# Statistical Analysis Plan

A cluster-randomised controlled trial to evaluate the effectiveness and cost-effectiveness of the GoActive programme to increase physical activity among 13-14 year-old adolescents**.**

Version 1.0 – September 2016

# Contents



## 1 Introduction

This is the plan for the main trial analyses of the primary and secondary outcome measures from a cluster-randomised controlled trial evaluating the effectiveness and cost-effectiveness of an intervention (GoActive) aiming to increase physical activity in 13-14 year-old adolescents.

Other analyses of data arising from this trial will be the subject of future analysis plans.

# 2 Study endpoints

## 2.1 Primary efficacy outcome (measured at baseline and follow-up)

The primary outcome of average daily minutes of objectively measured moderate-to-vigorous physical activity (MVPA) will be derived from Axivity data. Once returned, continuous waveform data from each device will be downloaded using Axivity software. Non-wear time will be removed, using a criterion of consecutive runs of zero counts for a minimum duration of 60 minutes.[1,2] Remaining data will be included if accelerometer wear time ≥480 mins, on at least two days. Cut-points comparable to those used previously for ActiGraph accelerometers will be used to classify time in moderate-vigorous intensity physical activity (equivalent to ≥2000 ActiGraph cpm) or appropriate vector magnitude equivalents.[3,4,5] Monitor output will be reviewed prior to analysis to confirm that these decisions are appropriate for the population. We will take appropriate action to ensure representativeness of the 24 hour day in the physical activity data used. Further, we will consult physical activity measurement experts to ensure we can be aware of relevant new methodology and apply where appropriate.

## 2.2 Secondary efficacy outcomes (measured at baseline and follow-up)

o *Secondary accelerometry outcomes: sedentary, light, vigorous and overall physical activity (cpm) during school, weekday evenings and weekends*

Data for secondary accelerometry outcomes will be treated as per the primary outcome (see Section 2.1). Cut-points identified by Evenson and colleagues will be used to classify time spent sedentary (equivalent to ≤100 ActiGraph cpm), or in light (equivalent to 101 - 1999 ActiGraph cpm) or vigorous intensity activity (equivalent to ≥2000 ActiGraph cpm).[6]

o *Self-efficacy and social support for physical activity*

Three items taken from Reynolds' work (psychosocial predictors of physical activity: self-esteem) will be used to assess self-esteem[7], and three from the European Youth Heart Study will assess social support for physical activity[8]. Responses to items will be summed, with higher scores indicating higher self-efficacy and social support, and data treated as continuous.

o *Friendship quality*

Eight items taken from the ROOTS project will be used to assess friendship quality[9]. Friendship quality will be rated based on the availability, adequacy and intimacy of current friendships. The questionnaire includes items related to number of friends, frequency of seeing friends, confiding in friends and episodes of teasing. Four to six response options are provided for each item. Responses to items will be summed, with higher scores indicating higher friendship quality, and data treated as continuous.

o *Well-being*

Well-being will be assessed using the 14-item Edinburgh-Warwick Wellbeing Scale.[10] Items will be answered on a five-point scale and responses summed (higher scores indicating lower levels of wellbeing). Data will be treated as continuous.

o *Social networks (group cohesion)*

Participants will be provided with an adapted social network modelling tool in which participants provided with a list of tutor group members and asked to select names of their friends. Summary data will be used to examine existing and developing friendship networks.

o *Self-esteem*

Self-esteem of participants will be assessed using the 10-item Rosenberg Self-Esteem Scale[11]. Each statement will be responded to on a four-point scale (strongly agree to strongly disagree), with higher scores denoting higher self-esteem. Data will be summed, and treated as continuous.

o *Shyness and Sociability*

Shyness and sociability will be assessed with two 5-item measures from the EAS (Emotionality, Activity, Shyness and Sociability) temperament scale[12]; each item was ranked by participants from 1 'not typical' to 5 'very typical'; questions included "I make friends easily" (shyness) and "I like to be with people" (sociability), items were summed so higher scores indicated lower shyness and higher sociability. Data will be treated as continuous.

o *School-level academic performance*

School-level attendance and academic performance will be collected from the National Pupil Database, which is publicly available (https://www.gov.uk/government/collections/national-pupil-database). Academic performance will be calculated as the sum of grade based points (A* = 58, A = 52…G = 16) and also as number of students gaining 5A*-C grades or the equivalent as per the national reporting standard. [13] Data will be treated as continuous.

o *Height, weight, body composition, waist circumference*

Body fat percentage will be calculated from bio-electrical impedance, and age- and sex-specific BMI z-score will be calculated from height and weight. These data, in addition to waist circumference values, will be treated as continuous variables for analysis.

### 2.3 Intermediate outcomes (measured at baseline and follow-up)

Self-efficacy, social support, friendship quality, group cohesion and self-esteem will also be examined as potential mediators of intervention effect. Treatment of these data will be as described in Section 2.2.

# 3 Analysis populations

The primary analysis of efficacy, intermediate and safety outcomes will use an **Intention To Treat (ITT) population**, which includes all participants in the group to which they were randomised, regardless of the intervention actually received.

A secondary analysis of efficacy will use a **Per Protocol (PP) population.** Inclusion in the PP population will be based on the degree of usage of the intervention website / submission of points and

will be defined once clean data are available (but before the start of any trial analyses), when the distributions of the degree of usage of the intervention website/points submission can be inspected.

# 4 Descriptive analyses

Baseline characteristics of the study population will be summarised separately within each randomised group. These characteristics include: age, sex, ethnicity, primary language spoken at home, parent education, family socio-economic status, body mass index, body fat percentage, and waist circumference.

For continuous variables, means and standard deviations will be presented, unless the variable has a highly skewed distribution, in which case medians, 25th and 75th percentiles will be presented. For categorical variables, the number and percentage of participants within each category will be presented. For each variable (continuous or categorical), the percentage of missing values will be reported.

# 5 Analyses of study outcomes

## 5.1 Primary efficacy outcome

The primary efficacy outcome, MVPA (mean min/day, measured on each individual), will be analysed using analysis of covariance (ANCOVA). The outcome in the ANCOVA model will be minutes of change in MVPA (mean mins MVPA at follow-up minus mean mins MVPA at baseline) with the baseline value included as a covariate in the model. Where baseline values of the outcome are missing, the missing indicator method will be used to enable these participants to be included in the analysis. Robust standard errors will be calculated to allow for the non-independence of individuals within each school. This model will be used to estimate the difference in mean change in MVPA and 95% confidence intervals between the intervention and control group, and also a p-value for this comparison.

## 5.2 Secondary efficacy and intermediate outcomes

For each continuous secondary and intermediate outcome, the difference between intervention and control group will be estimated, together with a 95% confidence interval, using the method described in section 5.1 (note; p-values will not be calculated for these outcomes). Any continuous outcome whose distribution is skewed will be log transformed prior to analysis, and a ratio of geometric means (and confidence interval) will be reported. We will subsequently conduct formal mediation analyses using the product of coefficient method[14] to assess the underlying causal effect of the intervention.

# 6 Considerations for analysis

## 6.1 Randomisation

Schools will be stratified based on socio-economic status (low/high – defined by pupil premium), and county (i.e. Cambridgeshire or Essex) to ensure a balance of socio-economic status and setting between groups. Randomisation will be conducted by an independent statistician using Stata after baseline measurements are completed.

## 6.2 Missing data

*Missing values of outcomes*

If an individual has a missing value for an efficacy outcome, they will be excluded from the analysis; this complete-case analysis is valid under the assumption that the outcome is missing at random (MAR) given randomised group and baseline.

The pattern of missing data will be described. Levels of missing data for the primary outcome are expected to be low, but if this is not the case, the potential impact of deviations from the MAR assumption on the results for the primary outcome will be explored in sensitivity analyses using a pattern mixture model[15].

*Missing baseline values of outcomes*

For continuous outcomes, those participants with a missing baseline value of the outcome variable will be included in the analysis using the missing indicator method[16], which is a valid method for pre-randomisation measures in trials ensuring that no further participants are excluded while maintaining the advantage of improved precision.

## 6.3 Subgroup analyses

Exploratory subgroup analyses by pre-specified categorical moderators (sex, socio-economic status, ethnicity, baseline physical activity, body mass index) will be performed for the primary efficacy outcome. Socio-economic status will be categorised 'high' or 'low' based on the sample median, ethnicity categorised by 18 ethnic groups (further collapsed according to the sample, e.g. white and non-white). Baseline physical activity will likely be categorised by <60 mins or ≥60 mins MVPA per day and weight status categorised by underweight (<2$^{nd}$ percentile for BMI z-score), normal weight (2$^{nd}$ < 85$^{th}$ percentile), overweight or obese (>85$^{th}$ percentile). The interaction between randomised group and each moderator will be tested, and if the p-value is <0.05, the intervention effect and 95% confidence interval will be estimated within each subgroup. Subgroup analyses by the potential moderators will be investigated for the primary efficacy outcome only.

### 6.4 Multiplicity

Given the number of outcome variables and comparisons, the focus of the results will be on estimated differences and 95% confidence intervals; p-values will only be reported for the primary efficacy outcome and for the interaction tests with respect to this outcome.

# 7 References


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