

Testing the combined effects of a brain stimulation technique with a computer training in a mildly depressed group

No registrations found.

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

Summary

ID

NL-OMON29196

Source

NTR

Health condition

The aim of this study is to test whether adding ABM to rTMS treatment in a single session intervention might amplify the effects or rTMS in reducing attentional bias and emotional vulnerability in a sample of dysphoric individuals.

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

Sponsors and support

Primary sponsor: Donders Centre for Cognitive Neuroimaging, Radboud University Nijmegen, the Netherlands

Source(s) of monetary or material Support: fund = initiator = sponsor

Intervention

Outcome measures

Primary outcome

We are interested in a change in attentional bias, as well as in a change in emotional

vulnerability in response to a challenging task.

Secondary outcome

We will investigate changes in attentional control as a results of the intervention. In addition, 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

Study objective

Major depressive disorder is the most frequent among all mental disorders. While there are several treatment options already available, a many patients do not benefit from these treatment options. In the recent years, attention has been drawn to a new technique in the treatment of depression, the so-called repetitive transcranial magnetic stimulation (rTMS). Aim of this study is to test in a single session study in participants with subclinical depressive symptoms, whether adding a computer training to alter attentional processing (Attention bias modification training, ABM) to rTMS treatment can maximize the beneficial effects. We chose to combine these techniques that are designed to reduce depressive symptoms, as both techniques have been shown to affect neural activity of the same brain region as well as an attentional bias towards negative stimuli. Attentional bias has been found to be causally related to the development and maintenance of emotional disorders.

Study design

We will assess changes in attentional bias by means of reaction times on the dot-probe task, and changes in attentional control by means of an adapted version of the Stroop task, comparing the performance from before the combined intervention to after the intervention. Additional measures of gaze-direction during the dot-probe task will be assessed by means of an eye-tracker.

Differences in emotional vulnerability will be compared between groups by assessing mood levels before and after a challenging memory task by means of visual analogue scales.

Three days after the combined intervention the Spielberger State-Trait Inventory, the Ruminative Response Scale as well as the Beck's Depression Inventory will be administered in order to assess levels of anxiety, rumination and depressive characteristics respectively.

Intervention

30 trains of rTMS stimulation with 10Hz for 5 seconds, with an inter-train interval of 25 seconds. Stimulation site is the left dorsolateral-prefrontal cortex (DLPFC).

This intervention will be compared to a sham-rTMS stimulation, while stimulation parameters will be held constant and only the coil will be tilted about 45 degrees.

In order to modify an attentional bias, a dot-probe training will be administered. During 250 trials, participants will always see two pictures (one positive and one negative picture) followed by an arrow pointing to the left or right. The participants will have to indicate the direction the arrow is pointing to as fast as possible. In order to modify the attentional bias, the arrow will appear behind the positive picture in 85% of the trials.

During the sham-ABM training, participants will receive the same intervention besides that the contingency will be changed to 50%.

In total there will be four groups, one receiving the rTMS intervention followed by the active ABM training, group 2 receiving the sham-rTMS stimulation followed by the active ABM training, group 3 receiving the real rTMS stimulation followed by the sham-ABM training, and the fourth group receiving a sham-rTMS stimulation followed by a sham-ABM training.

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Eligibility criteria

Inclusion criteria

- Healthy, 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
- Pregnancy
- History or current presence of any neurological or psychiatric diseases

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

Ethics review

Positive opinion
Date: 22-05-2014
Application type: First submission

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
NTR-new	NL4133
NTR-old	NTR4637
Other	METC nr. : 2013/090

Study results