Cost-effectiveness of interpretation bias modification in patients with major depressive disorder: a randomised controlled trial.

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To evaluate the cost-effectiveness of imagery-based Interpretation Bias Modification (IBM) for patients with major depressive disorder (MDD) in the outpatient mental health care setting compared to usual care.

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

Summary

ID

NL-OMON47198

Source
ToetsingOnline

Brief title
Interpretation Bias Modification for depression

Condition

- Mood disorders and disturbances NEC

Synonym
Major Depressive Disorder; Depression

Research involving
Human

Sponsors and support

Primary sponsor: Trimbos-instituut

Source(s) of monetary or material Support: ZonMw,Pro Persona;Trimbos-intstituut;Radboud universiteit Nijmegen

Intervention

Keyword: Cognitive bias modification, Depression, Interpretation, Randomised controlled trial

Outcome measures

Primary outcome

Clinical evaluation: The main outcome is the change in depressive symptoms as measured by the Beck depression Inventory.

Economic evaluation: The EQ-5D will be used to assess QALY*s and costs will be assessed with the TiC-P.

Secondary outcome

Interpretation biases, prospective and every day use of imagery, dysfunctional cognitions, levels of anxiety, diagnostic status, treatment expectancies and satisfaction with treatment.

Study description

Background summary

In the Netherlands, depressive disorder affects about 800,000 people annually, and over 160,000 depressed patients seek care at mental health services. Current treatment options, psycho-, pharmaco-, or combination therapies, are not always effective or acceptable for all patients. Depression-related disease burden can also be only partially alleviated by currently available treatment options, thus new treatment options are urgently needed. Interpretation biases are implied in the onset and maintenance of major depressive disorder (MDD). Experimental research shows that interpretation biases can be re-trained using simple computer tasks through Interpretation Bias Modification (IBM). In IBM, the aim is to modify the interpretation biases of depressed patients from negative to positive and consequently improve their depressive symptoms levels and achieve remission. Depressed people tend to show a deficit in generating

positive prospective imagery, which hampers positive interpretations and limits chances to alter negative interpretation biases. Importantly, our IBM training incorporates mental imagery: imagining oneself in the presented (positive) scenarios in the IBM tasks. Initial promising findings justify further research to strengthen the evidence-base and to draw robust conclusions regarding the clinical value of IBM in the treatment of MDD. Moreover, there is currently no information available regarding the cost-effectiveness of imagery-based IBM for depression.

Study objective

To evaluate the cost-effectiveness of imagery-based Interpretation Bias Modification (IBM) for patients with major depressive disorder (MDD) in the outpatient mental health care setting compared to usual care.

Study design

A health economic evaluation alongside a single blind randomised controlled trial, with assessments at 0, 1, 6 and 12 months.

Intervention

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 their mental health care location. All other sessions will be completed at home. To permit blinding of patients and therapists the comparison group will be offered a sham-IBM training closely matching the intervention condition.
Patients will be offered IBM before starting indicated care, of in addition to indicated care.

Study burden and risks

IBM is a non-invasive, safe procedure that is very unlikely to produce any side effects. It requires a minimum of time and effort from patients. Patients have to visit their mental health care location only three times in total, as 9 of the training sessions and all follow-up measures can be completed via the computer at home and need no site visit. The MINI, when this interview has not been done during the intake, will be conducted by phone. Benefits resulting from the treatment cannot be guaranteed to patients. However, all participants can start with their treatment (usual care) during the intervention, or receive the intervention in addition to their treatment.

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

- A diagnosis of major depressive disorder, first or recurrent, as assessed with the MINI (which makes use of DSM-IV-TR criteria).
- 18-65 years old.
- Waitlisted for treatment for depressive disorder or having received no more than 4 indicated psychotherapy sessions.
- 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:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	18-05-2017
Enrollment:	196
Type:	Actual

Ethics review

Approved WMO Date:	14-03-2016
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	28-06-2016
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)

Approved WMO Date:	15-09-2016
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	18-05-2017
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	03-08-2017
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	07-12-2017
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	16-05-2018
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: 27494
Source: NTR
Title:

In other registers

Register	ID
CCMO	NL55683.091.15

Register	ID
OMON	NL-OMON27494