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A pilot investigation of a single session of stimulation of the left frontal brain area applying a technique that delivers localised magnetic waves through the skull (repetitive transcranial magnetic stimulation [rTMS]) in people with a bulimic eating disorder (e.g. bulimia nervosa and binge-eating disorder) who engage in binge-eating behaviour and its effect on craving, bingeing behaviour and mood and stress

Submission date
26/10/2009

Recruitment status
No longer recruiting

Registration date
04/11/2009

Overall study status
Completed

Last Edited
18/06/2010

Condition category
Mental and Behavioural Disorders

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

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
07/H0807/90

Study information

Scientific Title
A pilot investigation of the effects of repetitive transcranial magnetic stimulation (rTMS) in bulimic disorders: a two-armed double-blind randomised sham (placebo)-controlled trial

Study objectives
Main hypothesis:
Compared to sham repetitive transcranial magnetic stimulation (rTMS), real rTMS applied to the left dorsolateral prefrontal cortex (DLPFC) will lead to greater reduction of cue-elicited food craving in people with a bulimic disorder.

The following subsidiary hypotheses will also be tested:
Compared to sham repetitive transcranial magnetic stimulation (rTMS), real rTMS applied to the left dorsolateral prefrontal cortex (DLPFC) in people with a bulimic disorder will lead to:
1. A greater reduction in bingeing behaviour in the 24 hours post-rTMS
2. A greater improvement in effect
3. A greater decrease in salivary cortisol levels (indicative of reduced stress levels)
4. A greater improvement in executive functioning (e.g. cognitive attentional control)

Ethics approval required
Old ethics approval format

Ethics approval(s)
The Joint South London and Maudsley and The Institute of Psychiatry NHS Research Ethics Committee approved on the 20th February 2008 (ref: 07/H0807/90)

Study design
Two-armed double-blind randomised sham (placebo)-controlled trial

Primary study design
Interventional

Secondary study design

Randomised controlled trial

Study setting(s)
Hospital

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
Bulimic eating disorders

Interventions
rTMS will be delivered with a Magstim Rapid device, with real and sham figure-eight coils (Magstim, Whitland, Wales, UK). Following mapping of the abductor pollicis brevis site in the left motor cortex, each participants motor threshold is established as the minimum stimulus required to induce contraction of the right thumb at least 5 of 10 times. The site for the left DLPFC stimulation is 5 cm anterior to the point of maximal abductor pollicis brevis stimulation. Twenty trains of 5 sec with 55-sec inter-train intervals are administered with a frequency of 10 Hz and intensity of 110% of the individuals motor threshold, providing 1000 pulses over 20 minutes. Sham stimulation is given at the same location and frequency. The randomisation was stratified.

The intervention consisted of a single session (duration 20 minutes) of rTMS. The follow-up in both arms was 24 hours after the rTMS session.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
The food craving score scored as 'urge to eat' on a 10 cm visual analogue scale (VAS) once before and once after real or sham rTMS (0 = no urge to eat at all; 10 extremely strong urge to eat).

Secondary outcome measures
1. The score on a 10 cm 'tension' VAS (0 = extremely calm; 10 = extreme tense) once just before and once just after real or sham rTMS
2. The score on a 10 cm 'mood' (0 = extremely low mood; 10 = extreme high mood) VAS once before and once after real or sham rTMS
3. The score on a 10 cm 'hunger' (0 = not hungry at all; 10 = extreme hungry) VAS once before and once after real or sham rTMS
4. The score on a 10 cm 'urge to binge-eat' (0 = no urge to binge eat; 10 = extreme strong urge to binge eat) VAS once before and once after real or sham rTMS
5. The score on a 10 cm 'urge to purge' (0 = no urge to be sick or purge; 10 extremely strong urge to be sick or purge) VAS once before and once after real or sham rTMS
6. The score on the Food Craving Questionnaire - State once before and once after real or sham

rTMS
7. The number or participants who have a binge in the 24 hours period after real or sham rTMS, measured 24 hours after the real or sham rTMS session
8. The 'interference' score on the Stroop Colour Word Task once before and once after real or sham rTMS (calculated as the difference between time to complete the 'colour word' card and time to complete the 'colour' card)
9. Salivary cortisol levels (Salivette®) at four time points, two before and two after real or sham rTMS
10. Percentage of drop-out in real and sham rTMS, measured at the end of the real or sham rTMS session
11. Percentage of people reporting adverse-events after real of sham rTMS immediately after the real or sham rTMS session and 24 hours after the real or sham rTMS session

Overall study start date
01/06/2008

Completion date
01/05/2009

Eligibility

Key inclusion criteria
1. Outpatients
2. Male and female
3. Aged 18 to 60 years
4. Body mass index (BMI) higher than 17.5 kg/m^2
5. Diagnostic and Statistical Manual of Mental Disorders, 4th Edition (DSM-IV) diagnosis of bulimia nervosa, binge eating disorder or eating disorder not otherwise specified (EDNOS) with a minimum of six binge episodes in the last 28 days (as assessed by the Eating Disorder Examination - Questionnaire [EDE-Q])

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
40 participants

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 metallic implants in the head

4. Being on a dose of any psychotropic medication that has not been stable for at least 14 days prior to participation in the study
5. Being pregnant
6. Smoking more than 10 cigarettes/day
7. Having any substance dependence
8. Participants who vomit on a regular basis (i.e. greater than 7 x a week), will be required to have a blood test to exclude those with electrolytes below the normal range
9. Participants will not have any other major psychiatric disorder needing treatment in its own right
10. Contraindications to rTMS as assessed with the Adult Safety Screen Questionnaire for rTMS
11. Being primarily left-handed

Date of first enrolment
01/06/2008

Date of final enrolment
01/05/2009

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
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Sponsor type
University/education

ROR
https://ror.org/0220mzb33

Funder(s)

Funder type
University/education

Funder Name
Kings College London (UK) - Institute of Psychiatry, Department of Psychological Medicine, Section of Eating Disorders

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	15/04/2010		Yes	No