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Lay title:	PLAN-A
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1) Background

1.1 Existing Research

Girls' physical activity and the transition to secondary school: Physical activity is associated with lower levels of cholesterol and blood lipids, favourable blood pressure and body composition among children and adolescents.[1] These risk factors are more prevalent in children of lower socioeconomic position.[2] Physical activity is also associated with young people's well-being, self-esteem[3] and academic performance[4], tracks moderately from early to late adolescence and into adulthood [5, 6] and is associated with reduced risk of heart disease, stroke, type 2 diabetes and all-cause mortality amongst adults.[7] Despite the benefits, physical activity levels decline during childhood (7% per year)[8] and adolescent girls are less active[9, 10] and more sedentary[9] than boys. Thus, there is a specific need to increase the physical activity of girls during early adolescence.

Systematic reviews show that psychological correlates of girls' physical activity participation include enjoyment, perceived competence, self-efficacy and their physical self-perceptions.[11] Changes to friendship groups, peer support, perceived competence, competing priorities, self-presentational concerns and "sporty" gender stereotypes experienced during the transition from primary to secondary school may contribute to the decline in girls' activity.[12-14] There is systematic review evidence that physical activity interventions aimed at young girls produce small positive effects, with larger effects for interventions that targeted girls only (vs. girls & boys), and that used educational and multi-component designs.[15] Promoting young people's health in schools is a public health priority[16] and school-based interventions can reach many girls over a sustained period. However, a recent meta-analysis of school-based interventions using objectively-assessed physical activity in adolescents showed only small non-significant effects.[17] Intervention components included traditional top-down strategies including active breaks, health education, information provision, extra lessons, and giving out pedometers.

Peers & physical activity: Peers play a central role in adolescents' physical activity through peer support, presence of peers during physical activity, peer norms, friendship quality, peer affiliation and peer victimisation[18] and there are consistent positive associations between peer support, presence, norms and quality and physical activity/determinants of activity. Social network research shows that adolescents choose friends who are similarly active and that they may alter their physical activity over time to be more like that of their friends.[19] Peer-led interventions therefore have the potential to increase adolescents' physical activity which is reflected in two ongoing physical activity RCTs, in addition to PLAN-A, which include a peer-component[20, 21]. The need to develop physical activity interventions, especially amongst girls, which capitalise on existing peer processes in schools by promoting peer support and enhancing peer communication skills has been highlighted.[18] We have developed the PLAN-A intervention specifically to address this need and demonstrated its acceptability and feasibility through a feasibility RCT. The study proposed herein will test the effectiveness of PLAN-A to increase girls' physical activity.

Peer-led health interventions: Peer-led interventions have targeted a range of health behaviours amongst young people including smoking, asthma, water consumption, alcohol consumption, drug use, physical activity and sedentary behaviour.[22-24] The majority have been delivered in secondary education and trained peer-leaders to educate other pupils through information provision and skill development.[25]

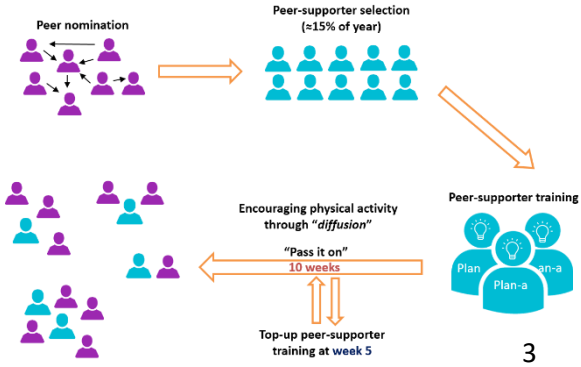

Figure 1. PLAN-A intervention concept An alternative peer-led approach is to train adolescents to informally diffuse health promotion messages to their peers (Figure 1). Based on Diffusion of Innovations Theory (DOI)[26] which sets out how ideas, beliefs or behaviours can be informally communicated through members of a social system (see section 2.2), this approach was adopted in the effective and nationally-disseminated ASSIST (A Stop Smoking in Schools

Trial) study (Principal Investigator – Prof Campbell).[22] The ASSIST study findings showed that informal school-based peer-led interventions can be effective in changing smoking behaviour. We used the same approach (in PHR:13/90/16) to develop the PLAN-A intervention (see section 7 for intervention details). The PLAN-A feasibility study suggested it has the potential to increase girls' physical activity.

1.2 Theoretical background

Interventions which target theoretical mediators of behaviour change are likely to be more effective than those that do not.[27] However, few peer-led physical activity interventions incorporate theoretical principles.[24] The present study combines two complementary theories: DOI Theory[26] and Self-determination Theory (SDT).[28] DOI provides a framework for harnessing the influential capacities of *change agents* (e.g., Year 9 girls identified as opinion leaders by their peers) who can informally diffuse positive messages about physical activity to their peers, influence attitudinal shifts 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 young people's motivation for physical activity[14, 29, 30] and guide interventions[31, 32]. In SDT, autonomous motivation for physical activity (based on choices, inherent satisfaction or personal value) is associated with positive behavioural and psychological outcomes, whereas controlled motivation (based on guilt or compliance with others' demands) undermines these outcomes. Autonomous motivation is supported by a social (e.g., peers) environment that supports three psychological needs; autonomy, competence and interpersonal belonging. Research amongst children, adolescents and adults has identified positive associations between autonomous versus controlled motivation and physical activity [30, 33 34] positive affect, challenge-seeking[34] and quality of life.[35] Autonomous motivation is associated with perceptions of autonomy, competence and social belonging.[30, 36] SDT is well suited to a peer-peer intervention because peers can create a social climate that can undermine or facilitate girls' interest in physical activity [24], autonomous motives, perceptions of competence, social support, and choices in how to be active.[12, 14]

SDT is built in to the PLAN-A intervention, layered into the delivery, resources and content of the peer-supporter training. *Delivery*: Peer-supporter trainers are guided in how to deliver training in an autonomy-supportive style to increase peer-supporter autonomy (e.g., empowerment to support peers and provide choice), competence (e.g., in how to be a peer-supporter) and belonging (e.g., supportive network of peer-supporters). *Peer-supporter training resources & content*: are designed to encourage peer-supporters to recognise and promote autonomous rather than controlled motivation for physical activity (focussing on health, challenge-seeking & social reasons rather than appearance & peer pressure), support peers' needs for autonomy, competence and belonging and use autonomy-supportive language when diffusing messages (e.g., *"I'm going to walk to school will you come with me"* vs. "*you need to be active so you don't get fat*"). Process evaluation of the PLAN-A feasibility study showed that SDT principles were accepted and delivered by peer-supporter trainers and peer-supporters reported changing their intuitive approach to motivating others from one of control to autonomy-support. Combining DOI and SDT will allow the intervention to target and identify psychosocial mediators of any intervention effect.

2) Formative work

We have undertaken extensive formative, pilot and feasibility research (NIHR PHR project 13/90/16) to inform the design of the PLAN-A intervention and research study including: formative qualitative work with Year 8 girls and a pilot to refine content and a feasibility trial including process and economic evaluations examining the acceptability, feasibility and evidence of promise of PLAN-A to increase girls' physical activity. [37] A breif overview is provided below.

(i) Formative qualitative work and intervention pilot to refine intervention content

Design: Iterative qualitative research was conducted to adapt the ASSIST peer-led smoking intervention model to target physical activity, including focus groups with the DECIPHer ALPHA young persons' advisory group and 16 Year 8 girls at two time points. Focus groups explored: the recruitment approach and materials, expectations for peer-supporter training, using social media and desired characteristics of peer-supporter trainers. Refinements were made, and the second

round of focus groups ensured the changes reflected the girls' ideas and gathered input on the project logo, peer-supporter training timetable, and adverse effects (e.g., bullying). The peer nomination, train-the-trainers and peer-supporter training components were piloted in a secondary school with 70 Year 8 girls, 11 peer-supporters and two trainers and the intervention content finalised.

(ii) Feasiblity study, process and economic evaluations
Design: A two-arm cluster randomised controlled trial was undertaken with school as the unit of allocation [37]. Six secondary schools (four intervention, two control) where pupil Index of Multiple Deprivation was greater than the local median (i.e., lower socioeconomic position) were recruited and the intervention and evaluation included all (consenting) Year 8 girls.

Intervention and control groups: The four intervention schools received the PLAN-A intervention (peer-nomination, peer-supporter selection, three days of peer-supporter training & ten week diffusion period - see Section 7). The two control schools received no intervention.

Measures: To assess the potential effect of the intervention on girls' MVPA levels, participants wore an ActiGraph wGT3X-BT accelerometer for seven days at the beginning of Year 8 (Time 0, pre-randomisation baseline) at the end of Year 8 (Time 1, post-intervention period) and at the beginning of Year 9 (Time 2, 12 months post-baseline, 5-6 months post-intervention). Participants were included in analysis if they provided ≥2 weekdays of data with ≥500 minutes of data between 6am and 12pm. Mean minutes of weekday MVPA (the *a priori* selected primary outcome for a definitive trial) was estimated using a cut point of ≥2296 counts per minute. Sedentary time was estimated using a cut point of ≤100 cpm. Participants completed a questionnaire assessing psychosocial variables (e.g., activity motivation, self-efficacy, peer-norms) at each time point.

Process evaluation: A comprehensive mixed-methods evaluation was undertaken
Qualitative: Following the 10-week intervention, focus groups were conducted with peer-supporters (N = 4, n pupils = 55) and non-peer-supporter pupils (N = 4, n pupils = 24) purposively selected across the spectrum of baseline physical activity levels. Interviews were conducted with school contacts (N = 6) and parents of peer-supporters (N = 12). Peer-supporter trainers (N = 5) were interviewed after delivering the 2-day and top-up day training. Focus groups and interviews focussed on experiences of intervention delivery, receipt, acceptability and improvements.
Quantitative: Trainers recorded attendance at the peer-supporter training, achievement of session objectives, peer-supporter engagement, involvement and interest and the training arrangements. Peer-supporters reported their enjoyment of each training day, views on training content and the trainers' delivery style. Peer-supporter training was observed (for each trainer pair) to assess fidelity. School context (e.g., policy, facilities, provision) was also assessed at each school.

Economic Data: The feasibility of collecting the data needed to cost the intervention and conduct a cost-effectiveness analysis in a definitive trial and the affordability and potential cost-effectiveness of the intervention were examined. Resource use for: (a) intervention development, (b) preparation for intervention delivery and (c) intervention delivery was collected using expense claim forms and proformas completed by the research team, peer-supporter trainers and school contacts. Public sector costs were estimated using national unit costs where available. Cost per pupil was calculated by dividing the costs of the peer-supporter programme at each school by the number of females in the school year group. An incremental cost-effectiveness ratio (ICER) was derived by dividing the mean cost of the intervention per student by the difference in weekday MVPA.

Results and implications:
Recruitment of schools, participants, peer-supporters and trainers: Six schools were recruited and 427 (94.7%) Year 8 girls participated; intervention n = 269, control n = 158. 55 peer-supporters were recruited and trained meeting the target proportion in each school (range = 17-24%). Five females with experience in youth work, drama, health promotion and/or coaching were trained as peer-supporter trainers.

Feasibility and acceptability of intervention implementation: Attendance at the peer-supporter training was high (Mean of 3 training days = 96.82%). Peer-supporters enjoyed the training (3-day Mean = 3.8/5), engaged well (3-day Mean = 2.6/3) and understood their role (Mean = 3.8/4) although there was some room for improvement in each indicator. Peer-supporters reported being prepared to go back to school and diffuse physical activity messages to their peers, however commonly wanted further support and confidence to start conversations. Qualitative, questionnaire and observation findings suggested trainers were successful in providing autonomy, competence and relatedness support consistent with the training manual.

Acceptability of intervention to schools: Peer-supporter training for three schools was held off-site as planned. In one school, training was held in school as the school was unable to release a member of staff to chaperone pupils. We therefore examined the implementation of the peer-supporter training in as well as out of school. The in-school training was highly acceptable to the pupils and attendance was as high as off-site training but there were disruptions from usual school activities which were not present off-site. School contacts found the intervention arrangements easy to manage.

Data provision: Questionnaire data provision exceeded 92% at all time points. Accelerometer return rates were high (>86%) and exceeded the progression criteria. Provision of two valid days of accelerometer data exceeded 70% at Time 0 and Time 1, and was 62% at Time 2.

Evidence of promise: Mean weekday MVPA did not differ between the trial arms at Time 1 (immediate post-intervention) after adjustment for baseline MVPA, school clustering, and local authority (1.1 mins, 95% CI = -4.3, 6.5). At Time 2 (when the diffusion had more time to work & participants had time to change behaviours) there was a 6.1 minute difference in weekday MVPA favouring the intervention arm after adjustment (95% CI =1.4 to 10.8). The intervention group also performed 32 (95%CI = -57.4, -6.2) minutes less sedentary time per day than control group participants at Time 1 and 23 (95%CI = -43.7, -2.8) minutes less at Time 2.

Economic Analysis: The economic evaluation demonstrated the programme has potential for cost-effective delivery from a public-sector perspective. The cost of intervention development (£6533) and training the trainers (£3430) were modest. The mean cost of intervention delivery was £2685 per school (range = £2309 to £3235) equating to £37 per Year 8 girl (range = £30 to £56). In a sensitivity analysis, assuming the intervention was delivered by Local Authority Health Improvement Officers, the estimated mean cost of intervention delivery was £2311 per school and £32 per Year 8 girl. The incremental cost-per-minute improvement in mean weekday MVPA at 12 months was £6.09.

Feasibility trial summary: The feasibility trial provided evidence that it is possible to recruit and retain schools, participants, trainers and peer-supporters. The intervention is deliverable, affordable and acceptable and the evaluation identified simple refinements (discussed below) that will further improve it. We have developed, tested and refined the trial methodology which can be implemented in a definitive trial. The study suggested that the intervention could lead to mean difference of 6 minutes of MVPA per weekday.

Implications for a definitive trial and refinements made for the current study: We will make minor changes to the peer-supporter training by increasing practical learning, simplifying activities, increasing time to practise peer-supporter conversations, providing further tips on how to start conversations, and overcoming challenges. To maximise provision of accelerometer data at follow up we will reduce participant burden by conducting the follow up measures (Time 1) 1 year after the baseline measures (participants are in Year 10, as the definitive trial will be conducted in Year 9 girls). We therefore propose only two measurement points. Finally, to ensure that the intervention is scalable (if found to be effective) we will recruit peer-supporter trainers in line with the model that is adopted within the Local Authorities (LA) involved in the study (i.e., if the LA delivers services we will recruit trainers from their delivery team, however if the LA commissions delivery by external agencies we will commission trainers who are free-lance or employed by agencies).

3) Risks & benefits

Benefits: If PLAN-A is shown to be effective, the intervention could be disseminated widely via Local Authorities and school academy chains and has the potential to increase the physical activity of adolescent girls in the UK. This would represent a significant advancement of the current position where most interventions have failed to increase physical activity.
Risks: No adverse outcomes were reported in the feasibility trial or identified in the process evaluation (e.g., no evidence of teasing or pressuring peers) and we do not expect a higher level of risk in the definitive trial. We will explore potential risks (e.g., disrupting peer groups, creating cliques) through the qualitative process evaluation.

4) Rationale for the current study

Physical activity during childhood is associated with physical and psychological health. Physical activity levels decline during childhood and by early adolescence, few girls are sufficiently active. School-based interventions have largely been ineffective and novel interventions are needed to address the barriers to girls' non-participation. Interventions embedded within girls' everyday lives represent a creative alternative to previous interventions and peers offer a powerful, natural and sustainable intervention opportunity which has received little attention in high quality trials. Having followed the MRC framework for the development of complex interventions[38] in our intervention refinement, piloting and feasibility trial **we are now ready to test, in a definitive trial, whether the PLAN-A intervention can increase adolescent girls' physical activity and be cost-effective.**

5) Research objectives:

1. To determine the effectiveness of the PLAN-A intervention (See section 7) to increase objectively-assessed (accelerometer) mean weekday minutes of MVPA among Year 9 girls 5-6 months (baseline + 1 year) after the end of the 10-week intervention (first follow-up).

2. To determine the effectiveness of PLAN-A to improve the following secondary outcomes among Year 9 girls 5-6 months after the end of the 10-week intervention (first follow-up):
   a. Mean weekend minutes of MVPA
   b. Mean weekday minutes of sedentary time (Accelerometer-derived)
   c. Mean weekend minutes of sedentary time (Accelerometer-derived)
   d. Self-esteem (reported by questionnaire[39])

3. To determine the extent to which any effects of the intervention on primary or secondary outcomes are mediated by autonomous and controlled motivation towards physical activity and perceptions of autonomy, competence and relatedness / peer-support in physical activity which are based on self-determination theory on which the PLAN-A intervention is based.

4. To determine the cost-effectiveness of the PLAN-A intervention from a public sector perspective.

6) Research design

A two-arm school-based cluster-randomised controlled trial with an embedded process and economic evaluation. Schools will be the unit of randomisation and outcomes will be assessed at two time points: baseline (Time 0: Autumn term of Year 9) and follow-up 1 (Time 1: Autumn term of Year 10, 5-6 months post-intervention). A comprehensive mixed-methods process evaluation and an economic evaluation to estimate cost-effectiveness at Time 1 and extrapolate beyond the end of the trial.

7) Study population

The target population is girls aged 13-14 (Year 9) attending schools in the Greater Bristol area. All female Year 9 pupils in intervention schools will be targeted in the intervention. A subgroup (≥15%) of the Year 9 girls in each intervention school will be trained as peer-supporters. *Inclusion criteria:* Participants will be required to provide parental opt-out consent and child consent. *Exclusion criteria:* Pupils whose parents opt them out or do not provide assent.

8) Socioeconomic position and inequalities

The study aims to reduce the disparity in physical activity levels amongst boys and girls. Boys are more active than girls[10] and girls face a distinct set of personal, social and physical barriers to staying active in adolescence.[12] The feasibility study showed that the participants engaged with the focus on girls' activity and the chance to discuss related issues away from boys. Further, the feasibility study showed that we can recruit and engage schools with pupils of lower SES (i.e., above the median on the Pupil Premium Indicator), that the intervention can be implemented as planned and is acceptable. We will measure multiple dimensions of socio-economic position as listed in the PROGRESS-Plus[40] framework which are appropriate for adolescent girls (e.g., Index of multiple deprivation, participant ethnicity & receipt of free school meals). In the feasibility study, 64% of girls responded, "Not sure" when asked about their parents' education. We will instead use the validated Family Affluence Scale[41] that we piloted as a proxy for family-level SES. To ensure that we are not reinforcing health inequalities, we will perform subgroup analysis to estimate whether the intervention is differentially effective in subgroups of socioeconomic position. Although the size of the trial would prevent us being fully-powered to detect effectiveness in subgroups, this analysis will provide an estimate.

9) Planned interventions

Setting: Eligible settings will be state-funded secondary schools in Southwest England. To include enough schools in the sampling frame, all schools (excluding special educational & independent schools) will be eligible however we will invite schools which are above the median of the local Pupil Premium Indicator (i.e., more deprived) to participate first. If this recruitment wave does not meet the school recruitment target, we will invite remaining schools in the sampling frame.

School recruitment: All schools which meet the inclusion criteria stated above will be invited to participate via a letter to the Head/Deputy Head Teacher. Non-responding schools will be followed up by email and phone. Schools wishing to participate will be provided with further information and asked to express their interest in participating. If more than 20 schools volunteer to participate, schools will be selected at random to enter the study. We will aim to recruit two additional schools who can be promoted to the study schools if a school withdraws prior to randomisation.

Allocation: School is the unit of allocation. 20 schools will be randomly allocated after completion of baseline data collection; ten intervention and ten control schools. Randomisation will be stratified by County and the England IMD score for the local super output area where the school is located (dichotomised as less than the median of sampled schools in the region versus greater than or equal to that median) and to ensure balance within each stratum.

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 school identity and independent of the fieldwork team.

Pupil recruitment: A presentation will be made to Year 9 girls to inform them about the study, including the nature of the intervention and control conditions and the chance of the school being in either arm. All girls will be invited to take part and given study information for themselves and their parents. Peer-supporters will be asked to agree to the role, training and process evaluation.

Intervention: The PLAN-A intervention was adapted from the ASSIST intervention model, a school-based peer-led programme which reduces smoking among UK adolescents[22] to focus on girls' physical activity. The intervention comprises: (A) peer-nomination, (B) peer-supporter training and (C) a 10-week informal peer-diffusion period.

A) Peer-nomination: Peer-supporters are identified by nomination in which Year 9 girls identify, by questionnaire, the female peers, in their year who they think are influential (e.g., who they respect, look up to, listen to). Based on DOI[26] the highest scoring 18% (those with most nominations) are invited to be peer-supporters, with the aim of ≥15% accepting the role.

B) Peer-supporter training: Peer-supporters attend an initial two-day course to develop the skills, knowledge and confidence to promote physical activity amongst their close peers. At the mid-point of the intervention (5 weeks) peer-supporters will attend a further top-up training day to revisit core messages, share successes and resolve problems. Training will be held off-site and led by external peer-supporter trainers who will have attended a 3-day training programme. The interactive peer-supporter training has been informed by our formative and feasibility research and addresses issues central to girls' physical activity including: physical activity 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 social support for being a peer-supporter, in relation to physical activity and when supporting their peers.

C) 10-week intervention: Peer-supporters will informally promote messages about increasing physical activity amongst their peers for 10 weeks, with the top-up training at 5-weeks. Whilst a cornerstone of the intervention is the informal peer-led diffusion approach (i.e., we are not asking peer supporters to deliver formal or structured support in the form of leading assemblies, having a regular peer-supporter time for example) we do provide peer-supporters with many ideas of techniques that they can use to support their friends' physical activity, including but not limited to: (a) having conversations (sharing facts about being active, the benefits, ways to build activity in to daily life, commenting on media stories regarding activity or girls' health), (b) co-participating (offering to be active together), (c) persuading (making suggestions for example to swap a passive form of transport for walking if with a friend / group of friends), (d) offering support or encouragement (e.g., to friends who may not like PE or school sport). Girls are also able to choose other / their own ways to support specific friends, based on their knowledge of them, their preferences, needs, confidence etc and the peer-supporter training helps girls to identify these factors and respond to them with empathy.

Who will deliver the intervention? The intervention will be delivered by Year 9 girls themselves, who will be trained as outlined above. Peer-supporter training will be delivered by female trainers who: (a) have physical activity subject knowledge (from related degree-level education or practice-based experience) and (b) have experience of teaching/working with groups of young people. Such individuals are representative of personnel employed in or commissioned by LAs to deliver health promotion programmes. Each peer training day will be led by two peer-supporter trainers who will attend three days of training and be provided with a manual for the peer-supporter training curriculum and resources. The train-the-trainers days will cover all elements of the intervention including; the principles of peer-diffusion, physical activity knowledge, pupil expectations, and peer-supporter training activities (including role-play delivery). In the feasibility study, trainers were recruited as free-lancers, or via local sports development teams. In this study, to enhance the scalability of the intervention we will recruit trainers from LA health improvement delivery teams, or providers that LAs commission to deliver physical activity-related provisions. Further, to more closely replicate the training of peer-supporter trainers in roll out, the 3-day train-the-trainers event will be co-delivered by an experienced PLAN-A trainer from the feasibility study alongside a member of the study team. Peer-supporter trainers will be paid an hourly rate to attend the training and deliver the peer-supporter training.

Control group provision: Ten schools will be randomly assigned to the control arm after baseline (T0) data collection and will not receive any form of intervention. Year 9 pupils in control schools will participate in data collection at T0 and T1 including peer-nomination to allow for sensitivity analysis exploring potential interaction effects by peer-supporter status (we examined this in the feasibility study and there was no evidence of such an effect).

Funding of intervention costs: The intervention costs will be funded by Sport England.

Public Involvement: An omitted element of the PLAN-A peer-supporter training was a learning activity about physical activity / exercise during menstruation. We will involve adolescent girls in the development of such an activity which will be added to the peer-supporter training. This topic is

very important to adolescent girls and the idea was forwarded during our feasibility study dissemination seminar. We will undertake formative work, comprising interviews with secondary school teachers (PE & PSHE) and focus groups with girls in Years 9 and 10 to understand what information would be desired and appropriate for Year 9 girls. The results will be used to co-develop a peer-supporter training exercise on this topic (i.e., draft a training exercise and seek participant input on it before using it in the intervention). This work will be conducted in 2018.

10) Outcome measures

i. **Primary outcome:** Accelerometer-determined minutes of MVPA on weekdays is the primary outcome. We will assess physical activity using ActiGraph accelerometers which are small devices that record bodily acceleration and have been used and validated amongst young people.[42] 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" and removed. Participants will be included in analysis if they provide ≥ 2 valid days (i.e., 500 minutes of data between 6am and 12pm). Mean minutes of daily MVPA will be estimated using the Evenson[43] cut-point which is the most accurate threshold for adolescents.[44] We will also estimate participants' sedentary time based on a cut-point of less than 100 CPM.[43]

ii. **Secondary outcomes:** The following accelerometer-derived variables will be secondary outcomes: (a) Mean weekend minutes of MVPA; (b) Mean weekday minutes of sedentary time, (c) Mean weekend minutes of sedentary time. Participants will report their self-esteem[39] to determine any intervention effect on this outcome.

iii. **Measures of Mediators:** In line with the hypothesised mediation model, self-determined physical activity motivation (BREQ-2[45]), autonomy[34], competence[46] and relatedness[34] and peer-support for physical activity will be assessed using validated questionnaires at each time point.

iv. **Descriptive variables:** For descriptive purposes, we will ask participants to report their home postcode to derive Index of Multiple Deprivation estimates, their ethnicity, family affluence[41], and whether they receive free school meals. We will also collect unique pupil identifier numbers from the schools to allow project data to be linked (e.g., to pupils' academic grades) in the future.

v. **Economic variables:** Resource use data, including intervention materials, venue costs, staff, trainer and pupil time, expenses, travel and administration costs, will be collected using proformas and expense claim forms. Quality of life measures will mirror the feasibility study and include the EQ-5D-Y and the KIDSCREEN-10.

vi. **Process evaluation and context:** A detailed process evaluation of the RCT using qualitative and quantitative methods will examine: (a) intervention implementation and fidelity, (b) receipt of the intervention by pupils (peer-supporters and non-peer supporters) and (c) the sustainability of the intervention and roll out if effectiveness is shown. We will assess school context[47] using scales that we adapted and piloted in the feasibility study[48, 49]. We will also ask all 20 school contacts to report termly any new physical activity interventions that start in the school for Year 9 girls. Data collection and analysis will be undertaken by the qualitative Research Associate using the following methods:

Table 1. Process evaluation methods

Informant	Method	Data
Peer-supporters	Post-training questionnaire (10 schools)	Quantitative ratings of training (e.g., enjoyment, knowledge), activities, confidence in peer-supporter role and trainers' delivery style (e.g., autonomy support).
	Week 5 & 10 questionnaire	Quantitative reports of: types, frequency and extent of peer support that they have given, number of friends supported and open ended questions to give qualitative examples of support.

	Focus groups (10 schools)	Perceptions of peer-supporter training and being a peer-supporter (actions taken, successes, challenges, impact), dissemination; recruiting peer-supporters in the future.
Non-peer supporter pupils	Time 1 questionnaire (all intervention pupils)	Items assessing perceived contact/conversations with peer-supporters
	Focus groups (10 schools)	Perceptions of receiving peer-support, mechanisms of impact
Peer-supporter trainers (all trainers)	Semi-structured interviews Observe training & trainer questionnaire	Views on train-the-trainers and peer-supporter training fidelity; success & challenge. Observation notes of peer-supporter training & trainer ratings of delivery of content *fully*, *partially* or *not at all*.
School contact	Semi-structured interviews (n = 10)	Logistical / organisational factors in delivery in school, dissemination, sustainability and marketing roll out.
Public health / Commissioners	Semi-structured interviews (n = 5)	Dissemination, intervention sustainability, funding landscape and marketing roll out.
School Context. School level data: size, pupil premium, questionnaires assessing physical activity provisions, budget, school policies, physical activity in the curriculum[48, 49].		

Methods to protect against bias

We will adopt the following strategies to reduce the risk of bias.

(1) Allocation: Allocation to trial arms will be performed after recruitment, consent and baseline data collection by a BRTC statistician blind to school identity and independent of the fieldwork team.

(2) Consent: As PLAN-A operates at a whole school year group level, opt-out parent consent and opt-in child assent will be used to minimise recruitment bias.

(3) Contamination: Whilst relocation of pupils between schools allocated to different trial arms is possible we did not see this in the feasibility study and anticipate that this will have little impact.

(4) Blinding: 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 we will measure physical activity using accelerometers which do not provide any behavioural feedback. The study statistician, statistics research associate and senior investigator team will be blind to school identity. It will not be possible to blind the fieldwork team.

(5) Incomplete outcome data: Every effort will be made to obtain data from all participants who do not withdraw consent. Imputation of missing data will also be conducted.

(6) Selective outcome reporting: A comprehensive statistical and health economic analysis plan will be developed for the trial and made publicly available before analysts are un-blinded. This will provide a parsimonious list of primary, secondary and subgroup analyses.

11) Assessment and follow up

i. Assessment of efficacy/effectiveness

As noted above, all outcomes and mediators will be assessed at two time points: Baseline (Time 0) will occur before randomisation to study arms in the Autumn term of Year 9 and the first follow-up assessment will be 1 year after baseline and 5-6 months post intervention end (Time 1: Autumn term Year 10).

ii. Assessment of harms

Adolescence is a vulnerable time for girls' body image/self-concept and these factors are associated with physical activity. The PLAN-A intervention acknowledges the role appearance plays in the lives of adolescent girls but, based on the SDT approach to motivation, seeks to minimise the promotion of physical activity through commonly cited extrinsic "quick-fix" motives such as appearance and weight loss[36] and instead focus on authentic, personal reasons such as health, choice, friendship and challenge seeking. Our formative work indicated that focussing on girls' appearance is considered "*dangerous*" and our positive/empowering intervention was supported. Our qualitative process evaluation revealed no negative body image issues because of the intervention and pupils endorsed our focus on appearance in terms of *healthy skin/glow*. We have implemented assessment of harm and clear reporting routes between: the peer-supporters,

school-contacts, peer-supporter trainers, the field team, Project Manager, PI, TMG and Ethics Committee. All harms will be reported to the TSC as a standing agenda item.

12) Sample size

The target between-arm difference is 10 minutes of MVPA per weekday (i.e., 50 minutes per week). Such an increase would be associated with favourable cardiometabolic outcomes in young people[50]. From the PLAN-A feasibility study, the confidence interval on the between-arm difference in mean weekday MVPA (1.4 to 10.8 minutes, point estimate = 6.1 minutes) suggests that this difference is achievable. We also believe that making the refinements to the intervention identified in the feasibility study has the potential to achieve a 10-minute difference. However, recognising that even smaller intervention effects on MVPA may also lead to meaningful differences in health at a population level, we have calculated the sample size necessary to detect a range of differences in weekday MVPA (i.e., 10, 8 & 6 minutes). Table 2 shows the power calculations where the following parameters are fixed: cluster size = 70 (informed by feasibility study), intra class correlation (ICC) on weekday MVPA = 0.01 (informed by the feasibility study; T0 = <.0, T1 = .02, T2 = <.0001 and other studies[51, 52]), MVPA standard deviation = 20 minutes (based on feasibility study), coefficient of variation in cluster size of 0.22, 5% two-sided alpha and inflation to account for 30% of participants not providing primary outcome data. 12 schools and 800 pupils are required to detect a 10-minute difference in MVPA with 90% power, however 20 schools and 1400 pupils would provide 90% power to detect a smaller 6-minute difference in MVPA and ample power to detect an 8-minute difference. Further accounting for correlation between baseline and follow-up measures of MVPA (ρ=0.4) slightly reduces the number of schools required (last column, Table 2).

Table 2. Sample size parameters

MVPA Difference (mins)	Power	N pupils (uninflated)	N pupils (inflated)	N Schools	N Schools when allowing for correlation between baseline and follow-up
10	90	560	800	12	10
10	80	420	600	10	10
8	90	700	1000	16	12
8	80	560	800	12	12
6	**90**	**980**	**1400**	**20**	**18**
6	80	840	1200	18	16

Given the inherent uncertainty in many of these assumptions, we will recruit 22 schools (20+2 reserves) and randomise 20 schools and 1400 pupils to detect a 6 minute difference in MVPA with at least 90% power.

13) Data analysis

Quantitative analysis: The analysis and presentation of results will adhere to CONSORT guidance, and a statistical analysis plan, written and agreed with the independent statistician member of the TSC, will be registered at as part of the ISCTRN submission. We will also use the TIDieR guidelines[53] to report all intervention components. The primary comparative analysis will be examined on an Intention-to-Treat (ITT) basis including all participants included in randomisation without imputation for missing data. To take account of the hierarchical nature of the data, we will use multivariable mixed effects linear regression to estimate difference in the primary outcome for intervention group versus control, adjusting for baseline outcome score (e.g., baseline MVPA) and randomisation variables (e.g., school IMD). In a secondary analysis, we will further adjust for any variables that are imbalanced between trial arms at baseline. Similar analyses will be repeated for secondary outcomes. We will conduct sensitivity analyses to assess the potential effect of missing data using an appropriate imputation method. P-values and 95% confidence intervals will be

calculated. We will perform a small number of pre-specified subgroup analyses to estimate whether the intervention is differentially effective/cost-effective in different subgroups such as by school-level socioeconomic position. These will be described in an approved statistical analysis plan prior to the end of data collection. The trial is not powered to detect effectiveness in subgroups, and these analyses will be treated as exploratory, presented using confidence intervals and interpreted with caution. We will also conduct mediation analysis to explore whether any effect of the intervention is mediated by autonomous motivation, competence and peer support/norms for physical activity. As the intervention is informal and reliant on diffusion of information, it is not possible to assess whether participants complied with a set protocol and we therefore do not propose a secondary per-protocol analysis on that basis. A per protocol analysis will be conducted, however, on the basis of whether or not the intervention schools delivered the intervention. If the audit of new school physical activity interventions during the period of the study shows imbalance between arms, we will conduct an additional sensitivity analysis of the intervention effect on the primary outcome adjusting for this variable.

Qualitative / process evaluation analysis: Quantitative process evaluation data (e.g., peer-supporter training attendance, enjoyment) will be analysed using appropriate descriptive statistics (e.g., n, %, m, sd). Interviews and focus group recordings will be transcribed verbatim. Thematic analysis techniques, utilising QSR NVivo, will be used to produce initial codes and emergent themes. We will examine divergence and similarities across sources to develop a comprehensive understanding of intervention fidelity the mechanisms of impact, implementation, sustainability and potential roll out.

Economic analysis: A public sector perspective will be taken in the economic 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. Time spent by peer supporters receiving training will be reported, but the opportunity cost of pupil training and dissemination will not be included in the cost-effectiveness analysis. 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 Year 9 at follow up. In line with the analysis of the primary outcome, imputation will be used as a sensitivity analysis. We will calculate an incremental cost effectiveness ratio (ICER) by dividing the mean cost per pupil of the intervention (weighted by the number of Year 9 girls) by the difference in daily MVPA in the intervention and control arms. This will be repeated in pre-specified subgroup analyses (i.e. socioeconomic position). EQ-5D-Y and KIDSCREEN-10 responses will be used in secondary analyses to explore whether the intervention has any short-term impact on health-related quality of life. Currently, there is no value set for the EQ-5D-Y[54], so comparison between arms will be based on raw responses to each of the five items. A mapping algorithm will be used to estimate utility scores from the KIDSCREEN-10 and compare them between arms[55]. Health economics data will be reported as outlined in the Consolidated Health Economic Evaluation Reporting Standards (CHEERS) statement checklist[56].

If there is evidence that the intervention increases MVPA, we will explore whether existing epidemiological models can be used to extrapolate how sustained increases in MVPA might affect health outcomes and healthcare utilisation in adulthood. The identification of suitable models and a pre-specified effectiveness threshold at which extrapolation would be explored will be agreed with the Trial Steering Committee and detailed in a health economics analysis plan.

14) Ethical arrangements

Ethical approval was obtained from the School for Policy Studies ethics and research committee at the University of Bristol on 24/5/2018 (REF - SPSREC17-18.C22). We will employ a dual parent and child consent process. Parents will be asked to provide opt-out consent after receiving study information. Pupils will be asked to provide their own consent to take part in the study. Both parent and child consent will be required for the child to take part in the study. Parents will provide written consent for their child to attend the peer-supporter training. Adult participants (e.g., peer-supporter

trainers & school contacts) will provide written informed consent. At all time points pupils will be able to withdraw should they wish. All research staff and those involved in peer-supporter training will have Disclosure and Barring Service checks where necessary and will work in accordance with school and University of Bristol safeguarding policies.

15) Research governance

The Principal Investigator (PI: Prof Jago) will have overall responsibility for the conduct of the study, also drawing upon the experience of the co-applicant team in conducting complex interventions. The Trial 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. These groups were run successfully in the feasibility study. A **Trial Management Group (TMG)** chaired by the Prof Jago will meet monthly and include all co-applicants and the Trial Manager to discuss progress, study design, problems and solutions and ethical issues. We will build on the **Local Advisory Group (LAG)** developed in the feasibility study which consists of representatives from the local council, public health personnel, third sector (e.g., Women in Sport have agreed) and secondary schools (teachers & pupils). 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, roll out and dissemination. An independent **Trial Steering Committee Advisory (TSC)** will be established consisting of an independent chair plus 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 and public health delivery / commissioning. The TSC will meet four times during the project and will provide independent scientific scrutiny of the project, guidance on progression to 2nd follow-up measurement and support to the project team. We have not planned to have a data monitoring and ethics committee (DMEC) however, we will seek guidance at the first TSC meeting and instigate a DMEC if the TSC deem such a group necessary.

Sponsorship & Trial registration: The University of Bristol has agreed to act as the sponsor for this study. We will register the trial with the ISRCTN registry prior to participant recruitment and will submit the trial protocol for publication in a peer-reviewed open-access journal.

16) Project timetable and milestones

The project Gantt chart is appended to this application (Appendix 2). The project will commence on 1 July 2018 and end on 31st December 2020 (30 months). Should follow-on funding be awarded the end date would be 30 November 2021 (42 months). Specific project milestones include:

End date	Milestone
Aug 2018	Staff recruited; ethical approval gained
Feb 2019	Baseline data collection / peer-nomination / randomisation complete
Apr 2019	Peer-supporter trainers trained
July 2019	Peer-supporter 10-week intervention & post-intervention process evaluation complete
Feb 2020	First follow-up (Time 1) data collection complete
May 2020	Time 1 trial data analysis and process evaluation analysis complete
Nov 2020	Trial outcomes paper submitted; report writing; dissemination

17) Expertise

The team have the skills and experience in evaluating school-based physical activity RCTs needed to deliver the research and have established strong collaborations during the feasibility study.

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 school-based physical activity RCTs with children and collecting and interpreting physical activity data. He will lead the study.

Dr 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 and full school-

based trials, integrating behavioural theory into interventions and process evaluation. He was PI for the PLAN-A feasibility study and will be Co-PI for this project.
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 RCTs with children, peer-led health interventions and process evaluation.
Will Hollingworth is Professor of Health Economics at the University of Bristol with extensive experience of conducting economic analyses alongside RCTs of public health interventions.
Dr Ruth Kipping is Senior Research Fellow in Public Health and Epidemiology at the University of Bristol and Honorary Consultant in Public Health with Public Health England. Dr Kipping has expertise in the public health relevance of the proposed research through her work in the NHS and expertise in developing and evaluating physical activity interventions.
Dr Athene Lane is Reader in Trials Research and co-director of the Bristol Randomised Trials Collaboration (BRTC) with experience in the design and conduct of randomised trials.
Dr Stephanie MacNeill is a Lecturer in Medical Statistics within the Bristol Randomised Trials Collaboration (BRTC) unit at the University of Bristol. She has expertise in quantitative analysis of definitive randomised trials.

18) Partner Collaboration

Interventions costs will be funded by Sport England. We will invite representatives from this partner and others (Women in Sport, WESPORT) and 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. The project is adopted by DECIPHer who will advise on academic and non-academic dissemination.

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