Emotional schema, sleep and TMS

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON27450

Source
Nationaal Trial Register

Health condition

Depression, Depressie

Sponsors and support

Primary sponsor: Donders Institute for Brain, Cognition, and Behaviour, Centre for Cognition, Radboud University Nijmegen, Radboud University Medical Center Nijmegen
Source(s) of monetary or material Support: Fund = Initiator = Sponsor

Intervention

Outcome measures

Primary outcome

To investigate the effect of rTMS on the mPFC and mood induction and its interaction on schema-related false memory as measured by the amount of remembered items and amount of critical lures that are remembered per valence category and in total.

Secondary outcome

To investigate the influence of rTMS on the mPFC and mood induction and its interaction on specific sleep parameters, namely the amount of REM sleep and frontal theta and gamma power during REM sleep.

Study description

Study objective

The endpoints of the study are to investigate the effect of rTMS on schema memory performance after mood induction and its effect on several sleep parameters.

Our aim is to investigate the effect of rTMS stimulation on the mPFC, mood induction and its interaction on schema-related false memory as measured by the amount of remembered items and amount of critical lures that are remembered per valence category and in total.

Study design

During the intake session, several questionnaires will be collected.

In the night between intake and test session, a night of sleep will be recorded at home.

During the first test session (one day later), the encoding task will be executed.

In the night between first and second test session, another night of sleep will be recorded at home.

At the last session, in the following morning, recall and retrieval of the memory task is executed.

Intervention

The intervention will consist of a standard continuous theta-burst stimulation (cTBS) procedure, consisting of a total of 600 pulses administered across 40 sec. The stimulation protocol is patterned, and consists of bursts of 3 pulses at 50 Hz, and each burst itself is repeated at a frequency of 5Hz. The stimulation intensity will be anchored relative to 80 % of the measured active motor threshold from the tibialis anterior, following previous studies (Klucharev, Munneke, Smidts, & Fernández, 2011). The reason for using aMT as measured from the tibialis anterior muscle instead of a distal hand muscle, is that the representational motor area for the tibialis anterior effector is located at a similar depth in the interhemisperic fissure to our target location in the medial prefrontal cortex. During the intake, we will determine the active motor-evoked threshold (aMT) of the tibialis anterior as well as the first dorsal interosseous, as measured by electromyographic recordings in response to single TMS-pulses delivered to the appropriate motor hotspots in the primary motor cortex following the method of limits (Rossini et al., 1994). Specifically, during moderate contraction of the tibialis anterior muscle respectively the first dorsal interosseous, the aMT will be determined as the minimal stimulation intensity at which 5 out of 10 pulses evokes a visible motor evoked potential (MEP) on the electromyographic recordings. The intensity at which the protocol of cTBS is applied is defined at 80% of the aMT of the tibialis anterior, unless the intensity defined in this manner falls above 120 % of aMT of the first dorsal interosseous. In the latter

case, we will employ a stimulation intensity for the cTBS-protocol that is anchored below 120 % of the aMT of the first dorsal interosseous. We use this precautionary upperthreshold of stimulation intensity, as the single case that is known (out of 4,500 total cases) where the application of cTBS induced a tonic-clonic seizure (Oberman, Edwards, Eldaief, & Pascual-Leone, 2011; Oberman & Pascual-Leone, 2009) used a threshold of approximately 120 % of the aMT as measured by electromyographic recordings on the first dorsal interosseous.

The cTBS-intervention will be delivered twice, once at the intake session to determine tolerability, and later in the first experimental session as an experimental intervention (see study design). Depending on the experimental group, the stimulation will be delivered to the medial prefrontal cortex (by neuronavigating and navigated by anatomical midline landmarks, moving the coil two thirds the distance from the vertex to the nasion) with the cTBS protocol or with a 5Hz control protocol where stimulation is assumed not to have an effect on the task.

For the negative mood induction we will follow the approach of Fitzgerald and colleagues (2011). They made use of short movie clips of the film Sophie's Choice in order to induce sad mood. Participants are instructed to emphasize with the protagonist in the movie.

Contacts

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Eligibility criteria

Inclusion criteria

Age between 18 and 35 years

Normal or corrected-to-normal vision

Willingness and ability to sign informed consent

Healthy

Right-handed

Exclusion criteria

(History of) epilepsy, convulsion or seizures

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 neurological or psychiatric diseases

(History of) neurological disorder/ treatment

Skin diseases at intended electrode sites

Any prescribed medication that can alter cortical excitability (e.g. antiepileptics, tricyclicanti-depressives or benzodiazepines) or can have an influence on the participant’s vigilance or cognitive performance within two weeks prior to participation
Intolerance of the stimulation protocol as determined by cTBS stimulation applied in the intake session

Not being able to reliably measure motor-evoked potentials as measured by electromyography of the tibialis anterior and first dorsal interosseous after stimulating the corresponding motor representation in the participants’ primary motor cortex

Having minimal sleep, or excess consumption of alcohol/recreational drugs/caffeine in the 24

hours prior to the experimental TMS session

Any MRI related exclusion criteria

Transmedial flights for the past month

(History of) sleep disorder

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	10-04-2017
Enrollment:	40
Type:	Anticipated

Ethics review

Positive opinion

Date:	08-03-2018
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 42896
Bron: ToetsingOnline
Titel:

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

No registrations found.

In other registers

Register	ID
NTR-new	NL6893
NTR-old	NTR7080
CCMO	NL57736.091.16
OMON	NL-OMON42896

Study results