An attention bias modification training as waitlist intervention for depression: A randomized controlled trial

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Aim of the study is to evaluate the effectiveness and cost-effectiveness of a positivity training based on attention bias modification as waitlist-intervention for adult outpatients with a major depressive disorder.

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

Summary

ID

NL-OMON40250

Source
ToetsingOnline

Brief title
Attention bias modification in depression

Condition

- Mood disorders and disturbances NEC

Synonym
depressive disorder, major depressive disorder

Research involving
Human

Sponsors and support

Primary sponsor: ProPersona (Nijmegen)
Source(s) of monetary or material Support: Pro Persona

Intervention

Keyword: attention, cognitive bias modification, depressive disorder, randomized controlled trial

Outcome measures

Primary outcome

Primary study parameter is a change in attentional bias as assessed by the *dot probe task*.

Secondary outcome

Next to investigating training effect on changes in bias, understanding the impact of the intervention on depressive symptomatology, emotional vulnerability and quality of life is important from a clinical perspective, while assessing the cost-effectiveness is important from a societal perspective. For these secondary (i.e., more distal) outcomes, a probabilistic medical decision-making approach is taken.

Secondary outcome measures are emotional vulnerability in response to a speech task and a decrease in depressive symptoms. Other secondary outcome measures are a change in attentional bias for verbal positive and negative information (*emotional Stroop task*), a change in positive imagery abilities, attentional control, ruminative thinking, resilience, positive and negative affect, memory bias, number of sessions of usual care, and quality of life and costs and diagnostic status at 12 months follow-up.

Study description

Background summary

Usual care for Major Depressive Disorder (MDD) consists of a mix of interventions, most of them evidence-based like psychotherapy and antidepressants. However, these interventions are costly and response and remission rates are rather low. Moreover, once referred to specialty care, patients often have to wait months until they actually do receive treatment. Hence, cost-effective and easily accessible treatment options that could be offered during waiting period are urgently needed. A recently developed, computerized training method, the so-called cognitive bias modification (CBM) may have the potential to be provided as cost-effective waitlist intervention for MDD. CBM aims at targeting the cognitive biases often found in depression. Due to these biases, patients suffering from this disorder, preferentially attend to negative information, or interpret and remember ambiguous situations in a more negative manner than healthy individuals do. However, depressed patients also lack positive biases (i.e., a heightened processing of positive information) usually found in healthy individuals. A growing body of literature suggests, that these biases play an important role in the development and maintenance of the disorder. One form of CBM, the so-called attention bias modification (ABM) trains participants to allocate their attention away from negative and towards neutral or positive information and thus aims at decreasing a negative and at increasing a positive attentional bias respectively. Studies on the effectiveness of ABM in depressed samples are scarce, but provide preliminary evidence that ABM can modify attentional processes in depression and may be of therapeutic value for this group. However, so far, no ABM study has been conducted in patients with a major depression yet, using the most promising training procedure, that is the dot-probe task, and no clinical studies are available using ABM as waitlist intervention for depression.

Study objective

Aim of the study is to evaluate the effectiveness and cost-effectiveness of a positivity training based on attention bias modification as waitlist-intervention for adult outpatients with a major depressive disorder.

Study design

A double blind randomized controlled trial in two groups with a 1, 6 and 12 months follow-up combined with an economic evaluation.

Intervention

A computerized positivity training, based on cognitive bias modification (CBM) for attention, is offered eight times during a period of two weeks (i.e., 4 weekly sessions), for 25 minutes per session. Besides the first, all training sessions are completed via the internet, at participant*s home. In the positivity training patients learn to attend to positive information and to avoid negative information. In the control condition, patients receive a sham-training, during which attentional bias is continuously assessed but not modified.

Study burden and risks

ABM is a non-invasive, safe procedure that it is very unlikely to produce any side effects and requires a minimum of time and effort from patients. Patients have to visit the lab only three times in total, as seven of the training sessions and all follow-up measures are completed via the internet at home and need no site visit. As recent research has shown, that even CBM sham training groups improve with regard to symptom severity from before to after the training (Enock & McNally, 2013; McNally, Enock, Tsai, & Tousian, 2013), which might be for instance due to a placebo effect or maybe even due to an increase in attentional control, both groups of participants can be expected to benefit to some extend from the training. However, only the positivity training is expected to induce a positive attentional bias and in turn should be more effective in reducing depressive symptoms than the sham training. Moreover, all participants receive standard care (i.e., cognitive behavioral therapy) delivered in the programme for mood disorders of Pro Persona.

Contacts

Public
ProPersona (Nijmegen)

Reinier Postlaan 6
Nijmegen 6500 HB
NL
Scientific
ProPersona (Nijmegen)

Reinier Postlaan 6
Nijmegen 6500 HB
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

- A diagnosis of major depressive disorder, first or recurrent according to the DSM- IV-TR, as assessed with the MINI.
- Wait-listed for Cognitive Behavioral Therapy
- Age: between 21-65 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 a computer task
- 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:	Active
Primary purpose:	Other

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	02-10-2014
Enrollment:	120
Type:	Actual

Ethics review

Approved WMO

Date:	18-06-2014
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)

Approved WMO

Date:	17-11-2014
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)

Approved WMO

Date:	13-07-2015
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: 24957
Source: NTR
Title:

In other registers

Register	ID
CCMO	NL45720.091.13
OMON	NL-OMON24957