

Transcranial direct current stimulation (tDCS) in anorexia nervosa and bulimia nervosa

Submission date 05/03/2014	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 29/04/2014	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
Last Edited 06/10/2020	Condition category Mental and Behavioural Disorders	<input type="checkbox"/> Individual participant data

Plain English summary of protocol

Background and study aims

Psychological therapies are often not effective for people with eating disorders such as anorexia nervosa (AN) and bulimia nervosa (BN), so there is a need for new treatments. Research shows that the frontal areas of the brain play an important role in the development and maintenance of these disorders. Stimulating these brain areas to alter their functioning could possibly reduce the symptoms. A technique that is capable of stimulating specific brain areas is called transcranial direct current stimulation (tDCS). This procedure involves the delivery of a low electrical current via small electrodes placed on the scalp, and is widely used in research. This study aims to find out the short-term effects of a single session of tDCS in people who suffer from AN or BN. In particular, we are interested in its effects on thought processes and emotions relating to food, eating, weight and body shape. In the long term, this may help us to develop improved treatments for eating disorders.

Who can participate?

We will be recruiting 36 people with a diagnosis of AN and 36 people with a diagnosis of BN. Participants can be male or female but must be over 18 years old.

What does the study involve?

Participants will come to the lab for three tDCS sessions with a gap of at least 48 hours between each one. Two of these sessions will be real and one will be a placebo (fake) session. On each day participants will complete a series of questionnaires and computer tasks before and after the stimulation session.

What are the possible benefits and risks of participating?

Although there are no direct benefits associated with taking part in this study, the information we get may help us to improve the treatment of eating disorders in the future. There are no known risks involved in taking part in this study, but participants may find the procedure slightly uncomfortable. Most people report feeling a mild tingling sensation during tDCS.

Where is the study run from?

The study will take place at the Institute of Psychiatry, Kings College London, UK.

When is the study starting and how long is it expected to run for?
The testing is expected to begin in April 2014 and continue until we have recruited and tested 72 participants (about 2 years).

Who is funding the study?
The study is being funded by the Institute of Psychiatry, Kings College London, UK.

Who is the main contact?
Ms Maria Kekic
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Study website
<http://www.kcl.ac.uk/iop/depts/pm/research/eatingdisorders/index.aspx>

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title

An experimental sham-controlled crossover study of prefrontal cortex transcranial direct current stimulation (tDCS) in patients with anorexia nervosa and bulimia nervosa

Acronym

TREAT

Study objectives

We aim to establish whether a single session of prefrontal tDCS can temporarily reduce eating disorder symptoms, improve mood, and alter cognitive functioning in patients with anorexia nervosa and bulimia nervosa.

Ethics approval required

Old ethics approval format

Ethics approval(s)

City Road and Hampstead National Research Ethics Service (NRES) committee;10/02/2014; ref: 14/LO/0025

Study design

Single-centre randomised double-blind placebo-controlled crossover study

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Other

Study type(s)

Treatment

Participant information sheet

Anorexia nervosa: <http://www.pdf.investintech.com/preview/1f56ce4c-a44f-11e3-a493-002590d31986/index.html>Bulimia nervosa: <http://www.pdf.investintech.com/preview/c6fa6e54-a451-11e3-a493-002590d31986/index.html>

Health condition(s) or problem(s) studied

Anorexia nervosa and bulimia nervosa

Interventions

This study has three interventions:

1. Anode right/cathode left tDCS (active)
2. Anode left/cathode right tDCS (active)
3. Placebo tDCS

All participants will receive all three interventions (the order of stimulation will be randomised and counterbalanced across participants). A minimum 48-hour interval will be used between sessions to avoid any carryover effects due to stimulation. Each session will be 20 minutes long.

Active tDCS will be delivered using a neuroConn® DC-STIMULATOR device at a constant current of 2 mA (with a 10-second fade in/out) using two 4 cm² surface sponge electrodes soaked in a sterile saline solution (0.9% sodium chloride). The anode and cathode will be placed over the right (F4) and left (F3) dorsolateral prefrontal cortex (DLPFC), respectively, for intervention 1, and vice versa for intervention 2. The sites of interest will be located using the International EEG 10-20 system.

For placebo tDCS, the electrodes will be placed at the same sites as in active tDCS but the stimulation will automatically turn off after 30 seconds. Participants will therefore experience the initial itching sensation but will receive no current for the rest of the 20-minute session.

Intervention Type

Other

Phase

Not Applicable

Primary outcome measure

The visual analogue scale (VAS) scores (0-10) obtained post-tDCS relating to hunger, urge to eat, urge to binge, urge to purge, urge to exercise, urge to restrict, feeling fat, and feeling full.

Secondary outcome measures

1. Post-tDCS VAS scores (0-10) relating to food ratings, stress, anxiety, tension, and mood.
2. Post-tDCS Mizes Eating Disorder Cognitions Questionnaire-Revised (MEDCQ-R) scores
3. Post-tDCS Profile of Mood States (POMS) scores
4. Post-tDCS delay discounting scores
5. Eating disorder symptoms (measured using VAS) at 24-hour follow-up
6. Blinding success
7. Tolerability of the intervention

Overall study start date

01/04/2014

Completion date

30/09/2016

Eligibility

Key inclusion criteria

1. Male or female
2. Aged over 18
3. Current DSM-V diagnosis of either:
 - 3.1. Anorexia nervosa-restricting type
 - 3.2. Anorexia nervosa-binge/purge type
 - 3.3. Eating disorder not otherwise specified-anorexia type
 - 3.4. Bulimia nervosa
 - 3.5. Eating disorder not otherwise specified-bulimia type

Participant type(s)

Patient

Age group

Adult

Lower age limit

18 Years

Sex

Both

Target number of participants

72

Total final enrolment

39

Key exclusion criteria

1. Having a history of head or eye injury
2. Having a history of a neurological disease including previous seizures of any kind
3. Having a history of frequent or severe headaches
4. Having metallic implants in the head
5. Being on a dose of any psychotropic medication that has not been stable for at least 14 days prior to participation in the study
6. Taking antipsychotic medication
7. Taking anticonvulsive medication
8. Being pregnant
9. Smoking more than 15 cigarettes per day
10. Having a current major psychiatric disorder other than the eating disorder (e.g. major depressive disorder, substance use disorder, schizophrenia, or bipolar disorder) needing treatment in its own right
11. Having severe abnormalities in a blood test during the 30 days prior to participation

Date of first enrolment

01/04/2014

Date of final enrolment

30/09/2016

Locations**Countries of recruitment**

England

United Kingdom

Study participating centre**Section of Eating Disorders**

London

United Kingdom

SE5 8AF

Sponsor information

Organisation

King's College London (UK)

Sponsor details

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Sponsor type

University/education

ROR

<https://ror.org/0220mzb33>

Funder(s)

Funder type

University/education

Funder Name

Institute of Psychiatry, Kings College London (UK)

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	25/01/2017	06/10/2020	Yes	No
HRA research summary			28/06/2023	No	No