Mindfulness Based Cognitive Therapy (MBCT) for treatment refractory anxiety disorders

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Objective: The primary aim of the present study is to investigate the effectiveness of MBCT in a group format versus TAU in a group format for treatment refractory anxiety disorders Furthermore; we will investigate mediators associated with...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Anxiety disorders and symptoms
Study type	Interventional

Summary

ID

NL-OMON39672

Source
ToetsingOnline

Brief title
MBCT for anxiety disorders

Condition

- Anxiety disorders and symptoms

Synonym
anxiety disorders

Research involving
Human

Sponsors and support

Primary sponsor: PsyQ
Source(s) of monetary or material Support: subsidiefonds wetenschappelijk onderzoek PsyQ

Intervention

Keyword: anxiety disorders, MBCT, mindfulness, treatment refractory

Outcome measures

Primary outcome

• Mini-International Neuropsychiatric Interview (MINI; Sheehan et al., 1998a, 1998b). The MINI+ will be used to obtain DSM-IV diagnoses. The validation of the Dutch translation of the clinician rated (CR) version of the MINI (van Vliet & de Beurs, 2007) against the Structured Clinical Interview DSM-III-R-patient version (SCID-P) and the Composite International Diagnostic Interview for ICD-10 (CIDI) showed good to very good kappa values (Sheehan et al., 1998b).

• Beck Anxiety Inventory (BAI) (Beck, Epstein, Brown, & Steer, 1988). The BAI is a self-report questionnaire which consists of 21 items, each describing a common symptom of anxiety over the past week on a 4-point likert scale ranging from 0 to 3 (total score is 63). The scale has good internal consistency (0.92) and convergent validity (0.51) and discriminates between depression and anxiety. Test-retest reliability also appeared to be sufficient (0.75). The BAI will be used as primary outcome measure.

Secondary outcome

• Fear Questionnaire (FQ) (Marks & Matthews, 1979). This self-report questionnaire consists of 3 subscales (agoraphobia, social phobia and blood/injury dimensions). Besides these subscales the FQ also incorporates one scale assessing severity of avoidance behavior, how troublesome and disturbing/disabling the present symptoms are according to the patient. A Dutch

validation study showed that all scales have sufficient internal consistency and convergent and discriminate validity (van Zuuren, 1988).

• Beck Depression Inventory-II (BDI-II) (Beck, Erbaugh, Ward, Mock, & Mendelsohn, 1961; Beck, Steer, Ball, & Ranieri, 1996). The BDI is a self-report questionnaire and consists of 21 items (rated 0 to 3), each describing a depressive symptom in four levels of severity. Total scores range from 0 to 63. The BDI-II has high internal consistency with a Cronbach*s alpha of .91 (Beck et al., 1996; van der Does, 2002).

• World Health Organization Quality of Life - Bref (WHOQOL-Bref) (Trompenaars, Masthoff, Van-Heck, Hodiamont, & De-Vries, 2005). The WHOQOL-Bref was developed as an international cross-culturally comparable self-report quality of life assessment instrument. It assesses the individual's perceptions of quality of life in the context of their culture and value systems, personal goals, standards and concerns across 4 domains: physical health, psychological health, social relationships, and environment. The internal consistency of the four domains of the WHOQOL-Bref ranged from 0.66 to 0.80. Domain scores of the WHOQOL-Bref correlated around 0.92 with the WHOQOL-100 domain scores. Relatively low correlations were found between demographic characteristics (age and sex) and WHOQOL-Bref domain scores. It is concluded that the content validity, construct validity, and the reliability of the WHOQOL-Bref in a population of adult Dutch psychiatric outpatients are good (Trompenaars et al., 2005).

Mechanisms of change:

• Difficulties in Emotion Regulation Scale (DERS) (Gratz & Roemer, 2004): The DERS is a 36-items self-report questionnaire consisting of 6 subscales: 1) Non-acceptance of emotional responses (6 items); 2) Difficulties engaging in goal-directed behavior (5 items); 3) Impulse control difficulties (6 items); 4) Lack of emotional awareness (6 items); 5) Limited access to emotion regulation strategies (8 items); 6) Lack of emotional clarity (5 items). The internal consistency for the total scale as well as for the subscales appeared to be adequate (varying between a Cronbach*s alpha of 0.80 and 0.93). The questionnaire also has adequate construct and predictive validity and good test-retest reliability.

• Five Facet Mindfulness Questionnaire (FFMQ) (Bear, Smith, Hopkins, Krietemeyer, & Toney, 2006). This 39 item questionnaire assesses five core dimensions of mindfulness on a 5 point likert scale, including observing (8 items), describing (8 items), acting with awareness (8 items), non-judging (8 items) and non-reacting (7 items).validity and reliability have been tested and are good. The FFMQ has been translated and validated in Dutch by Muskens and Kamphuis, publication of these results is expected in 2011.

• Penn State Worry Questionnaire (PSWQ): This self-report questionnaire assesses the general tendency to worry (Meyer, Miller, Metzger, & Borkovec, 1990; Van Rijsoort, Emmelkamp, & Vervaeke, 1999). The PSWQ is a 16-item inventory designed to capture the generality, excessiveness, and uncontrollability of pathological worry. It has been shown to have good internal consistency with samples consisting of older adults with GAD (Beck, Stanley, & Zebb, 1995), community subjects (Brown et al., 1992), and

undergraduates (Meyer et al., 1990). It has also demonstrated good test-retest reliability over 8-10 weeks (Meyer et al., 1990). The PSWQ is translated and validated for a Dutch population (van Rijsoort, Emmelkamp, & Vervaeke, 1999).

• Rumination on Sadness Scales (Conway, Csank, Holm & Blake, 2000; Raes, Hermans & Eelen, 2003) will be used to assess the role of rumination in the maintenance or decrease of depressive and anxiety symptoms. Psychometric properties of the rumination on sadness scale is good (Roelofs, Muris, Huibers, Peeters & Arntz, 2006).

• The amount of Attentional Control (AC), measured with an Negative Affective Priming (NAP) task (Raedt, De, Baert, Demeyer, et al., 2011; Joormann, 2004). The NAP task measures the cognitive processing of emotional information, through which the ammount of AC can be determined. Previous studies have shown that susceptibility towards anxiety is negatively correlated with the amount of AC (Eysenck et al. 2007). Studies investigating AC with depressed subjects have shown that the amount of AC increases after Mindfulness Based Cognitive Therapy (Raedt, De, Baert, Demeyer, et al., 2011).

Questionnaires related to treatment

• Medication and other psychological treatment: At the follow-up assessment (T4), use of medical (e.g., doctor visits, hospitalization, medication) and psychological (e.g., psychologist or social worker visits) health services will be recorded using cost-diaries. The total costs of these services will be calculated according to standard prices. In addition, cost diaries will be used

to record productivity losses (e.g. sickness leave). Participants will be

trained in the use of these diaries and accurate completion of the diaries will

be carefully monitored.

Study description

Background summary

Rationale: Anxiety disorders have the highest incidence and prevalence of all psychiatric disorders in the Netherlands and are the most economically costly, entailing large amounts of personal suffering, use of medical and psychosocial services, and productivity losses. Cognitive Behavioural Therapy (CBT) sometimes complemented with a pharmacological intervention, is the treatment of choice for the complete range of anxiety disorders. However, only 50% to 80% of patients undergoing treatment achieve a responder status. These percentages might even be overestimated because of selection and publication biases. Current multidisciplinary clinical guidelines do not prescribe further treatment options for treatment refractory patients, stressing the need for the development and investigation of new interventions. Mindfulness based cognitive therapy (MBCT) is innovative and research has shown that it holds promise for patients who are difficult to treat otherwise. The current study aims to investigate the effectiveness of MBCT compared to treatment as usual (TAU) for patients who did not benefit from existing evidence-based treatment protocols. If proven effective, MBCT can for instance be a second or third intervention after CBT or an pharmacological intervention in a stepped care approach, thereby increasing efficiency in mental health care processes.

Study objective

Objective: The primary aim of the present study is to investigate the effectiveness of MBCT in a group format versus TAU in a group format for treatment refractory anxiety disorders
Furthermore; we will investigate mediators associated with treatment outcome and the predictive effects of patient variables on treatment outcome, thereby increasing the possibilities to offer patients the most suitable treatment.
More specifically, the project tries to answer the following questions:
1. Is MCBT more effective in reducing anxious complaints compared to TAU?
2. Is improved emotion regulation associated with symptom reduction?
3. Which clinical and demographic factors are related to symptom improvement

Study design

The design of the study will be a 2 group (MBCT, TAU) randomized controlled clinical trial with repeated measurements at baseline (T0), midtest (T1), posttest (T2) and 6 months follow-up (T3). Patients will be screened during a shortened intake meeting in which they will be asked to complete a short computer task. The same computer task will be administered during debriefing. At each assessment, symptom questionnaires, a diagnostic interview, and emotion-regulation measures will be administered (see figure 1 for an overview of the study). After conclusion of the experimental part of the study patients will enter a naturalistic follow-up period in which they are allowed to seek help the way they would normally do when confronted with an increase of anxious symptoms (e.g., visiting one*s general practitioner or seeking sources of symptom relief, using pharmacotherapy). Patients will be asked to report meticulous the use of medication and psychotherapy or other forms of counseling over the follow-up period.
The study will be performed at PsyQ (Parnassia Bavo group), a large urban ambulatory mental health organization in the Hague at the department of anxiety disorders.

Intervention

Mindfulness-Based Cognitive Therapy (MBCT) (Condition 1)

MBCT will be offered according to the protocol of Segal, Williams, and Teasdale (2003). MBCT, adapted for anxiety disorders, and will be provided in 8 weekly 2-hour group sessions consisting of a maximum of 8 patients suffering from different anxiety disorders which is in line with the transdiagnostic starting point of MBCT. During these sessions, different skills will be taught to help patients to become more aware and to relate differently to their anxious thoughts, feelings, and sensations (Teasdale et al., 2000). Participants are expected to engage in "homework" between sessions, which can consist of up to an hour of mindfulness practice and exercises each day. Each MBCT course will be provided by two experienced therapists who received formal MBCT training and weekly supervision by a senior licensed psychotherapist with formal training and extensive experience in delivering MBCT. All sessions will be audiotaped to assess protocol adherence. The MBCT course covers the following topics. In session 1 and 2 patients are taught to become more aware of the habitual *automatic pilot* way in which information is processed and the distractibility of the mind by automatic thoughts and feelings. Session 3 is devoted to how focusing on breathing can be helpful to stay in the here-and-now. Sessions 4 and 5 focus on the counterproductive effect of avoiding and escaping negative thoughts and feelings compared to an accepting and tolerating stance. In session 6, patients are taught to disengage from negative thoughts by labeling them as thoughts instead of facts. Sessions 7 and 8 focus on relapse prevention.

Treatment as usual (TAU) (Condition 2)

Patients in the TAU condition will be offered a form of supportive follow-up care, which is routine procedure in the current and most mental health care programs. Follow-up care is also provided in a group consisting of a maximum of 8 patients with a duration of 8 weeks. The format of the MBCT and TAU group will be similar to a large extent to decrease the role of confounding non-specific factors, like participating in structured group therapy. In follow-up care, problems encountered in daily life and coping strategies can be discussed. Patients are asked to complete individual homework assignments between session (for example to practice new coping skills and engage in daily activities). Follow-up care is given by experienced cognitive behavioral therapists.

Study burden and risks

There are no risks associated with the present study. The only inconvenience for participating subjects could be that they have to fill in questionnaires 4 times during the study which will take approximately 2 hours the first time (screening) and 1 hour the following 3 times. Furthermore, patients have to be willing to adhere to the inclusion criteria during the active treatment phase. In case of serious adverse events deviation of the protocol is allowed. Except for therapeutic effects there will be no direct advantages associated with participation. In general the study will lead to more knowledge of effective treatments for anxiety disorders and a proposal for stepped care will be developed.

Contacts

Public
PsyQ

Lijnbaan 4
Den Haag 2512 VA
NL
Scientific
PsyQ

Lijnbaan 4
Den Haag 2512 VA
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

- still fullfilling the criteria for an DSM IV axis 1 anxiety disorder
- refrain from treatment and counseling more frequently than once a month during the intervention
- stable use of anti-depressant medication or Benzodiazepines at leatst 3 months before inclusion
- Willingness to keep the dosage on a constant level during the intervention
For MBCT:
-willingness to complete daily homework assignments between sessions during the MBCT course.

Exclusion criteria

Primary axis 1 diagnosis of substance abuse or dependence, suicidality or psychotic symptoms

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):	01-08-2012
Enrollment:	128
Type:	Actual

Ethics review

Approved WMO Date:	05-03-2012
Application type:	First submission
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Approved WMO Date:	17-03-2014
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

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	NL38961.058.12