Repetitive Transcranial Magnetic Stimulation (rTMS) versus sham rTMS in Body Dysmorphic Disorder

Published: 18-05-2022
Last updated: 06-04-2024

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Ethical review	Approved WMO
Status	Recruiting
Health condition type	Psychiatric disorders NEC
Study type	Interventional

Summary

ID

NL-OMON51678

Source
ToetsingOnline

Brief title
rTMS-BDD

Condition

- Psychiatric disorders NEC

Synonym
Body Dysmorphic Disorder

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: BDD, rTMS, sham, treatment

Outcome measures

Primary outcome

More than 30% decrease (defined as response) in BDD-YBOCS questionnaires from baseline till end, and clinical improvement.

Secondary outcome

Furthermore a decrease in BABS, CGI, Sheehan, HDRS and HAS questionnaires are desirable.

Study description

Background summary

Repetitive Transcranial Magnetic Stimulation (rTMS) is a non-invasive neuromodulating therapy, in which magnetic pulses given to cortical regions lead to changes in brain circuits involved in psychiatric disorders. rTMS is an emerging, evidence based and safe treatment option for major depressive disorder (MDD). Response rates for depression are estimated between 28 to 83%, depending on the protocol, cortical location, refractoriness or combined therapy. Furthermore there is current evidence that rTMS is an effective intervention in obsessive-compulsive disorder. It may be also a potential treatment option for other conditions, such as schizophrenia and substance abuse disorders.

A recent case series, by our research group, showed that when combining rTMS with medication and cognitive behavioral therapy (CBT), this has an additive effect on reducing depressive and more important, also body dysmorphic symptoms. The hypothesis behind this catalytic effect is that depressive networks can be coupled, after which rTMS induced neuroplasticity and its antidepressant effects may spread over networks throughout the brain during stimulation.

In individuals with body dysmorphic disorder (BDD) there is a preoccupation with non-existent or minor imperfections in their appearance. Even when there is a presence of visible blemishes, BDD could still be diagnosed. Obsessive

thoughts, repetitive compulsions, regularly checking or seeking for reassurance, could completely control the life of these individuals. This mental disorder is frequently associated with disturbing psychosocial impairment, depressive and anxiety comorbidity and even suicidality. Current evidence-based treatment options are psychotherapy (cognitive based therapy (CBT)) or antidepressant medication as SSRI*s. In 60-70% treatment is effective. Nevertheless there are opportunities for improvement in BDD treatment and neuromodulation is very scarce. We therefore propose a cross-over study design in BDD patients focusing on the clinical effect of rTMS.

Study objective

The main objective of this study is to investigate whether rTMS treatment will improve clinical outcomes in body dysmorphic disorder, by reducing BDD YBOCS outcomes. Furthermore to improve localization and rTMS treatment in the dorsolateral prefrontal cortex (dlPFC). Our secondary objectives will be to answer the questions what the effect of real rTMS treatment compared to sham rTMS treatment regarding psychological state (depression, anxiety) is. What the effect of rTMS treatment compared to sham rTMS treatment on preparation for cognitive behavioral therapy is and what the effect is of rTMS in the neurobiological mechanisms involved in BDD.

Study design

It will be a randomized controlled trial, with one group receiving rTMS treatment, and the other group sham rTMS, to see whether rTMS will improve their clinical and treatment outcome. They will be stimulated over the left dorsolateral prefrontal cortex (left-dlPFC). Individuals receiving real rTMS treatment will probably benefit.

Intervention

The study consist of two groups, one rTMS and one sham rTMS. Both will be treated with a high frequency 10 Hz rTMS (HF-rTMS) protocol on the left dorsolateral prefrontal cortex (dlPFC). rTMS treatment will be given for 15 times, once a day, 5 days/week, for 3 weeks. We will use several questionnaires, BDD-YBOCS, BABS, Sheehan, CGI, HDRS and HAS, every 5th rTMS session or sham rTMS session.

Study burden and risks

The risk and burden associated with participation can be considered minimal. In the clinical trial there will be 15 rTMS stimulation sessions on subsequent workdays. One session includes 5 minutes of preparation, 20-30 minutes of stimulation, with a total of 30-35 minutes per session. Psychometrics will be taken every 5th session, with a total of 30 minutes for all questionnaires. The

first baseline session will be (maximum) 1:30h, due to measurements and technical procedures, psychometrics, ECG and vitals. Furthermore, in all patients structured diagnostic interviews will be administered before start.

Minimal risk is associated with participation in this study. The risks associated with the stimulation are very low, as rTMS was shown non-invasive, safe and tolerable in large trials. All side-effects are mild and of short duration. The most common side-effects are neckpain/discomfort (±40%), local discomfort of the scalp (±39%), tension headaches during and after stimulation (±28%) and dizziness. The pain and discomfort mainly occur during the first sessions, and become less as the number of treatments progresses. The most severe - but extremely rare - side-effect is a seizure. The prevalence is 7:100.000 sessions.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)

Inclusion criteria

1. Age 18 to 65 years old;
2. Diagnosed with Body Dysmorphic Disorder (BDD), based on Body Dysmorphic Disorder - Yale Brown Obsessive Compulsive Scale (BDD-YBOCS);
3. Nonresponse (defined as <50% response on symptoms measured by the BDD-YBOCS) after one type of medication treatment, SSRI, maximum dose and adequate duration;
4. Medication is set 6 weeks prior to the start, and could not be changed during the study

Exclusion criteria

Exclusion criteria
1. Intracerebral metal implants (e.g. cochlear implant, brain stimulator);
2. (History of) epilepsy or epilepsy in a first degree relative;
3. Any other neurological disorder with seizure risk;
4. Acute suicidal ideations, or any psychological crisis (contact with the outpatient crisis service or admission in psychiatric hospital);
5. Bipolar disorder;
6. Current disorder in substance abuse (opiate, ketamine, LSD, (meth)amphetamine, cocaine, solvents, cannabis, benzodiazepines or barbiturate) or alcohol abuse;
7. Any known other serious somatic health problem;
8. Pregnancy;
9. Primarily autism spectrum disorder or primarily personality disorder (using SCID-5-P at baseline for personality disorders). Given that this is often seen secondarily in BDD patients.

rTMS Contraindications:
1. History of epileptic seizures or epilepsy in a first degree relative, irregular sleep/ wake rhythm;
2. Cardiac demand pacemakers;
3. Implanted defibrillators;
4. Implanted neurostimulators;
5. Cochlear implants.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)
Control:	Placebo
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	05-09-2022
Enrollment:	56
Type:	Actual

Medical products/devices used

Generic name:	repetitive transcranial magnetic stimulation
Registration:	Yes - CE intended use

Ethics review

Approved WMO

Date:	18-05-2022
Application type:	First submission
Review commission:	METC Amsterdam UMC

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	NL79989.018.22