

Peer-led physical activity intervention for girls aged 13 to 14 years: PLAN-A cluster RCT

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Scientific summary

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Scientific summary

Background

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

Schools are a common choice for interventions targeting girls' physical activity levels; however, recent review data suggest 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 adolescents' 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 to 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 that uses peers as agents of change for social and behavioural norms. Self-determination theory (SDT) underpins the intervention content and delivery style, as 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 a 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 refinements that could be made to the intervention to improve its reach and efficacy.

The aim of this trial was to test whether or not 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 (i.e. using an 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:
 - mean weekend minutes of MVPA (accelerometer derived)
 - mean weekday minutes of sedentary time (accelerometer derived)
 - mean weekend minutes of sedentary time (accelerometer derived)
 - 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

Trial design

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

Sample size

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

Recruitment

Prior to randomisation into treatment arms, baseline data were collected from all girls in Year 9 (i.e. aged 13–14 years) who provided written consent. In each school, girls received a briefing from project staff explaining the trial measures and the intervention that their school could receive. Detailed student and parent information sheets were provided, along 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 the trainers also delivered the intervention in the feasibility trial.

Trial measures

Measures were taken at two time points. At baseline/time 0 (T0), consenting participants completed a tablet-based questionnaire that included demographic, psychosocial and health-related quality-of-life questions. To answer research questions 1 and 2(a–c), participants were issued with a hip-worn accelerometer (ActiGraph GT3X+; ActiGraph LLC, Pensacola, FL, USA) to wear for 7 days. The follow-up measures at time 1 (T1) were identical and were conducted 12 months \pm 2 weeks after baseline to ensure seasonal consistency across time points.

Randomisation

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

Intervention

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- to 13-year-olds being a smoker up to 2 years post intervention by 22% [Campbell R, Starkey F, Holliday J, Audrey S, Bloor M, Parry-Langdon N, *et al.* An informal school-based peer-led intervention for smoking prevention in adolescence (ASSIST): a cluster randomised trial. *Lancet* 2008;**371**:1595–602]. Modified to focus on increasing adolescent girls' physical activity, PLAN-A 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 involved four elements:

1. Peer nomination. All Year 9 girls were asked to nominate influential girls in their year at school (i.e. girls whom they respect, trust, listen and look up to) when the baseline measures were taken. The 18% of girls in the year who were most frequently 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.

2. Train the trainers. Trainers received 3 days of training that 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 supporters' 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 trial.
3. 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 endeavoured to impart knowledge about physical activity and develop the girls' confidence and skills required to promote physical activity among their close peers in a manner that supports autonomy. In 8 out of 10 schools, the training was delivered in appropriate venues away from school. At the other two intervention schools, the training was delivered at school. Peer supporters also received a booklet containing summary information from the training.
4. Ten-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, they received no intervention or materials and continued with normal practice.

Economic evaluation

An economic evaluation of PLAN-A set out to determine its cost-effectiveness and its potential cost-utility [measured using quality-adjusted life-years (QALYs)]. 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 the EuroQol 5-Dimensions, Youth version (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 groups with peer supporters and non-peer supporters ($n = 6$ for 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 had an impact on 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 interviews were recorded using encrypted voice recorders. A school environment (i.e. physical activity provision and policy) audit was conducted in all 20 schools to explore differences by trial arm and the impact on intervention delivery. Public-sector stakeholders ($n = 19$) were interviewed once the trial results were known to explore alternative 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 [presented with 95% confidence intervals (CIs)] to estimate differences between trial arms, after adjustment for baseline physical activity and any variables showing imbalance at baseline. Analyses were conducted in Stata® (StataCorp LP, College Station, TX, USA), version 15. Qualitative process evaluation data (i.e. interviews and focus group recordings) were sent for independent transcription and then analysed thematically in NVivo (QSR International, Warrington, UK), version 11, using the framework method, allowing the 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 PLAN-A, 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 the cost per QALY gained. Cost and effectiveness data were combined to calculate an incremental cost-effectiveness ratio (ICER). A non-parametric 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 2018 and November 2018, exploring issues around menstruation and being physically active (i.e. 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 trial, 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, although 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. A total of 94.71% of the accelerometer files met the analysis inclusion criterion of two or more weekdays with ≥ 500 minutes of wear time. In total, 172 pupils were lost to follow-up. At follow-up, questionnaire and accelerometer completion rates were 88.83% and 87.03%, respectively, and 89.90% of the accelerometer files met the analysis inclusion criteria. The final number providing valid accelerometer data at both time points was 1219 pupils. At baseline, pupils in the control arm had slightly lower Index of Multiple Deprivation scores and exhibited a higher prevalence of active travel to and from school than pupils in the intervention arm, but, otherwise, the trial arms were balanced.

Trial and economic findings

The ITT 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 (mean difference -2.84 minutes, 95% CI -5.94 to 0.25 minutes; $p = 0.071$). There was no evidence of a clear difference in any secondary outcome between the arms after adjustments.

The intervention cost, on average, £2817 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 the control. The probability that the intervention was cost-effective was low over a

range of willingness-to-pay thresholds for improvements in MVPA. In unadjusted analyses, there was some evidence that deterioration in KIDSCREEN-10 and EQ-5D-Y visual analogue scale scores between baseline and follow-up was lower in the intervention group than in the control group. 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 probability of the intervention being cost-effective was < 0.5 .

Process evaluation findings

The intervention was delivered fully and successfully in 9 out of 10 schools; in one school, the top-up day was cut short because of a school event, thus reducing the dose for that school. Observation data indicated that delivery quality and fidelity to session plans and intervention objectives were good overall. The application of an autonomy-supportive delivery style was evident in all schools, in line with underpinning theory, although challenging behaviour in two schools was a barrier to this. Peer supporters' perceived enjoyment of and engagement with the training was high, and they reported learning new information and skills at the training. Trainers perceived delivery on the school site (which occurred in two schools) 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 participating in activities with them. Two intervention schools recorded markedly greater reductions in weekday MVPA between baseline and follow-up than the reductions recorded by 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 highlighted serious adverse conditions that would almost certainly have prevented outdoor physical activity, including organised sports and active travel. Therefore, this may explain the outlying change data from these two schools.

Conclusions

There was no evidence that PLAN-A was effective at increasing weekday MVPA compared with usual practice in 13- to 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 trial 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 a cost-effective means of increasing physical activity among adolescent girls and, therefore, 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 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.

Trial registration

This trial is registered as ISRCTN14539759.

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