ISRCTN84202126 https://doi.org/10.1186/ISRCTN84202126

Using functional Magnetic Resonance Imaging to assess the impact of Mandolean training on the neural control of obesity in young people: a feasibility study for the Bristol Nutrition BRU

Submission date
31/07/2013

Recruitment status
No longer recruiting

Registration date
22/02/2018

Overall study status
Completed

Last Edited
26/11/2018

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
Obesity is the most common disorder of childhood and adolescence, which often continues into adulthood leading to long-term health problems. Early-onset obesity is often caused by MC4R mutations. Recently, a study of a new device, the Mandolean, demonstrated a reduction in body mass index (BMI) in adolescents when used with a weight-management programme. The Mandolean is a weighing scale that measures rate of eating and satiety (fullness), and provides feedback to help children change their eating behaviours. Beneficial effects of Mandolean training have been found on hormones related to hunger and fullness. The first aim of this study is to use brain imaging to find out whether weight reduction following Mandolean training is associated with changes in activity in satiety-related brain regions. The second aim is to examine whether training with the Mandolean results in weight loss for those with MC4R mutation, and whether similar hormone and brain changes are seen as for those without the mutation.

Who can participate?
Obese adolescents without MC4R mutation, adolescents and adults with MC4R mutation, and normal weight adolescents

What does the study involve?
Obese adolescents without MC4R mutation are randomly allocated to receive either a weight-management programme, or the programme plus Mandolean training for 6 months. Adolescents and adults with MC4R mutation all receive the Mandolean intervention. Normal weight adolescents are also recruited as the control group. The weight-management programme consists of six appointments with a dietician who promotes lifestyle changes to aid weight loss. Those who receive the Mandolean receive additional training in order to eat one meal a day using the Mandolean. BMI, rate of eating and satiety are measured, and participants undergo two identical brain imaging sessions at the start of the study and after 6 months.

What are the possible benefits and risks of participating?
This study may benefit participants as previous research suggests that training to eat more slowly using the Mandolean may reduce BMI, and currently this treatment is not available through the NHS. By participating in this study, participants in both groups also receive a more intensive level of support with their weight management than might normally be offered in primary care. Participants are given £20 in Amazon vouchers as a thank you and to reimburse them for their time taken to attend the brain imaging sessions. Travel expenses are paid on presentation of receipts for journeys made to and from the imaging centre. If requested, participants are given a picture of their brain, taken from the structural brain scan. It will be made clear to the participants that the scans are not to be used for medical diagnosis. Some participants may become anxious in the MRI environment. Participants are informed of the confined space and noise that is to be expected during the scanning. If a participant wishes to leave the scanner during the procedure they are able to do so and are given full instructions as to how they can indicate any discomfort. There is a risk of anxiety and need for extra medical procedures in the unlikely event that brain abnormalities are detected during the MRI scan. There is a risk of bruising following insertion of the cannula (tube) for blood sample collection. This is usually minor, and every care will be taken to minimise bruising by the Lead Research Radiographer. There is a risk of fainting in some individuals during sample collection. A check is included in the screening form for those who have a fear of having blood taken, to minimise the number of participants for whom this process is anxiety provoking.

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

When is the study starting and how long is it expected to run for?
January 2013 to March 2017

Who is funding the study?
The NIHR Biomedical Research Unit in Nutrition, Diet and Lifestyle (University of Bristol and the University Hospitals Bristol NHS Foundation Trust) (UK)

Who is the main contact?
Prof. Julian Hamilton-Shield

Contact information

Type(s)
Scientific

Contact name
Prof Julian Hamilton-Shield

Contact details
University of Bristol
Level 6
UBHT Education Centre
Upper Maudlin Street

Bristol
United Kingdom
BS2 8AE

Additional identifiers

Protocol serial number
Protocol_040613_v2

Study information

Scientific Title
Using functional Magnetic Resonance Imaging to assess the impact of Mandolean training on the neural control of obesity in young people: a feasibility study for the Bristol Nutrition BRU

Acronym
MANDO

Study objectives
The principal research hypothesis is that Mandolean training (in addition to the standard weight--management care) will improve speed of eating, portion size determination and perceptions of satiety in obese young people, and that this will lead to greater weight loss than the standard care group alone. Moreover, it is hypothesised that Mandolean training will have a significant impact on the brain's control of food consumption and responsiveness to food cues in obese adolescents.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Frenchay NRES Committee, SouthWest, 06/06/2013, IRAS project ID: 124722, REC ref: 13/SW /0076

Study design
Feasibility/pilot study

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Childhood obesity and neuroimaging

Interventions
Participants will be randomly allocated to one of 2 groups: (1) Standard care or (2) Standard care plus Mandolean training.

Standard care intervention: Participants initially allocated to the standard care arm will receive a package of care specifically tailored for the treatment of obesity as per routine care at the Care

of Childhood Obesity (COCO) clinic in the Childrens Hospital. This will be referred to as 'standard care', although this is likely to reflect an enhanced level of care to that usually received in primary care settings.

In standard care, emphasis will be placed on implementing changes to increase levels of enjoyable physical activity to national recommended levels (60 minutes exercise a day for children) alongside a balanced diet, based on the 'Eatwell Plate' (Food Standards Agency). Families will be encouraged to set their own dietary goals and targets, with practical advice and guidance from the dietician. In encouraging activity, the approach is one of facilitation rather than prescription. Motivational interviewing techniques are used to engage patients and families in the decision-making process for lifestyle changes. This is consistent with self-determination principles and is more likely to lead to responsibility for long term change (Deci et al., 1990).

Standard care appointments will be delivered at 6 weekly intervals over a 6-month period, resulting in 6 contacts in total for this arm of the study.

Experimental intervention: During the Mandolean intervention, participants will receive the same standard care package as the control group with the addition of Mandolean therapy. The Mandolean is a portable weighing scale connected to a small computer which can generate a graphical representation of food removal from the plate with weight of food (grams) on the y axis and time (minutes) on the x axis. The patient puts a measured portion of food determined by a therapist on the scale and the computer records and displays, in real-time graphics, the removal of food from the plate as the patient eats. Patients are also asked to rate their satiety at regular intervals. During Mandolean training, the patient gradually adopts a more normal pattern of eating and satiety by following tailored training lines and curves provided by the dietician. Patients are asked to attend additional appointments with the dietician in order to be trained in the use of the scale. In total, there will be approximately 9 appointments for the patients to attend in person.

Intervention Type
Behavioural

Primary outcome(s)
Patient BMI SDS (standard deviation score) at the end of the intervention period, converted from measures of height and weight using a standard algorithm. Height (using a stadiometer) and weight (using calibrated weighing scales) will be measured at baseline and at 6 months

Key secondary outcome(s))
1. Maintained BMI or BMI SDS improvement at 6 months post therapy (12 months after study entry). Height (using a stadiometer) and weight (using calibrated weighing scales) will be measured at part of routine clinic appointments following participation in the study. Height and weight measurements will be recorded from medical notes from the closest clinic appointment to 12 months after study entry.
2. Eating speed and self-determined portion size measured using the Mandolean (weighing scale that records the rate at which food is removed from the plate) in test meals at time 0 (baseline) and 6 months (end of intervention)
3. Blood plasma levels of ghrelin and PYY, pre- and post-intervention. Blood samples will be taken during each of the two OGTT fMRI sessions at baseline and end of intervention. According to the OGTT, samples will be taken prior to glucose ingestion then 30, 60 and 90 minutes post-glucose ingestion. Blood samples will be processed and analysed using established protocols
4. Brain activity in response to (a) glucose ingestion, and (b) pictures of food, pre- and post-

intervention. Brain activity will be measured during each of the two OGTT fMRI sessions at baseline and end of intervention. The Blood Oxygen Level Dependent (BOLD) response will be measured in response to pictures of food

Completion date
30/03/2017

Eligibility

Key inclusion criteria
1.
The target population for the obese group will be obese adolescents and young adults aged 11 yea

BMI >/= 95th percentile (definition of obesity in National Child Measurement Programme)
2. The target population for the MC4-
R group will be adolescents and adults with obesity confirmed to be due to MC4-
R mutation (Cambridge Genetics of Simple Obesity Study)
3. The target population for the control group will be normal--
weight adolescents and young adults aged 11 years or above

Participant type(s)
Mixed

Healthy volunteers allowed
No

Age group
Mixed

Sex
All

Key exclusion criteria
1. Children and adults with learning difficulties, visual or hearing difficulties, dysmorphic features s

syndromes such as PraderWilli
2. Children and adults with endocrine disorders such as hypothyroidism
3. Children and adults with iatrogenic causes of obesity cranial surgery, anti-convulsant therapy
4. Children and adults whose first language is not English
5. Patients for whom it would not be safe to enter the MR environment. Contraindications for parti

5.1. Metal implants (internal defibrillator, cochlear implant, artificial heart valves, implanted drug ir

dental work if not removable, cardiac pacemaker, artificial limbs or metallic joint prostheses, metal

or surgical staples, intrauterine device)
5.2. Tattoos with metallic ink or unremovable body piercing which might be attracted to the magne

scanning and to avoid image distortion
5.3. Pregnancy, to avoid harm to the foetus
5.4. History of neurological disease, traumatic brain injury, mental illness

5.5. Claustrophobia, to avoid including participants with brain abnormalities or at risk of anxiety, in

related to being in enclosed places
5.6. Medical health problems requiring medication, to avoid disruption to brain function and respor

or test meals
5.7. Weight above 152kg due to the limits of the scanner bed, and girth of less than 210cm in order

diameter bore of the scanner
5.8. Vegetarian or vegan, so that the images of food shown in the cue--
reactivity task are not aversive to participants

Date of first enrolment
06/07/2013

Date of final enrolment
08/01/2015

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
University of Bristol
Bristol
United Kingdom
BS2 8AE

Sponsor information

Organisation
University of Bristol

ROR
https://ror.org/0524sp257

Funder(s)

Funder type
Research organisation

Funder Name
The NIHR Biomedical Research Unit in Nutrition, Diet and Lifestyle (University of Bristol and the University Hospitals Bristol NHS Foundation Trust).

Results and Publications

Individual participant data (IPD) sharing plan
The non-imaging datasets generated and/or analysed during this study will be included in the subsequent results publication. The imaging dataset analysed during the current study are currently available from the corresponding author on request, whilst under consideration for submission to a public repository.

IPD sharing plan summary
Other

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	22/11/2018		Yes	No
HRA research summary			28/06/2023	No	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes