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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
18/05/2010

Recruitment status
No longer recruiting

Registration date
19/05/2010

Overall study status
Completed

Last Edited
27/02/2020

Condition category
Nutritional, Metabolic, Endocrine

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

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
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Study website
www.beaches.bham.ac.uk/waves.shtml

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Secondary study design
Cluster randomised trial

Study setting(s)
School

Study type(s)
Prevention

Participant information sheet
http://www.birmingham.ac.uk/research/activity/mds/projects/HaPS/PHEB/WAVES/information/index.aspx

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 measure
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.

Secondary outcome measures
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.

Overall study start date
01/09/2010

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

Age group
Child

Sex
Both

Target number of participants
The total target number of participants is 1922, in 44 clusters (schools)

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
England

United Kingdom

Study participating centre
The University of Birmingham
Birmingham
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Sponsor information

Organisation
University of Birmingham (UK)

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Sponsor type
University/education

ROR
https://ror.org/03angcq70

Funder(s)

Funder type
Government

Funder Name
Health Technology Assessment Programme

Alternative Name(s)
NIHR Health Technology Assessment Programme, HTA

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date
01/09/2016

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?
Results article	pilot study results	01/02/2013		Yes	No
Other publications	process evaluation design	10/09/2014		Yes	No
Results article	teacher experiences results	07/11/2014		Yes	No
Protocol article	protocol	13/05/2015		Yes	No
Other publications	parent and child perceptions	09/12/2015		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