

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

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|--|---|--|
| Submission date 26/10/2009 | Recruitment status No longer recruiting | <input type="checkbox"/> Prospectively registered |
| Registration date 04/11/2009 | Overall study status Completed | <input type="checkbox"/> Protocol |
| Last Edited 18/06/2010 | Condition category Mental and Behavioural Disorders | <input type="checkbox"/> Statistical analysis plan |
| | | <input checked="" type="checkbox"/> Results |
| | | <input type="checkbox"/> 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

Protocol serial number

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

Study type(s)

Treatment

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(s)

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).

Key secondary outcome(s)

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 of 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 or sham rTMS immediately after the real or sham rTMS session and 24 hours after the real or sham rTMS session

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/m²
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

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Sex

All

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

United Kingdom

England

Study participating centre

Institute of Psychiatry

London

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Sponsor information

Organisation

King's College London (UK)

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

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 |

