Differences between EMG-MT, OM-MT, and NCG as methods to establish the cortical threshold in TMS.

Published: 19-05-2025
Last updated: 28-05-2025

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Ethical review	Approved WMO
Status	Pending
Health condition type	Mood disorders and disturbances NEC
Study type	Observational non invasive

Summary

ID

NL-OMON57548

Source
ToetsingOnline

Brief title
Differences between EMG-MT, OM-MT, and NCG

Condition

- Mood disorders and disturbances NEC

Synonym
depression, MDD mood disorders

Research involving
Human

Sponsors and support

Primary sponsor: Universiteit van Tilburg
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Cortical threshold, EMG-MT, NCG, OM-MT

Outcome measures

Primary outcome

The main endpoint of the study is the difference between the three different

methods in the established cortical threshold within each subject .

Secondary outcome

The secondary endpoint will be the amount of pain perceived within the

FDA-approved protocol for MDD based on either 120% machine output based upon

the EMG-MT or OM-MT.

Study description

Background summary

Transcranial Magnetic Stimulation (TMS) is an effective treatment in depression, especially in stubborn or treatment resistant depression. Since its discovery in 1985 by Anthony Barker (Barker et al., 1985), TMS was first used as a treatment for depression by Mark George in 1995 and it has been an FDA-approved treatment since 2008 (George, 2010). One critical step in the FDA-approved protocols is determining the resting Motor Threshold (MT) of the individual patient, allowing the clinician to estimate the minimal therapeutically effective stimulation strength. Today, three different methods can be used to establish the MT, each of which can produce a different MT estimates within the same patient. The three methods are as follows: measuring the electromyogram (EMG) of the abductor pollicis muscle in the thumb when applying TMS to the motor cortex responsible for thumb movement (EMG-MT), observing a muscle twitch in the hand when stimulating the same area (OM-MT) (Westin et al., 2014), or measuring whether there is a heart rate deceleration after stimulating the dorsolateral prefrontal cortex (DLPFC)(Dijkstra et al., 2023).

Study objective

The study will consist of two components. In the first component, OM-MT and

EMG-MT will be observed within subjects, with counterbalancing applied to prevent order effects. Pain will be measured by applying a small portion of the FDA-approved 10Hz TMS protocol at 120% of the machine output for both OM-MT and EMG-MT levels. The perceived pain will then be measured afterward.

In the second component, heart rate deceleration will be used to estimate the frontal threshold, relative to the OM-MT for each participant.

Study design

A repeated-measures experimental design will be applied, comparing three different methods of establishing the cortical threshold within each subject. The order in which these methods are applied will be partly counterbalanced across subjects. For the secondary objective a the amount of pain or discomfort during therapeutic stimulation will be compared within one subject between two conditions (either based upon the OM-MT or EMG-MT).

Study burden and risks

No immediate benefits are to be expected from participation in this study for the subjects. The total burden of this study will be 90 minutes of time of each subject for the whole experiment. TMS is considered to be a safe treatment option with few side effects. The most common side effect is local pain during stimulation, sometimes followed by headache. TMS is considered a safe and effective method if safety guidelines and recommendations for applying TMS to humans are followed (Rossi et al., 2021). If a subject is uncomfortable with any aspect of the procedure and wants to stop, the session will be terminated immediately.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)

Inclusion criteria

Healthy volunteers between 18-55 years old

Exclusion criteria

Exclusion Criteria for Receiving TMS

Participants will be excluded from the study if they meet any of the following criteria:

1. Neurological and Psychiatric Conditions:

History of epilepsy or seizure disorders,

Previous significant head trauma or traumatic brain injury with loss of consciousness >5 minutes.

Presence of a known neurological disorder (e.g., stroke, multiple sclerosis, Parkinson*s disease, brain tumors).

Current or past diagnosis of a severe psychiatric disorder (e.g., schizophrenia, bipolar disorder, psychotic disorder).

Current severe depression (e.g., suicidal ideation, recent hospitalization due to psychiatric reasons).

History of substance use disorder within the past six months.

2. Medical Conditions and Contraindications:

Presence of implanted metal objects or devices in or near the head (e.g., cochlear implants, deep brain stimulators, aneurysm clips, electrodes, metallic fragments).

Pacemaker, defibrillator, or any other implanted electrical medical device.

History of cardiac arrhythmias or other significant cardiovascular conditions.

Uncontrolled hypertension.

History of syncope or unexplained fainting episodes.

3. Medications and Substance Use:

Use of medications known to lower seizure threshold (see list below).

Recent use of recreational drugs or alcohol dependence.

4. Pregnancy and Hormonal Considerations:

Current pregnancy

Hormonal conditions that could influence cortical excitability (e.g., active hormone replacement therapy).

5. Other Exclusion Factors:

Age below 18 or above 55

History of hypersensitivity or significant discomfort with previous TMS exposure.

Participation in another clinical trial that may interfere with the results.

Inability to provide informed consent or understand study procedures.

Significant scalp abnormalities, infections, or skin conditions that could interfere with coil placement.

History of migraine with aura (depending on severity and frequency).

List of medication which exclude from this study:

1. Antipsychotics: • Clozapine • Chlorpromazine • Olanzapine • Haloperidol 2. Antidepressants: • Tricyclic antidepressants (TCAs): o Amitriptyline o Imipramine • Selective serotonin reuptake inhibitors (SSRIs): o Fluoxetine o Paroxetine • Bupropion

3. Mood Stabilizers: • Lithium

4. Stimulants: • Amphetamines (e.g., Adderall, Dexedrine) • Methylphenidate (e.g., Ritalin, Concerta)

5. Anesthetics and Analgesics: • Tramadol • Meperidine (Demerol)

6. Antibiotics: • Imipenem-cilastatin • Ciprofloxacin • Penicillins

7. Antihistamines: • Promethazine

8. Anti-malarial Drugs: • Chloroquine • Mefloquine

9. Theophylline: • Used for asthma and chronic obstructive pulmonary disease (COPD).

10. Illicit Substances: • Cocaine • Amphetamines • MDMA (Ecstasy)

Study design

Design

Study type: Observational non invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	02-06-2025
Enrollment:	38
Type:	Anticipated

Ethics review

Approved WMO Date:	19-05-2025
Application type:	First submission
Review commission:	METC Brabant (Tilburg)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
CCMO	NL88500.028.24