ISRCTN75594310 https://doi.org/10.1186/ISRCTN75594310

Increasing physical activity levels in children: the ACTIVE project

Submission date
02/02/2017

Recruitment status
No longer recruiting

Registration date
06/03/2017

Overall study status
Completed

Last Edited
26/04/2023

Condition category
Nutritional, Metabolic, Endocrine

[_] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Regular exercise helps keep teenagers fit and lowers their risk of heart disease. However, many teenagers do not have enough money to pay for activities and they feel there is too much focus on organised, competitive sports. This study aims to see whether giving teenagers vouchers to spend on activities of their choice can reduce the time they spend sedentary (inactive), improve their fitness, lower their risk of heart disease and improve general health.

Who can participate?
Pupils aged 13 - 14 at seven participating schools

What does the study involve?
Participating schools are randomly allocated to either the intervention group or the control group. Intervention school pupils receive £20 of vouchers per month over a 12-month period, and work to set up community activities and meet with local government to change activity opportunities available for teenagers. Control school pupils receive a course on dealing with stress. The intervention lasts for 12 months, with measurements of fitness, activity and heart health taken at the start of the study and after 6, 12 and 18 months. The control group continue normal practice during this 12-month period but measurements are taken at the same time points for comparison. In addition, the researchers look at who uses the scheme and how friendship networks influence activity levels.

What are the possible benefits and risks of participating?
The local council intends to use the findings of this study to inform their future strategy, such as reallocating funds to continue the intervention locally. If findings are favourable then the intervention could be used in other areas of the UK. Minimal risks to participants are expected, although measures have been put in place to minimise any risks. Participation is voluntary and participants are able to withdraw at any point without giving a reason and at no disadvantage to themselves. The fitness test can cause some physical distress, but it is widely used among young people and the participants may be familiar with the task having previously performed the test within the PE curriculum. Any participant suffering from asthma is encouraged to carry an asthma inhaler. For focus groups, the headteacher's advice is sought to check there are no potential issues with the group of pupils who have been chosen to take part. Should a pupil

become distressed during the intervention, the first port of call is initially a member of staff identified before the start of the focus group. Once the pupil has calmed down they are asked if they wish to continue with the study after being made clear that they are free to withdraw at any stage. Any issues are signposted to the same member of staff and dealt with in accordance with the school's existing policies.

Where is the study run from?
1. Cefn Hengoed Community School (UK)
2. Birchgrove Comprehensive School (UK)
3. Bishop Vaughan R.C. School (UK)
4. Ysgol Gyfun Gymraeg Bryn Tawe (UK)
5. Morriston Comprehensive School (UK)
6. Dylan Thomas Community School (UK)
7. Pentrehafod School (UK)

When is the study starting and how long is it expected to run for?
June 2016 to June 2018

Who is funding the study?
British Heart Foundation (UK)

Who is the main contact?
Michaela James
m.l.james@swansea.ac.uk

Study website
https://www.facebook.com/ActiveProjectSwansea/

Contact information

Type(s)
Scientific

Contact name
Miss Michaela James

Contact details
Swansea University
Singleton Park
Swansea
United Kingdom
SA2 8PP
+44 (0)1792 606716
m.l.james@swansea.ac.uk

Type(s)
Scientific

Contact name
Prof Sinead Brophy

ORCID ID
http://orcid.org/0000-0001-7417-2858

Contact details
Swansea University
Singleton Park
Swansea
United Kingdom
SA2 8PP

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
090516

Study information

Scientific Title
Randomised controlled trial of Active Children Through Individual Vouchers Evaluation (ACTIVE)

Acronym
ACTIVE

Study objectives
The provision of vouchers will increase physical activity and fitness levels of adolescents from low socio-economic backgrounds and improve socialisation.

Ethics approval required
Old ethics approval format

Ethics approval(s)
College of Human and Health Science, College of Medicine at Swansea University, ref: 12/05/2016, 20/04/2016

Study design
Randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)

School

Study type(s)
Prevention

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

Health condition(s) or problem(s) studied
Teenage obesity; heart disease

Interventions
ACTIVE is a randomized control trial by mixed methods where participating schools are assigned to either the control or intervention group via simple randomization:

Intervention: All Year 9 pupils receive £20 of vouchers per month over a 12-month period, and work to set up community activities and meet with local government to change activity opportunities available for teenagers
Control: Year 9 pupils receive a non-activity based course on dealing with stress (mindfulness)

Intervention duration will be 12 months (from January 2017 to December 2017) with fitness, activity and cardiovascular measures taken at baseline, 6 months, 12 months and 18 months (follow-up) in order to track changes in fitness and heart health during voucher usage. The control group will continue normal practice during this twelve month period but measurements will be taken at the same time points for comparison.

Intervention Type
Behavioural

Primary outcome measure
1. Fitness, measured using the cooper run test (CRT) at baseline, 6 months, 12 months and 18 months (follow up)
2. Activity, measured using accelerometers at baseline, 6 months, 12 months and 18 months (follow up)
3. Cardiovascular health, measured using blood pressure and pulse wave analysis at baseline, 6 months, 12 months and 18 months (follow-up)

Secondary outcome measures
Uptake of the scheme by local authorities, measured using a number of advocacy and stakeholder meetings throughout the project but most notably at 18 months (follow up)

Overall study start date
01/06/2016

Completion date
01/06/2018

Eligibility

Key inclusion criteria
1. Participants must be aged 13 - 14 years old
2. Must be from one of the 7 schools selected (selected via FSM eligibility)
3. Must provide informed consent

Participant type(s)
Other

Age group
Child

Lower age limit
13 Years

Upper age limit
14 Years

Sex
Both

Target number of participants
900

Total final enrolment
986

Key exclusion criteria
Unable to provide informed consent

Date of first enrolment
01/09/2016

Date of final enrolment
14/12/2016

Locations

Countries of recruitment
United Kingdom

Wales

Study participating centre
Cefn Hengoed Community School
United Kingdom
SA1 7HX

Study participating centre
Birchgrove Comprehensive School
United Kingdom
SA7 9NB

Study participating centre
Bishop Vaughan R.C. School
United Kingdom
SA6 7QG

Study participating centre
Ysgol Gyfun Gymraeg Bryn Tawe
United Kingdom
SA5 7BU

Study participating centre
Morriston Comprehensive School
United Kingdom
SA6 6NH

Study participating centre
Dylan Thomas Community School
United Kingdom
SA2 0FR

Study participating centre
Pentrehafod School
United Kingdom
SA1 2NN

Sponsor information

Organisation
Swansea University

Sponsor details

Singleton Park
Swansea
Wales
United Kingdom
SA2 8PP

Sponsor type
University/education

Website
http://www.swansea.ac.uk/

ROR
https://ror.org/053fq8t95

Funder(s)

Funder type
Charity

Funder Name
British Heart Foundation

Alternative Name(s)
the_bhf, The British Heart Foundation, BHF

Funding Body Type
Private sector organisation

Funding Body Subtype
Trusts, charities, foundations (both public and private)

Location
United Kingdom

Results and Publications

Publication and dissemination plan
The protocol will be published in November 2017 and the results will be published in February 2019.

Intention to publish date
01/02/2019

Individual participant data (IPD) sharing plan

The datasets generate and/or analysed during the current study is not expected to be made available due to participant confidentiality and certain characteristics of the groups (e.g. age) making them vulnerable.

IPD sharing plan summary

Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	11/07/2017		Yes	No
Basic results		04/06/2019	14/06/2019	No	No
Results article	qualitative results	20/03/2018	14/06/2019	Yes	No
Results article	qualitative results	10/05/2019	14/06/2019	Yes	No
Results article	results	01/02/2020	23/12/2019	Yes	No
Interim results article		28/10/2019	26/04/2023	Yes	No