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The role of mindfulness training in reducing rumination in recurrent depression

Submission date	Recruitment status
29/06/2018	No longer recruiting
Registration date	**Overall study status**
22/11/2018	Completed
Last Edited	**Condition category**
05/02/2024	Mental and Behavioural Disorders

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[X] Results
[ ] Individual participant data

Plain English summary of protocol

Background and study aims
Depression is a prevalent and recurrent disorder. It is defined by the World Health Organization Global Burden of Disease Study as “the single most burdensome disease in the world in terms of total disability-adjusted years among people in the middle-years of life”. One well-known risk factor for depressive relapse is the tendency to ruminate, creating tenacious and automatic thoughts and feelings that patients feel little control over. Mindfulness-Based Cognitive Therapy aims to reduce ruminative tendencies in depressive patients, and is thought to have effects on cognitive and emotion regulation. The aim of this study is to investigate the effects of an 8-week mindfulness program (Mindfulness-Based Cognitive Therapy) on attention and emotional regulation abilities in patients with recurrent depression.

Who can participate?
Patients aged 18 - 70 with recurrent depression (at least three previous depressive episodes) and in full/partial remission, and healthy volunteers

What does the study involve?
Participants are randomly allocated to either receive an 8-week MBCT program or to be put on a waiting list to receive MBCT after the 8-weeks assessment. All participants are assessed before and after the intervention and at 6 months, 1 and 2 years later.

What are the possible benefits and risks of participating?
All the participants are offered MBCT. All the measurements and assessments can be tiresome for the participants and may require that they take time off from school or work. The waiting list group does not have many benefits at the start of the study and after 8 weeks. They are then only experiencing the measurements and assessments as part of investigating the effects of MBCT in the group receiving treatment. MBCT is offered to the waiting list group because of these inconveniences, both from an ethical perspective and for motivating them to not withdraw from the study.

Where is the study run from?
University of Bergen (Norway)

When is the study starting and how long is it expected to run for?
April 2016 to December 2018

Who is funding the study?
University of Bergen (Norway)

Who is the main contact?
1. Dr Elisabeth Schanche
2. Dr Lin Sørensen

Contact information

Type(s)
Public

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Scientific

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Additional identifiers

Protocol serial number
2016/388

Study information

Scientific Title
The role of Mindfulness-Based Cognitive Therapy in reducing rumination in recurrent depression: the effect on attention and emotion regulation functions

Acronym
MBCT

Study objectives
Mindfulness-Based Cognitive Therapy will be superior to a waiting-list condition in decreasing maladaptive ruminative self-generated thought processes, and in enhancing attention and emotion control processes in individuals with recurrent Major Depressive Disorder.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Regional Ethics Committee (South East), Norway, 16/03/2016, ref: 2016/388

Primary study design
Interventional

Study design
Interventional randomized controlled trial with waiting list

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Recurrent major depressive disorder

Interventions
Mindfulness-based Cognitive Therapy with waiting list control. Standard randomization, stratified for gender. Blinded assessment pre- and post intervention.

Mindfulness Based Cognitive Therapy (MBCT) is a manualized eight-week group program aimed at raising awareness of rumination thought processes in patients with recurrent depression. The basis is that relapses occur due to automatic negative self-generative thought processes hindering flexible cognitive and emotional functioning. In MBCT, mindfulness practices (i.e., meditation techniques) in combination with psychoeducation are used to break the vicious circle of rumination fueling depressive moods. The patients learn to become aware of and experience negative thoughts and feelings with an attitude of acceptance. Experiencing difficult thoughts and feelings with a non-judgmental attitude is thought to increase the individual's ability to tolerate these without automatically starting a ruminative cycle of emotional stress. The goal of increasing patients' emotional tolerance will lead to them learning to take control over their self-generative thought processes.

The experimental group will receive the MBCT intervention a short time after pre-measurements. There will be eight weekly 2 hour sessions, and in addition, one longer session lasting for six hours between session 6 and 7. Each MBCT group will consist of 8-12 participants. The theme of the first session is "Beyond Automatic Pilot". The main focus is to discover how fast attention wanders and how bringing attention to something specific affects how we perceive that object. The participants get introduced to a structured mindfulness exercise focusing on physical sensations. Each exercise is followed by an inquiry where the participants get to share what they discovered during the exercise and how they experienced it. They also get a sound recording of this exercise to practice 45 min every day at home between sessions. The theme of the second session is "Another Way of Knowing". The main focus is to discover and practice the difference between thinking about something and tuning into something directly through sense perceptions. The link between perceptions, feelings and thoughts are also

investigated. The participants are asked to continue practicing 45 min at home between each session. In addition they are asked to register one positive episode each day, and notice how they sense something positive through bodily sensations, feelings and thoughts. The theme of the third session is “Coming Home to The Present. Gathering the Scattered Mind”. The main focus is practicing discovering when the mind/attention wanders in time (to the past or to the future) and gently bring it back to the present moment. Mindfulness through physical movement is also introduced. The participants are asked to continue practicing 45 min at home between each session. In addition they are asked to register one negative episode each day, and notice how they sense something negative through bodily sensations, feelings and thoughts. The theme of the forth session is “Recognizing Aversion”. The main focus is an exploration of how we can react to unpleasant and uncomfortable feelings in many different ways. The session also includes a practice where the goal is to create a breathing space between reaction and action, and thus breaks habitual patterns of reacting (that contributes to rumination and depressive spirals). The participants are asked to continue practicing 45 min at home between each session. In addition they are asked to practice this breathing space three times a day, in order to start making a new habit. The theme of the fifth session is “Allowing Things to Be as They Already Are”. The main focus is practicing noticing physical sensations, feelings and thoughts without trying to get rid of them or change them in any way. Through meeting own experience with accept and interest, the goal is to discover that unpleasant feelings pass of their own accord if we do not force them and that there is a kind of peace and contentment we can experience even in the presence of unpleasant feelings. The participants are asked to continue practicing 45 min at home between each session. The theme of the sixth session is “Seeing Thoughts as Thoughts”. The main focus is practicing how our minds are constantly working to make meaning of what comes to us through our senses often based on a few scraps of information. Through mindfulness exercises oriented towards thoughts, the participants can discover how we often end up adding extra to the information we receive, and that, through mindfulness, it is possible to return to our present moment sensations. The participants are asked to continue practicing 45 min at home between each session. Between the sixth and seventh session, there is a whole day of practice, lasting for 6 hours. The main intention this day, is to give the participants a chance to deepen their practice through continuous exercises. The whole day also includes experiences with silence over time, and eating a meal with mindful attention. The theme of the seventh session is “Kindness in Action”. The main focus is to explore how it is possible to change what you feel by changing what you do. The participants spend time reflecting and discussing what type of activities gives them energy or a sense of mastery. They also prepare an action plan to utilize when they notice first signs of a new depressive episode. The participants are asked to continue practicing 45 min at home between each session. The theme of the eighth session is “What Now?” The main focus of this session is to prepare for continued mindfulness practice after the course. The message that is communicated to the participants is that mindfulness is a quality of attention that needs to be continually strengthened. The participants reflect and discuss their intention in continuing this type of training and what might be potential challenges preventing them to do so. The session ends with giving the participants tips for mindfulness practices outside the course and a list of resources they can use in their continued practice.

The waiting list control arm will wait for the MBCT intervention. Participants within this arm will receive the MBCT intervention after all post-measures are collected from the experimental group.

Intervention Type
Behavioural

Primary outcome(s)

Attention regulation processes will be the primary outcome measures. Intra-individual variability in reaction times and default mode activity during cognitive control processing will be used as measures of attentional lapses. Attentional lapses and cognitive control will be measured with performance based test measures. In a subsample brain activation will be measured using functional Magnetic Resonance Imaging (fMRI). Further, self-reported questionnaire data will be applied to measure the degree of ruminative thought (RRQ), and the correlation between intra-individual variance of reaction times, Default Mode activity and ruminative thought processes. Heart Rate Variability (HRV) will be used as a psychophysiological measure of cognitive control.

All the outcome measures are administered at baseline and at 8 weeks following post treatment. The primary outcome of level of rumination (RRQ) is also measured after 6 months, 1, and 2 years.

Key secondary outcome(s)
1. Facets of mindfulness, emotion regulation, self-compassion, attachment, childhood trauma, personality traits, depression and anxiety symptoms, and early attention processing
2. Emotion regulation and self-compassion measured with self-report, qualitative interviews, emotion recognition task, and with HRV
3. Early attachment with significant others, traumatic childhood experiences, and personality traits measured with self-reports, and outcome of MBCT measured with change scores in depressive symptoms and in mindfulness facets from pre- to post-intervention
4. Early attention processing measured with cue conditions during cognitive control processing (the Attention Network Test Revised Version)
5. Basic abilities such as intelligence (assessed with Wechler Abbreviated Scale of Intelligence) and processing speed (assessed with trail making test)

All the outcome measures are administered at baseline and at 8 weeks following post treatment. After 6 months, 1, and 2 years, selected outcome measures are administered. This includes the primary outcome of level of rumination (RRQ) together with relapse of depressive episodes. Further, the participants also fill out the following self-report questionnaires:
1. Depressive symptoms, measured with Beck Depression Inventory (BDI)
2. Anxiety, measured with Beck Anxiety Inventory (BAI)
3. Difficulties with emotion regulation, measured with Difficulties in Emotion Regulation Scale (DERS)
4. Self-compassion, measured with Self-Compassion Scale (SCS)
5. Mindfulness, measured with the Five Facet Mindfulness Questionnaire (FFMQ)

Completion date
31/12/2018

Eligibility

Key inclusion criteria
Clinical group:
1. Age: 18 - 70 years old
2. Both genders
3. At least three previous depressive episodes, and to currently fulfill the diagnostic criteria for recurrent depression, and in full/partial remission from depression
4. Patients may continue on antidepressant while participating in the study. It is, however, important that they do not discontinue or change dosage of medication while receiving the interventions of MBCT

5. No current neurological, cardiac or hormonal diseases
6. Borderline Personality Disorder (as assessed by SCID-II)

Healthy control group:
1. Age: 18-70 years old
2. No current or prior psychiatric illness (as indicated by M.I.N.I.)
3. No current neurological, cardiac or hormonal diseases

Participant type(s)
Mixed

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 Years

Upper age limit
70 Years

Sex
All

Total final enrolment
68

Key exclusion criteria
1. Acute suicidal danger, a lifetime history of psychosis/schizophrenia, bipolar disorder, substance use disorders
2. Ongoing or mindfulness based treatment past 2 years
3. Ongoing psychotherapy
4. Pregnant/lactating

Date of first enrolment
01/05/2016

Date of final enrolment
30/08/2018

Locations

Countries of recruitment
Norway

Study participating centre

University of Bergen
Faculty of Psychology
Christiesgate 12
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Sponsor information

Organisation
University of Bergen

ROR
https://ror.org/03zga2b32

Funder(s)

Funder type
University/education

Funder Name
Universitetet i Bergen

Alternative Name(s)
University of Bergen, University of Bergen, Norway, Universitas Bergensis, UiB

Funding Body Type
Government organisation

Funding Body Subtype
Universities (academic only)

Location
Norway

Funder Name
Helse Vest Regionalt Helseføretak

Alternative Name(s)
Western Norway Regional Health Authority, Helse Vest RHF

Funding Body Type

Government organisation

Funding Body Subtype
Local government

Location
Norway

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are not expected to be made available.

IPD sharing plan summary
Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	05/06/2020	08/06/2020	Yes	No
Other publications		18/10/2019	03/01/2023	Yes	No
Other publications		07/03/2022	03/01/2023	Yes	No
Other publications	Secondary analyses	19/01/2024	05/02/2024	Yes	No
Study website	Study website	11/11/2025	11/11/2025	No	Yes