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Helping pre-school children to avoid obesity

Submission date
15/12/2016

Recruitment status
No longer recruiting

Registration date
21/12/2016

Overall study status
Completed

Last Edited
20/11/2019

Condition category
Nutritional, Metabolic, Endocrine

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] 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
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Additional identifiers

Protocol serial number
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

Primary study design
Interventional

Study design

Cluster randomised controlled trial

Study type(s)
Prevention

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

Key secondary outcome(s)
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

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

Healthy volunteers allowed
No

Age group
Mixed

Sex
All

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
United Kingdom

England

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

Sponsor information

Organisation
University of Central Lancashire

ROR
https://ror.org/010jbqd54

Funder(s)

Funder type
Government

Funder Name
Lancashire County Council

Results and Publications

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