

Helping pre-school children to avoid obesity

Submission date 15/12/2016	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 21/12/2016	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 20/11/2019	Condition category Nutritional, Metabolic, Endocrine	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data

Plain English summary of protocol

Background and study aims

Childhood obesity is a growing concern worldwide, which can lead to serious health problems such as diabetes, heart disease and even cancer. Many children aged 2 to 4 years in England attend Early Years Centres and this provides an opportunity to see if a healthy lifestyle programme can prevent obesity before children enter the formal school system at age 4 years. The aim of this study is to test the effectiveness of a healthy lifestyle programme in preventing obesity in children aged two-four years old.

Who can participate?

Parents and their two-year old children who attend participating Early Years Centres.

What does the study involve?

Participating Early years centres are randomly allocated to one of two groups. In the first group, staff are trained to deliver an educational resource 'Be Active, Eat Healthy'. In these centres, the Healthy Heroes educational package of activities (which encourages healthy eating and physical activity) is delivered to two-year old children and their parents. In the second group, staff do not receive any training and work with attending families as normal. Staff in all centres are interviewed before and after the 'training' to assess their policies and health promotion activities. All children in the study are weighed at the start of the study and at 6 months, 12 months and 2 years after the start. Parents complete a number of questionnaires about their child's eating behaviour, style of feeding their child, and about their own mental and physical wellbeing. These questionnaires are completed at the start and at two years after the start of the study.

What are the possible benefits and risks of participation?

Parents and children will learn about the benefits of healthy eating and being active. Monitoring weight, eating behaviour and physical activity may help children achieve and maintain a health weight. There are no risks involved in this study.

Where is the study run from?

The study is run from University of Central Lancashire and takes place in 10 Early Years Centres in Lancashire (UK)

When is the study starting and how long is it expected to run for?
September 2010 to July 2016

Who is the main contact?
Professor Janice Abbott
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Contact information

Type(s)
Scientific

Contact name
Prof Janice Abbott

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
AH201016

Study information

Scientific Title
An educational intervention to avoid overweight in the pre-school years

Study objectives
Children in the intervention group will have a different change in BMI z-score between 2 and 4 years of age compared to children in a control group not receiving the intervention.

Ethics approval required
Old ethics approval format

Ethics approval(s)
University of Central Lancashire Ethics Committee, 03/03/20111, ref: PSYAH11

Study design

Cluster randomised controlled trial

Primary study design

Interventional

Secondary study design

Cluster randomised trial

Study setting(s)

Community

Study type(s)

Prevention

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

Childhood obesity

Interventions

Early Years Centres will be selected and matched in terms of their locality and the social and economic status of the children attending the centres. The matched centres will be randomly allocated to be intervention or control centres.

Interventions group: Staff receive training at Early Years Centres in the educational resource 'Be Active, Eat Healthy'. This will be provided by Lancashire County Council's Children and Young People's Team, NHS Public Health personnel and NHS Early Years Health Practitioners. Policies, provision and health promotion on healthy eating and physical activity will be assessed in the Early Years Centres at baseline and at 12 month follow-up. The 'Healthy Heroes Activity Pack' for participating parents and children is then delivered by trained Early Years staff (www.lhsp.org.uk/healthyheroes).

Control group: Staff do not receive any training and work with attending families as normal.

For all participants, interviews will be arranged for each family for assessments at baseline, 6 months, 12 months and 2 years post baseline. At each assessment, the parent and child will be weighed, and have their height and waist circumference measured. A parent-report battery of valid and reliable questionnaires will be administered at baseline and at 2 years.

Intervention Type

Behavioural

Primary outcome measure

Child BMI z-score is measured using height and weight measurements taken at baseline, 6 months, 1 and 2 years.

Secondary outcome measures

1. Child eating behaviour is assessed using the Child Eating Behaviour Questionnaire at baseline and 2 years
2. Parent style of feeding their child is assessed using the Parental Feeding Style Questionnaire at baseline and 2 years
3. Mental wellbeing is assessed using the Warwick and Edinburgh Mental Wellbeing Scale at baseline and 2 years

Overall study start date

01/09/2010

Completion date

09/07/2016

Eligibility

Key inclusion criteria

Parent of a two year old child attending an Early Years Centre in Lancashire, England.

Participant type(s)

Healthy volunteer

Age group

Mixed

Sex

Both

Target number of participants

100 parent-child pairs

Total final enrolment

162

Key exclusion criteria

Previous access to the Educational Resource

Date of first enrolment

18/03/2011

Date of final enrolment

21/07/2014

Locations

Countries of recruitment

England

United Kingdom

Study participating centre
University of Central Lancashire
Fylde Road
Preston
United Kingdom
PR1 2HE

Sponsor information

Organisation
University of Central Lancashire

Sponsor details
Corporation Street
Preston
England
United Kingdom
PR1 2HE

Sponsor type
University/education

ROR
<https://ror.org/010jbqd54>

Funder(s)

Funder type
Government

Funder Name
Lancashire County Council

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer reviewed journal in 2017.

Intention to publish date
31/12/2017

Individual participant data (IPD) sharing plan

The current data sharing plans for the current study are unknown and will be made available at a later date.

IPD sharing plan summary

Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/12/2019	20/11/2019	Yes	No