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The Icelandic depression vulnerability and mindfulness study: A randomized controlled trial

Submission date
13/02/2018

Recruitment status
No longer recruiting

Registration date
19/02/2018

Overall study status
Completed

Last Edited
01/07/2020

Condition category
Mental and Behavioural Disorders

[X] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
Major Depressive Disorder (MDD) is a prevalent and troubling episodic condition that is difficult both for patients and for society as a whole. MDD is one of the largest threats to health in the world, imposing challenges for health care providers to treat and researchers to understand. Risk factors for recurrence have been identified but are hard to modify and therefore have limited clinical impact. Identifying vulnerabilities that can be shaped is needed to inform development of more effective treatments and prevention strategies. Despite almost 25 years of research into these two constructs in clinical psychology, there are still important issues to be raised. Mindfulness Based Cognitive Therapy could be used a treatment for MDD The aim of this study is to increase our understanding of the functioning and role of two established cognitive vulnerabilities and to evaluate the impact of MBCT may have on cognitive vulnerabilities to depression.

Who can participate?
Adults aged 18 to 65 years old who have a history of MDD.

What does the study involve?
Participants are randomly allocated to one of two groups. Those in the first group receive eight weekly sessions of MBCT. Those in the second group are put on the no-treatment waiting-list. Cognitive vulnerabilities and related constructs are assessed before and after treatment/waiting period, to evaluate the influence MBCT may have on cognitive vulnerabilities to depression. Participants on a waiting-list also receive MBCT after the waiting period in order to assess the relationship between changes in cognitive vulnerabilities following MBCT treatment and risk of relapse or recurrence of major depression episodes one and two years following treatment completion.

What are the possible benefits and risks of participating?
Participants may benefit from the treatment. Benefits may include reduced risk of depression reoccurrence given results from previous studies of MBCT in previously depressed samples. There are no direct risks for those taking part in the study.

Where is the study run from?
University of Iceland (Iceland)

When is the study starting and how long is it expected to run for?
September 2016 to August 2022

Who is funding the study?
1. Icelandic Research Fund (IRF) (Iceland)
2. Heilsugæslan (Primary Health Care of the Capital Area in Iceland) (Iceland)

Who is the main contact?
Dr Ragnar Ólafsson (Scientific)
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
173803-051

Study information

Scientific Title

Vulnerability to recurrent depression: Reactivity, content and habitual characteristics of dynamic cognitive processes and the effect of MBCT on their functioning

Acronym
DVM-Ice

Study objectives
The following hypotheses will be tested in a group of participants with previous history of depression episodes (recurrent major depression):
1. Compared to a wait-list control condition (WL), Mindfulness-Based Cognitive Therapy (MBCT) prevention to depression relapse, will lead to greater reductions on measures of cognitive reactivity and depressive rumination (i.e. measures of cognitive vulnerabilities to depression).
2. Compared to WL, MBCT will lead to greater reductions on measures of habitual characteristics of negative and ruminative thoughts.
3. Greater reductions on measures of cognitive vulnerabilities (cognitive reactivity, depressive rumination) and habitual characteristics of negative thoughts following MBCT, will reduce risk of relapse to major depression over a 2 year follow-up period.

Ethics approval required
Old ethics approval format

Ethics approval(s)
The Icelandic National Bioethics Committee, 05/12/2017, ref:17-235

Study design
Randomized controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Other

Study type(s)
Prevention

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied
Recurrent major depression

Interventions
Participants are randomised to an 8 week Mindfulness-Based Cognitive Therapy group prevention strategy for depressive episodes (MBCT) or a no-treatment waiting-list for the same duration.

Block randomisation (block size 4) is used to randomly allocate participants (in a 1:1 ratio) to either study group using computer-generated random numbers. Randomisation is stratified according to current use of antidepressant medication (yes; no) and symptom status at intake using the Beck Depression Inventory – II (asymptomatic = 0-13; partially symptomatic = 14-19). The MBCT treatment consists of eight weekly 2-hour-long group sessions with 10 to 14 participants in each group. The treatment is delivered following the treatment protocol of Segal et al. (2002). Session content includes guided mindfulness practices (i.e. body scan, sitting meditation, yoga), enquiring into participants´ experiences of these practices, review of homework, and teaching/discussion of cognitive-behavioural skills. In line with the previous MBCT trials, an adequate dose of MBCT is defined as participation in at least four of the eight MBCT group sessions. All group sessions are led by a licensed clinical psychologist with extensive experience in providing MBCT. No intervention is delivered to participants in the wait-list condition during the 8 week waiting period but will receive MBCT after this period. All particpants in the study are followed for 2 years to monitor depression recurrence. This is achieved through visits to researchers 12 and 24 months after treatment ended where mental status and history is assessed along with other outcomes and processes measured in the study.

Added 01/07/2020:
Our aim was to run Mindfulness-Based Cognitive Therapy in groups of 10 to 14 participants, as stated in the description of the intervention. However, actual group sizes vary from 7 to 14 participants. In addition to this, one group included 5 participants. Participants in this group entered the trial at the start of the COVID-19 pandemic (along with 10 participants randomly assigned to the wait-list condition) and received the first two MBCT sessions in a face-to-face group setting according to protocol. However, because of restrictions posed in March 2020 by Icelandic authorities, and with participant‘s safety in mind, the remaining six sessions of the treatment in this group, were provided through the internet using a web-based meeting software, that patients could sit in on from their homes. Treatment delivery followed the MBCT manual in these sessions, as in all other sessions in the trial.

Intervention Type
Behavioural

Primary outcome measure
1. Cognitive reactivity is measured at pre/post treatment, and 1 and 2 year follow-up using:
1.1. Leiden Index of Depression Sensitivity-Revised (LEIDS-R)
1.2. Mood-linked changes in dysfunctional attitudes that are measured with the Dysfunctional Attitudes Scales (DAS); added 19/08/2019: only measured at pre/post treatment
1.3. Repeated assessment of negative thoughts during a 6 day experience sampling period via smartphone
2. Depressive rumination is measured pre/post treatment, and at 1 and 2 year follow-up:
2.1. The brooding and reflective pondering scales of the Ruminative Responses Scales (RRS).
2.2. Rumination Induction task following mood-induction; added 19/08/2019: only measured at pre/post treatment
2.3. Repeated assessment of ruminative thinking during a 6 day experience sampling period via smart-phone 3. Habitual characteristics of negative and ruminative thoughts are measured pre /post treatment, and at 1 and 2 year follow-up using:
3.1. Habit Index of Negative Thinking (HINT) that measures habitual characteristics of negative thoughts.
3.2. Repeated assessment of habitual characteristics of negative and ruminative thinking during a 6 day experience sampling period via smartphone
4. Relapse or recurrence of major depression episodes are assessed with the MINI 5.0 (according

to the DSM-IV criteria) that is a semi-structured clinical interview (including additional questions on age of onset, time of episodes) as well as the second version of the Beck Depression Inventory measured pre/post treatment, and at 1 and 2 year follow-up

Secondary outcome measures
Measures relevant to depression risk and/or relapse/recurrence are assessed and are used to examine mediation and moderation of treatment outcome. The following measures are used (including assessment points):
1. Kentucky Inventory of Mindfulness Skills (KIMS) that measures four different facets of mindfulness skills (assessed at pre/post treatment, 1 and 2 year follow-up)
2. The Self-Compassion Scale (SCS) that measures self-kindness, self-judgement and common humanity and has been used in previous MBCT studies (assessed at pre/post treatment, 1 and 2 year follow-up)
3. Treatment history will be assessed in a short interview constructed by researchers. Questions focus on participants' history of cognitive behavioural therapy and pharmacotherapy with anti-depressives (assessed at pre/post treatment, 1 and 2 year follow-up)
4. The Snaith-Hamilton Pleasure Scale (SHAPS) will be used to measure anhedonia (assessed at pre/post treatment, 1 and 2 year follow-up)
5. The Positive and Negative Affect Scale (PANAS) will be used to measure state negative and positive affect (assessed at pre/post treatment, 1 and 2 year follow-up)
6. The Beck Anxiety Inventory (BAI) will be used to measure severity of symptoms of anxiety (assessed at pre/post treatment, 1 and 2 year follow-up)
7. The creature of Habit Scale (COHS) will be used to assess respondent's general tendency to habitual behaviours (assessed at pre treatment)
8. The Fabolous Fruit Game (FFG) is a computerised outcome-devaluation tasks that taps peoples ability to alter behaviour when an outcome's value changes. The task measures goal-directed vs. habit-related behaviour control (assessed at pre treatment).
9. The Childhood Traumatic Event Scale (TES) is a self-report questionnaire and is used to assess history of traumatic events (assessed at pre treatment)
10. The Difficulties in Emotion Regulation Scale (DERS) and Emotion Reactivity Scale (ERS) will be used to measure emotion regulation ability and emotional reactivity (assessed at pre treatment)
11. The Depression Stigma Scale (DSS) will be used to measure peoples stigma associated with depression (assessed at pre treatment)
12. Daily mood ratings during a six-day experience sampling period via smart-phones (assessed at pre/post treatment, 1 and 2 year follow-up)

Overall study start date
01/09/2016

Completion date
01/08/2022

Eligibility

Key inclusion criteria
1. Participants have to be between 18 and 65 years of age at study entry
2. History of 3 or more major depressive episode (according to the DSM-IV diagnostic criteria evaluated in the MINI diagnostic interview) with, at least, two episodes within the last five years

of which one must have occurred within the last two years
3. There are at least 2 months since the last depressive episode ended
4. Giving informed consent

Participant type(s)
Other

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
100

Total final enrolment
103

Key exclusion criteria
1. Current major depressive episode
2. Moderate or severe depression symptoms (a score >19 on the Beck Depression Inventory - II)
3. Unstable anti-depressive medication treatment during past 8 weeks and/or changes to current treatment planned or anticipated during the next four months
4. Psychotherapy targeting depression, current or during the past month and/or participation in psychotherapy targeting depression scheduled during the next four months
5. Practices mediation and/or yoga on a regular basis
6. Current or past manic or hypomanic episodes
7. Current or past psychotic disorder
8. Presence of substance abuse within last 12 months
9. Presence of active and serious suicidal thoughts
10. Inability to complete baseline assessment (e.g. due to language or cognitive difficulties)

Date of first enrolment
20/02/2018

Date of final enrolment
01/05/2020

Locations

Countries of recruitment
Iceland

Study participating centre

University of Iceland
Sæmundargata 2
Reykjavík
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101

Study participating centre
Heilsugæslan (Primary Health Care of the Capital Area in Iceland)
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Sponsor information

Organisation
The National Bioethics Committee

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Sponsor type
Government

Funder(s)

Funder type
Research organisation

Funder Name
The Icelandic Research Fund

Funder Name
University of Iceland

Results and Publications

Publication and dissemination plan
Our aim is to publish the results in high-impact peer reviewed journals. Our plan is to publish results comparing the differential influence of MBCT vs. Wait-list on measures of cognitive vulnerabilities in 2019 and to publish results on the relationship between changes in cognitive vulnerabilities and risk of depression relapse/recurrence over a 2 year follow-up period in 2021.

Additional documents (e.g. protocol, statistical analysis plan) have not been published. Our plan is to make these documents available in some way, when ready for publication, either as PDF documents on the ISRCTN website, or as manuscripts submitted for publication.

Updated 19/08/2019:
The date of the first publication is estimated 02/01/2021and reports results of the tests of hypotheses 1 and 2. Date of a publication describing results testing hypothesis 3 is estimated 02 /01/2023.

Intention to publish date
02/01/2021

Individual participant data (IPD) sharing plan
Our current position is that our data sharing plans for the current study are unknown and will be made available at a later date.

IPD sharing plan summary
Data sharing statement to be made available at a later date