Active for Life Year 5

Submission date	Recruitment status	[X] Prospectively registered		
17/12/2010	No longer recruiting	[X] Protocol		
Registration date	Overall study status	Statistical analysis plan		
17/03/2011	Completed	[X] Results		
Last Edited	Condition category	Individual participant data		
20/09/2016	Other			

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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Contact details

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

09/3005/04

Study information

Scientific Title

Active For Life Year 5: a cluster randomised controlled trial of a primary school-based intervention to increase levels of physical activity, decrease sedentary behaviour and improve diet

Acronym

AFLY5

Study objectives

A school-based intervention (AFLY5) that consists of teacher training and delivery of 16 lessons with 10 related homeworks (all lesson and homework plans provided) increases levels of physical activity, decreases sedentary behaviour and increases consumption of fruit and vegetables in Year 5 school children.

Ethics approval required

Old ethics approval format

Ethics approval(s)

University of Bristol Faculty of Medicine and Dentistry Ethics Committee, approval pending as of 10/01/2011

Study design

Cluster randomised 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

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

Health condition(s) or problem(s) studied

Public health

Interventions

The intervention is called 'Active for Life Year 5'. It consists of:

- 1. Training for classroom teachers
- 2. 16 lesson-plans including pictures, CDs and journals
- 3. 10 parental-child homework activities

- 4. Information for school newsletters
- 5. Information for parents on how to encourage their children to eat healthily and be active
- 6. A healthy activity day at school for parents, teachers and children

The control group will be 'standard lessons and school activity' for the duration of the study. Providing there is no evidence of harm the control group will be offered the intervention once the study is completed.

The total duration of the intervention is 8 months. Total duration of follow-up for both arms (both identical) is 24 months.

Intervention Type

Behavioural

Primary outcome measure

Measured at baseline, 12 months and 24 months:

- 1. Accelerometer assessed moderate/vigorous physical activity
- 2. Accelerometer assessed mean sedentary time
- 3. Portions of fruit and vegetables consumed

Secondary outcome measures

Measured at baseline, 12 months and 24 months:

- 1. Self-report of mean time spent screen-viewing
- 2. Portions of snacks, high-fat foods and high energy drinks consumed per day
- 3. Mean body mass index
- 4. Mean waist circumference
- 5. Odds of overweight/obesity

Overall study start date

01/04/2011

Completion date

30/09/2014

Eligibility

Key inclusion criteria

State Primary/Junior Schools in the South West of England. Within these schools the participants will be school children in Year 5 (9 - 10 year olds, either sex)

Participant type(s)

Other

Age group

Child

Lower age limit

9 Years

Upper age limit

Sex

Both

Target number of participants

60 schools; ~1500 school children

Key exclusion criteria

Private schools and special schools will be excluded

Date of first enrolment

01/04/2011

Date of final enrolment

30/09/2014

Locations

Countries of recruitment

England

United Kingdom

Study participating centre University of Bristol

Bristol United Kingdom BS8 2BN

Sponsor information

Organisation

University of Bristol (UK)

Sponsor details

c/o Teirnan Williams Research and Enterprise Department Senate House Tyndall Avenue Bristol England United Kingdom BS8 1TH +44 (0)117 928 8483 Tiernan.Williams@bristol.ac.uk

Sponsor type

University/education

Website

http://www.bris.ac.uk/

ROR

https://ror.org/0524sp257

Funder(s)

Funder type

Government

Funder Name

National Institute for Health Research (NIHR) (UK) - Public Health Research Programme (ref: 09 /3005/04)

Results and Publications

Publication and dissemination plan

Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?	
Output type		Date Created	Date added	reel leviewed:	racient-racing:	
Protocol article	<u>e</u> protocol	24/07/2011		Yes	No	
Protocol article	protocol update	24/07/2013		Yes	No	
Results article	results	27/05/2014		Yes	No	
Results article	results	11/11/2015		Yes	No	
Results article	results	22/01/2016		Yes	No	

Results article results 01/06/2016 Yes No