Advancing addiction treatment using neuromodulation: a rTMS enhanced CBT trial

Published: 12-06-2015
Last updated: 16-04-2024

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON47612

Source
ToetsingOnline

Brief title
Advancing addiction treatment

Condition

- Other condition
- Personality disorders and disturbances in behaviour

Synonym
alcohol addiction, Alcohol dependence

Health condition

alcoholverslaving

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum
Source(s) of monetary or material Support: ZonMW van NWO (VIDI beurs)

Intervention

Keyword: alcohol addiction, fMRI, rTMS, treatment

Outcome measures

Primary outcome

- In the clinical trial the main study parameter is self-reported level of craving as measured by the alcohol urge questionnaire (AUQ).

- In the neurobiological trial the main study parameters are baseline brain activity patterns during fMRI session in comparison to brain activity patterns after ten rTMS sessions (within subject comparison). These differences in brain activity patterns will also be assessed between the sham rTMS stimulation group and the real rTMS stimulation group.

Secondary outcome

- In the clinical trial the secondary study parameters are relapse into alcohol dependence, changes in measures of impulsivity and compulsivity and changes in obsessive and compulsive behaviour. Furthermore changes in neuropsychological reporting will be used as study parameters.

- In the neurobiological trial the secondary study parameters are correlations of brain activity patterns with behavioural and neuropsychological measurements.

Study description

Background summary

Traditional treatments for addictive disorders (psychotherapy, medication) are moderately effective at best and very few novel therapies or compounds are in the pipeline. However, recent studies on neuromodulation have shown promising results with a single-administration of high-frequency repetitive Transcranial Magnetic Stimulation (rTMS) resulting in improved prefrontal functioning and reduced craving [effect size for active stimulation versus sham stimulation d=.48; as reviewed in a meta-analysis by our group (Jansen, Daams, Koeter, Veltman, & Goudriaan, 2013)]. Unfortunately, clinical neuromodulation trials using a series of neuromodulation sessions are very scarce. We therefore propose a RCT in alcohol dependent patients focusing on the working mechanism of rTMS and the add-on clinical effect of rTMS, combined with cognitive behavioural therapy.

Study objective

The main objective of this study is to investigate whether rTMS add-on treatment will improve clinical outcomes in alcohol dependence. The secondary objective will be to answer the question through which mechanism rTMS will improve treatment outcome in alcohol dependent patients.

Study design

Behavioural outcome measures will be used to test whether rTMS add-on treatment combined with cognitive behavioural therapy, improves clinical outcomes of alcohol dependent individuals. Furthermore a subgroup of the participants will undergo a MR scanning protocol in order to investigate the neurobiological mechanism by which rTMS functions.

Intervention

One group will receive rTMS treatment, and the other group will receive sham rTMS treatment.

Study burden and risks

The risk and burden associated with participation can be considered minimal. In the clinical trial there will be 10 rTMS stimulation sessions on subsequent workdays, and filling in of several craving questionnaires at multiple time points. In the neurobiological trial there will be two additional scanning sessions of approximately 1 hour. Furthermore, in both groups structured diagnostic interviews for psychiatric disorders and personality questionnaires

will be administered. Minimal risk is associated with participation in this study.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

The recruitment of participants will take place as follows. Practitioners at Jellinek will inform patients about our study and we will give presentations at Jellinek to inform patients about this study. If somebody is willing to participate in the study, we will personally visit them at Jellinek and explain the entire procedure. Furthermore they will receive an information letter by email to make sure they can read the information again carefully. If they are still interested in participation they will sign informed consent and we will perform screening for inclusion and exclusion criteria. Demographics,

psychiatric disorders (MINI), TMS contraindications and MR contraindications are questioned to make sure that the individual can participate.
If a participant meets any of the exclusion criteria that they are excluded from participation in this study. , Inclusion criteria
- Men and women.
- Age between 25-65.
- Recent DSM-V diagnosis (mild, moderate and severe) of alcohol abuse (<4 months after detox).
- Currently in treatment (>3 weeks after detox) and will be in treatment during the entire stimulation period (2 weeks after inclusion).
- Sufficient speaking and understanding of Dutch language.

Exclusion criteria

Exclusion criteria
- A DSM-V diagnosis of schizophrenia or another psychotic disorder, personality disorder or sleep disorder.
- TMS contraindications: history of epileptic seizures or epilepsy in a first degree relative, irregular sleep/ wake rhythm.
- MR contraindications (only relevant for the 40 participants who will undergo MR scanning): metal implants, claustrophobia.

Study design

Design

Study phase:	4
Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)
Control:	Placebo
Primary purpose:	Basic science

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	09-02-2016

Enrollment:	80
Type:	Actual

Medical products/devices used

Generic name:	Transcranial Magnetic Stimulation
Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	12-06-2015
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	NL52774.018.15