# Increasing physical activity levels in children: the ACTIVE project

Submission date	Recruitment status	<ul><li>Prospectively registered</li></ul>		
02/02/2017	No longer recruiting	[X] Protocol		
Registration date	Overall study status	Statistical analysis plan		
06/03/2017	Completed	[X] Results		
Last Edited	Condition category	[] Individual participant data		
26/04/2023	Nutritional, Metabolic, Endocrine			

# 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

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#### Type(s)

Scientific

#### Contact name

**Prof Sinead Brophy** 

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# 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)

# 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