Cognition in Mindfulness: Negativity and Depression

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Mood disorders and disturbances NEC
Study type	Observational invasive

Summary

ID

NL-OMON50017

Source
ToetsingOnline

Brief title
CogMiND

Condition

- Mood disorders and disturbances NEC

Synonym
depression; major depressive disorder

Research involving
Human

Sponsors and support

Primary sponsor: Radboud Universitair Medisch Centrum
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: depression, mindfulness, negativity, rumination

Outcome measures

Primary outcome

Our primary objective is to understand the role of rumination in depressive symptoms changes in chronic and recurrent MDD patients as a result of MBCT treatment. Therefore we will assess rumination and depressive symptoms repeatedly during MBCT and will investigate the effect of MBCT on a novel, on-line behavioural task of rumination, namely the Breathing Focus Task (BFT). We will also use questionnaires to assess rumination and depressive symptoms.

Secondary outcome

Our secondary aim is to elucidate the cognitive mechanisms concerning negative inhibitory processing in working memory and behaviour that possibly underlie depression and rumination and the effect of MBCT. For this, we will look at aversive PIT and evaluate its relation with depression. We will also test emotion specific working memory function and evaluate its relation with rumination. Additionally, the effect of MBCT on these parameters will be assessed.

For this we will use the Pavlovian-Instrumental Transfer (PIT) task and the Working Memory Update/Ignore Emotion Task (WMUIET), together with questionnaires and the BFT task to assess rumination.

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 in MDD. However, the mechanisms underlying this 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. We will look into two factors that are thought to be important in the effect of MBCT on depression: rumination and the processing of external negative information.

Study objective

We propose to study the role of rumination (moderation and mediation) in the effect of MBCT on depressive symptoms and risk factors for relapse in crMDD patients, by means of repeated questionnaire measures and an innovative on-line behavioral task (Breathing Focus Task) before, after and during MBCT treatment. Additionally, we will investigate the extent and role of abnormally processed negative information in crMDD patients, using two innovative, task-based neurocognitive measures both before and after treatment, focusing on negativity in working memory processing and aversive inhibition.

Thus, the objectives are to:
1. Replicate beneficial effects of MBCT on depressive symptoms, rumination and quality of life in patients with recurrent or chronic major depression.
2. Test moderating and mediating effects of rumination:
2.1.1. Does rumination on baseline moderate the effect of MBCT versus TAU on depressive symptoms in patients with moderate to severe depressive symptoms?
2.1.2. Does rumination mediate the effect of MBCT on depressive symptoms in recurrent depressed and chronic depressed patients?
3. Assess the relation between aversive inhibition and emotion-specific working memory on the one hand and rumination and depressive symptoms before MBCT on the other.
4. Assess whether MBCT changes aversive inhibition and emotion-specific working memory in patients with crMDD.
5. Assess whether (changes in) aversive inhibition and emotion specific working memory moderate and/or mediate the effect of MBCT on depressive symptoms.

Study design

Waitlist controlled trial, where division in the two groups is determined by the sign-up date for the start of the training, as usual in clinical routine.

Study burden and risks

All subjects will fill in questionnaires and perform three tasks. Patients will be divided in two groups, who both do the same tasks and questionnaires, but have a different amount of appointments:

For group 1, behavioural tasks and questionnaires will be administered at 3 moments: once before (2,5 hours), once during (50 min) and once after the MBCT (2,5 hours). In addition, short questionnaires will be filled in by the subject after each weekly MBCT session (8x 10 mins = 1 hr 20 min). This adds up to an extra time investment of 7 hours and 10 minutes for participants in group 1. Subjects in group 2 will complete the same behavioural task measurements in three appointments before MBCT (2x2,5 hours + 50 min = 5 hr 50) and will fill in the short questionnaires weekly (8x 10 mins = 1 hr 20 min) during their waiting period. During MBCT they follow the same procedure as Group 1 (8x10 min + 1x 50 min = 2 hr 10) . The measurement moment after MBCT will consist of less tasks for this group (50 mins). This adds up to 10 hr 10 min.

*Participants from ProPersona will be asked to fill in questionnaires and to perform a breathing task (BFT - see below) during their appointments. The computer tasks will not be administered. Therefore, the time investment for ProPersona participants in group 1 adds up to 3 hours 50 min and to 6 hours and 50 min in group 2.

Healthy controls will be invited to one measurement moment (3 hours) after a phone call of approximately 30 minutes, for a total of 3,5 hours.

The used questionnaires are:
• Rumination: Rumination is measured with the extended version of the Ruminative Response Scale (RRS; F. Raes & Hermans, 2007; Treynor, Gonzalez, & Nolen-Hoeksema, 2003). The total score and the 5-item subscale *brooding* (Schoofs, Hermans, & Raes, 2010) will be used.
• 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.
• Depressive symptoms: Inventory of Depressive Symptomatology Self-Report (IDS-SR; Rush, Gullion, Basco, Jarrett, & Trivedi, 1996) is a 30-items measure of depressive symptom severity. During the weekly measures the 16-item Quick Inventory of Depressive Symptomatology Self-Report (QIDS-SR) will be used.
• 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).

The tasks consist of:
• Breathing Focus Task (BFT), 20 minutes: participants are asked to focus on their breathing and to once in a while indicate whether they are focussing on their breath, or are distracted. If they are distracted, they are asked whether it is by a positive, negative or neutral thought.
• Pavlovian-Instrumental Transfer (PIT) task, 30 minutes: participants are asked to collect mushrooms on the computer, where mushrooms have either a reward or loss of money. They are asked to collect the mushroom with the reward and avoid mushrooms with a loss.
• Working Memory Update/Ignore Emotion Task (WMUIET), 40 minutes: participants are asked to remember faces that are shown on the computer screen, which either have sad or neutral facial expressions.

Contacts

Public
Radboud Universitair Medisch Centrum

Reinier Postlaan 4
Nijmegen 6500 HB
NL
Scientific
Radboud Universitair Medisch Centrum

Reinier Postlaan 4
Nijmegen 6500 HB
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

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

Exclusion criteria

• 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 invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)

Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	07-06-2019
Enrollment:	230
Type:	Actual

Ethics review

Approved WMO Date:	04-03-2019
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	16-06-2020
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

ID: 24838
Source: NTR
Title:

In other registers

Register	ID
CCMO	NL68398.091.18
Other	NL7842
OMON	NL-OMON24838