

# Clinical effectiveness of repetitive transcranial magnetic stimulation (rTMS) as an adjunctive therapy in depression - a catchment area-based randomised controlled trial

**Submission date**  
07/02/2007

**Recruitment status**  
No longer recruiting

☐ Prospectively registered

☐ Protocol

**Registration date**  
05/03/2007

**Overall study status**  
Completed

☐ Statistical analysis plan

☒ Results

**Last Edited**  
03/05/2011

**Condition category**  
Mental and Behavioural Disorders

☐ Individual participant data

## Plain English summary of protocol

Not provided at time of registration

## Contact information

### Type(s)

Scientific

### Contact name

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### Contact details

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## Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

**Secondary identifying numbers**

N/A

## **Study information**

**Scientific Title****Acronym**

TMSplus Trial

**Study objectives**

TMS can be used as an adjunctive treatment for depression

**Ethics approval required**

Old ethics approval format

**Ethics approval(s)**

Institute of Psychiatry Ethical Committee (Research), ref: 251/00

**Study design**

Parallel group randomised placebo-controlled trial

**Primary study design**

Interventional

**Secondary study design**

Randomised controlled trial

**Study setting(s)**

Not specified

**Study type(s)**

Treatment

**Participant information sheet****Health condition(s) or problem(s) studied**

Major depressive disorder

**Interventions**

Real or sham repetitive transcranial magnetic stimulation (rTMS)

**Intervention Type**

Other

**Phase**

Not Specified

**Primary outcome measure**

Hamilton Rating Scale for Depression (HDRS)

**Secondary outcome measures**

Clinical:

1. Beck Depression Inventory-II (BDI-II)
2. Visual Analogue Mood Scales (VAMS)
3. Brief Psychiatric Rating Scale (BPRS)

Subjective side-effects:

1. Modified Columbia ECT Subjective Side Effects Schedule (CSSES)

Cognition:

1. CAMCOG, digit-span test
2. Digit symbols modalities test
3. Grooved pegboard test

Quality of life:

SF-36 questionnaire

Economic:

Client Service Receipt Inventory (CSRI)

**Overall study start date**

01/03/2002

**Completion date**

31/12/2005

**Eligibility****Key inclusion criteria**

Over 18 years old, right-handed and have a diagnosis of major depressive disorder (DSM-IV)

**Participant type(s)**

Patient

**Age group**

Adult

**Lower age limit**

18 Years

**Sex**

Not Specified

**Target number of participants**

54

**Key exclusion criteria**

1. History of seizures
2. Head injury with loss of consciousness
3. Brain surgery
4. Presence of metallic implants
5. Evidence of dementia or other Axis 1 diagnosis
6. Substance misuse within the previous six months
7. Previous treatment with rTMS
8. Inability to provide informed consent

**Date of first enrolment**

01/03/2002

**Date of final enrolment**

31/12/2005

## **Locations**

**Countries of recruitment**

England

United Kingdom

**Study participating centre**

**Section of Old Age Psychiatry PO70**

London

United Kingdom

SE5 8AF

## **Sponsor information**

**Organisation**

South London and Maudsley NHS Trust (UK)

**Sponsor details**

Denmark Hill

London

SE5 8AZ

London

England

United Kingdom

SE5 8AZ

**Sponsor type**

Hospital/treatment centre

**Website**

<http://www.slam.nhs.uk/>

**ROR**

<https://ror.org/015803449>

## Funder(s)

**Funder type**

Charity

**Funder Name**

Guy's & St Thomas' Charitable Foundation (R001126) (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?
<a href="#">Results article</a>	results	01/03/2008		Yes	No