Attention Bias Modification (ABM) for Major Depressive Disorder

No registrations found.

Ethical review	Positive opinion
Status	Recruitment stopped
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON24957

Source
NTR

Brief title
CogniTrain (Cognitieve Trainingen bij Depressie)

Health condition

Major Depressive Disorder (MDD)

Sponsors and support

Primary sponsor: Pro Persona, Center for Mental Health Care, Nijmegen, The Netherlands Wolfheze 2, 6874 Wolfheze
Source(s) of monetary or material Support: fund = initiator = sponsor

Intervention

Outcome measures

Primary outcome

• Attentional bias (dot-probe task)

• Depression level as assessed by the Inventory of Depressive Symptomatology self-report (IDS-SR)

• Emotional vulnerability in response to a speech task as measured by the Spielberger State Anxiety Inventory (STAI-S) and the Positive and Negative Affect Scale (PANAS)

Secondary outcome

• Attentional control, as measured by the classical Stroop task

• Attentional bias for verbal positive and negative information ('emotional Stroop task'),

• Ruminative Response Scale (RRS-NL)

• Positive and Negative Affect (PANAS)

• Prospective Imagery Task (PIT)

• Resilience Scale (RS)

• Number of sessions of out-patient therapy needed

• Credibility/Expectancy Questionnaire (CEQ)

• Quality of life (EuroQol; EQ-5D) and costs/ health care utilization (Trimbos/iMTA questionnaire; TicP)

• Diagnostic status of depression according to the DSM-IV-TR as assessed by the MINI Neuropsychiatric Interview

Study description

Background summary

Attention bias modification aims at targeting the attentional bias often found in depression (a difficulty to disengage attention from negative information), by training participants´ attention away from negative and towards positive stimuli. Studies provide preliminary evidence that ABM can modify cognitive biases in depressed samples (in mild and remitted depression) and may be of therapeutic value by reducing symptoms. In this double blind, randomized controlled trial, we primarily aim to investigate whether, in clinically depressed patients, (1) a positive attentional bias (i.e., relatively more attention for positive than for negative stimuli) can be induced and if the training attenuates (2) stress reactivity (3) and general levels of depression.

Study objective

We expect that a positivity training based on attention bias modification (ABM), can induce

(1) a positive attentional bias (i.e., relatively more attention for positive than for negative stimuli), (2) attenuates stress reactivity (3) and reduces general levels of depression in patients with Major Depressive Disorder (MDD).

Study design

Primary outcome measures:

• Attentional bias – Dot-probe task (pre to post)

• Depression level – IDS-SR (pre to post, 1 & 6 months follow-up)

• Emotional vulnerability in response to a speech task (post)

Secondary outcome measures:

• Classical & emotional Stroop task (pre to post)

• RRS-NL (pre to post, 1 & 6 months follow-up)

• PANAS (pre to post, 1 & 6 months follow-up)

• PIT (pre to post)

• RS (pre to post & 6 months follow-up)

• Number of sessions of out-patient therapy needed (follow-up)

• CEQ (after the first training session)

• EQ-5D (pre to post, 1, 6 & 12 months follow-up)

• TicP (pre & 12 months follow-up)

• Diagnostic status of depression according to the DSM-IV-TR as assessed by the MINI Neuropsychiatric Interview (pre & 12 months follow-up)

Intervention

Attention Bias Modification (ABM)

A computerized, cognitive bias modification (CBM) training for attention (i.e., Attention Bias Modification) is offered eight times during a period of two weeks (i.e., 4 weekly sessions). As ABM paradigm, the dot-probe task is used. On each trial during this task, two pictures (always

one positive and one negative picture) are displayed next to each other for 1000-1500 ms. Thereafter, a probe (i.e., an arrow pointing up versus down) appears behind one of the pictures. Participants have to identify the probe as quickly as possible. Each session contains 210 trials and takes about 20 minutes. Besides the first, all training sessions are completed via the internet, at participant's home.

Positivity training:

In the positivity training the probe replaces the positive pictures in 90% of the cases and the negative pictures in 10 % of the cases. Hence, patients are trained to attend to positive pictures and to avoid negative pictures.

Control training:

In the control condition, patients receive a sham-training, during which the probe appears equally often behind positive and negative pictures, hence attentional bias is only assessed, but not modified.

Contacts

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Eligibility criteria

Inclusion criteria

• A diagnosis of major depressive disorder, first or recurrent according to the DSM- IV-TR, as assessed with the MINI Neuropsychiatric Interview

• Age: between 18-65 years

Exclusion criteria

• Any psychotic disorder (current or previous)

• Current mania or hypomania or a history of bipolar disorder

• Cognitive disabilities (IQ < 80)

• Visual disabilities that interfere with the computer tasks

• Acute suicidal risk

• No sufficient command of Dutch language to participate in the study

• No regular access to a computer at home

• Lack of experience with the use of computers (based on subjective estimation of the patient).

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	02-10-2014
Enrollment:	126
Type:	Actual

Ethics review

Positive opinion

Date:	20-07-2015
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 40250
Bron: ToetsingOnline
Titel:

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

No registrations found.

In other registers

Register	ID
NTR-new	NL5144
NTR-old	NTR5285
CCMO	NL45720.091.13
OMON	NL-OMON40250

Study results