Cognition in Mindfulness: Negativity and Depression

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

Ethische beoordeling	Positief advies
Status	Werving gestart
Type aandoening	-
Onderzoekstype	Observationeel onderzoek, zonder invasieve metingen

Samenvatting

ID

NL-OMON24838

Bron
NTR

Verkorte titel
CogMIND

Aandoening

Major depression

Ondersteuning

Primaire sponsor: Radboudumc, Pro Persona
Overige ondersteuning: Radboud Centrum Sociale Wetenschappen, Radboudumc, Pro Persona

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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).

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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

Onderzoeksopzet

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

Onderzoeksproduct en/of interventie

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.

Contactpersonen

Publiek

Pro Persona
Mira Cladder-Micus

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

• 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

Onderzoeksopzet

Opzet

Type:	Observationeel onderzoek, zonder invasieve metingen
Onderzoeksmodel:	Parallel
Toewijzing:	Niet-gerandomiseerd
Blindering:	Open / niet geblindeerd
Controle:	Geneesmiddel

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	24-06-2019
Aantal proefpersonen:	200
Type:	Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nog niet bepaald

Ethische beoordeling

Positief advies

Datum:	24-06-2019
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 50017
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

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

Resultaten