ISRCTN30067246 https://doi.org/10.1186/ISRCTN30067246

How to tell who will benefit from magnetic stimulation for depression

Submission date	Recruitment status	[X] Prospectively registered
16/09/2025	Not yet recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
18/09/2025	Ongoing	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
17/09/2025	Mental and Behavioural Disorders	[X] Record updated in last year

Plain English summary of protocol

Background and study aims

Depression symptoms can be complex and vary greatly from person to person. If you're depressed, you may feel sad, hopeless, and lose interest in activities you once enjoyed. Transcranial magnetic stimulation (TMS) is a noninvasive procedure that uses magnetic fields to stimulate nerve cells in the brain, helping to improve depression symptoms. TMS is typically recommended when medications have not been effective. This study aims to determine whether combining brain imaging data with clinical information can predict who will benefit most from TMS treatment. A secondary goal is to investigate whether the orientation of the magnetic coil affects the treatment's effectiveness.

Who can participate?

Patients aged 18 to 67 years referred to the Helsinki University Central Hospital for TMS for major depressive disorder (MDD).

What does the study involve?

The study includes several steps:

-A clinical interview conducted by phone or face-to-face (about 30 minutes).

-Completing digital questionnaires up to five times during the study to monitor symptoms, personality, anxiety, and functioning.

-Providing a blood sample for genetic and biological analysis, or a saliva sample that you can collect at home and mail.

-Brain imaging using Magnetoencephalography (MEG) and Magnetic Resonance Imaging (MRI), both before and after treatment. MEG measures brain activity via magnetic fields, and MRI provides detailed anatomical images. Each imaging session takes about 1 to 2 hours.

-Receiving transcranial direct current stimulation (tDCS) treatment before TMS, if you choose to.

-36 sessions of TMS treatment.

What are the possible benefits and risks of participating?

Possible benefits of the study include better outcomes from TMS treatment, as participants receive more sessions than typically offered in Finnish public health care (36 instead of 20). The risks are similar to those of standard TMS treatment and may include uncomfortable sensations at the stimulation site.

Where is the study run from?
Helsinki University Central Hospital Department of Psychiatry (Finland)

When is the study starting and how long is it expected to run for?
January 2025 to December 2028

Who is funding the study?
Business Finland

Who is the main contact?
Dr Tuukka Raij, tuukka.raij@hus.fi

Contact information

Type(s)
Public, Scientific, Principal Investigator

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
9137

Study information

Scientific Title
Models of treatment response prediction in depression based on brain structure and function

Study objectives
A model combining clinical and brain data can predict who will benefit from TMS treatment. Positioning the coil perpendicular to the main local gyrus in the dorsolateral prefrontal cortex leads to better outcomes.

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 08/07/2025, HUS regional medical research ethics committee (HUS Keskuskirjaamo, Helsinki, PO Box 200, Finland; +358 (0)403594618; eettiset.toimikunnat@hus.fi), ref: HUS/6633/2025

Study design
Longitudinal predictor study including an Interventional double-blind randomized controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Home, Hospital, Internet/virtual, Laboratory, Telephone

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Major depressive disorder

Interventions
Participants enrolled in this study will be involved for a total duration of approximately 24 to 36 weeks, depending on whether they receive both the transcranial direct current stimulation (tDCS) and repetitive transcranial magnetic stimulation (rTMS) interventions.

Enrollment and Consent:
Participants provide electronic informed consent via the REDCap system, a secure, web-based tool for data collection.

Baseline Assessments:
A clinical interview is conducted by a trained nurse or psychologist via telephone or face-to-face to confirm eligibility and assess depression symptoms using the MINI International Neuropsychiatric Interview (MINI 6.0, Finnish version) and Montgomery–Åsberg Depression Rating Scale (MADRS). Participants complete baseline digital symptom questionnaires assessing depression, anxiety, personality, and other relevant factors.

Biological Sampling:
Participants provide either a blood sample at HUSLAB Tullinpuomi laboratory or a saliva sample collected at home via a mailed kit for genetic and biological analyses.

Brain Imaging:
Magnetoencephalography (MEG) and magnetic resonance imaging (MRI) scans are performed twice—once before any intervention and once after—to assess brain function and structure.

Randomisation:
Participants who have consented to receive tDCS undergo 12 weeks of home-based tDCS treatment. Those who do not remit after tDCS, as well as participants who opt out of tDCS, are randomized in a 1:1 ratio to receive rTMS with two different orientations of the magnetic field (orthogonal or parallel to cortical gyri). Randomisation is performed using block randomisation via a computer program to minimize bias from temporal recruitment variations.

Treatments:
tDCS: Participants self-administer daily (up to 5 days/week for the first 6 weeks, then 3 days /week for the following 6 weeks) 30-minute tDCS sessions at home using a CE-marked Sooma device delivering 2 mA direct current over the dorsolateral prefrontal cortex (DLPFC). Treatment adherence and guidance are supported via a mobile application.

rTMS: Administered by a trained nurse at the HUS neuromodulation unit 3–5 times per week over 12 weeks (total 36 sessions). Treatment involves 3.5-minute intermittent theta burst stimulation (iTBS) targeting the left DLPFC.

Follow-Up and Assessments:
Symptom questionnaires are completed digitally up to five times throughout the study: at baseline and end-points of each intervention phase, and at 12 weeks post-rTMS to monitor treatment effects and symptom changes.

Intervention Type
Device

Pharmaceutical study type(s)
Not Applicable

Phase
Phase IV

Drug/device/biological/vaccine name(s)
Transcranial magnetic stimulation

Primary outcome measure
Severity of depression measured using the self-evaluated Patient health questionnaire (PHQ-9) before and within 2 weeks after treatment

Secondary outcome measures
1. Remission defined as PHQ-9 < 5 within 2 weeks after treatment
2. Response defined as PHQ-9 within 2 weeks after treatment >50 % less than MADRS before

treatment
3. Severity of depression measured using the Montgomery Åsberg Depression Rating Scale (MADRS) rated before and within 2 weeks after treatment

Overall study start date
01/01/2025

Completion date
31/12/2028

Eligibility

Key inclusion criteria
1. Age 18–67 years
2. PHQ-9 score > 10 before treatment
3. Signed informed consent

Participant type(s)
Patient

Age group
Mixed

Lower age limit
18 Years

Upper age limit
67 Years

Sex
Both

Target number of participants
100

Key exclusion criteria
1. Safety risks, such as a concrete and imminent suicide plan, pregnancy or breastfeeding, magnetic metal parts in the upper body, or a significant risk of seizures.
2. Severe neurological conditions such as epilepsy or brain injury, as well as psychotic disorders
3. Impaired decision-making capacity
4. Those serving a prison sentence and those involved in forensic psychiatric proceedings

Date of first enrolment
06/10/2025

Date of final enrolment
31/12/2027

Locations

Countries of recruitment
Finland

Study participating centre
Helsinki University Central Hospital Department of Psychiatry
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Sponsor information

Organisation
Hospital District of Helsinki and Uusimaa

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Sponsor type
Hospital/treatment centre

Website
https://www.helsinki.fi/fi/laaketieteellinen-tiedekunta/tutkimus/tieteenalat/psykiatrian-osasto

ROR
https://ror.org/020cpqb94

Funder(s)

Funder type
Government

Funder Name
Business Finland

Alternative Name(s)

Funding Body Type
Government organisation

Funding Body Subtype
Local government

Location
Finland

Results and Publications

Publication and dissemination plan
Planned publication in a peer-reviewed journal

Intention to publish date
10/12/2028

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are not expected to be made available due to the need to protect privacy of the participants.

IPD sharing plan summary
Not expected to be made available