Effects of rTMS on emotional memory schemas acquired after mood induction and sleep.

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

Summary

ID

NL-OMON42896

Source
ToetsingOnline

Brief title
Emotional schema, sleep and TMS

Condition

- Other condition
- Mood disorders and disturbances NEC

Synonym
dejection, mood

Health condition

neurowetenschappelijk onderzoek

Research involving
Human

Sponsors and support

Primary sponsor: Radboud Universiteit Nijmegen
Source(s) of monetary or material Support: DCN Radboudumc junior researcher grant

Intervention

Keyword: memory, mood, schema, TMS

Outcome measures

Primary outcome

The main study parameters are the amount of items remembered (hits), amount of critical lures remembered (FA) in all groups and subjective measures (e.g. mood induction check).

Secondary outcome

The secondary study parameters are the measured sleep parameters e.g. amount of REM sleep and amount of frontal theta and gamma power.

Study description

Background summary

Medial prefrontal cortex (mPFC) related schema processing appears readily as a candidate mechanism accounting for memory bias in depressed patients. Furthermore, REM sleep has been suggested as pivotal for the processing of affective memories and as an alternative pathway of consolidation for schema-conformant memories. The intimate interactions between schema memory, memory bias in depression and sleep have however not been systematically investigated yet. This study could provide us with a deeper understanding of mechanisms underlying memory biases in depression and lead to possible therapeutic advances.

Study objective

This study attempts to explore the relation between the functioning of the schema-related mPFC, REM sleep and affective memory bias, by simulating a depressive-like state in healthy subjects through negative mood induction and

applying rTMS to inhibit mPFC processing before the encoding of a schema-related false memory task, followed by full-night sleep recordings.

Study design

A between-subject design will be employed with four groups of healthy adult volunteers, balanced between mood induction (neutral or negative) and TMS stimulation (on the mPFC or primary somatosensory cortex control region). The study will include one initial intake session and two experimental sessions and two nights of sleep recording at home. On the first experimental session, after mood induction (neu/neg) and cTBS rTMS (mPFC/leg representational area of the primary motor cortex), the encoding session of an adapted DRM (false memory) paradigm will probe mood-related schema memory. On the second experimental session, participants will be tested on their memory in a recall/recognition task. Two nights of sleep will be recorded at home with an ambulant sleep recording device, one after intake and one between the two experimental sessions

Intervention

The intervention includes a previously established off-line rTMS-protocol with the intention to produce short-term inhibitory effects on the functioning of the target region (mPFC). The intervention will consist of a standard continuous theta-stimulation (cTBS) procedure, consisting of a total of 600 pulses across 40 sec at 80% of the measured aMT of the tibialis anterior and 120% of the first dorsal interosseous. The stimulation protocol is patterned, and consists of bursts of 3 pulses at 50 Hz, and each burst is repeated at 5Hz.

Study burden and risks

All measurements will be administered during three visits at the institute and during two nights of sleep. For the assessment of risks and burden associated with transcranial brain stimulation in this study please refer section 10.2, as well as paragraph 5.2 of the approved Standard Operating Procedure for Non-Invasive Brain Stimulation (v. 2.1., CMO No. 2013/245) at the Donders Institute for Brain, Cognition and Behaviour. This study will be conducted in accordance with the guidelines implemented within the SOP NIBS. All participants are screened for their relevant medical history and other TMS safety aspects. There are no risk factors related neither to the false memory task nor to the sleep recording. Subjects are asked to sleep with an ambulant sleep recording device on two consecutive nights during the study. A small amount of electrodes are attached to the scalp and a band will be placed across the chest, which may be experienced as a small burden during sleep initiation. The study will broaden our understanding of the involvement of mPFC related schema memories and the effect rTMS effect on mood congruent memories, which

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

Only healthy, competent participants, 18*45 years old, with normal vision or corrected to normal vision by means of contact lenses.

Exclusion criteria

Skin diseases at intended electrode sites (EMG, EEG, tCS)
(History of) psychiatric disorder/ treatment

(History of) neurological disorder/ treatment
Disorders of vision (i.e., deviation from *normal or corrected-to-normal vision*)
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
Having minimal sleep, or excess consumption of alcohol/recreational drugs/caffeine in the 24 hours prior to the experimental TMS session.
(History of) sleep disorder
Shift work for the past 3 months
Transmedial flights for the past month
Extreme chronotype
Regular nappers
Extreme caffeine consumers
Heavy smokers

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	10-04-2017
Enrollment:	83
Type:	Actual

Ethics review

Approved WMO

Date:	08-09-2016

Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	16-01-2017
Application type:	Amendment
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

ID: 27450
Source: Nationaal Trial Register
Title:

In other registers

Register	ID
CCMO	NL57736.091.16
OMON	NL-OMON27450