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

Statistical Analysis Plan

Version 1 (6/2/2020)

Based on Protocol version 1.2 (dated 28/3/2019)

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

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National Institute for Health Research

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List of abbreviations

Acronym	Details
ACME	Average causal mediated effect
ADE	Average direct effect
ASSIST	A Stop Smoking In Schools Trial
BREQ-2	Behavioural regulations in exercise questionnaire
BRTC	Bristol Randomised Trials Collaboration
CACE	Complier average causal effect
CI	Confidence interval
CONSORT	Consolidated Standards of Reporting Trials
CPM	Counts per minute
DMEC	Data monitoring and ethics committee
DOI	Diffusion of ideas
EQ5D-Y	EuroQol 5-dimension (youth)
ICC	Intra-cluster-coefficient
IMD	Index of multiple deprivation
IQR	Inter-quartile range
ITT	Intention-to-treat
LA	Local authority
LAG	Local advisory group
MVPA	Moderate to vigorous physical activity
PA	Physical activity
PE	Physical education
PLAN-A	A cluster randomised trial of a Peer-led physical Activity iNtervention for Adolescent girls
SAP	Statistical analysis plan
SD	Standard deviation
SDQ	Self-description questionnaire
SDT	Self-determination theory
SES	Socio-economic status
T0	Time 0: Baseline
T1	Time 1: Follow-up 1 year after baseline
TMG	Trial management group
TSC	Trial steering committee

1. INTRODUCTION AND PURPOSE

This document details the rules proposed and the presentation that will be followed, as closely as possible, when analysing and reporting the main results from PLAN-A. This document is written by the Bristol Randomised Trials Collaboration (BRTC) who will conduct the statistical analysis for this trial. This plan acts as a stand-alone document so that any BRTC statistician has the required trial information needed to perform the statistical analysis. The information in this document is adapted from the official trial protocol.

The purpose of the plan is to:

1. Ensure that the analysis is appropriate for the aims of the trial, reflects good statistical practice, and that interpretation of a priori and post hoc analyses respectively is appropriate.
2. Explain in detail how the data will be handled and analysed to enable others to perform the actual analysis in the event of sickness or other absence

Additional exploratory or auxiliary analyses of data not specified in the protocol are permitted but fall outside the scope of this analysis plan (although such analyses would be expected to follow Good Statistical Practice).

The analysis strategy will be made available if required by journal editors or referees when the main papers are submitted for publication. Additional analyses suggested by reviewers or editors will, if considered appropriate, be performed in accordance with the Analysis Plan, but if reported the source of such a post-hoc analysis will be declared.

Amendments to the statistical analysis plan will be described and justified in the final report of the trial.

2. SYNOPSIS OF STUDY DESIGN AND PROCEDURES

2.1 Background and rationale

Physical activity (PA) during childhood is associated with physical and psychological health. PA levels decline during childhood and by early adolescence, few girls are sufficiently active. School-based interventions have largely been ineffective and novel interventions are needed to address the barriers to girls' non-participation. Interventions embedded within girls' everyday lives represent a creative alternative to previous interventions and peers offer a powerful, natural and sustainable intervention opportunity which has received little attention in high quality trials.

This trial tests whether the PLAN-A intervention - developed in an earlier feasibility study – can increase adolescent girls' PA and be cost effective.

2.2 Trial objectives and aims

2.2.1 Primary objective

To determine the effectiveness of the PLAN-A intervention (described in section 2.5) to increase objectively-assessed (accelerometer) mean weekday minutes of moderate to vigorous physical exercise (MVPA) among Year 9 girls 5-6 months (T1: baseline + 1 year) after the end of the 10-week intervention.

2.2.2 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 questionnaire(1))
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.

2.3 Trial design and configuration

PLAN-A is a two-arm school-based cluster-randomised controlled superiority trial with an embedded process and economic evaluation. Schools are the unit of randomisation and outcomes are assessed at two time points: baseline (Time 0: Autumn term to March of Year 9) and follow-up 1 (Time 1: Autumn term of Year 10, 5-6 months post-intervention).

2.4 Eligibility criteria

2.4.1 School recruitment

Schools were approached in two ways. Firstly, we used existing contacts in local authority (LA) offices to distribute the school advert amongst their network of local school contacts. These were screened to ensure we were only taking state-funded schools. Secondly, we identified secondary schools in Bristol and neighbouring counties that were above the local median for pupil premium and invited them directly via letters/emails to the head teacher. If these schools declined or did not respond we approached the next one on the list, etc. All positive expressions of interest were followed up by email/phone and the first 22 schools to return signed study agreement forms were included. Once we reached this target number we stopped recruiting.

2.4.2 Student recruitment

The target population are girls aged 13-14 years (Year 9) attending schools in the South West area.

2.4.2.1 Inclusion criteria

All girls in Year 9 providing parental opt-out consent and child consent are eligible for inclusion.

2.4.2.2 Exclusion criteria

Girls whose parents opt them out or who themselves do not provide assent are excluded.

2.5 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 (2) 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.

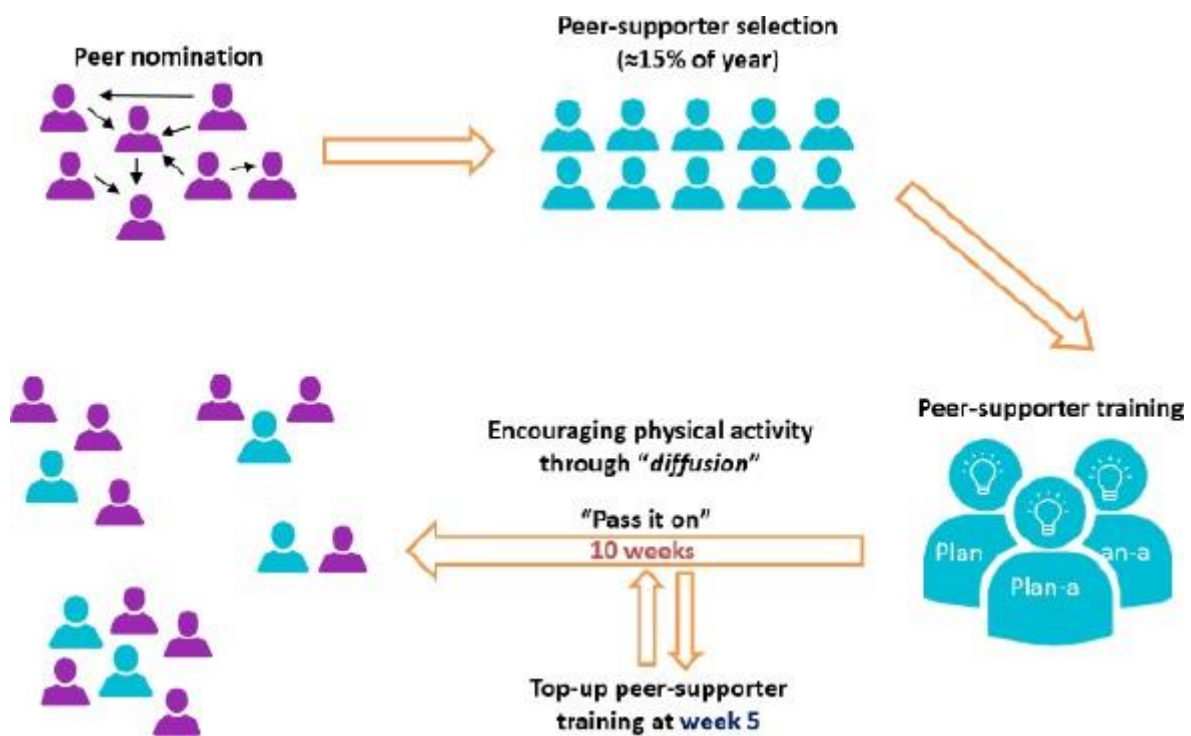
A) Peer-nomination: Peer-supporters are identified by nomination in which Year 9 girls identify, by questionnaire, the female peers, in their year who they think are influential (e.g., who they respect, look up to, listen to). Based on Diffusion of Innovations (DOI) (3) the highest scoring 18% (those with most nominations) are invited to be peer-supporters, with the aim of $\geq 15\%$ 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.

C) 10-week peer-diffusion: Peer-supporters will informally promote messages about increasing physical activity amongst their peers for 10 weeks, with the top-up training at 5-weeks.

The PLAN-A intervention concept is described below:



2.6 Description of the comparator arm

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

2.7 Recruitment, screening and consent

All schools which meet the inclusion criteria stated above were invited to participate via a letter to the Head/Deputy Head Teacher. Schools wishing to participate were provided with further information and asked to express their interest in participating. Two additional schools who can be promoted to the study schools if a school withdraws prior to randomisation were recruited.

A presentation was made to Year 9 girls to inform them about the study, including the nature of the intervention and control conditions and the chance of the school being in either arm. All girls were invited to take part and given study information for themselves and their parents. Peer-supporters will be asked to agree to the role, training and process evaluation.

2.8 Data collection

Data will be collected at two time points; baseline (T0) and 12 months post-baseline (T1, 5-6 months post-intervention). Data will be collected in schools by the Project Manager supported by Fieldworkers. At each time point, pupils will wear an ActiGraph accelerometer (see below) for seven days to estimate levels of PA and sedentary time.



All girls enrolled in the study will be required to wear an ActiGraph accelerometer (see picture), a small plastic device attached to a strap and worn on top of clothing around the hip.

The amount of activity done by the user is determined by the 'counts per minute' (CPM) that the accelerometer records. The accelerometers will be programmed to the correct date and time before being worn by the girls and the data is retrieved by USB connection to a computer and downloaded into useable software (ActiLife 6). Thus, the level of activity (CPM) and the date and time will all be recorded in the accelerometer. Periods of ≥ 60 minutes of zero values will be defined as accelerometer "non-wear" time and discarded. Moderate-to-vigorous physical activity (MVPA) is defined as ≥ 2296 CPM and ≤ 100 CPM is sedentary time.

At each time point, each girl will be asked to wear an accelerometer for 7 days. To be included in the analysis, a girl must have a minimum of 2 full days of valid weekday data with each day contributing a minimum of 500 minutes between 5am and 23:59pm (at both T0 and T1). Therefore, the mean weekday accelerometer data for each girl might be an average of only two day's wear or seven days. Thus the "number of valid days" will be included in the statistical model.

Pupils will also complete a questionnaire assessing demographics, psychosocial variables (e.g., self-esteem) and potential effect mediators (e.g. peer support/perceptions of autonomy) at each time point.

2.9 Randomisation procedures

Randomisation of the schools will be stratified by area (Avon, Devon and Wiltshire) and area-level deprivation of the schools to ensure balance within each stratum. Deprivation is measured using the England Index of Multiple Deprivation (IMD) score for the middle-layer super output area of the postcode of the school. IMD data are routinely available at the lower super output area level and to get the middle-layer score the population weighted average IMD score across all lower super output areas within the middle layer was calculated. For the purposes of stratification, the median deprivation score for the participating schools within each study area is calculated and schools are stratified by whether their deprivation score is above or below that median.

Allocation will be performed by a member of the Bristol Randomised Trials Collaboration (BRTC) blind to school identity and independent of the fieldwork team.

2.10 Sample size justification

The target between-arm difference is 10 minutes of MVPA per weekday (i.e., 50 minutes per week). Such an increase would be associated with favourable cardiometabolic outcomes in young people (4). From the PLAN-A feasibility study, the confidence interval on the between-arm difference in mean weekday MVPA (1.4 to 10.8 minutes, point estimate = 6.1 minutes) suggests that this difference is achievable. We also believe that making the refinements to the intervention identified in the feasibility study has the potential to achieve a 10-minute difference. However, recognising that even smaller intervention effects on MVPA may also lead to meaningful differences in health at a population level, we have calculated the sample size necessary to detect

a range of differences in weekday MVPA (i.e., 10, 8 & 6 minutes). The table below shows the power calculations where the following parameters are fixed: cluster size = 70 (informed by feasibility study), intra class correlation (ICC) on weekday MVPA = 0.01 (informed by the feasibility study; baseline = <.01, one year post-baseline = <.0001 and other studies (5, 6)), MVPA standard deviation = 20 minutes (based on feasibility study), coefficient of variability in cluster size=0.22, 5% two-sided alpha and inflation to account for 30% of participants not providing primary outcome data. 12 schools and 800 pupils are required to detect a 10-minute difference in MVPA with 90% power, however 20 schools and 1400 pupils would provide 90% power to detect a smaller 6-minute difference in MVPA and ample power to detect an 8-minute difference. Further accounting for correlation between baseline and follow-up measures of MVPA (correlation=0.4) slightly reduces the number of schools required (see last column in table below).

Sample size parameters

MVPA Difference (mins)	Power (%)	N pupils (uninflated)	N pupils (inflated for loss to follow-up)	N Schools	N schools when allowing for correlation between baseline and follow-up
10	90	560	800	12	10
10	80	420	600	10	10
8	90	700	1000	16	12
8	80	560	800	12	12
6	90	980	1400	20	18
6	80	840	1200	18	16

Given the inherent uncertainty in many of these assumptions, we will recruit 22 schools (20+2 reserves) and randomise 20 schools and 1400 pupils to detect a 6-minute difference in MVPA with at least 90% power.

Calculations were performed using the “clustersampsi” command in Stata.

2.11 Blinding

Given the nature of the intervention it is not possible to blind participants to its aim. To reduce self-report biases for the main outcome we will measure physical activity using accelerometers which do not provide any behavioural feedback. The senior investigator team, senior statistician and trial statistician will be blind to school identity. It will not be possible to blind the fieldwork team.

2.12 Trial oversight

2.12.1 Trial management group

A Trial Management Group (TMG) chaired by the Prof Jago will meet monthly and include all co-applicants and the Trial Manager to discuss progress, study design, problems and solutions and ethical issues.

2.12.2 Local advisory group

A Local Advisory Group (LAG) was built on the LAG developed in the feasibility study which consists of representatives from the local council, public health personnel, third sector and secondary schools. The LAG is chaired by Dr Kipping (Co-applicant) and will meet four times during the award to provide guidance on practical issues that relate to the conduct of the research in schools, school recruitment, roll out and dissemination.

2.12.3 Trial steering committee

An independent Trial Steering Committee Advisory (TSC) has been established consisting of an independent chair plus three independent members and senior members of the study team. The independent members have experience in developing and conducting complex interventions within schools, trial methodology and statistics and public health delivery / commissioning. The TSC will meet four times during the project and will provide independent scientific scrutiny of the project.

2.13 Outcome measures

2.13.1 Primary outcome

The primary endpoint is the mean accelerometer-determined minutes of MVPA on weekdays. We will assess physical activity using ActiGraph accelerometers.

2.13.2 Secondary outcomes

The following accelerometer-derived variables will be secondary outcomes:

- Mean weekend minutes of MVPA;
- Mean weekday minutes of sedentary time,
- Mean weekend minutes of sedentary time

Participants will report their self-esteem (1).

2.14 Interim analyses

No formal interim analyses of efficacy are planned.

2.15 Timing of final analysis

Final analyses will be conducted after data entry and data cleaning is complete after the final school visit of T1.

3. GENERAL ANALYSIS CONSIDERATIONS

3.1 Analysis populations

The Full Analysis set includes all consenting girls from randomised schools. The primary intention-to-treat (ITT) analysis will be conducted using this dataset and safety analyses will be conducted on this dataset. A per protocol analysis will be conducted using the Full Analysis set but excluding those schools allocated to the intervention arm who did not deliver the intervention. The primary analysis of accelerometer-based outcomes will exclude those participants who do not have 2 days of valid accelerometer data although we will conduct sensitivity analyses imputing the missing data (described in section 6.4.2) where conditions are met. These participants will be included in all analyses of non-accelerometer secondary outcomes where they provide non-missing data.

3.2 Derived variables

The algorithms for the calculation of derived variables in this study are described below:

Age at baseline	Age at baseline will be calculated from the self-reported date of birth and date of baseline measurement
Ethnicity	Ethnic background will be self-reported by selecting one of 13 descriptions based on the UK Census
Socio-economic position	Participant's socio-economic position will be estimated using the following parameters: <ul style="list-style-type: none"> • Using the self-reported home postcode we will calculate the index of multiple deprivation (IMD) • Using self-report of the receipt of free school meals • Using participant-completed four-item family affluence scale which assesses family car ownership, whether the child had their own

	<p>bedroom, the number of family holidays in the past year and family computer ownership (7, 8).</p> <p>School-level SES is estimated as:</p> <ul style="list-style-type: none"> the proportion of students receiving free school meal the median distance from home to school (calculated as the median straight line distance from home to school across participating students at the school)
Mean accelerometer-determined minutes of MVPA on weekdays	We will assess physical activity using ActiGraph accelerometers which are small devices that record bodily acceleration and have been used and validated amongst young people. (9) Participants will be asked to wear an accelerometer for seven days at T0 and T1. Periods of ≥ 60 minutes of zero counts will be recorded as “non-wear” and removed. Participants will be included in analysis if they provide ≥ 2 valid days (i.e., 500 minutes of data between 6am and 12pm). Mean minutes of daily MVPA will be estimated using the Evenson (10) cut-point of ≥ 2296 CPM which is the most accurate threshold for adolescents. (11)
Mean weekend minutes of MVPA	This will be calculated as above, but across Saturday and Sunday of T0 and T1
Mean weekday minutes of sedentary time	Sedentary time will be calculated as for MVPA but using a cut-point of ≤ 100 CPM (10) at T0 and T1
Mean weekend minutes of sedentary time	This will be calculated as the mean weekday minutes of sedentary time, but across Saturday and Sunday of T0 and T1
Self-esteem	Self-esteem will be derived from the Self-Description Questionnaire II (1) issued at T0 and T1. The questionnaire contains four positively worded (e.g., <i>Most things I do, I do well</i>) and five negatively worded (e.g., <i>I don't have much to be proud of</i>) items. Pupils rate how <i>true</i> or <i>false</i> each description was for them using a six-point Likert scale ranging from 1 (<i>False – not like me at all</i>) to 6 (<i>True – very much like me</i>). A mean of the items is then calculated.
Physical activity motivation (autonomous and controlled)	Pupils complete a 19-item version of the behavioural regulations in exercise questionnaire (BREQ-2) (12) assessing, 1) intrinsic motivation (four items. E.g., <i>I value the benefits of exercise</i>), 2) identified motivation (four items. E.g., <i>I am physically active because it's fun</i>), 3) introjected motivation (three items. E.g., <i>I feel guilty when I'm not physically active</i>), 4) external motivation (four items. E.g., <i>I am physically active because other people say I should be</i>) and 5) amotivation (four items. E.g., <i>I think being physically active is a waste of time</i>). Pupils indicate their agreement with each statement using a five-point Likert scale ranging from 0 (<i>Not true for me</i>) to 4 (<i>Very true for me</i>). Composite autonomous (mean of intrinsic & identified) and controlled (mean of introjected and external) are then calculated.
Physical activity psychological need satisfaction	Pupils' perceptions of autonomy (six items, e.g., <i>I feel I'm active because I want to be</i>), competence (six items, e.g., <i>I am pretty skilled at different physical activities</i>) and relatedness (five items, e.g., <i>I feel understood</i>) are assessed using a seven-point Likert scale ranging from 1 (Not at all true) to 7 (Very true) (13, 14) at T0 and T1. Participants rate how <i>like them</i> each statement was. Item means for each need variable are then calculated.
Physical activity self efficacy	Eight items are used to assess participants' self-efficacy to be physically active in different situations (e.g., <i>I can be physically active most days after school</i>) at T0 and T1 (15). Pupils indicate their endorsement of each statement using

	three responses (<i>No, not sure</i> and <i>yes</i>). A mean of the items is then calculated.
Physical activity social support	<p>Six items assessing social support from friends for PA are taken from a broader questionnaire measuring factors associated with PA in adolescents (16) at T0 and T1. Pupils read the stem "<i>Thinking about your close friendship group how often do they do the following</i>" and rated each item (e.g., <i>Invite you to engage in physical activity with them</i>) using a four-point Likert scale ranging from 0 (<i>Never</i>) to 3 (<i>Always</i>). Items cover social support in the form of encouragement, involvement, co-participation, talking about PA and giving positive comments. A mean of the items is then calculated.</p> <p>Pupils are asked two questions to assess their perceptions that others in their year: (1) spoke to them about physical activity (<i>Has anyone in your year group talked with you recently about physical activity?</i>, Response options: Yes, No, Not sure) and (2) whether they felt it helped them be more active (<i>Did talking to anyone in your year help you to be more active?</i>, Response options: Yes, No, Not sure, NA).</p>
Peer norms for physical activity	<p>The six-item Social Support Scale (17) is used to measure three factors of peer-based social support at T0 and T1. Prevalence of friends' PA is assessed with two items (e.g., <i>How many of your close friends would you say are physically active?</i>), scored using a four-point scale (0 = <i>None</i> to 3 = <i>All</i>). Perceived importance placed on PA by peers is measured using two items (e.g., <i>How important do you think it is to your close friends to be physically active?</i>), scored using a three-point scale (0 = <i>Not important at all</i> to 2 = <i>Very important</i>). Peer acceptance of the participant's level of PA is assessed using two items (e.g., <i>My friends encourage me to be physically active</i>), scored using a four-point scale (0 = <i>Disagree a lot</i> to 3 = <i>Agree a lot</i>). A mean of the items is then calculated for prevalence, importance and acceptance.</p>

3.3 Procedures for missing data

Every effort will be made to obtain data from all participants who do not withdraw consent. Patterns of missing data will be explored by group, however. Multiple imputation techniques will be used to generate missing values in the dataset if more than 5% of the data of any outcome variable is missing. In this case, we will adopt the Multiple Imputation by Chained Equation (MICE) approach to deal with missing values if relevant assumptions are met.

3.4 Outliers

Prior to analysis the trial statistician will use graphs and descriptive statistics to identify potential outliers in the data. These will be queried with the trial manager.

3.5 Visit windows

All baseline data will be collected prior to randomisation of the schools. All follow-up data are collected in the autumn term of 2019.

3.6 Withdrawals

A person may withdraw from the study at any point and not provide further data from this point. The timing and reasons for withdrawal from each arm will be tabulated. Participants are given the option at withdrawal

of either allowing or not allowing data prior to withdrawal to be used. Where the latter is chosen (ie the person has specified that they do not want previously provided data to be used) and the data has not yet been processed, the data provided prior to withdrawal is deleted.

4. DESCRIPTION OF PARTICIPANT CHARACTERISTICS

4.1 Disposition

The flow of schools and children through the trial will be summarised in a CONSORT diagram that will include the eligibility, reasons for exclusion, numbers randomised to the two groups, losses to follow up and the numbers analysed.

4.2 Baseline characteristics

Baseline characteristics of schools and pupils will be compared between the two arms by reporting relevant summary statistics in order to determine whether any potentially influential imbalance occurred by chance. The data collected at baseline are age, ethnicity, SES (IMD), family affluence, parental education, self-esteem, well-being as measured with the KIDSCREEN questionnaire, EQ5D-Y quality of life and MVPA/accelerometer variables.

Baseline characteristics will be summarised using means (SD), medians (Inter-quartile-range; IQR) or number (%) depending on the nature of the data and its respective distribution. If the baseline characteristics of the groups differ by more than 10% or half a standard deviation then the effect of this variable on the outcome will be investigated in sensitivity analyses.

5. ASSESSMENT OF STUDY QUALITY

5.1 Eligibility checks

The numbers of participants excluded and reasons for exclusions will be described.

5.2 Data validation

Once the data are downloaded by the trial statistician internal consistency checks will be performed by them in preparing the data for analysis in Stata. They will aim to identify spurious values or inconsistencies in responses. When inconsistencies are identified, these will be reported to the trial manager.

5.3 Study completion

Follow-up is complete after the T1 data collection visits.

5.4 Protocol deviations

As the intervention is informal and reliant on diffusion of information, it is not possible to assess whether participants complied with a set protocol and we therefore do not propose reporting protocol deviations. We will, however, conduct a per protocol analysis excluding those schools allocated to the intervention arm who did not deliver the intervention at all.

6. ANALYSIS OF EFFECTIVENESS

Stata version 15 (or higher) will be used for all PLAN-A analyses. Two-tailed tests will be used with effect estimates, 95% confidence intervals (CI) and p-values presented. There will be no adjustment for multiple testing. Analyses using regression models will adjust for stratification variables as well as baseline values of the outcome studied. The primary approach for analysis will be on an intention-to-treat (ITT) basis defined as analysing participants as randomised.

6.1 Mis-randomised schools

In general, participants will be analysed as their schools were randomised.

6.2 Summary of primary and secondary endpoints

The primary and secondary endpoints are summarised below:

Outcome	Measure	Timepoints	Interpretation	Range
Primary				
Mean accelerometer-determined minutes of MVPA on weekdays	Accelerometer	T0 and T1	Minutes of activity	0-1440
Secondary				
Mean weekend minutes of MVPA	Accelerometer	T0 and T1	Minutes of activity	0-1440
Mean weekday minutes of sedentary time	Accelerometer	T0 and T1	Minutes of activity	0-1440
Mean weekend minutes of sedentary time	Accelerometer	T0 and T1	Minutes of activity	0-1440
Self-esteem	Derived from the Self-Description Questionnaire II	T0 and T1	Higher scores indicate higher self-esteem	1-6

6.3 Primary analysis

The primary outcome is the accelerometer-determined minutes of MVPA on weekdays collected at Time 1. It will be described in each group using means and standard deviations. Comparisons between arms will be made using a multivariable mixed effects linear regression model to allow for clustering within schools and adjusting for baseline MVPA scores (random school effects to account for clustering and random pupil-within-school effects to account for repeated measures), the number of valid days of accelerometer data and randomisation variables.

We will check the normality assumptions of the residuals from the fixed part of the multi-level model and the random effects at the cluster level using graphs. Appropriate transformations will be considered if the assumptions of the model are not met.

6.4 Sensitivity analyses

A number of analyses are proposed to assess the sensitivity of the primary analysis to various assumptions. These are described below. Sensitivity analyses will be presented alongside those of the primary analysis in

order for them to be compared and contrasted. As these will be exploratory in nature, 95% confidence intervals and p-values will be presented but will be interpreted with due caution.

6.4.1 Imbalance between groups

Should there be evidence of imbalance between groups on important baseline characteristics, sensitivity analyses will be conducted where the primary analysis is repeated adjusting for variables showing an imbalance.

If the audit of new school physical activity interventions during the period of the study shows imbalance between arms, we will conduct an additional sensitivity analysis of the intervention effect on the primary outcome adjusting for this variable.

6.4.2 Missing outcome data

We will explore patterns of missing MVPA data and consider possible mechanisms for this. Based on these and observed data, appropriate methods for imputing missing data will be considered in sensitivity analyses, including both “best” and “worst” case scenarios. Where assumptions are met, this may include multiple imputation by chained equations. Analyses with imputed data will be compared with the primary analysis.

6.4.3 Month of data measurement

The primary analysis will be repeated adjusting additionally for the month of year when the MVPA measurements are taken.

6.5 Secondary outcomes analyses

Mean weekend and weekday minutes of sedentary time, mean weekend minutes of MVPA and self-esteem are continuous measures and will be analysed using the same modelling approach as for the primary outcome.

6.6 Per protocol and complier average causal effect analysis

A per protocol analysis will be conducted of those children attending schools allocated to the control arm and those allocated to schools where the intervention was delivered.

As per protocol analyses are likely to be biased, we will also use the complier average causal effect (CACE) approach as these provide unbiased estimates for the treatment effect for those schools who have complied with the intervention. In this case, compliance is defined as delivering the intervention. The CACE estimate and its confidence interval will be obtained using the Stata two-stage least squares (2SLS) approach.

6.7 Subgroup analyses

We will perform subgroup analyses to estimate whether the intervention is differentially effective in subgroups of socioeconomic position, nominated peer supporter training (peer supporters vs non-peer supporters) and the proportion of sedentary time at baseline. This will involve including interaction terms between arms and moderator (socioeconomic position, peer-supporter training or proportion of sedentary time at baseline) in our primary analysis models and using the likelihood ratio test for hypothesis testing.

The trial is not powered to detect effectiveness in subgroups, and this analysis will be treated as exploratory, presented using confidence intervals and interpreted with caution.

6.8 Mediation analysis

We will also conduct mediation analysis to explore whether any effect of the intervention is mediated by self-determined physical autonomous motivation (12), autonomy (13), competence (14) and relatedness (13).

These concepts are measured using the following variables described below and described in further detail in section 3.2:

Mediator	Measure	Timepoints	Interpretation	Range
Physical activity motivation: Autonomous	Self-completed BREQ-2 questionnaire	T0 and T1	Higher scores reflect high levels of autonomous motivation for physical activity	0-4
Physical activity motivation: Controlled	Self-completed BREQ-2 questionnaire	T0 and T1	Higher scores reflect higher levels of controlled motivation for physical activity	0-4
Physical activity psychological need satisfaction: autonomy	Self-completed questions	T0 and T1	Higher scores reflect higher levels of perceived autonomy	1-7
Physical activity psychological need satisfaction: competence	Self-completed questions	T0 and T1	Higher scores reflect higher levels of perceived competence	1-7
Physical activity psychological need satisfaction: relatedness	Self-completed questions	T0 and T1	Higher scores reflect higher levels of perceived relatedness	1-7
Physical activity self-efficacy	Self-completed questions	T0 and T1	Higher scores reflect higher levels of self-efficacy	0-2
Physical activity social support	Self-completed questions (16)	T0 and T1	Higher scores reflect higher levels of social support for physical activity	0-3
Peer norms for physical activity: prevalence	Self-completed Social Support scale (17)	T0 and T1	Higher scores reflect higher prevalence of PA	0-3
Peer norms for physical activity: importance	Self-completed Social Support scale (17)	T0 and T1	Higher scores reflect higher perceived importance	0-2
Peer norms for physical activity: acceptance	Self-completed Social Support scale (17)	T0 and T1	Higher scores reflect higher levels of acceptance	0-3

The mediators will be treated as continuously measured variables and they will be described using the mean scores stratified by intervention and control group. The distribution of the mediators will be explored and – where necessary – transformations of the data will be made.

To estimate the causal effects of the intervention, we will use the `paramed` command in Stata where the baseline measures of the mediator and outcome are included in the model describing the treatment effect on the mediator and the model describing the joint effects of the mediator and intervention on the outcome.

7. ANALYSIS OF SAFETY

Adolescence is a vulnerable time for girls' body image/self-concept and these factors are associated with physical activity. The PLAN-A intervention acknowledges the role appearance plays in the lives of adolescent girls but, based on the SDT approach to motivation, seeks to minimise the promotion of physical activity through commonly cited extrinsic "quick-fix" motives such as appearance and weight loss (18) and instead focus on authentic, personal reasons such as health, choice, friendship and challenge seeking.

We have implemented assessment of harm and clear reporting routes between: the peer-supporters, school-contacts, peer-supporter trainers, the field team, Project Manager, Chief Investigator, TMG and Ethics Committee. All harms will be reported to the TSC as a standing agenda item. Events will be tabulated by allocated group. The number of events, number of participants having at least one event and the number of participants with more than one event will be tabulated.

8. CHANGES TO THE SAP

All changes made to the planned statistical analyses are described below:

Previous version	Previous date	New version	New date	Brief summary of changes

9. FINAL REPORT TABLES AND FIGURES (SUBJECT TO CHANGE)

9.1 Populations: Tables, figures and listings detailing the study population

Figure 1	CONSORT diagram
Table 1	Pupil and peer supporter recruitment rates across schools
Table 2	Follow-up rates
Table 3	Withdrawals from the study

9.2: Baseline data: Summary tables of baseline information

Table 4	Baseline characteristics of randomised schools
Table 5	Baseline characteristics of pupils
Table 6	Baseline characteristics of peer supporters and non-peer supporter pupils
Table 7	Baseline characteristics of pupils with and without missing weekday MVPA data at baseline
Table 8	Baseline characteristics of pupils with and without missing weekday MVPA data at follow-up
Table 9	Timings of accelerometer measurements
Table 10	Data provision at baseline and follow-up

9.3: Outcomes: Summary data and intervention effect estimates

Table 11	Primary outcome: mean and difference in mean MVPA on weekdays (mins)
Table 12	Secondary outcome: mean and difference in mean MVPA on weekends (mins)
Table 13	Secondary outcomes: mean and difference in mean sedentary time on weekdays and at weekends (min)

Table 14	Secondary outcome: mean and difference in mean self-esteem scores
Table 15	Comparison of results of ITT analysis of complete cases with ITT analysis where missing data were imputed using multiple imputation for the primary outcome of MVPA on weekdays (mean)
Table 16	Comparison of results from primary analysis of the primary outcome of MVPA on weekdays with analyses adjusting for variables showing an imbalance at baseline and additionally adjusting for month of data measurement
Table 17	Comparison of results from ITT, per protocol and CACE analyses for the primary outcome of MVPA on weekdays
Table 18	Descriptive statistics of mediators over the duration of the study
Table 19	Correlation between mediators and weekday MVPA over the study
Table 20	Mediated effects

9.4 Safety data: Summary tables and listings of all adverse events

Table 21	Adverse events
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9.1 Populations: Tables, figures and listings detailing the study population

Figure 1: CONSORT diagram

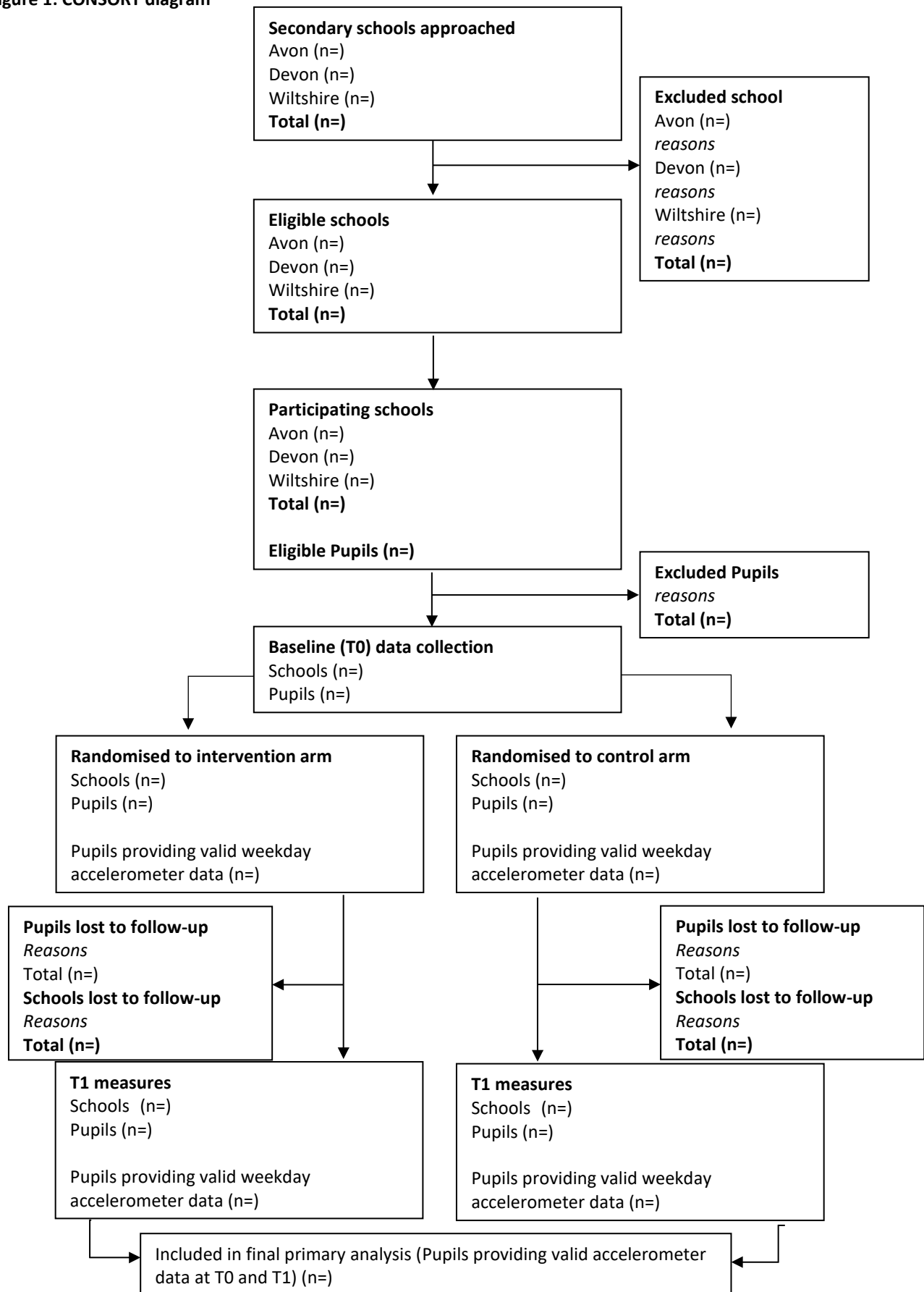


Table 2: Follow-up rates

School	Arm	Girls in Year 9 (N)	Baseline (T0) accelerometer data; N (%)	Baseline (T0) questionnaire data; N(%)	Follow-up (T1) accelerometer data; N (%)	Follow-up (T1) questionnaire data; N(%)
1						
2						
3						
4						
5						
6						
7						
8						
9						
10						
11						
12						
13						
14						
15						
16						
17						
18						
19						
20						
All schools						
Intervention arm						
Control arm						

Table 3: Pupil withdrawals from the study

Pupil ID	School ID	Arm	Days between delivery of intervention and withdrawal	Reason

9.2 Baseline data: Summary tables of baseline information

Table 4: Baseline characteristics of randomised schools

	Intervention arm (Number of schools=)			Control arm (Number of schools=)		
	Number of schools with data	Median (LQ, UQ)	N (%)	Number of schools with data	Median (LQ, UQ)	N (%)
Area Avon Devon Wiltshire						
IMD						

LQ: 25th percentile (lower quartile)

UQ: 75th percentile (upper quartile)

Table 5: Baseline characteristics of pupils

Variable	Intervention arm (N schools=; N pupils=)	Control arm (N schools=; N pupils=)
Socio-demographic characteristics		
Age; mean (SD)		
Area; N(%) Avon Devon Wiltshire		
Ethnicity; N(%) White Mixed Asian/Asian-British Black/African/Caribbean/Black British Other		
IMD score; mean (SD)		
Family affluence; mean (SD)		
Receiving free school meals; N(%)		
Measures of physical activity		
Weekday MVPA (min); mean (SD)		
Weekend MVPA (min); mean (SD)		
Overall MVPA (min); mean (SD)		
Weekday sedentary (min); mean (SD)		
Weekend sedentary (min); mean (SD)		
Overall sedentary (min); mean (SD)		
60 minutes MVPA per weekday; N(%)		
60 minutes MVPA per weekend day; N(%)		
Travel mode to school		
Walk; N(%)		
Cycle; N(%)		
Car; N(%)		
Bus/train; N(%)		
Travel mode from school		
Walk; N(%)		
Cycle; N(%)		
Car; N(%)		
Bus/train; N(%)		
Psychosocial variables		
Self-esteem; mean(SD)		

Autonomous motivation; mean(SD)		
Controlled motivation; mean(SD)		
Amotivation; mean(SD)		
Autonomy need satisfaction; mean(SD)		
Competence need satisfaction; mean(SD)		
Relatedness need satisfaction; mean(SD)		
PA self-efficacy; mean(SD)		
Peer PA norm – Importance; mean(SD)		
Peer PA norm – Acceptance; mean(SD)		
Peer PA norm – Prevalence; mean(SD)		
PA social support from friends; mean(SD)		
KidScreen 10 (T-score) ; mean(SD)		
KidScreen 10 (Q-score) ; mean(SD)		
EQ-5D Y visual analogue scale; mean(SD)		

Number of missing observations by study arm:

Table 6: Baseline characteristics of peer supporters and non-peer supporter pupils

Variable	Peer supporters (N pupils=)	Non-peer supporters (N pupils=)
Socio-demographic characteristics		
Age; mean (SD)		
Area; N(%)		
Avon		
Devon		
Wiltshire		
Ethnicity; N(%)		
White		
Mixed		
Asian/Asian-British		
Black/African/Caribbean/Black British		
Other		
IMD score; mean (SD)		
Family affluence; N (%)		
Receiving free school meals; N(%)		
Measures of physical activity		
Weekday MVPA (min); mean (SD)		
Weekend MVPA (min); mean (SD)		
Overall MVPA (min); mean (SD)		
Weekday sedentary (min); mean (SD)		
Weekend sedentary (min); mean (SD)		
Overall sedentary (min); mean (SD)		
60 minutes MVPA per weekday; N(%)		
60 minutes MVPA per weekend day; N(%)		
Travel mode to school		
Walk; N(%)		
Cycle; N(%)		
Car; N(%)		
Bus/train; N(%)		
Travel mode from school		
Walk; N(%)		
Cycle; N(%)		

Car; N(%)		
Bus/train; N(%)		
Psychosocial variables		
Self-esteem; mean(SD)		
Autonomous motivation; mean(SD)		
Controlled motivation; mean(SD)		
Amotivation; mean(SD)		
Autonomy need satisfaction; mean(SD)		
Competence need satisfaction; mean(SD)		
Relatedness need satisfaction; mean(SD)		
PA self-efficacy; mean(SD)		
Peer PA norm – Importance; mean(SD)		
Peer PA norm – Acceptance; mean(SD)		
Peer PA norm – Prevalence; mean(SD)		
PA social support from friends; mean(SD)		
KidScreen 10 (T-score) ; mean(SD)		
KidScreen 10 (Q-score) ; mean(SD)		
EQ-5D Y visual analogue scale; mean(SD)		

Number of missing observations by study arm:

Table 7: Baseline characteristics of pupils with and without missing weekday MVPA data at baseline

Variable	Missing (N pupils=)	Present (N pupils=)
Socio-demographic characteristics		
Age; mean (SD)		
Area; N(%) Avon Devon Wiltshire		
Ethnicity; N(%) White Mixed Asian/Asian-British Black/African/Caribbean/Black British Other		
IMD score; mean (SD)		
Family affluence; N (%)		
Receiving free school meals; N(%)		
Measures of physical activity		
Weekend MVPA (min); mean (SD)		
Weekend sedentary (min); mean (SD)		
60 minutes MVPA per weekend day; N(%)		
Travel mode to school		
Walk; N(%)		
Cycle; N(%)		
Car; N(%)		
Bus/train; N(%)		
Travel mode from school		
Walk; N(%)		
Cycle; N(%)		

Car; N(%)		
Bus/train; N(%)		
Psychosocial variables		
Self-esteem; mean(SD)		
Autonomous motivation; mean(SD)		
Controlled motivation; mean(SD)		
Amotivation; mean(SD)		
Autonomy need satisfaction; mean(SD)		
Competence need satisfaction; mean(SD)		
Relatedness need satisfaction; mean(SD)		
PA self-efficacy; mean(SD)		
Peer PA norm – Importance; mean(SD)		
Peer PA norm – Acceptance; mean(SD)		
Peer PA norm – Prevalence; mean(SD)		
PA social support from friends; mean(SD)		
KidScreen 10 (T-score) ; mean(SD)		
KidScreen 10 (Q-score) ; mean(SD)		
EQ-5D Y visual analogue scale; mean(SD)		

Number of missing observations by study arm:

Table 8: Baseline characteristics of pupils with and without missing weekday MVPA data at T1

Variable	Peer supporters (N pupils=)	Non-peer supporters (N pupils=)
Socio-demographic characteristics		
Age; mean (SD)		
Area; N(%)		
Avon		
Devon		
Wiltshire		
Ethnicity; N(%)		
White		
Mixed		
Asian/Asian-British		
Black/African/Caribbean/Black British		
Other		
IMD score; mean (SD)		
Family affluence; N (%)		
Receiving free school meals; N(%)		
Measures of physical activity		
Weekday MVPA (min); mean (SD)		
Weekend MVPA (min); mean (SD)		
Overall MVPA (min); mean (SD)		
Weekday sedentary (min); mean (SD)		
Weekend sedentary (min); mean (SD)		
Overall sedentary (min); mean (SD)		
60 minutes MVPA per weekday; N(%)		
60 minutes MVPA per weekend day; N(%)		
Travel mode to school		
Walk; N(%)		
Cycle; N(%)		
Car; N(%)		

Bus/train; N(%)		
Travel mode from school		
Walk; N(%)		
Cycle; N(%)		
Car; N(%)		
Bus/train; N(%)		
Psychosocial variables		
Self-esteem; mean(SD)		
Autonomous motivation; mean(SD)		
Controlled motivation; mean(SD)		
Amotivation; mean(SD)		
Autonomy need satisfaction; mean(SD)		
Competence need satisfaction; mean(SD)		
Relatedness need satisfaction; mean(SD)		
PA self-efficacy; mean(SD)		
Peer PA norm – Importance; mean(SD)		
Peer PA norm – Acceptance; mean(SD)		
Peer PA norm – Prevalence; mean(SD)		
PA social support from friends; mean(SD)		
KidScreen 10 (T-score) ; mean(SD)		
KidScreen 10 (Q-score) ; mean(SD)		
EQ-5D Y visual analogue scale; mean(SD)		

Number of missing observations by study arm:

Table 9: Timings of accelerometer measurements

	Intervention arm (N schools=; N pupils=)	Control arm (N schools=; N pupils=)
Baseline accelerometer measurements October 2018; n(%) November 2018; n(%) December 2018; n(%) January 2019; n(%) February 2019; n(%)		
Follow-up accelerometer measurements September 2019; n(%) October 2019; n(%) November 2019; n(%) December 2019 ; n(%) January 2020; n(%) February 2020; n(%)		

Table 10: Data provision at baseline and follow-up; n(%)

	Intervention; n(%)	Control; n(%)	Total; n(%)
Baseline (T0)			
Accelerometer data			
Accelerometer returned; n(%)			

Invalid; n(%)			
Missing; n(%)			
Questionnaire			
Tablet; n(%)			
Kidscreen 10; n(%)			
EQ5D-Y; n(%)			
Follow-up (T1)			
Accelerometer data			
Accelerometer returned; n(%)			
Invalid; n(%)			
Missing; n(%)			
Questionnaire			
Tablet; n(%)			
Kidscreen 10; n(%)			
EQ5D-Y; n(%)			

9.3 Outcomes: Summary data and intervention effect estimates

Table 11: Primary outcome: mean and difference in mean MVPA on weekdays (mins)

Randomisation groups	n	Mean	SD
Intervention			
Control			
Difference in means (95% CI) ^a :			p-value =
Difference in means (95% CI) ^b :			p-value =

^a ITT analysis adjusted for baseline mean weekday MVPA, the number of days of valid data and the stratification variables

^b ITT analysis additionally adjusted for additional variables that show an imbalance between groups at baseline

Table 12: Secondary outcome: mean and difference in mean MVPA at weekends (min)

Randomisation groups	n	Mean	SD
Intervention			
Control			
Difference in means (95% CI) ^a :			p-value =
Difference in means (95% CI) ^b :			p-value =

^a ITT analysis adjusted for baseline mean weekend MVPA, the number of days of valid data and the stratification variables

^b ITT analysis additionally adjusted for additional variables that show an imbalance between groups at baseline

Table 13: Secondary outcomes: mean and difference in mean sedentary time on weekdays and at weekends (min)

Randomisation groups	n	Mean	SD
Weekdays			
Intervention			
Control			
Difference in means (95% CI) ^a :			p-value =
Difference in means (95% CI) ^b :			p-value =
Weekends			
Intervention			
Control			
Difference in means (95% CI) ^a :			p-value =
Difference in means (95% CI) ^b :			p-value =

^a ITT analysis adjusted for the outcome at baseline, the number of days of valid data and the stratification variables

^b ITT analysis additionally adjusted for additional variables that show an imbalance between groups at baseline

Table 14: Secondary outcome: mean and difference in mean self-esteem scores

Randomisation groups	n	Mean	SD
Intervention			
Control			
Difference in means (95% CI) ^a :			p-value =
Difference in means (95% CI) ^b :			p-value =

^a ITT analysis adjusted for baseline self-esteem score and the stratification variables

^b ITT analysis additionally adjusted for additional variables that show an imbalance between groups at baseline

Table 15: Comparison of results of ITT analysis of complete cases with ITT analysis where missing data were imputed using multiple imputation for the primary outcome of MVPA on weekdays (mean)

	n	Difference in means ^a	95% CI	p-value
Complete case				
Multiple imputation				

^a Adjusted for baseline MVPA on weekdays, number of days with valid accelerometer data, stratification variables and additional variables showing an imbalance between groups at baseline

Table 16: Comparison of results from primary analysis of the primary outcome of MVPA on weekdays with analyses adjusting for variables showing an imbalance at baseline and additionally adjusting for month of data measurement

	n	Difference in means	95% CI	p-value
Model A: Adjusting for baseline MVPA on weekdays, number of days with valid accelerometer data, and stratification variables (as presented in Table 11)				
Model A with additional adjustment for variables showing an imbalance between groups at baseline (as presented in Table 11)				
Model A with additional adjustment for variables showing an imbalance between groups at baseline and month MVPA measurement is taken				

Table 17: Comparison of results from ITT, per protocol and CACE analyses for the primary outcome of MVPA on weekdays

	N	Difference in means ^a	95% CI	p-value
ITT				
Per protocol				
CACE				

^a Adjusted for baseline MVPA on weekdays, number of days with valid accelerometer data, stratification variables and additional variables showing an imbalance between groups at baseline

Table 18: Descriptive statistics of mediators over the duration of the study

Variable	Intervention		Control	
	N	Mean (SD)	N	Mean (SD)
Physical activity motivation: Autonomous				
T0				
T1				
Physical activity motivation: Controlled				
T0				
T1				

Physical activity psychological need satisfaction: Autonomy T0 T1				
Physical activity psychological need satisfaction: Competence T0 T1				
Physical activity psychological need satisfaction: Relatedness T0 T1				
PA self-efficacy T0 T1				
Physical activity social support T0 T1				
Peer norms for physical activity: prevalence T0 T1				
Peer norms for physical activity: importance T0 T1				
Peer norms for physical activity: acceptance T0 T1				

Table 19: Correlation between mediators and weekday MVPA over the study

	T0	T1
Physical activity motivation: Autonomous		
Physical activity motivation: Controlled		
Physical activity psychological need satisfaction: Autonomy		
Physical activity psychological need satisfaction: Competence		
Physical activity psychological need satisfaction:		

Relatedness		
PA self-efficacy		
Physical activity social support		
Peer norms for physical activity: prevalence		
Peer norms for physical activity: importance		
Peer norms for physical activity: acceptance		

Table 20: Mediated effects

Outcome at T1	Mediator	ADE (95% CI)	ACME (95% CI)	Total effect (95% CI)	Proportion of effect mediated, % (95% CI)
Weekday MVPA	Physical activity motivation: Autonomous				
	Physical activity motivation: Controlled				
	Physical activity psychological need satisfaction: Autonomy				
	Physical activity psychological need satisfaction: Competence				
	Physical activity psychological need satisfaction: Relatedness				
	PA self-efficacy				
	Physical activity social support				
	Peer norms for physical activity: prevalence				
	Peer norms for physical activity: importance				
	Peer norms for physical activity: acceptance				

ADE: average direct effect

ACME: average causal mediated effect

9.4 Safety data: Summary tables and listings of all adverse events

Table 21: Adverse events

School ID	Pupil ID	Date	Details of activity and event	Treatment	Outcome

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