ISRCTN35717198 https://doi.org/10.1186/ISRCTN35717198

Cognitive Training with Non-invasive Brain Stimulation to Treat Binge Eating Disorder

Submission date
03/05/2018

Recruitment status
No longer recruiting

Registration date
18/05/2018

Overall study status
Completed

Last Edited
29/03/2022

Condition category
Mental and Behavioural Disorders

[X] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Psychological therapy as a main treatment for Binge Eating Disorder (BED) may not be effective for many people and may not be readily accessible in some areas. Medical treatments for BED can have side effects and often do not remain effective in the long-term. Therefore, there is an ongoing need for the development of new treatments. Computerised approach bias modification training (ABM) is a specific form of cognitive bias modification (CBM) that has been used to successfully treat mental disorders such as anxiety, depression, and addictive disorders. This technique involves several sessions of computerised training, a procedure which has shown to be effective in reducing the severity of some eating disorder symptoms in people with BED and Bulimia Nervosa (BN). ABM works by using repeated training of arm movements in front of a computer screen to modify automatic approach and avoidance tendencies towards food-related cues. ABM has shown to reduce approach tendencies and attention towards food cues in a subclinical sample of eating disorders involving binge eating, but its effectiveness on these features in people with full-syndrome eating disorders remains unclear. Further research is needed to examine if ABM is effective in reducing the frequency of binge eating episodes in people with BED. Transcranial direct current stimulation (tDCS) is a non-invasive technique that is capable of stimulating specific brain areas. Research shows that the frontal areas of the brain play a role in the development and maintenance of eating disorders, including BED. Stimulating these brain areas to alter their functioning is therefore believed to have the potential to reduce eating disorder symptoms. This involves the delivery of a low electrical current via small electrodes placed on the scalp. This procedure is widely used in research and is being applied in clinical settings. Recent research using tDCS on people with BED has suggested that it may be helpful in reducing immediate food intake and cravings, and may decrease the frequency of a desire to binge eat at home after the treatment. Previous studies suggest that these two techniques potentially help people better regulate their behaviours through similar mechanisms in the brain. Delivering both treatments together at the same time may have a stronger effect on reducing eating disorder symptoms in people with BED than either of the treatments alone. This will be the first time that this specific combination of interventions has been used on people with an eating disorder. The aim of this study is to investigate combined ABM and tDCS as a treatment for BED by comparing the effect of 6 sessions of ABM with either real or placebo tDCS across a 3-week period in patients with BED.

Who can participate?
Community-dwelling adults aged 18 to 70 who are overweight or obese and meet clinical criteria for full-syndrome or sub-threshold Binge Eating Disorder (BED)

What does the study involve?
Participants are randomly allocated to either one of two intervention groups, or to the control group. Participants in the intervention groups receive 6 sessions of ABM delivered simultaneously with either real tDCS or a placebo (dummy) version of tDCS. Participants in the control group do not receive any intervention. Eating disorder symptoms and other outcomes are measured in all participants at the start of the study, after treatment, and at the 4-week follow-up, in particular the changes in the frequency of binge eating and craving, and thought processes and emotions related to food and eating. Participants are also asked about their experience of this treatment. Participants in the control group are offered 6 sessions of ABM and real tDCS after they have completed their involvement in the study.

What are the possible benefits and risks of participating?
Aside from monetary payment for participation, there are no direct benefits to taking part in this study, but the results may help to improve the treatment of BED in the future. TDCS has been shown to be safe when used correctly in a clinical setting. However, participants may find the procedure slightly uncomfortable. This is because a number of sensations can occur beneath the electrodes during stimulation including tingling, pain, itching, and burning. Not everyone feels these sensations or finds them uncomfortable, but if you do, remember you are free to stop the study at any point without giving an explanation. In some rarer cases, tDCS has been known to cause a headache, but this can be treated with mild painkillers (e.g. paracetamol). No side effects of ABM are known. The researchers will assess any discomfort during intervention sessions.

Where is the study run from?
King's College London (UK)

When is the study starting and how long is it expected to run for?
January 2018 to March 2020 (updated 04/08/2020, previously: August 2020 (updated 07/04/2020, previously: July 2020))

Who is funding the study?
National Institute for Health Research (NIHR) (UK)

Who is the main contact?
Gemma Gordon
gemma.gordon@kcl.ac.uk

Contact information

Type(s)
Public

Contact name
Ms Gemma Gordon

ORCID ID
http://orcid.org/0000-0003-3888-0202

Contact details
Section of Eating Disorders
103 Denmark Hill
De Crespigny Park
Institute of Psychiatry, Psychology and Neuroscience
King's College London
London
United Kingdom
SE5 8AF
+44 (0)207 848 5608
gemma.gordon@kcl.ac.uk

Additional identifiers

EudraCT/CTIS number

IRAS number
244170

ClinicalTrials.gov number

Secondary identifying numbers
IRAS 244170

Study information

Scientific Title
Investigating concurrent cognitive bias modification training and transcranial direct current stimulation in binge eating disorder

Acronym
ICARUS

Study objectives
This study aims to investigate the feasibility of combining approach bias modification training (ABM) and transcranial direct current stimulation (tDCS) to treat Binge Eating Disorder. The study will assess if there are synergistic effects of concurrent sessions of [ABM + tDCS] on clinical outcomes in a patient population, compared to [ABM + sham tDCS] and a wait-list control group.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 06/11/2018, North West - Liverpool East Research Ethics Committee (Barlow House 3rd Floor 4 Minshull Street Manchester M1 3DZ, UK; Tel: +44 (0)2071048127; Email: nrescommittee.northwest-liverpooleast@nhs.net), REC ref: 18/NW/0648

Study design

Single-centre randomised sham-controlled feasibility study

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Other

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use contact details to request a participant information sheet

Health condition(s) or problem(s) studied
Binge eating disorder

Interventions
Participants will be allocated to either one of the two intervention conditions or the control condition in a randomised order. Randomisation will be performed by the clinical trials unit at the Institute of Psychiatry, Psychology and Neuroscience.

All participants are randomly assigned to one of two blinded intervention groups [ABM + real tDCS], [ABM + sham tDCS] or an (unblinded) inactive wait-list control group. Those in the intervention group will receive six sessions of concurrent ABM and real or sham (placebo) tDCS over three weeks. The study's trained researcher will place the anode over the right dorsolateral prefrontal cortex (dlPFC) and the cathode over the left dlPFC to administer real or sham tDCS. The ABM programme will use an implicit learning paradigm, in which participants are systematically trained to show avoidance behaviour (via a computer joystick) in response to visual cues of high calorie food. ABM and tDCS will be delivered at the same time, i.e. participants will engage in ABM training whilst receiving brain stimulation. Each session will last 20 minutes. Those randomly allocated to the control group will not receive any intervention administered by the research team. They will be offered 6 sessions of (ABM + real tDCS) after they have completed their involvement in the study.

Eating disorder symptoms and other outcomes will be measured in all participants at baseline, post-treatment, and at the 4-week follow-up to assess outcomes of each study group. In particular, the trialists are interested in changes in the frequency of binge eating and craving, and thought processes and emotions related to food and eating. They will also ask participants about their experience of this treatment.

Intervention Type
Mixed

Primary outcome measure
The primary outcome for this proof-of-concept feasibility study is to establish the feasibility of adding concurrent [ABM + tDCS] to treatment as usual in a binge eating disorder patient group

and acquire key information to inform the development of a large-scale randomised sham-controlled trial (RCT). In line with recommendations of Eldridge et al. (2016), the primary outcomes of the proposed feasibility study are to:
1. Establish the feasibility of conducting a large-scale RCT of [ABM and real/sham tDCS] with a wait-list control in patients with BED by assessing recruitment, attendance, and retention rates
2. Determine the feasibility of administering both ABM and tDCS simultaneously
3. Determine the best instruments for measuring outcomes in a full trial by examining the quality, completeness, and variability in the data
4. Estimate the treatment effect sizes and standard deviations for outcome measures to inform the sample size calculation for a large-scale RCT
5. Evaluate whether the treatment is operating as it is designed by analysing process measures, such as within session visual analogue scales
6. Determine whether patients with BED view [ABM and real/sham tDCS] as acceptable and credible
7. Obtain information about patients' willingness to undergo random allocation to ABM paired with real or sham tDCS, and to the wait-list control

Secondary outcome measures
1. Scores in the EDE-Q, specifically indicators of change in the frequency of objective binge eating episodes from baseline, post-assessment and the 4-week follow-up time points
2. Differences between pre [ABM and real/sham tDCS] VAS scores and post [ABM and real/sham tDCS] VAS scores (per each of the 6 treatment sessions and cumulatively over sessions)
3. Changes in scores on the questionnaires and performance in tasks regarding eating disorder and general psychopathology, food, hunger and craving, impulsivity, delayed gratification and inhibitory control, measured at baseline, post-assessment and the 4-week follow-up

Overall study start date
01/01/2018

Completion date
18/03/2020

Eligibility

Key inclusion criteria
1. Male and female community-dwelling adults between 18 and 70 years of age, who are overweight or obese according to WHO criteria (BMI ≥25 kg/m2)
2. Full-syndrome or sub-threshold DSM-5 Binge Eating Disorder (BED) clinical criteria met

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
66

Key exclusion criteria
1. Individuals with a significant/unstable medical or psychiatric disorders needing acute treatment in its own right (e.g., substance dependence), major psychiatric disorders (e.g., psychosis or acute suicidality)
2. Individuals taking antidepressant medication who have not been on a stable dose for at least 2 weeks
3. Individuals with a history of epileptic seizures, stroke, or brain injury, who have any implanted metal devices in the head, frequent or severe headaches or dizziness, or are pregnant or sexually active without using contraception (all contraindications to tDCS use are outlined in Brunoni et al. 2012)
4. Individuals with severe abnormalities in a blood test during the 30 days prior to participation
5. Individuals with allergies to any of the foods presented in the study
6. Individuals who smoke >10 cigarettes per day
7. Individuals who drink >3-4 units (men) or 2-3 units (women) of alcohol per day
8. A tDCS safety questionnaire will also be administered and if considered not safe to deliver tDCS, individuals will subsequently be excluded on this basis

Date of first enrolment
12/03/2019

Date of final enrolment
06/07/2020

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
King's College London, Institute of Psychiatry, Psychology and Neuroscience
Denmark Hill
London
United Kingdom
SE5 8AF

Sponsor information

Organisation
King's College London

Sponsor details
NIHR Biomedical Research Centre
Guy's & St Thomas' NHS Foundation Trust & King's College London
16th Floor, Tower Wing
Guy's Hospital
Great Maze Pond
London
England
United Kingdom
SE1 9RT

Sponsor type
University/education

ROR
https://ror.org/0220mzb33

Funder(s)

Funder type
Government

Funder Name
NIHR Maudsley BRC PhD Fully Funded Studentship for translational research

Results and Publications

Publication and dissemination plan
The protocol is being submitted for publication as a trial protocol paper. It is intended that the results of this feasibility study will be reported and disseminated at national conferences in order to stimulate enthusiasm for centres to participate in any intended future trial. Research findings may also be disseminated through internal newsletters and publications in collaboration with Beat, the UK’s largest eating disorder charity.

Intention to publish date
31/05/2021

Individual participant data (IPD) sharing plan
At the present time, there are no plans to make the data available to ensure utmost security and respect for information collected during this trial on a clinical sample. The data will be held in password secured files on the university server in the IoPPN, King’s College London. This decision may be subject to revision at a later point.

IPD sharing plan summary
Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	22/10/2019	08/12/2020	Yes	No
Results article		01/11/2021	29/03/2022	Yes	No
HRA research summary			28/06/2023	No	No