Probing neuroprotective effects of single session rTMS on subsequent mood and emotional processing

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To examine the protective effects of a single session of high frequency rTMS over the left dorsolateral prefrontal cortex on negative mood and motivated attention.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Mood disorders and disturbances NEC
Study type	Interventional

Summary

ID

NL-OMON40849

Source
ToetsingOnline

Brief title
rTMS effects on mood-induced biases

Condition

- Mood disorders and disturbances NEC

Synonym
Depression, Major depressive disorder

Research involving
Human

Sponsors and support

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

Intervention

Keyword: depression vulnerability, mood induction, rTMS

Outcome measures

Primary outcome

To investigate the effect of rTMS and sham rTMS on mood as measured with changes in visual analogue scales and PANAS before and after negative mood induction.

Secondary outcome

To investigate the effect of rTMS and sham rTMS on motivated attention for sad and facial expressions after sad mood induction.

Study description

Background summary

In spite of a wide variety of treatment options, the prognosis of major depression is still poor: chronicity affects at least a third of patients and relapses are common. Optimisation of existing treatment strategies are urgently needed.Repetitive transcranial magnetic stimulation (rTMS) of the dorsolateral prefrontal cortex (DLPFC) has been introduced more than a decade ago as an antidepressive treatment option, but its acute effects on mood and cognitive functioning remain unclear. Furthermore, it remains unknown whether rTMS can have neuroprotective effects that prevents relapse during remission.By inducing an electric current in the TMS coil, a magnetic field is created leading to the induction of a secondary electric current in the stimulated brain area (for an extended description see, Schutter, 2011)
. Depending on the frequency by which a magnetic pulse is emitted, a stimulation or inhibition on a neuronal level is induced (Siebner & Rothwell, 2003), which effects can last longer than the stimulation itself, if applied over an extended period of time (Hallett, 2007). In this way, high frequency (10Hz or faster) stimulation lasting several minutes can enhance the excitability of the stimulated area for a prolonged period of time (Fitzgerald et al., 2006; Schutter, 2009) therefore likely to change not only mood but also attentional biases that are thought to play a causal role in onset and maintenance of depression. While clinical research is ongoing, testing more

standardized forms of rTMS treatment in a randomized controlled trial set-up, more fundamental knowledge is also needed to investigate the potential neuroprotective effects of rTMS. May it be useful in the future to weaken the effects of external factors by influencing mood resilience in subjects.

Study objective

To examine the protective effects of a single session of high frequency rTMS over the left dorsolateral prefrontal cortex on negative mood and motivated attention.

Study design

In the present sham-controlled crossover study a single session of active and sham high frequency rTMS will be applied to the left dorsolateral prefrontal cortex in healthy volunteers. A validated sad mood induction procedure will be applied after rTMS to measure its mood protective effects. Furthermore, the effects on motivated attention and resting state electric brain activity (EEG) will be assessed.

Intervention

All 24 participants will experience the rTMS treatment. Once real rTMS and once sham-rTMS, both will take 30 minutes. The two intervention sessions will be separated by at least 1 week with a maximum of four weeks.

Study burden and risks

All measurements will be administered during two visits of 2 hrs at our outpatient depression unit. The actual rTMS treatment will take about 30 minutes. Except for financial compensation or course credit points, possible benefit resulting from the treatment cannot be guaranteed to participants. Transcranial magnetic stimulation (TMS) is a widely used non-invasive brain stimulation technique, based on the principle of electromagnetic induction. During stimulation the participant will likely hear the clicks of the TMS pulses and experience stimulation of nerves and muscles of the head. The most common side effect is a light transient headache (2-4% occurrence). A severe headache is uncommon (0.3-0.5% occurrence). In the current study healthy participants will be stimulated with a protocol that falls within the safety guidelines. All participants are screened for their relevant medical history and other TMS safety aspects (e.g. presence of metal parts in the head). There are no risk factors related to the computerized attention training. There is no direct benefit for the participants. The study will broaden our understanding of how rTMS influences mood and cognition that may have clinical implications.

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

24 healthy, right-handed women using oral contraceptives and men (aged 18-35) with normal or corrected-to-normal vision

Exclusion criteria

* Epilepsy, convulsion or seizure (TMS)
* Serious head trauma or brain surgery
* Large or ferromagnetic metal parts in the head (except for a dental wire)
* Implanted cardiac pacemaker or neurostimulator
* Pregnancy
* History or current presence of any neurologic or psychiatric disease

* Any prescribed medication that can alter cortical excitability (e.g. antiepileptics, tricyclic anti-depressives or benzodiazepines) or can have an influence on the participant*s vigilance or cognitive performance within two weeks prior to participation
* Color blind

Study design

Design

Study type:	Interventional
Intervention model:	Crossover
Masking:	Single blinded (masking used)
Control:	Uncontrolled
Primary purpose:	Prevention

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	16-03-2015
Enrollment:	24
Type:	Actual

Medical products/devices used

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

Ethics review

Approved WMO

Date:	26-01-2015
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)

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	NL50753.091.14