interpretation Bias Modification (IBM) in patients with Major Depressive Disorder

No registrations found.

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

Summary

ID

NL-OMON27494

Source
NTR

Health condition

Major Depressive Disorder (MDD)

Sponsors and support

Primary sponsor: Pro Persona, Trimbos Institute
Source(s) of monetary or material Support: ZonMw

Intervention

Outcome measures

Primary outcome

For testing the main hypothesis, that IBM is able to reduce depressive symptom levels, the Beck’s Depression Inventory II (BDI) will be used.

Secondary outcome

-Depressive symptomatology (IDS-SR; as part of routine care).

-Current use of antidepressant medication (as part of the TiC-P questionnaire).

-Dysfunctional cognitions (17- item Dysfunctional Attitude Scale, DAS).

-Levels of anxiety (20-item Spielberger State-Trait Anxiety Inventory-Trait version, STAI).

-Prospective mental imagery (20-item Prospective Mental Imagery Task, PIT).

-Everyday use of imagery (12-item Spontaneous use of imagery scale, SUIS).

-Interpretation Bias (Ambiguous Scenarios Test, AST)
-Expectancies with respect to the training (3-item expectancy questionnaire, EQ), derived from the expectancy/credibility questionnaire).

-Quality of life and costs, (the 5-item EuroQoL, EQ-5D) and Trimbos Institute and iMTA Cost questionnaire for Psychiatry (TiC-P).

-Diagnostic status of depression according to the DSM-IV-TR as assessed by the MINI.

-Patient satisfaction questionnaire.

-In depth patient satisfaction interviews with the 10 most content and the 10 most discontent participants according to the patient satisfaction questionnaire.

Study description

Background summary

The summary is not public yet, because of the quality of the study.

Study objective

The hypothesis is not public yet, because of the quality of the study.

Study design

Primary outcome measure

-BDI (baseline, 2 weeks, 1 month, 6 months, 12 months)

Secondary outcome measures

-AST (baseline, 2 weeks, 1 month)

-PIT (baseline, 1 month, 6 months)

-IDS-SR (baseline, 1 months, 6 months, 12 months)

-STAI (baseline, 1 month, 6 months)

-SUIS (baseline, 1 month, 6 months)

-DAS (baseline, 1 month, 6 months)

-EQ (baseline, 1 month)

-TIC-P (baseline, 1 month, 6 months, 12 months)

-EQ-5D (baseline, 1 month, 6 months, 12 months)

-MINI (baseline, 12 months)

-Patient satisfaction questionnaire (1 month, 6 months)

-Patient satisfaction interview (12 months)

-Demographic items (baseline, 1 month)

Intervention

Interpretation Bias Modification (IBM)

Patients will be offered IBM when just starting their treatment (maximum of 4 sessions) or when waitlisted for treatment, accompanied or followed by further indicated care. IBM entails 10 20-minute computer training sessions over the course of 4 weeks: 7 daily sessions during in week 1, followed by weekly sessions during the following 3 weeks. The first session will be completed at Pro Persona. All other sessions will be completed via the internet at home.

Both groups will receive a mixture of auditory and picture-word training sessions.

Not all of the information about the intervention is public yet, because of the quality of the study.

Contacts

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Eligibility criteria

Inclusion criteria

-A diagnosis of major depressive disorder, first or recurrent according to the DSM- IV-TR (APA; American Psychiatric Association, 2000), as assessed with the MINI
-18-65 years old
-Provides informed consent

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

-Lack of sufficient 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:	Single blinded (masking used)
Control:	Placebo

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-06-2017
Enrollment:	198
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Positive opinion

Date:	19-07-2016
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 47198
Bron: ToetsingOnline

Titel:

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

No registrations found.

In other registers

Register	ID
NTR-new	NL5786
NTR-old	NTR5949
CCMO	NL55683.091.15
OMON	NL-OMON47198

Study results