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Peer reviewed version

University of BRISTOL

Bristol Randomised Trials Collaboration

PLAN-A

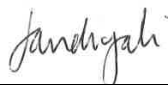
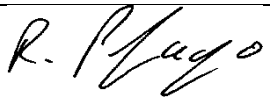
PEER POWER . ACTIVE GIRLS

PLAN-A: A cluster randomised trial of a Peer-led physical Activity iNtervention for Adolescent girls (ISRCTN14539759)

Health Economic Analysis Plan

Version 1 (13.02.20)

The following people have reviewed the Statistical Analysis Plan and are in agreement with the contents

	NAME	TITLE	SIGNATURE	DATE
Author	Rebecca Kandiyali	Research Fellow in Health Economic Evaluation		29.1.20
Lead Health Economist	Will Hollingworth	Professor in Health Economics		29.1.20
PI	Prof Russ Jago	Chief investigator		29.1.20

NHS National Institute for Health Research

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1. OVERVIEW

1.0 Purpose of HEAP

The purpose of the HEAP is to describe the analysis and reporting procedure intended for the economic analyses alongside the PLAN-A RCT. The analysis plan is designed to ensure that there is no conflict with the protocol and associated SAP and Process Evaluation Analysis Plan and it should be read in conjunction with them. Any deviation from HEAP will be described and justified in the final report and publications (e.g. NIHR-PHR monograph).

1.1 Trial protocol version

This document has been written based on information contained in the trial protocol version 1.0, dated 31/05/2018

1.2 Trial Statistical Analysis Plan (SAP) version

Plan A SAP v1.0 (dated 7.02.2020)

1.3 Trial HEAP version

Plan A HEAP version 1.0 (dated 13.02.2020)

1.4 HEAP revisions

Any revisions to the HEAP following formal sign-off and approval will be presented in a table format with the following column headings: Protocol version, Updated HEAP Version No, Section number changed, Description of and reason for change, Individual making the change, Date changed. Each row subsequently added to the table will indicate each HEAP revision change

1.5 Roles and responsibilities

The HEAP was prepared by Dr Rebecca Kandiyali and approved by Prof Will Hollingworth. The trial health economist(s) are responsible for conducting and reporting the economic evaluation in accordance with the HEAP.

1.6 Trial background and rationale

Adolescent girls are less active than boys. Previously tested school-based interventions in physical activity (PA) can be resource intensive and have limited evidence of effectiveness. The theory-based intervention being evaluated here was based on the ASSIST stop smoking in schools trial and taps into naturally occurring and sustainable health improvement mechanisms.

1.7 Aim(s) of the trial

Primary outcome: Determine effectiveness of PLAN-A intervention on objectively measured mean weekday moderate and vigorous physical activity (MVPA). Secondary outcomes: mean weekend MVPA, sedentary time in week, sedentary time at weekend, self-esteem, Quality of Life (QoL). Additional outcomes collected: measures of mediators and descriptive variables index of multiple deprivation and unique pupil identifier numbers to allow future linkage. Process measures which include (but not limited to) assessment of intervention fidelity and implementation. Economic objectives and resource outcomes are described in section 2 of this HEAP.

1.8 Objectives and /or research hypotheses of the trial

Trial objectives and aims

Primary objective

To determine the effectiveness of the PLAN-A intervention to increase objectively-assessed (accelerometer) mean weekday minutes of moderate to vigorous physical exercise (MVPA) among Year 9 girls 5-6 months after the end of the 10-week intervention.

Secondary objectives

1. 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:
    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 Self-description questionnaire (SDQ, Marsh 1992))

2. 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.

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

1.9 Intervention and comparator(s)

This section as per SAP

1.9.1 Description of intervention

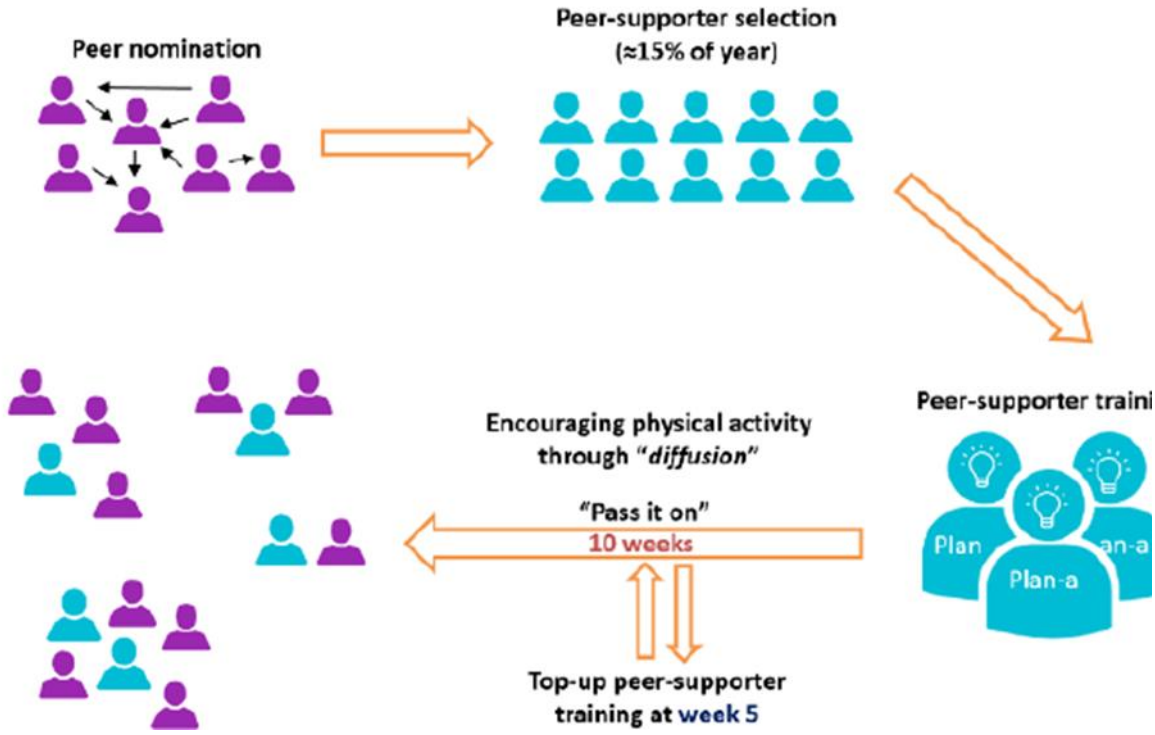
Ten schools will be randomly allocated to the intervention arm. The PLAN-A intervention was adapted from the A Stop Smoking Intervention in Schools Trial (ASSIST) intervention model, a school-based peer-led programme which reduces smoking among UK adolescents (Campbell, Starkey et al. 2008) to focus 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 Diffusion of Innovations (DOI) (Rogers, 1983) 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. The content will be grounded in Self-Determination Theory (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. Trainers to deliver the peer-supporter training will be employed as free-lancers. In keeping with a public sector approach, the opportunity to become a PLAN-A trainer will be advertised via Local Authority health improvement teams.

C) 10-week intervention: Peer-supporters will informally promote messages about increasing physical activity amongst their peers for 10 weeks.

The PLAN-A intervention concept is described below:



1.9.2 Description of comparator

Ten schools will be randomly allocated to the control arm after baseline (T0) data collection and will not receive any form of intervention and will continue with normal practice. 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).

1.10 Trial design

Randomised cluster, allocation at unit of school. Unblinded.

1.11 Trial start and end dates

Trial start – June 2018. Trial end date Dec 2020.
July - November 2018: Recruitment of schools,
Oct 2018 - Feb 2019: baseline data collection (including peer nomination) - complete (T0)
Feb 2019: school randomisation complete
Mar 2019: train the trainer (6^{th} -8^{th} March)
March - June 2019: peer supporters trained
July 2019: End of intervention, and process evaluation measures complete
Oct 2019 – Jan 2020: completion of follow up data collection (T1)
May-Nov 2020: Analysis.

2.0 Aim(s) of economic evaluation

The aim of the economic evaluation is to address the question "What is the cost- effectiveness of a peer-led school-based physical activity intervention programme in adolescent girls"?

2.1 Objective(s) of economic evaluation

The primary objective of the health economic evaluation is to establish whether the PLAN-A intervention is a cost- effective method of increasing physical activity of adolescent girls at T1 (5-6 months after the end of the 10-week intervention) with further consideration of long-term impact.

2.2 Overview of economic analysis

The within-trial economic analysis will be performed using individual participant level data on physical activity and school level data on intervention costs from the PLAN-A trial. The analytical approaches will take the form of analysis of costs, cost-effectiveness analysis and cost consequences analysis. Based on trial evidence, incremental cost-effectiveness ratios will be calculated by taking a ratio of the difference in the mean costs and mean effects (mean weekday MVPA).

2.3 Jurisdiction

The trial is conducted in state funded schools in the UK which has a publicly funded national health system – the NHS.

2.4 Perspective(s)

This is an intervention within an education setting that would ultimately be funded from local authority or academy budgets, therefore, the within trial economic analysis will be from a public sector perspective. However, as part of the process evaluation, we are discussing girls' out-of-pocket expenditure for activity which will potentially provide insights about personal costs. When we consider longer-term impacts, we will endeavour to discuss the possible broader societal impacts and also delineate the health versus other public sector consequences to explore inter-sectoral consequences of public health interventions in physical activity.

2.5 Time horizon

The within trial analysis will be conducted after data entry and cleaning is complete and after the final school visit of T1. If the trial provides evidence that the intervention is potentially effective in increasing weekday MVPA (defined below), then we will explore methods to extrapolate the within trial analysis to a longer time horizon.

2.6 Statistical software used for HE analysis

All analyses will use Stata 15 or higher.

2.7 Identification of resources

We are collecting resource use data on all aspects of the intervention set-up and delivery. These include school staff, trainer and pupil time, expenses, travel and materials, venue and administration. The health economic analysis will not collect any resources used by control schools, as the comparator is normal practice (i.e. 'physical activity education as usual'). Although the intervention has the potential to influence participants healthcare use long-term, we will not collect this information within the trial as we wish to minimise participant burden and do not believe the intervention is likely to influence healthcare use in the short term. Additionally, there are issues with the accuracy of recall or healthcare use from T0 to T1. Obtaining information on private costs of physical activity of girls and families would also increase the questionnaire burden and is outside of the public sector perspective of this evaluation. However, information on private costs will be explored qualitatively. Focus groups conducted in intervention schools with peer supporters, non-peer supporters and school contacts will probe for resource(cost) implications of the interventions.

Table 1 (see appendix) outlines all intervention resource use identified. This outlines each item of resource use, how that resource use will be identified (e.g. by pro-forma, expense claim or study budget). An electronic version of this table (restricted to the trial team only), will additionally detail who within the Plan-A study team will be responsible for collecting the data, and where it will be saved. We have excluded research costs.

2.8 Measurement of resource use data

Details of the methods of resource use measurement are provided in Table 1 (appendix).

2.9 Valuation of resource use data

All resource use will be valued in monetary terms using appropriate UK unit costs (e.g. Department for Education for teacher and trainer costs) where applicable and prevailing market prices (where they exist) for other intervention delivery or set-up costs. Pupil time (i.e. peer supporter training days) has an opportunity cost in terms of educational time foregone, but there is no accepted method for placing a value on pupil time; we propose that this will be described descriptively and not given a monetary value. Adjustments will be made for inflation if necessary (for instance in order to present valuations for a single price year) using the ONS GDP deflator index.

2.10 Identification of outcome(s)

The primary outcome used in the cost-effectiveness analysis will be (mean) minutes of MVPA on weekdays. We will also collect data on EQ-5D-Y and KIDSCREEN-10.

2.11 Measurement of outcomes

EQ-5D-Y and the KIDSCREEN-10 at T0 (baseline) and T1

2.12 Valuation of outcomes

For the primary economic outcome, outcomes will be valued in natural units (i.e. mean weekday MVPA).

In the absence of a value set for the EQ-5D-Y, and concerns about the legitimacy of applying adult weights (Kind, Klose et al. 2015), we will restrict reporting of this to the mean and standard deviation of the EQ-5D visual analogue scale along with response frequencies at dimension-level.

In exploratory analysis, we will map from the KIDSCREEN-10 to the CHU-9D utility scores using a published algorithm. (Chen, Stevens et al. 2014, Ratcliffe, Huynh et al. 2016)

2.13 Analysis population

Full analysis set:
All consenting girls from randomised schools (intention-to-treat (ITT)). A per protocol analysis will only be carried out if one or more of the intervention schools does not deliver the peer-supporter training (as per the SAP).

2.14 Timing of analyses

The within-trial primary ("final") analysis will be conducted once all participants have been followed for 5-6 months after the end of the intervention.

2.15 Discount rates for costs and benefits

There will be no discounting for the within trial analysis as the time horizon is limited to a single year. Costs and benefits in the extrapolation model (if used) will be discounted at 1.5% p.a. as recommended by NICE in their Methods for the development of NICE public health guidance. (NICE 2012).

2.16 Cost-effectiveness threshold(s)

We note that there is no accepted cost-effectiveness threshold for the primary outcome (MVPA), making interpretation difficult. However, PA studies in this population often report in MVPA (Hollis, Sutherland et al. 2017); therefore use of the cost per minute metric allows comparison with other PA studies in similar populations (Gc, Wilson et al. 2016, Anokye, Mansfield et al. 2018, Gc, Suhrcke et al. 2018, Gc, Suhrcke et al. 2019) thus facilitating assessment of technical efficiency across PA studies.

2.17 Statistical decision rule(s)

We follow the same convention as per the statistical analysis plan in terms of statistical significance level i.e. Two-tailed tests will be used with effect estimates, 95% confidence intervals (CI) and p-values presented.

2.18 Analysis of resource use

The resource use for intervention set-up and delivery (and as itemised in Table 1) will be described in terms of average per school and average per year 9 female pupil.

2.19 Analysis of costs

The intervention will also affect pupils who haven't provided consent to follow-up. To better reflect cost per student most likely to be affected by the intervention we will estimate intervention school costs by dividing the costs of the peer-supporter programme at that school by the number of Y9 girls on the register at follow-up. Control schools will not be running the programme and will are assumed to have zero costs. An appropriate linear or generalised linear model (with the appropriate transformation informed by inspection of residuals and regression diagnostics) will be used to estimate an overall mean intervention cost per pupil potentially adjusting for the same variables used in the primary analysis of the SAP (See 6.3).

2.20 Analysis of outcomes

Analysis of EQ-5D-Y and KIDSCREEN-10 are described in the SAP. An exploratory analysis will report descriptive statistics (SD, 95% CI, range) around the (mapped) mean CHU-9D score.

2.21 Data Cleaning for analysis

Face validity tests will be conducted on data (e.g. to identify misspelt text) and checked against the source documents. Corrections identified will be documented in the Stata code.

2.22 Missing data

Our primary analysis will be complete case analysis. Trial data will however be examined for missing data. We will examine patterns of missingness. In secondary analysis will explore the robustness of our findings using an appropriate method of imputation.

2.23 Analysis of cost effectiveness

The primary economic outcome for the within trial economic evaluation will be cost per pupil for a unit change in weekday MVPA 5-6 months after the end of the intervention. This will be expressed in terms of cost per additional minute of MVPA which allows comparison with other, similar studies. In addition, we will estimate the incremental cost per pupil achieving a 5-minute increase in MVPA (considered a meaningful increase) between baseline and T1.

Cost and effectiveness data will be combined to calculate an incremental cost-effectiveness ratio (ICER) and confidence interval. In cost-effectiveness analysis we normally apply a method to account for the correlation between the costs and the effects which also takes into the account the effect of cluster-level correlation (Gomes, Ng et al. 2012). However, in this case we need to consider the appropriateness of such methods when there are no costs in the control arm.

A secondary economic analysis will take a cost consequences approach. This will present resource use, disaggregated costs and all trial outcomes (primary, secondary and outcomes mentioned within this HEAP) in a tabular format with outcomes and costs kept separate such that a decision maker can make their own conclusions on the breadth of evidence.

The exploratory analysis using mapped CHU-9D utilities will allow for consideration of cost-utility analysis (cost per QALY). We will estimate the incremental net monetary benefit at conventional NICE thresholds (£20,000 and £30,000 per QALY) with 95% confidence intervals.

2.24 Sampling uncertainty

The nonparametric bootstrapping approach will be used to determine the level of sampling uncertainty surrounding the mean ICER by generating 10,000 estimates of incremental costs and benefits and presenting results on cost-effectiveness acceptability curves (CEACs).

2.25 Subgroup analyses/Analysis of heterogeneity

As per the SAP, should there be evidence of imbalance between treatment groups on important baseline characteristics, subgroup analyses will be conducted where the effect of the variable on the primary economic outcome will be investigated.

2.26 Sensitivity analyses

We have not pre-specified sensitivity analyses. Should a post-hoc sensitivity analysis be proposed, this will be discussed by the management group, and reported as such.

2.27 Reporting standards

CHEERS guidelines will be followed when reporting the health economic evaluation, in a format appropriate to stakeholders and policy makers (Husereau, Drummond et al.).

3. CONSIDERATION OF LONG-TERM CONSEQUENCES

3.0 Approach

We propose to use conceptual/logic modelling techniques initially to explore the potential long-term consequences of PA in adolescence (NICE 2014, Deidda, Geue et al. 2019). We propose to do this by extending the evaluation framework in the process evaluation analysis plan (Figure 1b, p.4) to allow for long-term outcomes.

We aim to incorporate an extrapolation model if two conditions are met: 1. Evidence of promise; 2. Availability of a model linking changes in adolescent PA to long term health outcomes.

Evidence of promise does not require a statistically significant MCID (5 minutes of weekday MVPA). However, we will only extrapolate if the point estimate of MVPA is positive and the 95% confidence interval includes the possibility of a meaningful (5 minutes of weekday MVPA) positive intervention effect.

If no suitable long-term physical activity cost-effectiveness models are available, we are not resourced to develop a *de novo* model. In this instance, we will limit our analysis to the within trial time horizon with further discussion of the potential long-term health and economic effects with reference to the relevant literature.

3.1 Extrapolation/ Decision analytic modelling

An initial scoping review identified one physical activity cost-effectiveness model in the public domain for children in the UK (the NICE ROI model in Physical activity) (NICE 2019), which was limited to a 12-month time horizon and would not be suitable for extrapolation. A periodic review in November 2019 indicated that there is a recently published model that may be suitable for adaption subject to negotiation with study authors. (Gc, Suhrcke et al. 2019). We will update this review periodically and prior to unblinded analysis (Feb2021).

Appendix

Table 1 Resource use collected for set-up and delivery of the PLAN-A intervention in intervention schools

Resource category	Detail on included resource	Detail on excluded resource (& rationale)	How recorded?
Intervention set-up			
Intervention development time	Researcher time to prepare training materials	-	Time taken: Estimate from PLAN-A feasibility
Additional development from feasibility	Researcher time to edit and add new content to training materials (including grade of researcher)	-	Time taken: Description of task/activity. Researcher time logged and collated by research team
Facilitator of peer nomination process	Facilitator time (and payscale) associated with process of peer nomination Facilitator time (and payscale) for the subsequent cleaning and scoring of peer nomination data.	Pupil time collected but not costed. The time engaged in these activities represent an opportunity cost. As the time is quite small, and there is no financial cost, we do not propose using an imputed cost	For each school: Time taken (as taken from researcher time logs): split into 2 components I. Process II. Cleaning and scoring results Travel: from research staff expense claim
Train the Trainer resource and costs			
Train the trainer time (Lead trainer)	Prep & Delivery time		Time: Hourly/Daily fee:
Delivery agents time	Attendance time		
Venue			Venue costs: invoices (if applicable)
Travel	Lead trainers Delivery agents		Travel: from research staff claim
Printing			Printing: expenses
Equipment			Equipment: expenses (if applicable)
Refreshments			Refreshment: expenses (if applicable)
School resource use logistics			
School staff time	School staff time co-ordinating peer nomination	May not be costed but aim to capture time and role information	Time: (based on researcher time log for this measure)

Resource category	Detail on included resource	Detail on excluded resource (& rationale)	How recorded?
			Role of school staff member within school
	School staff time co-ordinating peer supporter training for pupils		Time: (log completed by researcher recording interactions with school staff) Role of school staff member within school
Peer supporter trainer (LA physical activity direct or commissioned) resource			
Peer supporter trainer time			Time: Hourly rate (state if includes on-costs):
Venue			Venue costs: invoices (if applicable)
Travel			Travel: expenses
Printing			Printing: expenses
Equipment			Equipment: expenses (if applicable)
Refreshments			Refreshment: expenses (if applicable)
Peer supporter (pupil) time:			
Attendance at training	Peer supporter attendance (N) and training time	Time collected but not costed	On sheet, as per Process Evaluation Plan 0.1. Table shell 4.1
Delivering intervention	Peer supporter time	Informal intervention makes quantification difficult. Assumption may be that peer supporter time has similar benefits to time spent elsewhere in education. The extent to which the peer supporter enjoys or values the role could also be relevant to a narrative around opportunity cost.	No further recording required
Staff contact time			
Staff contact time (grade)	Log of activities; e.g. chaperone for pupils peer-training; helping to co-ordinate peer nomination process		Time involved: (log completed by researcher of staff involvement/interactions) Job role (band/salary level):

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