Mindfulness Based Cognitive Therapy for bipolar disorder

Published: 26-03-2018
Last updated: 12-04-2024

As there are limited data on how to improve outcomes for those patients who do not benefit sufficiently from the availabletreatments, this study aims to compare MBCT to TAU as an adjunctive treatment to reduce depressive symptoms in patientswith...

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

Summary

ID

NL-OMON44175

Source
ToetsingOnline

Brief title
MBCT for bipolar disorder

Condition

- Manic and bipolar mood disorders and disturbances

Synonym
Bipolar disorder; Manic-Depressive disorder

Research involving
Human

Sponsors and support

Primary sponsor: Radboudumc
Source(s) of monetary or material Support: ZonMW

Intervention

Keyword: Bipolar Disorder, Depressive symptoms, Mindfulness, Randomized Controlled Trial

Outcome measures

Primary outcome

Primary endpoint of the study is severity of depressive symptoms at 3 months follow-up (T1), assessed with the Inventory of Depressive Symptomatology * Clinician administered (IDS-C; Akkerhuis, 1997). The IDS-C has good psychometric qualities (Rush et al. 1996; Trivedi et al. 2004) and will be administered by trained research assistants.

Secondary outcome

Clinician-administered measures:

- Structured Clinical Interview for DSM-IV-TR Disorders (SCID; First, 2002) or its successor for DSM 5 when available, to assess depressive and manic relapses. The SCID will be used to retrospectively assess possible relapses/recurrences in the past 3 months at each time point.
- Young Mania Rating Scale (YMRS; Young, 1978), an 11-item clinician-administered rating scale to assess the level of (hypo)manic symptoms. It has good inter-rater reliability.
- Functioning Assessment Short Test (FAST; Rosa, 2007), Dutch translation. The FAST is a brief instrument designed to assess the main functioning problems experienced by psychiatric patients, particularly

bipolar patients. It comprises 24 items that
assess impairment or disability in six specific areas of functioning: autonomy, occupational functioning, cognitive functioning, financial issues, interpersonal relationships and leisure time. It has been shown to have strong psychometrics properties in terms of high internal consistency, test-retest reliability, and concurrent validity, and its ability to detect differences between euthymic and acute BD patients (Rosa, 2007).

Self-report measures:

- State/Trait Anxiety Inventory (STAI; Spielberger, 1983). The STAI is a self-report measure which has been proven reliable and sensitive in the assessment of both state and trait levels of anxiety. It is a standard international measure in anxiety research and its Dutch translation has been validated (van der Ploeg, 2000).
- Brooding subscale of the extended version of the Ruminative Response Scale (RRS-EXT; Treynor, 2003). The authors reported adequate internal consistency a = .79 and test*retest stability (a = .62, 1 year time interval) for the brooding subscale, which consists of 5 items. We select the brooding subscale because over time, brooding has been related to higher levels of depression, whereas the reflection subscale has been linked to lower levels of

depression (Treynor et al. 2003).

- Five Facet Mindfulness Questionnaire, short form (FFMQ-SF Dutch form; Bohlmeijer et al 2011). The FFMQ-SF consists of 24 items divided into the subscales observing, describing, acting with awareness, non-judging and non-reactivity. The Dutch version of the FFMQ-SF has been found reliable, valid, and sensitive to change in a Dutch sample of depressed individuals (Bohlmeijer et al. 2011).

- Self-compassion will be measured with the 12-item Dutch short-form version of the Self-Compassion Scale (SCS-SF; Raes et al., 2011). The scale consists of six components: self-kindness, self-judgment, common humanity, isolation, mindfulness and over-identification. The SCS-SF has good reliability and validity.

-Mental Health Continuum * short form (MHC-SF; Lamers, 2011). The MHC-SF is a 14-item self-report questionnaire that assesses emotional, psychological and social well-being. It has adequate psychometric qualities in terms of good internal consistency, (moderate) test-retest reliability, and good divergent and convergent validity.

- For the economic evaluation evaluation patients will complete a QALY instruments (EQ-5D-5L; EuroQoL Group, 1995) and a resource use measurement instrument (Tic-P; Hakkaart - van Roijen et al. 2002).

Study description

Background summary

In the Netherlands, the lifetime prevalence of bipolar disorder (BD) is about 1.2% for men and 1.4% for women (de Graaf et al 2010). BD usually manifests itself during late adolescence or early adulthood. Its course is often chronic, with patients suffering from recurrent depressive, (hypo)manic, or mixed episodes, being symptomatic about half of the time (Judd 2002). Although hospital admissions are more common during manic episodes, illness-related disability is more strongly influenced by depressive episodes (Judd 2003). It has been estimated that about 25-50% of the patients with BD attempts suicide at least once and that the risk of suicide is about 5%(Hawton 2005).

Depressive symptoms in BD are common and have been associated with negative effects on the course of bipolar disorder in terms of functional impairment and quality of life (Gutiérrez-Rojas 2008). There are limited data on how to optimize the treatment of persistent or residual depressive symptoms in BD or to improve outcomes for those patients who do not benefit sufficiently from the available treatments. In addition, there is a need for interventions that not only target symptom reduction but also help patients to cope with their illness from a wider perspective, i.e. in terms of their personal values, goals, and social roles.

Mindfulness-Based Cognitive Therapy (MBCT) is an innovative intervention that has been shown effective in reducing depressive symptoms in unipolar recurrent depression (Aalderen 2012, Kuyken 2016) and appears promising for coping with severe mental illness (Davis and Kurzban 2012). Little is known about the effectiveness of MBCT for BD, with a number of pilot studies showing reductions in depressive symptoms, and one RCT showing reduction of anxiety symptoms. Considering the need for additional psychosocial treatments that not only target symptomatic but also personal recovery, these preliminary but encouraging findings warrant a larger RCT examining the efficacy of MBCT for BD in the Netherlands.

Study objective

As there are limited data on how to improve outcomes for those patients who do not benefit sufficiently from the available treatments, this study aims to compare MBCT to TAU as an adjunctive treatment

to reduce depressive symptoms in patients
with bipolar disorder. We aim to examine outcomes of MBCT for BD patients both on a symptom level (depression, mania,
anxiety, risk of relapse/recurrence) and in terms of functioning and mental health/well-being, including its possible working
mechanisms such as improvements of mindfulness and self-compassion skills.

Study design

A randomized, multicenter, prospective, evaluator-blinded clinical trial of MBCT added to treatment as usual (TAU) versus TAU
alone is proposed. Assessments will be conducted at baseline and at 3, 6, 9, 12 and 15 months follow-up.

Intervention

The intervention will consist of usual care, and for half of the participants MBCT will be offered in adjunct. MBCT is a manualised group skills-training program (Segal, Williams & Teasdale 2012) designed as a relapse prevention programme for patients with recurrent depression. The training consists of eight weekly sessions of 2.5 hours, plus one day of silent practice. The program includes both formal and informal meditation exercises. Cognitive techniques that are part of the program are education, monitoring and scheduling of activities, identification of negative automatic thoughts and devising a relapse prevention plan.

The MBCT treatment will based on the 8-week MBCT course developed by Segal, Williams and Teasdale (2012), but will be adapted to address the needs of patients with a bipolar disorder. A few examples of these adaptations are: (more)
psychoeducation about manic symptoms in addition to the psychoeduction about depression; introducing the 3-minute
breathing space earlier in the programme and more often during sessions, especially when strong emotions are present;
repeatedly bringing the focus to self-care; and making use of the mindful movement (yoga) exercises more frequently.
All group sessions will be conducted at the respective mental health centres, with each group comprising 8-12 participants.
MBCT courses will be taught by experienced and qualified mindfulness teachers, together with a health care professional
specialised in the care for BD patients. Teacher competency will be assessed with the Mindfulness-Based Interventions *
Teaching Assessment Criteria (Crane et al 2013), for which all trial sessions will be videotaped.

Usual care will consist of pharmacotherapy, psycho-education and

self-management interventions (usually with a psychiatric nurse).

Study burden and risks

The burden associated with participation in MBCT is relatively high: participants are asked to attend 8 weekly group sessions of 2,5 hours and one silent day (6 hours), and to practice at home for about 45 minutes a day. In addition, participants are invited for 6 research assessments, 3 face-to-face (1-2 hours) and 3 by telephone (about 30 minutes). Assessments consist of interviews and questionnaires that ask about psychological symptoms, functioning, and quality of life. Before and after the intervention the assessment will include computer tasks.
Although the effort requested from patients is high, we expect that the large amount of practice will be associated with enduring changes in patients' coping, and that patients are increasingly able to apply mindfulness in their daily life. In this way, the intervention (and effort) can increase participants' autonomy and self-efficacy.

The risks associated with participated are expected to be low. Participants learn mindfulness skills to cope with psychological distress in a more effective way. This may include increased awareness of difficult emotions, which may at first be confronting or overwhelming. This is a major topic that will be discussed during MBCT and if participants show a clear increase in symptoms, additional guidance will be offered. Participants are encouraged to respect their boundaries (both physical and psychological) and are always free to quit or adapt the practice as needed.

Contacts

Public
Radboudumc

Reinier Postlaan 10
Nijmegen 6525 GC
NL
Scientific
Radboudumc

Reinier Postlaan 10
Nijmegen 6525 GC
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

- bipolar I or II disorder
- having suffered at least two lifetime depressive episodes, either current or in (partial) remission at baseline (according to SCID assessment)
-having suffered at least one episode (depressed or (hypo)manic) within the year prior to baseline.
- Young Mania Rating Scale score < 8

Exclusion criteria

- a (hypo)manic episode in the 3 months before the start of the trial
- lifetime diagnosis of schizophrenia or schizoaffective disorder, current substance abuse disorder, organic brain syndrome, antisocial or borderline personality disorder
- risk of suicide or aggression
- the presence of a concurrent significant medical condition impeding the ability to participate

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:	Recruitment stopped
Start date (anticipated):	25-04-2018
Enrollment:	160
Type:	Actual

Ethics review

Approved WMO Date:	26-03-2018
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	04-04-2018
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	14-06-2018
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	07-11-2018
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	18-09-2019
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	03-10-2019

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

No registrations found.

In other registers

Register	ID
ClinicalTrials.gov	NCTnotyetassigned
CCMO	NL63319.091.17

Study results

Date completed:	01-09-2022
Actual enrolment:	144