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The GoActive! study

Submission date 31/10/2013	**Recruitment status** No longer recruiting	[X] Prospectively registered [X] Protocol [X] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 18/02/2014	**Overall study status** Completed	
Last Edited 09/01/2024	**Condition category** Other	

Plain English summary of protocol

Background and study aims
A lack of physical activity among young people can result in them becoming obese, developing mental health problems and suffering from poor bone development. Children tend to exercise less as they become adolescents and remain physically inactive once they become an adult. This makes them more at risk of developing long-term health problems including diabetes and cancer. GoActive! stands for Get Others Active and is designed to increase physical activity in young people, aged 13 to 14 (Year 9). It has been designed to include all students and be particularly appealing to students who do not do a lot of exercise, are shy and are not happy with their relationship with others at school. The aim is to find out whether GoActive! helps to increase physical activity of year 9 students when in the school environment. This study has two phases. The pilot phase tests to see if GoActive! can be run successfully in a small number of schools and whether its effective in helping students to become more physically active. The main cluster randomised controlled trial expands the study to include 16 schools in total.

Who can participate?
Selected schools in Cambridgeshire and Essex

What does the study involve?
Schools are randomly allocated to one of two groups: the intervention group or the control group. Year 9 students in the intervention schools have the opportunity to engage in GoActive! during the study period. Year 9 students in the control school have no changes to their normal school day during the study period. For the pilot study, there are two schools in the intervention group and one school in the control group. For the main cluster randomised controlled trial, there are 8 schools in the intervention group and 8 schools in the control group. Students are assessed four times: before the programme starts, during the programme when schools have help to run it, and when schools are running the programme without help, and one year later. Measurements include physical activity measured using a wrist worn device similar to a pedometer, height, weight, waist circumference, body fat percentage and questionnaires about physical activity, social support, friendship quality and mood. Programme participation rates, acceptability and delivery cost, as well as student attendance and academic performance are also examined.

What are the possible benefits and risks of participating?
Students who take part in the study receive a small gift in appreciation of taking part in each

measurement session: a GoActive! pen after the baseline (first) measurement session. Participation in research of this type can be an interesting and valuable educational experience for young people. The trialists are happy to talk about or present any aspect of our work to small groups, classes or in school assemblies. Schools receive £200 worth of PE/sports equipment vouchers as a thank you for taking part in the study. This is a very low risk study employing non-intrusive measures of height, weight, body composition and free-living (everyday) physical activity. The GoActive! programme encourages participation in new types of physical activity. Participating in new types of physical activity brings with it a small risk of injury. The aim is to reduce this risk by providing safety information for students and their teachers on all suggested activities.

Where is the study run from?
The study is run from the CEDAR hub. CEDAR is a UKCRC Public Health Centre of Excellence and the CEDAR hub is located within the MRC Epidemiology Unit on the Cambridge Biomedical Campus (UK). The study takes place in schools.

When is the study starting and how long is it expected to run for?
September 2015 to February 2019

Who is funding the study?
1. The pilot study is funded by University of Cambridge (UK) - UK CRC Centre for Diet and Activity Research (CEDAR)
2. The cluster randomised controlled trial is funded by National Institute of Health Research Public Health Research grant (NIHR-PHR) 13/90/18

Who is the main contact?
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Study website
http://www.goactive-uk.com/

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
R130313/148; PHR 13/90/18

Study information

Scientific Title
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

Acronym
GoActive

Study objectives
The trialists hypothesize that participation in the “GoActive” programme (intervention) will result in increased daily physical activity. The null hypothesis is that participation in “GoActive” will result in no change to physical activity levels.

Ethics approval required
Old ethics approval format

Ethics approval(s)
1. Pilot study: University of Cambridge Psychology Research Ethics Committee, 22/04/2013, ref: Pre.2013.40
2. Cluster RCT: University of Cambridge Psychology Research Ethics Committee, 21/04/2016, ref: Pre.2015.126

Study design
Pilot study and cluster randomized controlled trial

Primary study design
Interventional

Secondary study design
Cluster randomised trial

Study setting(s)
School

Study type(s)
Quality of life

Participant information sheet
'Infovites' for schools, parents, students and mentors will be available on the trial website

Health condition(s) or problem(s) studied
Physical activity

Interventions
School level randomisation with individual participants as the unit of analysis; eight schools randomised to the intervention group and eight schools randomised to the control group. An independent statistician will conduct randomisation after completion of the baseline measurement sessions. The control schools will not run the GoActive programme during the study period but students will participate in PE lessons as per the usual school curriculum.

GoActive is implemented using a tiered-leadership system where mentors (older adolescents within the school) and peer-leaders (within each class) encourage students to try these activities each week. The mentors remain paired with each class for the duration of the programme whereas the peer-leaders (two per class each week) change every week. Teachers are encouraged to use one tutor time weekly to do one of the chosen activities as a class, however, students gain points for trying these new activities in or out of school. Points are gained every time they try an activity; there is no expectation of time spent in the activity as points are rewarded for the taking part itself. Individual students keep track of their own points privately on the study website and their points are entered into the between-class competition so that each class competes against each other. Class rankings are circulated each week to encourage teacher support and students receive small rewards (e.g. frisbee, water bottle) for reaching points thresholds.

Intervention Type
Behavioural

Primary outcome measure
1. Pilot study:
Objectively measured free-living moderate and vigorous physical activity measured at baseline and week 4-8 of the programme

2. Randomised controlled trial:
Accelerometry-assessed change in average daily MVPA. Measurements will be conducted at four time points; (T1) baseline, pre-randomisation (T2) interim assessment (week 6), (T3) post intervention (week 14-16), and (T4) 10-month follow-up (primary outcome).

Secondary outcome measures
1. Pilot study:
1.1. Body mass index (BMI)
1.2. Body fat percentage
1.3. Other objectively measured physical activity intensities
1.4. Self-reported physical activity
1.5. Self-efficacy for physical activity
1.6. Peer and parental support for physical activity
All measured at baseline and week 4-8 of the programme.

2. Randomised controlled trial:
2.1. Accelerometer-assessed sedentary, light, overall physical activity during school time, weekday evenings, weekends
2.2. Self-reported physical activity, self-efficacy, self-esteem, peer support, friendship quality, mood, school-reported absence and academic performance, body fat %, BMI, waist circumference (added 26/07/2017)
2.3. Within-trial, long term cost-effectiveness and cost-utility analyses
2.4. Mixed methods process evaluation assessing programme acceptability, uptake, maintenance, and dose; and putative moderators/mediators

Overall study start date
01/09/2015

Completion date
28/02/2019

Eligibility

Key inclusion criteria
All Year 9 students at participating secondary schools are eligible for inclusion into this study

Participant type(s)
Patient

Age group
Child

Sex
Both

Target number of participants
Approximately 600 for pilot study, 2400 for randomised controlled trial

Total final enrolment
2838

Key exclusion criteria
There are no formal exclusion criteria for the GoActive study
1. Language support will be sought for any student/parent who is not fluent in the English language
2. In the unlikely case that a student or parent lacks the capacity to give fully informed consent they will not be included in the study

Date of first enrolment
22/04/2016

Date of final enrolment
03/02/2017

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
UK CRC Centre for Diet and Activity Research (CEDAR)
Cambridge
United Kingdom
CB2 0QQ

Sponsor information

Organisation
University of Cambridge (UK)

Sponsor details
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Sponsor type
University/education

ROR
https://ror.org/013meh722

Funder(s)

Funder type
University/education

Funder Name
University of Cambridge - UK CRC Centre for Diet and Activity Research (CEDAR)

Funder Name
Public Health Research Programme

Alternative Name(s)
NIHR Public Health Research Programme, PHR

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Publication and dissemination plan
The protocol for the main trial will be published as a peer-reviewed paper. In addition to the final report, at least six peer reviewed publications will be published as a result of this project. The aim is for the main outcome paper to be submitted in January 2019. Evidence Briefs will also be produced, which will be developed with stakeholder feedback and are an effective way of disseminating key information to practitioners and policymakers. It is anticipated that the final one will be disseminated February 2019.

Intention to publish date
07/01/2019

Individual participant data (IPD) sharing plan
The data sharing plans for the current study are unknown and will be made available at a later date. The research team is expected to agree data sharing plans later in 2017.

IPD sharing plan summary
Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results (development of intervention)	25/08/2015		Yes	No
Protocol file	version V2	30/06/2016	26/10/2016	No	No
Statistical Analysis Plan		01/09/2016	26/10/2016	No	No
Results article	results (development and pilot study)	11/11/2016		Yes	No
Protocol article	protocol	21/05/2018		Yes	No
Other publications	Exploratory post-hoc secondary data analysis	13/03/2023	14/03	Yes	No

Other publications	Secondary analysis		08/01/2024	09/01/2023	Yes	No