Cognition in Mindfulness: Negativity and Depression

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON24838

Source
NTR

Brief title
CogMIND

Health condition

Major depression

Sponsors and support

Primary sponsor: Radboudumc, Pro Persona
Source(s) of monetary or material Support: Radboud Centrum Sociale Wetenschappen, Radboudumc, Pro Persona

Intervention

Outcome measures

Primary outcome

The primary objective of our study is to assess mediation of MBCT-induced effects on MDD symptoms by RNT. The primary clinical endpoint thus is MDD symptoms, whereas our primary study parameter to assess mediation is RNT.
MDD symptoms will be assessed with the Inventory of depressive symptomatology (IDS) and

RNT with the brooding subscale of the Ruminative Response scale (RRS- brooding) subscale and the Pereservative Thinking Questionnaire (PTQ).

Secondary outcome

Experimental tasks:
1. The Breathing Focus Task (BFT), to measure the intrusiveness of ruminative thoughts
2. The Pavlovian to instrumental transfer (PIT) task, to measure cognitive control operationalized by behavioural inhibition invoked by negative cues.
3. The Working Memory Update/Ignore Emotion Task (WMUIET), to measure cognitive control operationalized by the capacity to inhibit or disengage from negative information in working memory.

Questionnaires:
Repetitive Negative Thinking: The Perseverative Thinking Questionnaire (PTQ; Ehring et al., 2011) is used to assess repetitive negative thinking before and after MBCT/intermediate period of 8 weeks. The PTQ consists of 15-items.

Mindfulness skills: Mindfulness skills will be assessed with the 24-item Five Facet Mindfulness Questionnaire – Short Form (FFMQ-SF; Bohlmeijer, ten Klooster, Fledderus, Veehof, & Baer, 2011). The subscale non-judging of inner experience, consisting of 6 items, is used to assess this facet of mindfulness skills during the weekly measures.

Anxiety symptoms: Anxiety symptoms will be assessed with the Spielberger State-Trait Anxiety Inventory (STAI; Spielberger, 1971).The STAI-trait scale consists of 20 items and is scored on a 4-point-lickert scale.

General well-being: The general well-being will be assessed with the Outcome Questionnaire (OQ; Lambert et al., 1996). The OQ consists of 45 items.

Self-compassion: Self-compassion will be assessed with the 12-items Self Compassion Scale-Short Form (SCS-SF; Neff, 2003; Filip Raes, Pommier, Neff, & Van Gucht, 2011).

Study description

Background summary

Depression is highly prevalent and is ranked by the WHO as the number one contributor to disability worldwide. The highly recurrent nature of the disorder contributes greatly to the burden of Major Depressive Disorder (MDD) and with every new depressive episode, outcome prospective worsen. Mindfulness Based Cognitive Therapy (MBCT) is an effective treatment to reduce relapse rates and (residual) symptoms that contribute to recurrence in MDD. However, the mechanisms underlying this MBCT-induced effect are far from clear.
Elucidating these mechanisms will provide insight in the existing individual differences in

effectiveness of MBCT. Consequently, this insight will help to improve effectiveness of treatment and possibly even personalize treatment regimes.
One likely candidate that could play a major role in the positive effects of MBCT on depressive symptoms, is repetitive negative thinking (RNT or depressive rumination). Here, we will investigate individual levels of RNT before, during and after MBCT by using a selfreport questionnaire. We will use this information to assess whether MBCT reduces MDD symptoms through its effect on RNT. In other words, we will assess whether RNT mediates the effect of MBCT on MDD symptoms. In addition, we will assess whether pre-treatment levels of RNT on the individual level, predict treatment outcome. Thus, we ask whether baseline levels of RNT moderate the effect of MBCT on an individual level.
Thus, we will assess the mediating and moderating role of RNT in the effect of MBCT on MDD.
In addition (secondary), we will explore which exact processes of RNT are altered by MBCT and when this change occurs. Therefore, we will ask participants to fill in short-self report measures after each session of MBCT. This will give us information about the temporal order of change in RNT and depressive symptoms. However, self-report questionnaires can only provide limited information. We will therefore also use experimental tasks to further investigate the exact processes of RNT that are modified by MBCT. First of all, we will use a behavioural task (breathing focus task) to assess the repetitive nature of ruminative thoughts.
Furthermore, we will focus on important aspects of cognitive control putatively related to RNT. We will measure emotional working memory processing and behavioural inhibition, before and after MBCT with two innovative behavioural tasks. We will use this behavioural data to assess whether emotional working memory and inhibition are indeed (1) related to RNT and MDD, (2) are changed by MBCT and (3) whether these changes are indeed related to clinical effects of MBCT.
In toto, these findings will shed light on the psychological and cognitive working mechanisms through which MBCT sorts its clinical effect.

Our objectives thereby are the following:
1. Replicate beneficial effects of MBCT on depressive symptoms and RNT in patients with recurrent or chronic major depression.
2. Test moderating and mediating effects of RNT:
2.1.1. Does rumination mediate the effect of MBCT on depressive symptoms in recurrent depressed and chronic depressed patients?
2.1.2. Does RNT at baseline moderate the effect of MBCT versus treatment as usual on depressive symptoms in patients with moderate to severe depressive symptoms?
3. Assess the influence of MBCT on a behavioural measure of RNT focused on the intrusiveness of negative thoughts (breathing focus task).
4. Explore the timing of change in RNT during MBCT by using repeated self-report measures after each session of MBCT.
5. Assess the relation between cognitive control (operationalized by working memory and inhibition) on the one hand and RNT and depressive symptoms on the other.
6. Assess whether MBCT changes cognitive control in patients with crMDD.
7. Assess whether (changes in) cognitive control moderate and/or mediate the effect of MBCT on depressive symptoms.

Study design: Controlled trial with sampling based on date of regular clinical assessment procedure and start of treatment groups: Patients with crMDD will get assigned to one of two groups, based on the date of intake. Group 1 will perform measurements once before, during and once after MBCT treatment, whereas group 2 will perform measurements once before, once during and once after an 8 weeks waiting period. Group 2 will receive MBCT after this waiting period, where they will also have measurements during and once after the MBCT. Note that with this procedure we do not interfere with current clinical practice, i.e. if patients have to wait > 2 months for the next MBCT group they will be invited to participate in group 2,
if they have to wait < 2 months they will be allocated to group 1.

Additionally, healthy controls will be tested, necessary for benchmarking the innovative cognitive control tasks.

Study objective

Primary hypothesis:
The effects of MBCT on depressive symptoms will be mediated by RNT in patients following MBCT compared with waitlist

Study design

Group 1: Baseline, weekly measures after each MBCT session, halfway trough MBCT, after completing MBCT
Group 2: Baseline, halfway trough TAU/waitlist, after TAU/waitlist, weekly measures during TAU/waitlist and after each MBCT session, halfway through MBCT, after MBCT

Intervention

Participants will follow Mindfulness based cognitive therapy (MBCT). MBCT is a group program that teaches formal and informal mindfulness practices. It is an 8-week program of weekly sessions of two and a half-hour with one full retreat day (6 hours), and daily home practice (about 45 min/day). Core components include practices of the body
scan, sitting meditation, walking meditation and mindful movement. It has an attitudinal framework of kindness, curiosity and willingness to be present, which are embodied in the teacher.

Contacts

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Eligibility criteria

Inclusion criteria

• Age: 18+ years old
• Chronic or recurrent MDD diagnosis, both with current episode or in remission
• Able to give informed consent

Exclusion criteria

• In remission of first (not chronic) depressive episode
• Impossibility to obtain a valid informed consent
• Insufficient comprehension of the Dutch language
• Physical, cognitive, or intellectual impairments interfering with participation, such as
• deafness, blindness, or sensorimotor handicaps
• Formerly/currently involved in MBCT or MBSR training
• Meets criteria for bipolar disorder, schizophrenia, schizophreniform disorder,
• schizoaffective illness or anorexia nervosa.
• Current psychosis
• High level of suicidality
• Drug or alcohol addiction in the past 6 months

Study design

Design

Study type:	Observational non invasive
Intervention model:	Parallel
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	24-06-2019
Enrollment:	200
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Positive opinion

Date:	24-06-2019
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 50017
Bron: ToetsingOnline
Titel:

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

No registrations found.

In other registers

Register	ID
NTR-new	NL7842
CCMO	NL68398.091.18
OMON	NL-OMON50017

Study results