

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

Submission date 31/01/2012	Recruitment status No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 31/01/2012	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 08/09/2015	Condition category Nutritional, Metabolic, Endocrine	<input type="checkbox"/> Individual participant data

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
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Additional identifiers

Protocol serial number
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

Study type(s)

Treatment

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 management 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(s)

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

Key secondary outcome(s)

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

Completion date

31/12/2014

Eligibility

Key inclusion criteria

Obese children aged 5 - 11 years with a BMI \geq 95th percentile

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Child

Lower age limit

5 years

Upper age limit

11 years

Sex

All

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

United Kingdom

England

Study participating centre

University of Bristol

Bristol

United Kingdom

BS8 2PS

Sponsor information

Organisation

University of Bristol (UK)

ROR

<https://ror.org/0524sp257>

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	results	01/07/2014		Yes	No