

# Results of a cluster randomised controlled definitive trial of a Peer-Led physical Activity iNtervention for Adolescent girls (PLAN-A)

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## Scientific summary

### Background

Physical activity confers known health benefits for children and adolescents. However, a large proportion of adolescents do not do the minimum recommended daily physical activity to improve or maintain health. Physical activity levels decline during adolescence, with the decline starting earlier and becoming steeper for girls than for boys. There is therefore a clear need to increase physical activity for girls.

Schools are a common choice for interventions targeting girls' physical activity levels, however recent review data suggests that traditional top-down school-based interventions are minimally effective. Novel approaches are needed to target this group. Peers play a pivotal role in influencing adolescent's physical activity levels through social support, peer norms and peer affiliation. Peer-based interventions, which have been successful in changing teen smoking prevalence, could also be an effective means of helping adolescent girls become more physically active.

The Peer-Led physical Activity iNtervention for Adolescent girls (PLAN-A) was developed using Diffusion of Innovations (DOI) theory to frame a design which uses peers as agents of change to social and behavioural norms. Self-Determination Theory (SDT) underpins the intervention content and delivery style, since previous research has shown that interventions with theoretical underpinning are more likely to be effective in changing adolescent girls' physical activity.

Formative pilot and feasibility studies of PLAN-A tested the intervention model which identifies and trains the most influential girls in one year-group to be peer supporters in promoting physical activity to their peers and equips them with information and skills to perform their role. The intervention showed promise as a scalable approach that increased girls' daily physical activity levels. Evaluation work indicated where refinements could be made to the intervention to improve its reach and efficacy.

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The aim of this study was to test whether PLAN-A is effective and cost effective at scale at increasing adolescent girls' physical activity levels.

## Objectives

1. Determine the effectiveness of PLAN-A to increase objectively-assessed (accelerometer) mean weekday minutes of moderate-to-vigorous physical activity (MVPA) among Year 9 girls 5–6 months after the end of a 10-week intervention.
2. Determine the effectiveness of PLAN-A to improve the following secondary outcomes among Year 9 girls 5–6 months after the end of a 10-week intervention:
  - a. Mean weekend minutes of MVPA (accelerometer-derived)
  - b. Mean weekday minutes of sedentary time (accelerometer-derived)
  - c. Mean weekend minutes of sedentary time (accelerometer-derived)
  - d. Self-esteem (self-reported)
3. 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.
4. Determine the cost-effectiveness of PLAN-A from a public sector perspective.

## Methods

### Study design

PLAN-A was a cluster randomised controlled trial in UK secondary schools, using schools as the unit of randomisation, to compare the PLAN-A intervention against a usual-practice control. The trial included quantitative, process and economic evaluations.

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## Sample size

Twenty secondary schools were recruited from three local authority regions (11 in Avon [Bristol, South Gloucestershire, North Somerset and Bath and North East Somerset combined], five in Wiltshire, and four in Devon). Recruiting 20 schools provided 90 per cent statistical power to detect a difference in MVPA of at least 6 minutes.

## Recruitment

Prior to randomisation into treatment arms, baseline data were collected from all girls providing written consent in Year 9 (aged 13-14 years). In each school, girls received a briefing from project staff explaining the study measures and the intervention that their school could receive. Detailed student and parent information sheets were provided with student consent forms and parental opt-out forms. Freelance female trainers were recruited locally to deliver the intervention, selected for their teaching or coaching experience and a relevant background in physical activity promotion. Two of them also delivered the intervention in the feasibility study.

## Study measures

Measures took place at two time points. At baseline (T0), consenting participants completed a tablet-based questionnaire which included demographic, psychosocial and health-related quality of life questions. To answer research questions one and two (a-c), participants were issued with a hip-worn accelerometer (ActiGraph GT3x+; ActiGraph, LLC, Pensacola, FL, USA) to wear for 7 days. Follow-up measures (T1) were identical and were conducted 12 months +/- 2 weeks after baseline to ensure seasonal consistency across time points.

## Randomisation

Schools were randomised on a 1:1 randomisation ratio (control: intervention) after baseline data collection. Randomisation was stratified by region and area-level deprivation of school.

## Intervention

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The intervention design was adapted from the intervention model used in ASSIST (A Stop Smoking in Schools Trial) which was successful in reducing the odds of 12–13-year-olds being a smoker up to 2 years post intervention by 22 per cent. Modified to focus on increasing adolescent girls' physical activity, the PLAN-A intervention used DOI to underpin the diffusion of new behavioural norms and SDT principles were layered into the delivery, resources and content of the peer-supporter training. SDT principles include the support of autonomy (enacted through empowering peer-supporters with deeper knowledge of the topic and choices about who and how they supported their peers, coupled with strategic use of child-led activities in the training), relatedness (achieved through group activities promoting empathy and collaboration) and competence (enacted using varied learning techniques in the training including role play to reinforce contextual peer-supporter confidence). The intervention comprised four elements:

- A) *Peer nomination*: All Year 9 girls were asked to nominate influential girls in their year at school (i.e. who they respect, trust, listen and look up to) concurrently with baseline measures. The 18 per cent of the year most nominated by their peers were identified as potential peer supporters and, if the school was randomised to the intervention arm, invited to attend peer-supporter training.
- B) *Train-the-trainers*: Trainers received 3 days of training which covered the PLAN-A design and concept, role-play delivery of each activity in the peer-supporter training, how to deal with challenging behaviour, the principles behind DOI and SDT, and how to deliver the training in a manner that would support peer supporter autonomy (i.e., empowerment to support peers and provide choice). This training was delivered by a member of the research team and a 'lead trainer' who had delivered the intervention in the feasibility study.
- C) *Peer-supporter training*: Peer supporters at schools in the intervention arm attended two training days initially, followed by a top up day after 5 weeks. Using blended learning formats, and designed to be mentally and physically engaging, the training

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endeavoured to impart knowledge about physical activity and develop the confidence and skills required to promote physical activity amongst their close peers in a manner that supports autonomy. In eight out of ten schools the training was delivered in appropriate venues away from school. At the two other intervention schools the training was delivered at school. Peer supporters also received a booklet containing summary information from the training.

D) *10-week diffusion period:* After the initial 2-day training, peer supporters were encouraged to informally promote physical activity among their female school friends for 10 weeks (with the top-up training day after 5 weeks).

Consenting Year 9 pupils in control schools participated in baseline and follow-up measures, including peer nomination, however received no intervention or materials and continued with normal practice.

#### Economic evaluation

An economic evaluation of PLAN-A set out to determine the cost-effectiveness of PLAN-A and its potential cost utility (cost per quality-adjusted life year (QALY)). Resource use data were collected on all aspects of intervention set up and delivery. This included physical resources (e.g., venue hire) to deliver the intervention and time burden and expenses for school staff and trainers. Where possible, national unit costs for trainer and teacher time were used to increase generalisability. Health-related quality of life measures (KIDSCREEN-10 and EQ-5D-Y) were completed by pupils at baseline and follow up.

#### Process evaluation

A mixed-methods process evaluation was conducted to explore implementation and theoretical fidelity, receipt of the intervention by pupils, and the potential sustainability of PLAN-A in community settings. Measures included attendance registers, observations of the peer-supporter training, peer supporter and train-the-trainers evaluation questionnaires, post-intervention interviews with trainers (n=7) and intervention school contacts (n=10) and focus

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groups with peer supporters and non-peer supporters (n=6 of each). The focus groups were designed to explore the receipt of the intervention from the peer-supporters and non-peer supporters' perspectives. The interviews with school contacts were used to explore school-specific factors that may have impacted how the intervention was delivered or received. The interviews with trainers were used to capture detail about factors affecting delivery from their perspective, and explore possible improvements to the intervention. All were recorded using encrypted voice recorders. A school environment (physical activity provision and policy) audit was conducted in all 20 schools to explore differences by trial arm and impact on intervention delivery. Public sector stakeholders (n=19) were interviewed following the trial results being known to explore alternate physical activity intervention models for young people and discuss how research could support new approaches.

### Data analysis

School and pupil recruitment and retention were reported via a Consolidated Standards of Reporting Trials (CONSORT) flow diagram. Baseline characteristics of schools and pupils were compared between trial arms by reporting relevant summary statistics to identify any potentially influential imbalance. Primary and secondary comparative trial analyses were examined on an Intention-to-Treat (ITT) basis, using multivariable mixed effects linear regression (and presented with 95 per cent confidence intervals) to estimate differences between trial arms after adjustment for baseline physical activity and any variables showing imbalance at baseline. Analyses were conducted in Stata® (version 15; StataCorp LP, College Station, TX, USA). Qualitative process evaluation data (interviews and focus group recordings) were sent for independent transcription and then analysed thematically in NVivo (version 11; QSR International, Warrington, UK) using the framework method, allowing comparison of the data from all stakeholders. Quantitative process evaluation data were analysed using appropriate descriptive summary statistics.

For the economic analysis we used a mapping algorithm to indirectly estimate QALYs from KIDSCREEN-10 responses. To assess the cost-effectiveness of the PLAN-A intervention, © Queen's Printer and Controller of HMSO 2021. This work was produced by Jago *et al.* under the terms of a commissioning contract issued by the Secretary of State for Health and Social Care. This 'first look' scientific summary may be freely reproduced for the purposes of private research and study and extracts may be included in professional journals provided that suitable acknowledgement is made and the reproduction is not associated with any form of advertising. Applications for commercial reproduction should be addressed to: NIHR Journals Library, National Institute for Health Research, Evaluation, Trials and Studies Coordinating Centre, Alpha House, University of Southampton Science Park, Southampton SO16 7NS, UK.

individual pupil MVPA in intervention and control schools and school level incremental costs in intervention schools were calculated. The primary economic outcome was cost per additional minute of MVPA. Exploratory analysis estimated cost per QALY gained. Cost and effectiveness data were combined to calculate an incremental cost-effectiveness ratio (ICER). A nonparametric bootstrapping approach was used to determine the level of sampling uncertainty and results were presented using cost-effectiveness acceptability curves (CEACs) and a cost-effectiveness plane (CEP).

### Patient and public involvement

Focus groups were conducted with adolescent girls between September and November 2018 exploring issues around menstruation and being physically active – the perceived and real barriers, and strategies to overcome them. The findings of these focus groups were woven through new intervention content during intervention refinement.

## Results

### Recruitment

In total, 20 schools and 1558 pupils consented to participate in the study, reflecting an 85% pupil recruitment rate. In the intervention group, 166 out of 191 (86.91%) invited girls agreed to be peer supporters; an average of 18.36% of the year group, though this ranged from 13.41% to 23.21% between schools. Seven female trainers with physical activity promotion and/or youth work experience were recruited via local authority networks to deliver the intervention.

### Data provision

At baseline, complete questionnaire and accelerometer data were provided by 99.94% and 96.92% of pupils, respectively. 94.71% of those accelerometer files met the analysis inclusion criteria of two-or-more weekdays of  $\geq 500$  minutes of wear time. In total, 172 pupils

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were lost to follow up. At follow up, questionnaire and accelerometer completion rates were 88.83% and 87.03% respectively and 89.90% of those accelerometer files met the analysis inclusion criteria. The final sample providing valid accelerometer data at both time points was 1219 pupils. At baseline, the control arm was slightly less deprived and exhibited a higher prevalence of active travel to and from school, but otherwise the trial arms were balanced.

### Trial and economic findings

Intention to treat analysis found that there was no intervention effect on the primary outcome of weekday MVPA minutes at T1, with weak evidence of a negative treatment effect in the intervention arm (-2.84 minutes; 95% CI -5.94, 0.25;  $p=0.071$ ). There was no evidence of clear differences in any secondary outcomes between arms after adjustments.

The PLAN-A intervention, on average, cost £2,817 per school (£31.16 per Year 9 girl). Most of the cost would be borne by the local authority providing the training. The intervention was more costly and less beneficial than control. The probability that the intervention was cost-effective is low over a range of willingness to pay thresholds for improvements in MVPA. In unadjusted analyses, there was some evidence that KIDSCREEN-10 and EQ-5D-Y VAS scores deteriorated less in the intervention group at follow up. However, differences were small and consistent with no effect of the intervention in adjusted analyses. At conventional threshold values of willingness to pay per QALY, the intervention had less than 0.5 probability of being cost-effective.

### Process evaluation findings

The intervention was delivered fully and successfully in nine out of ten schools; in one school the top-up day was cut short due to a school event, thus reducing the dose for that school. Observation data indicate that delivery quality and fidelity to session plans and intervention objectives was good overall. The application of an autonomy-supportive delivery style was evident in all schools, in line with underpinning theory, though challenging behaviour in two

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schools was a barrier to this. Peer-supporters' perceived enjoyment and engagement of the training was high, and they reported learning new information and skills at the training. Delivery on the school site (two schools) was perceived by trainers to negatively affect delivery quality and pupil engagement. Peer supporters reported being subtle in their attempts at encouraging their friends to be active as well as co-participating in activities with them. Two intervention schools recorded markedly greater reductions in weekday MVPA between baseline and follow-up compared with other schools. There was no indication that the intervention was poorly delivered or received in these schools, however regional weather data during the follow up measures highlights serious adverse conditions which would almost certainly prevent outdoor physical activity including organised sports and active travel, and therefore may explain the outlying change data for these two schools.

## Conclusions

There was no evidence that the PLAN-A intervention was effective at increasing weekday MVPA compared to usual practice in 13-14-year-old girls and, consequently, the intervention was not cost-effective. The process data show that this is despite the intervention having high acceptance and being delivered with good fidelity. Challenges included the accurate measurement of peer-supporting behaviour and connecting that exposure to changes in physical activity in the face of myriad confounding factors. Possible explanations for a lack of positive effect of the intervention include a change in year group from the feasibility study and diluted intervention dose, however it is difficult to accurately estimate the impact of these factors on the complex intersection between environment, motivation and behaviour. The findings therefore provide strong evidence that the PLAN-A intervention is neither an effective nor cost-effective means of increasing PA among adolescent girls and as such it should not be implemented or disseminated. It has been argued that single individual-level interventions implemented in schools are insufficient to bring about increases in physical

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activity for the masses, and more system-wide approaches may be needed. This report recommends further research exploring the implementation considerations and utility of using a whole-school approach to promote physical activity in young people.

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