

# Impact of magnetic stimulation on depression and brain health

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<b>Registration date</b> 10/03/2025	<b>Overall study status</b> Completed	<input type="checkbox"/> Protocol
<b>Last Edited</b> 10/03/2025	<b>Condition category</b> Mental and Behavioural Disorders	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> Record updated in last year

## Plain English summary of protocol

### Background and study aims

Major depressive disorder (MDD) is a severe psychiatric condition affecting millions of people worldwide. Some individuals with MDD do not respond adequately to standard antidepressant treatments, a condition known as treatment-resistant depression (TRD). One promising alternative treatment is repetitive transcranial magnetic stimulation (rTMS), a non-invasive brain stimulation technique. This study aims to assess the impact of rTMS on depressive symptoms, cognitive functions, and blood levels of a protein called brain-derived neurotrophic factor (BDNF), which is involved in brain plasticity, the brain's ability to change its structure and function.

### Who can participate?

Adult patients diagnosed with TRD who are aged between 18 and 70 years old

### What does the study involve?

Participants are divided into two groups:

rTMS group (13 patients): Receives 20 sessions of rTMS over 4 weeks.

Control group (12 patients): Continue their regular treatment without rTMS.

Both groups undergo clinical and cognitive assessments before and after the treatment period. The researchers will measure depressive symptoms, cognitive functions (e.g., memory, verbal fluency), and blood BDNF levels at two time points.

### What are the possible benefits and risks of participating?

Potential benefits: Participants in the rTMS group may experience improvements in mood and cognitive function, contributing to a better quality of life.

Possible risks: rTMS is generally safe but can cause mild side effects such as headaches, scalp discomfort, or temporary fatigue.

### Where is the study run from?

The University of Cagliari and Studio Corona, within a specialized outpatient psychiatric clinic.

### When is the study starting and how long is it expected to run for?

March 2018 to December 2024

Who is funding the study?

Section of Psychiatry, Department of Medical Sciences and Public Health, University of Cagliari  
(internal funding)

Who is the main contact?

Prof. Mirko Manchia, mirko.manchia@unica.it

## Contact information

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Public, Scientific

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## Additional identifiers

### Clinical Trials Information System (CTIS)

Nil known

### Protocol serial number

Nil known

## Study information

**Scientific Title**

Impact of repetitive transcranial magnetic stimulation on clinical and cognitive outcomes, and brain-derived neurotrophic factor (BDNF) levels in treatment-resistant depression

**Acronym**

rTMS-TRD

**Study objectives**

Our main hypothesis is that rTMS reduces depressive symptoms, improves cognitive performance, and raises BDNF levels, in our sample of treatment-resistant depression patients.

**Ethics approval required**

Ethics approval required

**Ethics approval(s)**

approved 28/03/2018, Comitato Etico Indipendente (Independent Ethical Committee) (Azienda Ospedaliero Universitaria - P.O. San Giovanni di Dio - via Ospedale 54, Cagliari, 09124, Italy; +39 0706092547; sperimentazioni.cliniche@aoucagliari.it), ref: NP/2018/1647

**Study design**

Single-center observational within-subject study

**Primary study design**

Observational

**Study type(s)**

Treatment, Efficacy

**Health condition(s) or problem(s) studied**

Treatment-resistant depression

**Interventions**

This is a single-center, observational, within-subject study designed to evaluate the effects of repetitive transcranial magnetic stimulation (rTMS) on treatment-resistant depression (TRD). The study includes 25 patients diagnosed with TRD, all undergoing a total of 20 rTMS sessions over four weeks. Clinical, cognitive, and biological assessments are conducted at baseline (T0) and post-treatment (T1) to measure changes in depressive symptoms (HAM-D, CGI), cognitive function (MMSE, Digit Span, Verbal Fluency), and BDNF blood levels.

**Intervention Type**

Procedure/Surgery

**Primary outcome(s)**

Depressive symptoms measured using the Hamilton Depression Rating Scale (HAM-D) at baseline and 4 weeks

**Key secondary outcome(s)**

The following secondary outcome measures are assessed at baseline and 4 weeks:

1. Serum BDNF levels measured using a Human-BDNF ELISA kit
2. Cognitive performance measured using a series of cognitive tests: Mini-Mental State Examination (MMSE), Trail-Making Test (TMT), Digit Span Test (DST), and Verbal Fluency Test

**Completion date**

31/12/2024

## Eligibility

**Key inclusion criteria**

1. Aged 18-70 years
2. DSM-5 MDD diagnosis with treatment resistance (TRD) ( $\geq 2$  failed antidepressants)
3. Available for full rTMS treatment and assessments
4. Signed informed consent

**Participant type(s)**

Patient

**Healthy volunteers allowed**

No

**Age group**

Mixed

**Lower age limit**

18 years

**Upper age limit**

70 years

**Sex**

All

**Total final enrolment**

25

**Key exclusion criteria**

1. Psychiatric comorbidities (bipolar, schizophrenia, active substance use disorder)
2. Neurological conditions (epilepsy, stroke, TBI, neurodegenerative diseases)
3. Metal implants (pacemaker, neurostimulator, cochlear implants)
4. Severe cognitive impairment (low MMSE score)
5. Pregnancy/lactation
6. Recent medication changes (<4 weeks)
7. Participation in another clinical trial

**Date of first enrolment**

28/03/2018

**Date of final enrolment**

30/06/2018

## Locations

**Countries of recruitment**

Italy

**Study participating centre****Studio Corona**

Via Tolmino, 25

Cagliari

Italy

09122

## Sponsor information

**Organisation**

Azienda Ospedaliero-Universitaria Cagliari

**ROR**

<https://ror.org/034qxt397>

## Funder(s)

**Funder type**

University/education

**Funder Name**

University of Cagliari

**Alternative Name(s)**

Università degli Studi di Cagliari, Università di Cagliari, UNICA

**Funding Body Type**

Government organisation

**Funding Body Subtype**

Universities (academic only)

**Location**

Italy

# Results and Publications

## Individual participant data (IPD) sharing plan

The dataset generated will be published as a supplement to the results publication.

## IPD sharing plan summary

Published as a supplement to the results publication