA, participants will self-report their travel mode (active vs. passive) to/from school in the preceding week using a questionnaire that has been used previously amongst young people.[52]
iii. **Sedentary behaviour.** Self-reported leisure-based sedentary behaviour (hours spent TV viewing, using PC/laptop, games console, mobile phone or tablet and multi-screen viewing) will be measured using a questionnaire used previously with this age group.
iv. **Psychosocial outcomes/mediators.** The potential for the intervention to influence psychosocial outcomes such as self-esteem (self-description questionnaire[53]) and health-related quality of life (KIDSCREEN-10[54], EQ-5D-Y[42]) and potential mediators of the intervention such as self-determined PA motivation (BREQ-2[55]) and peer-norms[56] will be assessed using validated questionnaires at T0, T1 and T2.
v. **Feasibility of linkage to educational and health datasets.** The proportion of demographic data collected from pupils that are of sufficient quality and completeness to link study participant data to educational attainment data held on school-based and local authority databases and to health data (NHS Personal Demographic Spine). Feasibility will be assessed through a series of

test cases in which we will attempt to match participant identities (not study data) to databases held by schools, local authorities and the NHS.

10) Assessment and follow up

a. Assessment of efficacy/effectiveness

The primary outcomes for the feasibility study will be collected through the detailed quantitative and qualitative process evaluation. The secondary outcomes will be measured at baseline (T0), immediately after the intervention has ended (T1) and 5/6 months after the end of the intervention (T2) when the participants have transitioned from Year 8 into Year 9.

The feasibility study is primarily designed to assess acceptability and feasibility and not efficacy, effectiveness or cost-effectiveness. The timing of the T2 follow up in this study allows us to follow participants over the transition from Year 8 to 9 which will inform the methods that we adopt in a future definitive trial to facilitate longer term follow-up. In a definitive trial we would propose the following follow-up schedule in the first instance: Baseline [T0], immediately post intervention [T1] and 12 months post-intervention [T2]. We would assess the effectiveness of the intervention to increase daily MVPA at T2 as the primary outcome. Should effectiveness be shown at T2, we would apply for further funds to follow-up participants 12 months later (T3: 24 months post-intervention), a strategy that was used successfully in ASSIST.[21] In this model, at T3 participants would still be within secondary school (Year 10) which would facilitate follow-up as previous research conducted in the South West of England and Wales shows that the proportion of participants within school-based trials who leave school between data collection time points is small- ASSIST (<1%) and classroom-based CBT for adolescents at high risk of depression (11%).

b. Assessment of harms

Adolescence is a time of vulnerability for girls' body image/self-concept and these factors are associated with inclination to be active or not. The intervention seeks to minimise the promotion of PA through appearance motives and is guided by a theoretical approach to motivation (SDT) which is based on more authentic, personal reasons (e.g., health, social affiliation, challenge seeking) rather than commonly used quick fixes such as social recognition, appearance, weight loss.[35] Our PPI work revealed the perception that focussing on girls' appearance is considered "*dangerous*" and our proposed positive/empowering approach was supported. The proposed qualitative process evaluation with peer-supporters and non-peer-supporter pupils will examine the extent to which the intervention raised negative body image issues.

We will record any evident harms, or potential harms (e.g., bullying by or of a peer-supporter, inappropriate conduct on project social media) and report these to the school contact. We will provide school contacts with the contact details of the Project Manager, to report any incidents that they believe are study-related for recording. Any adverse events will be reported to the PI who will report to the co-applicants and Chair of the Ethics Committee.

11) Proposed sample size

As the research is a feasibility study, a formal power calculation based on detecting evidence for effectiveness has not been conducted. The feasibility RCT will be conducted in 6 schools (4 intervention, 2 control). Based on recent experience in local secondary schools, we expect approximately 110 Year 8 girls per school. Therefore the sample size will be approximately 660 girls (equally distributed between intervention and control arms) including approximately 77 peer-supporters. This is a pragmatically chosen sample and should be sufficient to identify evidence of feasibility, recruitment rates and any problems with the intervention or research methods.

A secondary outcome of the study is to estimate the 95% confidence intervals (CIs) for change in daily mean MVPA between arms. As the ICC for MVPA will be based on data from only four schools, the school-related ICC will be compared to that observed in our previous research among adolescents of a similar age (e.g., Bristol Girls' Dance Project & Active 7) to obtain a more accurate ICC estimate to include in a power calculation for a full trial.

12) Data analysis

Quantitative analysis: analysis of the feasibility study data will be primarily descriptive (e.g., frequencies, percentages, means & standard deviations) to examine consent, recruitment,

retention and data provision rates. Descriptive comparisons of these data will be made between intervention and control arms. Evidence of promise (i.e., whether the intervention could lead to an increase in daily MVPA) will be examined through linear regression models to compare between group differences in means and 95% CIs adjusted for baseline PA, and clustering of participants within schools. As the study is not powered to detect effectiveness, p-values will not be reported. Sample sizes for a future definitive trial will be estimated using the ICC for MVPA and based on combinations of key parameters (type I & type II error rates). Analysis will be conducted in Stata.

Qualitative analysis: Digital recordings of all interviews and focus groups will be transcribed verbatim. 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 then be iteratively refined to produce emergent themes. We will examine divergence and similarities across interviews and compare the experiences of the intervention across school contacts, peer-supporters, non-peer supporters and peer-supporter educators to develop a comprehensive understanding of the intervention acceptability, implementation and mechanisms of impact.

Economic analysis: A public sector perspective will be taken in the analysis, including costs to Local Authorities and schools. Where available, national unit costs for trainer and teacher time (e.g. from the Department of Education) will be used to increase the generalisability of findings. Cost per student within each school will be estimated by dividing the costs of the peer-supporter programme at that school by the total number of female students in the school year at study initiation. We will calculate an incremental cost effectiveness ratio (ICER) by dividing the mean cost per student of the intervention (weighted by year group size) by the difference in daily MVPA in the intervention and control arms. However, this analysis is designed to explore the affordability and potential cost-effectiveness of the intervention rather than provide a definitive comparison.

13) Ethical arrangements

We will apply for ethical approval from the University of Bristol, School for Policy Studies Research Ethics Committee. Consent for pupils to participate will be sought through parent opt-out consent in which parents/carers of Year 8 girls in the study schools will be sent a letter providing study information and requested to opt their child out of the study should they wish. This approach was found to be very successful in ASSIST, AHEAD and Welsh School Health studies.[3,21,37] Parents will be asked to: (a) opt their child out of the study in its entirety or (b) opt their child out of the data linkage component only (specifically for data linkage to educational attainment and health data). Assent will be sought from the children and those agreeing will be asked to provide sufficient information for data linkage to take place. This approach has been approved by a number of research ethics committees for previous studies. In a full trial all data would be anonymously linked and stored in secure privacy protecting remote analysis facility and made available to the research team as fully anonymised data.[57] In addition, parents will be asked to provide written informed consent to their child participating in the peer supporter training, in depth interviews or focus groups. Children will also be asked to assent to these activities. Adult participants (e.g., peer-education providers and school contacts) will be asked to 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 someone is at risk of harm. All research staff and those involved in peer-supporter training will have Disclosure and Barring Service checks and will work in accordance with school and University of Bristol safeguarding policies.

14) Research governance

The Principal Investigator (PI) will have overall responsibility for the conduct of the study. He will also draw upon the experience of the co-applicant team in conducting complex interventions. The Project Manager will run the project on a day-to-day basis, supervised by the Principal Investigator. The qualitative Research Assistant will lead the process evaluation supervised by the Principal Investigator. We will convene three groups to support the guidance and governance of the study. A **Trial Management Group (TMG)** chaired by the PI will meet monthly initially and include all co-applicants and the Project Manager. It will discuss progress, study design, problems and solutions and ethical issues. A smaller sub-group of key personnel (Sebire, Jago, Campbell, Edwards) will meet more frequently. We will develop a **Local Advisory Group (LAG)** which will consist of representatives from the local council, public health personnel and secondary schools. The LAG will be chaired by Dr Kipping (Co-applicant) and meet four times during the award to provide guidance on practical issues that relate to the conduct of the research in schools, school recruitment, dissemination and intervention delivery. An independent **Trial Steering Committee (TSC)** will be established consisting of three independent members and senior members of the study team. The independent members will have experience in developing and conducting complex interventions within schools, trial methodology and statistics. The TSC will meet approximately four times during the project and will provide independent scientific scrutiny of the project, guidance on progression to a definitive trial and support to the project team. As the study is a feasibility trial we do not propose to establish a separate DMEC, we will however seek guidance from our TSC and instigate a DMEC should the TSC advise that such a group is necessary.

15) Project timetable and milestones

The project Gantt chart is appended to this application. The project will commence on 1 April 2015 and end on 31 July 2017. Specific project milestones include:

End date	Milestone
April 2015	Staff recruited; phase 1 ethical approval gained
July 2015	Phase 1 qualitative work completed; 9 schools recruited; parental consent sought; trial protocol paper submitted
Aug 2015	Intervention refined; peer educator training developed
Nov 2015	Pilot intervention (1 school) complete; Phase 2 trial pupil recruitment, T0 data collection/peer nomination complete
April 2016	Randomisation; peer-educators trained; peer-supporters trained, intervention underway
July 2016	Intervention completed; T1 data collected; process evaluation qualitative completed
Dec 2016	T2 data collection, process evaluation data collected
March 2017	Data analysis completed
July 2017	Trial outcomes paper submitted; report writing; dissemination

16) Expertise

The research team have the skills and experience needed to deliver the research. The team builds on previous collaborations which have successfully developed and evaluated PA-based feasibility RCTs and develops new collaborations to strengthen the 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.

Simon Sebire is Lecturer in Physical Activity/Exercise Psychology at the University of Bristol. He has experience in designing, implementing and evaluating complex feasibility and full school-based trials, integrating behavioural theory into interventions and process evaluation. He will be PI.
Pete Blair is Senior Research Fellow in Medical Statistics and consultant methodologist for both the Bristol Randomised Trials Collaboration (BRTC) unit at the University of Bristol and the Research Design Service. He has expertise in trial methodology and experience of supporting the design, conduct, and statistical analysis of feasibility and full scale randomised trials.
Rona Campbell is Professor of Public Health Research, School of Social and Community Medicine, University of Bristol and Director of DECIPHer. Prof Campbell is experienced in leading

complex feasibility and full RCTs with children, with specific expertise in peer-led health interventions and process evaluation.
Mark Edwards is an experienced post-doctoral Project Manager (PM). He is currently PM for the NIHR-funded BGDP/Active 7 project and has developed protocols relevant to school and participant recruitment and accelerometer and questionnaire data collection and instructor training.
Will Hollingworth is Professor of Health Economics at the University of Bristol with extensive experience of designing economic analyses alongside RCTs of public health/other interventions.
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-scale PA-based RCTs with children, optimising recruitment and retention and measuring PA.
Ruth Kipping is Research Fellow in Public Health and Epidemiology at the University of Bristol and Consultant in Public Health at North Somerset Council. Dr Kipping has expertise in the public health relevance of the proposed research through her work in the NHS and expertise in developing a feasibility and pilot RCT to increase PA.
Ronan Lyons is Professor of Public Health at Swansea University, Director of the Centre for Improvement of Population Health through E-records Research, a component of the Farr Institute of Health Informatics Research, and co-Director of DECIPHer. Prof. Lyons will lead the data linkage aspect of the project to examine the feasibility of collecting the data necessary to test the broad educational and health outcomes of the intervention.

17) Partner Collaboration

The intervention costs will be met by Wiltshire ([redacted]) and South Gloucestershire ([redacted]) Councils. The Directors of Public Health and a Public Health Consultant will collaborate from each Council. We will invite representatives from both Local Authorities to sit on the LAG.
The study is affiliated to the Bristol Randomised Trials Collaboration (BRTC) a UKCRC/NCRI-accredited trials unit which will support study design, randomisation, data management, analysis and governance. A representative from the BRTC will sit on the TMG. The project is also adopted by DECIPHer (Prof. Campbell is Director & Prof. Lyons is Co-Director). We have worked with the DECIPHer ALPHA group to gain user group input into the intervention design and methods (e.g., recruitment). DECIPHer will advise on academic and non-academic dissemination as appropriate.

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