Combining cognitive bias modification with rTMS: Evidence from a single session intervention in a dysphoric student population

Published: 26-07-2013
Last updated: 24-04-2024

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

Summary

ID

NL-OMON38877

Source
ToetsingOnline

Brief title
Combining CBM with rTMS

Condition

- Mood disorders and disturbances NEC

Synonym
Depression, mood disorder

Research involving
Human

Sponsors and support

Primary sponsor: Radboud Universiteit Nijmegen

Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Attention bias, Cognitive bias modification, Dysphoric sample, rTMS

Outcome measures

Primary outcome

We are interested in a change in attention bias, as well as in a change in emotional vulnerability in response to a challenging memory task.

Secondary outcome

Furthermore, we investigate differences in attentional control, as a result of the intervention. In addition to that, we will conduct a three-day follow-up measure to assess differences in trait anxiety, tendency to ruminate as well as depressive characteristics.

Study description

Background summary

In recent years, a number of studies on the use of high frequency rTMS applied to the left DLPFC have proven its favorable effect in reducing depressive symptoms in a population suffering from recurrent major depressive disorder (MDD). Next to this therapeutic effect, the stimulation of the left DLPFC has been found to affect attention allocation towards negative pictorial stimuli during a dot-probe task, an instrument measuring attentional biases. A second line of research has tried to affect these attentional biases, as they have been found to play a causal role in the development and maintenance of emotional disorders. Studies on this attention bias modification (ABM) training have proven its effectiveness in reducing an attentional bias towards negative pictorial stimuli in depression, and even more important, its therapeutic effects in reducing emotional vulnerability. ABM has been further suggested to increase attentional control. Recently, a study has examined the neural substrates underlying this form of ABM training, revealing that ABM modulates the activity of the DLPFC. In sum, both techniques that are designed to ultimately reduce depressive symptoms seem to affect neural activity of the

DLPFC as well as an attentional bias towards negative stimuli. Adding ABM to the rTMS treatment thereby might amplify the beneficial effects on depressive symptomatology and attentional processing.

Study objective

The aim of this study is to test in a single session study in participants with subclinical depressive symptoms, whether adding ABM to rTMS treatment might maximize the beneficial effects on attentional bias, attentional control and emotional vulnerability.

Study design

For this study, 188 participants will be randomly assigned to one of four groups (each n=47). The first group will first receive an active rTMS treatment followed by a computerized ABM training. The second group will receive the same rTMS treatment followed by a sham ABM training whereas the third group will receive a sham-rTMS treatment followed by a usual ABM training. The fourth group will function as a control group and therefore receive a sham-rTMS treatment followed by a sham ABM training.

Intervention

We will administer offline high frequency TMS to the left DLPFC with an intensity of 110%rMT, in 30 trains of 10Hz pulses with a duration of 5 seconds and an inter-train interval of 25 seconds (50 pulses per train, 1500 pulses per session).
Besides the TMS stimulation we will also make use of an attention bias modification (ABM) training, in the form of a modified version of the dot-probe task. Positive and negative pictures, equivalent in low-intensity will be selected. Fifty percent of these pictures will exclusively contain faces (i.e., sad or happy expression) and the other half will depict scenes (e.g., puppies, grave yard). During the training, always one positive and one negative picture will be presented on the screen simultaneously, whereby only the positive picture will get replaced by the probe. Participants are asked to react to the probe as fast as possible by means of a button press.

Study burden and risks

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 and it will be applied only once to half of the participants. 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 TMS studies of patient populations (e.g. epilepsy) or in studies that exceeded the standard protocols (e.g. in intensity or frequency) epileptic seizures have been reported in rare cases. 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 ABM training. In summary, because the risk and burden associated with participation can be considered negligible-to-minimal, we do not expect any serious adverse events during the project.

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

heatlhy, right-handed participants, between 18 and 50 years, with normal or corrected-to-normal vision.
Participants with an BDI-II score between 9 and 25.

Exclusion criteria

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
Pregancy
History or current presence of any neurologic or psychiatric diseases

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):	19-11-2013
Enrollment:	188
Type:	Actual

Ethics review

Approved WMO Date:	26-07-2013
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	31-12-2013
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

No registrations found.

In other registers

Register	ID
CCMO	NL43562.091.13