

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

<b>Submission date</b> 31/01/2012	<b>Recruitment status</b> No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 31/01/2012	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 08/09/2015	<b>Condition category</b> 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  
gwen.brierley@bristol.ac.uk

## 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 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 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  $\geq$  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

Whiteladies Road

Bristol

England

United Kingdom

BS8 2PR

**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?
<a href="#">Results article</a>	results	01/07/2014		Yes	No