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Changing eating behaviours to treat childhood obesity in the community using Mandolean

Submission date	Recruitment status	[X] Prospectively registered
31/01/2012	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
31/01/2012	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
08/09/2015	Nutritional, Metabolic, Endocrine	

Plain English summary of protocol

Background and study aims
Obesity is the most common disorder of childhood and adolescence. Childhood obesity can have immediate health consequences, including diabetes, a worsening of asthma, and liver disease., Obesity often continues into adulthood, leading to long-term health problems such as heart disease and cancer. Evidence on treatments for childhood obesity is limited. Most treatments designed to promote weight loss in children have so far been unsuccessful. Recently, a new device, the Mandolean, was found to help with weight loss in adolescents when used with a weight management programme. The Mandolean is a weighing scale which measures the user's rate of eating and satiety (fullness) and provides feedback to help change eating behaviours. This study aims to establish the clinical and cost-effectiveness of the addition of Mandolean to a weight management programme for children aged 5-11 years.

Who can participate?
Obese children aged 5 – 11 and their parents.

What does the study involve?
Participants are randomly allocated to receive either a weight management programme alone or a weight management programme plus the Mandolean device. Body mass index (BMI), rate of eating, satiety ratings and overall health will be measured at the start of the study. Participants will have five appointments over a year with a nurse who will promote lifestyle changes to aid weight loss. Those who receive the Mandolean will be asked to eat one meal a day using the Mandolean for one year. At 1 and 2 years after entering the study we will find out if there are any differences between the groups and whether these are maintained after treatment has ended.

What are the possible benefits and risks of participating?
Not provided at time of registration.

Where is the study run from?
University of Bristol (UK).

When is the study starting and how long is it expected to run for?
April 2012 to December 2014.

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

Who is the main contact?
Mrs Gwen Brierley
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Contact information

Type(s)
Scientific

Contact name
Mrs Gwen Brierley

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
11533

Study information

Scientific Title
Changing eating behaviours to treat childhood obesity in the community using Mandolean: the ComMando (Community Mandolean) randomised trial

Acronym
ComMando

Study objectives

To establish the clinical and cost effectiveness of the addition of Mandolean treatment to a primary care weight management programme for obese children over a 12 and 24 month follow-up period

More details can be found at http://public.ukcrn.org.uk/search/StudyDetail.aspx?StudyID=11533

Ethics approval required
Old ethics approval format

Ethics approval(s)
Frenchay, South West Research Ethics Committee First MREC approval date 05/12/2012, ref:11/SW/0286

Study design
Randomised; Interventional; Design type: Treatment

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
GP practice

Study type(s)
Treatment

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
Topic: Primary Care Research Network for England; Subtopic: Not Assigned; Disease: All Diseases

Interventions
640 parent-child pairs will be randomised on a 1:1 ratio to either the control (weight managment programme alone) or intervention (weight management programme plus Mandolean) arm.

1. Control arm: Weight management programme delivered in Primary Care.
2. Intervention arm: Weight management programme delivered in primary care plus training and use of Mandolean at home for 1 year.

Follow Up Length: 24 month(s); Study Entry : Single Randomisation only

Intervention Type
Device

Primary outcome measure
Child BMI standard deviation scores (SDS); Timepoint(s): 12 months

Secondary outcome measures
1. Adult eating rate; Timepoint(s): 12 & 24 months
2. Child BMI SDS; Timepoint(s): 24 months
3. Child eating rate; Timepoint(s): 12 & 24 months
4. Child ideal portion size choice; Timepoint(s): 12 & 24 months
5. Child self determined portion size; Timepoint(s): 12 & 24 months
6. Child Health Utility Index 9D (CHU9D); Timepoint(s): 3, 6, 9, 12 & 24 months
7. EQ5D; Timepoint(s): 3, 6, 9, 12 & 24 months
8. EQ5D-Y; Timepoint(s): 3, 6, 9, 12 & 24 months
9. Parent BMI; Timepoint(s): 12 & 24 months
10. Parent ideal portion size choice; Timepoint(s): 12 and 24 months
11. Parent self determined portion size; Timepoint(s): 12 and 24 months
12. PedsQL; Timepoint(s): 12 & 24 months

Overall study start date
02/04/2012

Completion date
31/12/2014

Eligibility

Key inclusion criteria
Obese children aged 5 - 11 years with a BMI >/= 95th percentile

Participant type(s)
Patient

Age group
Child

Lower age limit
5 Years

Upper age limit
11 Years

Sex
Both

Target number of participants
Planned Sample Size: 640; UK Sample Size: 640

Key exclusion criteria
Children whose weight management requires secondary care consultation as the intervention under investigation is focused on management in primary care. Exclusion criteria will be identified by the referring GP using a standardised checklist.

Date of first enrolment
02/04/2012

Date of final enrolment
31/12/2014

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
University of Bristol
Bristol
United Kingdom
BS8 2PS

Sponsor information

Organisation
University of Bristol (UK)

Sponsor details
Department of Social Medicine
Canynge Hall
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England
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Sponsor type
University/education

ROR
https://ror.org/0524sp257

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

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	results	01/07/2014		Yes	No