Development and feasibility cluster randomised controlled trial of a Peer-Led physical Activity iNtervention for Adolescent girls (PLAN-A)

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Scientific summary

Background

Girls are less physically active than boys and the majority of adolescent girls in the UK do not meet government physical activity recommendations. Current intervention approaches have had limited success in increasing girls' physical activity and new approaches are needed. Adolescents' peers (including their opinions, behaviours, support and norms) create an important and influential social system in that their physical activity occurs. However, peer-based interventions have been largely limited to older pupils mentoring younger pupils which do not harness the potential power within close friendships of girls in the same school year. This research project aimed to evaluate the feasibility of PLAN-A, a peer-led physical activity intervention for Year 8 girls.

Objectives

The study comprised two phases: Phase 1, refinement and piloting and Phase 2, a feasibility study. An *a priori* list of progression criteria was used to inform a decision to progress to a definitive trial.

The Phase 1 objectives were:

1. Adapt and refine the ASSIST (peer-led stop smoking) intervention to develop a peer-based training programme which focuses on promoting physical activity amongst Year 8 girls.
2. Develop an intervention logic model.

The Phase 2 objectives were:

1. Estimate the recruitment rate of year 8 girls and peer-supporters and monitor attendance at the peer-supporter training.
2. Qualitatively examine the acceptability of the intervention to students, peer-supporter trainers, schools and parents and identify necessary refinements.
3. Report accelerometer and questionnaire data provision rates, examine data quality and explore the implications of missing accelerometer data.

4. Estimate the potential effect of the intervention on daily accelerometer-derived moderate-to-vigorous physical activity (MVPA) secondary activity-related and psychological variables immediately after the intervention and 12 months after baseline.
5. Estimate the school-related intra-class correlation (ICC) for daily MVPA
6. Estimate the sample size for definitive trial evaluation.
7. Identify and test the feasibility of collecting the data needed to cost the intervention and conduct a cost-effectiveness analysis in a definitive trial.
8. Qualitatively examine parental views data linkage and the completeness of data required to link participant data to educational attainment.

Methods

Phase 1

Formative, iterative, qualitative research (N = 16) was conducted comprising extensive public involvement to refine the PLAN-A intervention (i.e., peer-supporter training content & trainer characteristics, recruitment materials, study logo). One secondary school (N = 70 Year 8 girls) was recruited to conduct a pilot of the PLAN-A intervention (details below) and qualitative and quantitative process evaluation was used to identify refinements before conducting the feasibility study in Phase 2.

Phase 2

Study design

A two-arm cluster randomised controlled feasibility study in six secondary schools to compare the PLAN-A intervention (four schools) against a usual-practice control (two schools) was conducted, alongside a mixed-methods process evaluation and health economics evaluation (Trial registration: ISRCTN12543546). Ethical approval was granted by a University of Bristol Ethics Committee.

Inclusion Criteria

School eligibility criteria were: State-maintained mainstream secondary schools, located in Wiltshire and South Gloucestershire, with girls in Year 8, above the

median of the local Student Premium Indicator and not currently implementing the ASSIST intervention.

School & Participant Recruitment

Eligible schools (N = 16) were invited and those that expressed an interest were provided with study information and gave study consent. All Year 8 girls were invited to participate, and were provided with young persons and parent information sheets and parent opt-out details. All adult participants (peer-supporter trainers, teachers & parents) provided written informed consent.

Measures

Measurements were taken at three time points:

1. Time 0 [T0 (baseline)]: The beginning of Year 8, September - October 2015
2. Time 1 [T1 (follow up 1)]: The end of Year 8, May - June 2016
3. Time 2 [T2 (follow up 2)]: The beginning of Year 9, September -October 2016 (T2 was the likely primary outcome point in a definitive trial)

At each time point, participants wore an accelerometer (Actigraph GT3x+) for seven days and completed a questionnaire assessing psychosocial constructs and health-related quality of life. Following baseline data collection six schools were randomly allocated, stratified at an intervention:control ratio of 2:1 within LA area (Wiltshire and South Gloucestershire). Two schools were allocated to the control arm and four schools were allocated to the intervention arm.

A mixed methods process evaluation was conducted. This comprised of observations of the peer-supporter training, post-intervention qualitative interviews and/or focus groups with students (N = 64 peer-supporters, non-peer-supporters & control school pupils), peer-supporter trainers (N = 5), parents of peer-supporters (N =12) and school teachers (N = 6), quantitative peer-supporter and trainer evaluation surveys, and assessment of school context (including school physical activity facility and policy audits).

An economic evaluation aimed to assess the feasibility of collecting the data required to cost the intervention and conduct a cost-effectiveness analysis in a definitive trial

and explore the affordability and potential cost-effectiveness of the intervention. Resource use was recorded and students' quality of life was assessed using the EQ-5D-Y.

Data analysis

Quantitative data were analysed using appropriate descriptive summary statistics. School and student recruitment and retention through the study were presented as a CONSORT flow chart. Summary statistics for the (definitive trial) primary (i.e., weekday MVPA and secondary outcomes (other physical activity and psychosocial outcomes) were presented, by intervention and control group according to the allocation of the student's school (i.e., an intention to treat analysis). The adjusted differences in means between intervention and control groups were estimated using mixed effects linear regression presented with their 95 per cent confidence interval. Sensitivity analyses were undertaken exploring implications of missing data and data imputation. Analyses were conducted in Stata. Qualitative process evaluation data were analysed using the Framework Method allowing comparison of the data from all stakeholders. Analyses were conducted in NVivo. Quantitative process evaluation and health economic evaluation data were analysed using appropriate descriptive summary statistics.

Intervention

The PLAN-A intervention comprised: (1) peer-nomination, (2) recruitment and training of peer-supporter trainers, (3) peer-supporter training and (4) a ten-week informal peer-diffusion period. Year 8 girls identified influential female peers in their year using a peer-nomination questionnaire (i.e., who they respect, look up to, listen to) and the highest scoring 18% (those with most nominations) were invited to be peer-supporters. Consenting peer-supporters attended 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 (five weeks) peer-supporters attended a further top-up training day to revisit core messages, share successes and resolve problems. Training was held off the school site and was led by external peer-supporter trainers who had attended a three-day training programme. The training

was informed by Phase 1 findings 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 was grounded in self-determination theory. Peer-supporters then informally promoted messages about increasing physical activity amongst their peers for ten weeks, with the top-up training at five-weeks.

Results

Phase 1 resulted in the co-production of the PLAN-A intervention which was successfully piloted amongst 70 Year 8 girls and ten peer-supporters and refined based on stakeholder input. The logic model was created. Key findings included changes to terminology, identification of important peer-supporter trainer characteristics, guidance on balancing active and less active learning and specific changes to peer-supporter training activities.

In Phase 2, 427 Year 8 girls from six secondary schools were recruited (intervention arm n =269; control arm n =158) reflecting a 95% recruitment rate. 55 girls consented (96.49% of those invited) to be a peer-supporter and 94% attended all three training days. Peer-supporter training was delivered by five females with experience of health promotion, sport coaching, youth work, and theatre. The intervention was acceptable to students, teachers, trainers and parents. Peer-supporters engaged well with and enjoyed the training and reported various peer-support strategies (encouragement, co-participation, knowledge sharing, using empathy and being subtle). Refinements to the intervention were identified including adding more active learning and group activities and providing more support on how to start conversations with peers.

Accelerometer return rates were high (>85%) at each time point and the wear time criteria was met by 82.63%, 71.13% and 62.21% of participants at Time 0, 1 and 2 respectively. Questionnaire data provision exceeded 90% at each time point. The three variables needed to perform linkage to education data (i.e., full name, date of

birth & home postcode) were collected for 89% of students. The complete-case adjusted regression analysis showed that there was no between-arms difference in weekday MVPA at Time 1. At Time 2, there was evidence for a between-arms difference in weekday MVPA in favour of the intervention arm (6.09 minutes, 95% CI = 1.43, 10.76). This represented a prevention in the decline of weekday MVPA in the intervention group from the beginning of Year 8 to Year 9. Results of sensitivity analysis where missing data were imputed were very similar to the complete case analysis. There was no evidence that the intervention changed the psychosocial or quality of life variables. The economic evaluation showed that the information required to estimate the cost of the intervention could be collected and that on average PLAN-A cost £2685 per school to deliver (£37 per Year 8 girl). The cost per 10-minute increase in mean weekday MVPA was £61 per Year 8 girl at 12 months. Sample size calculations suggested that a definitive trial conducted with 20 schools and 1400 girls would be adequately powered to detect a between-arms difference in weekday MVPA of at least six minutes.

Conclusions

PLAN-A is a feasible and acceptable school-based peer-led physical activity intervention for Year 8 girls. The intervention showed evidence of promise to positively affect girls' physical activity levels. The progression criteria were met, supporting further testing of intervention effectiveness and cost-effectiveness in a definitive cluster randomised controlled trial.

Trial registration

Trial registered as ISRCTN12543546

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