# A study to assess the effectiveness and value for money of a programme to prevent primary school age children becoming overweight and obese

Submission date	<b>Recruitment status</b> No longer recruiting	[X] Prospectively registered		
18/05/2010		[X] Protocol		
Registration date	Overall study status	Statistical analysis plan		
19/05/2010	Completed	[X] Results		
<b>Last Edited</b> 27/02/2020	<b>Condition category</b> Nutritional, Metabolic, Endocrine	[] Individual participant data		
21/02/2020	Nutritional, Metabolic, Endocrine			

#### Plain English summary of protocol

Background and study aims

The number of children in the UK who are overweight is rising. This can lead to several health problems both in childhood and as an adult. So far, ways of preventing children becoming overweight that have been tried have not been successful. The programme that we are testing in this study has been developed in a previous study in Birmingham, and the initial results show that the programme may reduce the likelihood of children becoming overweight. This larger study will enable us to assess more accurately the success of the programme in helping children to keep their weight at a healthy level.

#### Who can participate?

Children in year 1 (age 5-6) at 50 primary schools across the West Midlands, and their parents.

#### What does the study involve?

Participating schools are randomly allocated into two groups. The programme of activities is run in one group of schools and not run in the other group. We can then compare the schools that have received the programme with those who have not. The programme consists of several elements: activities to increase the amount of physical activity children do in school, healthy cooking sessions for parents and children, a healthy eating and physical activity course run by Aston Villa football club, and information and ideas on local leisure activities for families. Measurements are necessary to properly assess the effects of the programme. We measure your child's height, weight, waist and blood pressure. We also measure the thickness of the skin (at the waist, on the arm, on the thigh and on the upper back), and proportion of body fat (this involves your child standing on a special type of weighing scales). Children also wear a physical activity monitor for 5 days. Children are asked some simple questions about how they see themselves and their life in general. Parents of children taking part are asked to help fill in a simple 24 hour food questionnaire for their child and a questionnaire asking about the lifestyles

of family members and other aspects of family life. We repeat the measurements and questionnaires at further points in the study. Later in the study parents may be contacted to ask if they would be happy to participate in an interview or focus group.

What are the possible benefits and risks of participating?

While there are no direct benefits to children taking part in this study, the results will help us to assess the success of a programme to prevent children becoming overweight, and therefore prevent them from having health problems that are related to obesity. If this study shows that the programme is successful, it can be introduced in schools across the country. All the measurements are completely safe. There is a very small risk of a mild skin reaction to the sticky pads that are used to attach the physical activity monitor. In the unlikely event that this happens, the monitor and sticky pads can be removed and it will clear up on its own.

Where is the study run from? The University of Birmingham (UK)

When is the study starting and how long is it expected to run for? September 2010 to August 2015

Who is funding the study? Health Technology Assessment Programme (UK)

Who is the main contact? Dr Peymane Adab p.adab@bham.ac.uk

# Contact information

# Type(s)

Scientific

#### Contact name

Dr Peymane Adab

#### Contact details

Department of Public Health, Epidemiology & Biostatistics The University of Birmingham Edgbaston Birmingham United Kingdom B15 2TT

p.adab@bham.ac.uk

# Additional identifiers

Protocol serial number HTA 06/85/11

# Study information

#### Scientific Title

A cluster randomised controlled trial of the effectiveness and cost-effectiveness of an obesity prevention intervention in primary school age children

#### **Study objectives**

- 1. Research objectives
- 1.1. To compare the effectiveness of a theory based intervention package delivered at school level, to prevent obesity in children aged 6-7 with usual care
- 1.2. To assess costs and compare cost-effectiveness of the intervention with no intervention from the societal perspective
- 1.3. To explore differences in outcomes, uptake and adherence to the intervention by gender, ethnicity, socioeconomic status, baseline BMI and rural/urban residence
- 1.4. Use qualitative approaches to describe the implementation of, uptake, motivation to participate and adherence to the intervention components
- 2. The study will seek to address the following research questions:
- 2.1. How effective is the intervention package, delivered through schools, in preventing overweight and obesity in children, compared to usual practice?
- 2.2. For how long do any observed effects persist, after active intervention has ceased?
- 2.3. What is the incremental cost associated with supplying the obesity prevention intervention?
- 2.4. What is the incremental benefit associated with supplying the obesity prevention intervention?
- 2.5. What is the incremental cost-effectiveness ratio of supplying the obesity prevention intervention?
- 2.6. How effective is the intervention package in improving diet and increasing physical activity, compared to usual practice?
- 2.7. What is the effect of the intervention on quality of life and perceived self worth?
- 2.8. Is there a trend in difference in outcomes by sex, ethnicity, social class or urban/rural living?

More details can be found at http://www.nets.nihr.ac.uk/projects/hta/068511 Protocol can be found at http://www.nets.nihr.ac.uk/\_\_data/assets/pdf\_file/0010/51499/PRO-06-85-11.pdf

#### Ethics approval required

Old ethics approval format

# Ethics approval(s)

Application for ethical approval will be submitted to one of the Research Ethics Committees in Birmingham (Birmingham East, North and Solihull, or South Birmingham), in the coming month – submission pending

# Study design

Single-centre open-label cluster (school-level) randomised controlled trial

# Primary study design

Interventional

# Study type(s)

Prevention

#### Health condition(s) or problem(s) studied

Childhood obesity

#### **Interventions**

A childhood obesity prevention programme will be delivered to schools in the intervention arm for 1 year. The programme consists of:

- 1. Activities to increase the time spent doing physical activity within the school day
- 2. School participation in the 'Villa Vitality' programme, which provides interactive learning and opportunities for physical activity and healthy eating, delivered by an iconic sport institution (Aston Villa Football Club; an English Premier League club)
- 3. Healthy cooking sessions in school time for parents and children
- 4. Provision of information to families signposting local leisure opportunities The schools in the control arm will receive 'usual practice' with regard to healthy eating and physical activity.

Schools will be divided into two waves, the first wave will be followed up at 3 timepoints following the intervention (immediately after the intervention year, one year later and two years later). The second wave will be followed up at two timepoints (immediately after the intervention year, and one year later).

#### Intervention Type

Behavioural

#### Primary outcome(s)

The difference in percentage of children categorised as normal weight, overweight and obese in control compared to intervention schools.

- 1. The categorisation will be based primarily on height and weight measures and defined by BMI using cut-offs at the 85th and 95th percentiles on the UK 1990 reference charts for BMI centiles for boys and girls.
- 2. Additional measures of obesity will also be used:
- 2.1. Waist circumference
- 2.2. Skinfold thickness at 4 sites (biceps, suprailiac, subscapular and thigh)
- 2.3. Body fat calculated from a measure of bioimpedance (obtained from a Tanita body composition analyser)

All participants will undergo these measures at baseline, 1 year and 2 years. Wave one participants will undergo these measures a further time at 3 years.

# Key secondary outcome(s))

- 1. 24 hour dietary assessment using a Child and Diet Evaluation Tool (CADET) tick list
- 2. Physical activity levels measured over 5 days using an Actiheart monitor (combined heart rate monitor and accelerometer)
- 3. Health-related quality of life measured by the Pediatric Quality of Life Inventory (PedsQL)
- 4. Body image measure using an adapted version of the Collins Figure Rating Scale
- 5. A further quality of life measure for use in the cost-effectiveness study will be developed at the start of the trial

All participants will undergo these measures at baseline, 1 year and 2 years. Wave one participants will undergo these measures a further time at 3 years.

#### Completion date

31/08/2015

# **Eligibility**

#### Key inclusion criteria

All children (boys and girls) in year 1 (age 5-6) in schools participating in the trial

#### Participant type(s)

Healthy volunteer

## Healthy volunteers allowed

No

#### Age group

Child

#### Sex

All

#### Total final enrolment

1397

# Key exclusion criteria

Does not meet inclusion criteria

#### Date of first enrolment

01/09/2010

#### Date of final enrolment

31/08/2015

# Locations

#### Countries of recruitment

United Kingdom

England

# Study participating centre The University of Birmingham

Birmingham United Kingdom B15 2TT

# Sponsor information

## Organisation

University of Birmingham (UK)

#### **ROR**

https://ror.org/03angcq70

# Funder(s)

## Funder type

Government

#### **Funder Name**

Health Technology Assessment Programme

## Alternative Name(s)

NIHR Health Technology Assessment Programme, Health Technology Assessment (HTA), HTA

## **Funding Body Type**

Government organisation

# **Funding Body Subtype**

National government

#### Location

**United Kingdom** 

# **Results and Publications**

Individual participant data (IPD) sharing plan

# IPD sharing plan summary

# Study outputs

Output type	Details	Date created Date added	Peer reviewed?	Patient-facing?
Results article	pilot study results	01/02/2013	Yes	No
Results article	teacher experiences results	07/11/2014	Yes	No
Results article	results	16/12/2015	Yes	No
Results article	results	01/02/2018	Yes	No
Results article	results	07/02/2018	Yes	No
Results article	results	10/07/2019 27/02/2020	Yes	No

Protocol article	protocol	13/05/2015	Yes	No
Other publications	process evaluation design	10/09/2014	Yes	No
Other publications	parent and child perceptions	09/12/2015	Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025 No	Yes
Study website	Study website	11/11/2025	11/11/2025 No	Yes