The effect of EMDR therapy in patients with bipolar disorder and a history of traumatic events: a randomized controlled trial.

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Objective: The primary objective is to examine whether EMDR therapy has mood-stabilizing effects in traumatized patients with mild depressive and/or manic symptoms. The secondary objective is to examine the hypothesis that EMDR is an effective and...

Ethical review	Approved WMO
Status	Pending
Health condition type	Manic and bipolar mood disorders and disturbances
Study type	Interventional

Summary

ID

NL-OMON46084

Source
ToetsingOnline

Brief title
The effect of EMDR in traumatized patients with bipolar disorder.

Condition

- Manic and bipolar mood disorders and disturbances

Synonym
bipolar disorder, manic depressive illness

Research involving
Human

Sponsors and support

Primary sponsor: Altrecht GGZ (Den Dolder)

Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: bipolar disorder, EMDR, Randomized controlled trial, trauma

Outcome measures

Primary outcome

The main study parameter is a significant decrease in affective symptoms measured by daily mood reports with the National Institute of Mental Health Life Chart Methodology (NIMH LCM), Altman Selfrating Mania Scale-NL (ASRM-NL) and/or the Inventory of Depressive Symptoms-Self Report (IDS-SR).

Secondary outcome

The secondary study parameter is a significant reduction of trauma symptoms measured by the Clinician Administered PTSD Scale (CAPS) and the PTSD Checklist for Diagnostic and Statistical Manual of Mental Disorders (DSM)-5 (PCL-5).

Another study parameter is that EMDR does not lead to mood episodes or an increase of mood symptoms.

Study description

Background summary

Traumatic events are frequently experienced by patients with bipolar disorder (BD) and can lead to symptoms of post-traumatic stress disorder (PTSD). There is a high prevalence rate of lifetime PTSD in patients with bipolar disorder, much higher than lifetime prevalence in the general population. A history of traumatic events is associated with a poorer outcome of the bipolar disorder, and this comorbidity may also have a negative impact on response to treatment for the mood symptoms. Still, psychotherapeutic interventions directed to this comorbidity are seldom studied so far. Eye Movement Desensitization and

Reprocessing therapy (EMDR) has found to be very effective to treat PTSD, but bipolar disorder is an exclusion criterion in most PTSD trials. Recently there are studies that prove EMDR to be a safe and effective intervention to treat PTSD, also in patients with a severe mental illness, such as psychotic disorder. There is only one randomized controlled pilot-study that studied the effect of EMDR in patients with bipolar disorder and mild depressive and/or manic symptoms (subsyndromal mood symptoms) and a history of traumatic events which suggests EMDR may be an effective and safe intervention to treat not only trauma symptoms but also subsyndromal mood symptoms. This research aims to study the mood-stabilizing effect of augmenting EMDR to treatment as usual in patients with bipolar disorder and trauma symptoms, by using daily monitoring of mood symptoms. We hypothesize that the EMDR intervention leads to a decrease in lability and intensity of (subsyndromal) depressive and/or manic symptoms.

Study objective

Objective: The primary objective is to examine whether EMDR therapy has mood-stabilizing effects in traumatized patients with mild depressive and/or manic symptoms. The secondary objective is to examine the hypothesis that EMDR is an effective and safe intervention in patients with a bipolar disorder, thus whether trauma symptoms reduce and EMDR does not lead to an increase of affective symptoms or full blown episodes.

Study design

A single-centre randomized clinical trial with 2 arms: a treatment as usual condition (TAU) and a condition in which EMDR is augmented to treatment is usual. The two groups will be compared at baseline (T0), posttreatment (T1) and at 8-weeks follow-up (T2).
In addition to this a case series design will be used, involving a baseline, a treatment and a follow-up phase.

Intervention

Participants are randomized to receive 8 90-minute sessions of EMDR next to treatment as usual or to receive only treatment as usual. Standard protocols are used, and treatment is not preceded by stabilizing psychotherapeutic interventions.

Study burden and risks

All participants that agree to participate in this study are submitted to a baseline measurement which consists of several selfreport questionnaires and a clinical interview to assess the frequency and intensity of the clinician*s rated PTSD symptoms. This is above the standard measurements that patients are

submitted to that are referred for treatment of the bipolar disorder, and takes time for each participant. In both groups, participants are submitted to extra questionnaires to assess the level of PTSD and affective symptoms on two occasions more. They are also asked to register their mood daily but that*s also standard in treatment as usual for bipolar patients. In the intervention group participants will have 8 sessions of EMDR. EMDR is found to be a safe intervention for patients in the treatment of PTSD symptoms, but in the first three days after an EMDR session patients can experience an increase of images and feelings associated with the experienced trauma. Patients will be well informed of this possibility.
We hypothesize that the EMDR intervention leads to a decrease in lability and intensity of (subsyndromal) depressive and/or manic symptoms.

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

- * 18 years of age
- A primary diagnosis of DSM-5 bipolar I or II disorder
- A history of (a) traumatic event(s) that is still causing clinically relevant distress

Exclusion criteria

- Organic brain disorder
- Mental retardation
- Dependency of drugs and/or alcohol
- Severe suicidality or psychosis in the last month
- Moderate to severe depressive or hypomanic symptoms at the start of the intervention (CGI-BP mania > 4, CGI-BP depression > 5).
- Patients are currently in some other form of psychological treatment for trauma

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	03-09-2018
Enrollment:	36
Type:	Anticipated

Ethics review

Approved WMO Date:	07-01-2019
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)

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
CCMO	NL66729.041.18