PLAN-A: Assessment of whether a peer-led program increases the physical activity of year 9 girls

Submission date	Recruitment status No longer recruiting	[X] Prospectively registered		
30/05/2018		[X] Protocol		
Registration date	Overall study status	Statistical analysis plan		
31/05/2018	Completed	[X] Results		
Last Edited 05/08/2021	Condition category Not Specified	[] Individual participant data		

Plain English summary of protocol

Background and study aims

Being physically active is good for children's health. Few adolescent girls are active enough to get these health benefits and teenage girls face lots of barriers to being physically active. Research shows that most school-based programs to increase adolescents' physical activity do not work, but few high quality studies have been tried in the UK. A peer-led program called PLAN-A has been developed in which adolescent girls inspire their peers to take part in more physical activity. Preliminary work has shown that PLAN-A has the potential to help adolescent girls to be more physically active.

This study aims to examine whether girls who take part in the PLAN-A program in 10 intervention schools obtain more moderate to vigorous intensity physical activity (MVPA) a year after the baseline assessment has been made than girls in 10 comparison schools. It also assesses how much the program costs and conducts qualitative research to understand how the program was received by schools and pupils and if it could be improved or adapted before using widely.

Who can participate? Year 9 girls in participating schools.

What does the study involve?

The study is based on a feasibility trial in which a peer-led physical activity intervention for 13-14 year old girls was developed. The study is conducted in 20 schools, ten of which receive the intervention. In these schools, peer supporters are trained by experts in physical activity and youth work. Ten schools are "comparison schools" and do not do the peer-training. Schools are allocated to intervention or comparison at random.

Year 9 girls in all twenty schools are asked to provide information at two times: before the schools are chosen to be project or comparison schools, and 1 year after the first measurements. Participants' physical activity levels are measured using activity monitors and their motivation for being active using questionnaires. The cost of delivering the intervention is also assessed.

Interviews and group discussions with peer-supporters, pupils, school staff, trainers and public health commissioners are used to find out what was successful and what could be changed in future.

What are the possible benefits and risks of participating?

The benefits of participation for peer-supporters include an increased awareness of physical activity and the health benefits of being more active, improved teamwork, communication, empathy and problem solving skills, and a potential increase in physical activity levels due to the ideas and knowledge gained during the training and intervention period. The benefits of participation for Year 9 girls who are not peer-supporters include being encouraged to be more active from their peers, greater exposure to new ideas about how to incorporate physical activity into their day-to-day life, and the potential health benefits this holds. Schools benefit by having a number of their pupils attending a training course which may increase their skills, confidence and leadership abilities. Additionally, physical activity levels throughout the Year 9 female cohort may be increased.

The potential risks to participants are minimal. Peer-supporters may face instances of bullying /teasing, but we ensure reporting procedures are in place to minimise such instances and effectively deal with any that do arise. Non-peer-supporters may feel pressured to be active, but the training that peer-supporters receive covers empathy and effective communication.

Where is the study run from? University of Bristol (UK)

When is the study starting and how long is it expected to run for? May 2018 to January 2021

Who is funding the study? National Institute for Health Research (Public Health Research Programme) (UK)

Who is the main contact? Prof Russ Jago (scientific) russ.jago@bristol.ac.uk

Study website

http://www.bristol.ac.uk/sps/plan-a/

Contact information

Type(s)

Scientific

Contact name

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers PHR 17/50/01

Study information

Scientific Title

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

Acronym

PLAN-A

Study objectives

The hypothesis is that girls in the intervention arm will engage in more minutes of weekday MVPA at time 1 than girls in the comparison arm. We also hypothesise that there will be secondary effects on Weekend MVPA as well as both Weekday and Weekend sedentary time.

Ethics approval required

Old ethics approval format

Ethics approval(s)

School for Policy Studies Ethics Committee University of Bristol, 24/05/2018, ref: SPSREC17-18. C22

Study design

Cluster randomised controlled trial

Primary study design

Interventional

Secondary study design

Cluster randomised trial

Study setting(s)

Study type(s)

Prevention

Participant information sheet

Not available in web format, please use the contact details below to request a patient information

Health condition(s) or problem(s) studied

Physical activity

Interventions

Ten schools are chosen at random to run the peer-training project and ten schools are comparison schools and do not do the peer-training.

1. Peer-nomination:

Peer-supporters are identified by peer nomination in which consenting Year 9 girls identify, by questionnaire, the female peers they perceive to be influential. The highest scoring 18% (those with most nominations) are invited to be peer-supporters, with the aim of ensuring that ≥15% take on this role

2. Peer-supporter training:

Peer-supporters attend a two-day course to develop the skills, knowledge and confidence to promote physical activity amongst their peers. Training is held off-site and led by external peer-supporter educators who themselves have attended a training programme. The peer-supporter training is informed by our developmental work with Year 9 girls, is interactive and address issues central to girls' PA, including: PA benefits, active choices, developing an active identity, being active with friends, sedentary behaviour, communicating with confidence, empathy and supporting motivation. The content is grounded in self-determination theory to build the girls' perceived autonomy, competence and sense of social support, both for being a peer-supporter and to promote physical activity. Peer-supporters are encouraged to keep these concepts in mind when having conversations with their peers.

3. 10-week informal health message peer-diffusion component:

Peer-supporters informally promote messages about increasing physical activity amongst their peers for 10 weeks. At the mid-point of the intervention peer-supporters attend a 1 day off-site top-up session to revisit core messages, share successes and collaboratively resolve problems. Year 9 girls in all twenty schools are asked to provide information at two times: before the schools are chosen to be project or comparison schools and 1 year after the first measurements.

Intervention Type

Behavioural

Primary outcome measure

Accelerometer determined mean minutes of Weekday MVPA at T1 (baseline + 1 year)

Secondary outcome measures

- 1. Accelerometer determined mean minutes of Weekend MVPA at T1 (baseline + 1 year)
- 2. Accelerometer determined mean minutes of Weekday sedentary time at T1 (baseline + 1 year)
- 3. Accelerometer determined mean minutes of Weekend sedentary time at T1 (baseline + 1 year)
- 4. Cost-effectiveness of the PLAN-A intervention from a public-sector perspective

Overall study start date

Completion date

31/01/2021

Eligibility

Key inclusion criteria

Year 9 girls in participating schools

Participant type(s)

Other

Age group

Child

Sex

Female

Target number of participants

1400

Total final enrolment

1558

Key exclusion criteria

No participant exclusion criteria

Date of first enrolment

01/09/2018

Date of final enrolment

08/02/2019

Locations

Countries of recruitment

England

United Kingdom

Study participating centre University of Bristol

Centre for Exercise, Nutrition and Health Sciences, School for Policy Studies, 8 Priory Road

Sponsor information

Organisation

University of Bristol

Sponsor details

Research and Enterprise Development
3rd Floor
Senate House
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England
United Kingdom
BS8 1TH

Sponsor type

University/education

Website

www.bristol.ac.uk/red/

ROR

https://ror.org/0524sp257

Funder(s)

Funder type

Government

Funder Name

NIHR Public Health Research Programme - (REF PHR 17/50/01)

Results and Publications

Publication and dissemination plan

We plan to publish up to four study papers. 1) study protocol paper; 2) main trial (cost and cost effectiveness) paper; 3) process evaluation paper; and 4) mediation paper.

1. 2020 non-peer-reviewed Statistical Analysis Plan in https://research-information.bris.ac.uk/en/publications/plan-a-a-cluster-randomised-trial-of-a-peerled-physical-activity-intervention-for-adolescent-girls(feb11711-90bf-4925-8e00-1fbc615dd850).html (added 17/02/2020)
2. 2020 non-peer-reviewed Health Economics Analysis Plan in https://research-information.bris. ac.uk/en/publications/plana-a-cluster-randomised-trial-of-a-peerled-physical-activity-intervention-for-adolescent-girls-health-economic-analysis-plan(a134a04c-ae2b-4126-96cc-798db0a3dbfd).html (added 17/02/2020)

Intention to publish date

31/12/2021

Individual participant data (IPD) sharing plan

In line with the NIHR research contract, anonymised data from this study will be made available to other researchers. This will be done using the University of Bristol's Research Data Repository.

IPD sharing plan summary

Stored in repository

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<u>Protocol article</u>	protocol	28/05/2019	13/01/2020	Yes	No
Results article		13/05/2021	17/05/2021	Yes	No
Results article	qualitative results	18/07/2021	05/08/2021	Yes	No