Understanding mechanisms of prevention of depression: a mechanistic cross-over trial of mindfulness vs. fantasizing to reduce perseverative cognition underlying vulnerability for depression

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Ethical review	Approved WMO
Status	Recruiting
Health condition type	Mood disorders and disturbances NEC
Study type	Interventional

Summary

ID

NL-OMON52825

Source
ToetsingOnline

Brief title
MINDCOG

Condition

- Mood disorders and disturbances NEC

Synonym
depression, Major Depressive Disorder

Research involving

Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Groningen
Source(s) of monetary or material Support: Ministerie van OC&W,NWA Idea Generator Grant

Intervention

Keyword: cognitive (neuro)science, Major Depressive Disorder, perseverative cognition, therapeutic mechanisms

Outcome measures

Primary outcome

The main study parameters of study 1 and 2 concern: i) indices of PC, namely daily fluctuations in self-reported PC (using ESM), reported PC during an experimental task (using SART), physiological correlates of PC (using HR/HRV) and electrophysiological correlates of PC (using EEG). The endpoint of study 1 is within-subject (fantasizing vs. mindfulness) differences in the extent to which PC changes pre- and peri-intervention performance of the interventions as measured with the main study parameters. The endpoint of study 2 is between-group (remitted MDD vs. HC) differences in the extent to which PC changes pre- and peri-intervention performance of the interventions as measured with the main study parameters. The main study parameters of study 3 concern measures of potential individual treatment markers (e.g. PC characteristics, physiological characteristics, personality). The endpoint of study 3 is the correlation between pre-intervention individual characteristics and the efficacy of mindfulness and fantasizing.

Secondary outcome

Secondary parameters of study 1 concern: i) measures of depressive symptoms and other factors that are potent in being influenced by the interventions (measures with self-report questionnaires: IDS-SR [depressive symptomology], FFMQ [mindfulness], PANAS [positive and negative affect states], LARSS [ruminative thinking on sadness], ERQ [emotion regulation strategies], RPA-NL [ruminative thought in response to positive affect], PTQ [perseverative thinking]) and ii) actigraphy measures reflecting sleep patterns and iii) indices of PC as measured with self-report questions (during SART tasks and ESM), EEG and ICG/ECG (during the SART and emotion regulation).

Study description

Background summary

Major Depressive Disorder (MDD) is the most prevalent psychiatric disorder with high relapse rates. Given its high personal and economic burden, it is key to develop strategies to prevent relapse. Crucial factors underlying relapse are persistent negative thinking and rumination (i.e. perseverative cognition [PC]). PC is also common in individuals never affected by depression. Though, PC is more negative and persistent in nature in individuals familiar with depressive episodes. Targeting those maladaptive thought processes in the remitted phase of depression is a potentially powerful strategy for preventing relapse. Two psychological intervention techniques, namely positive fantasizing and mindfulness have proven potent in affecting PC. However, they may exert their effects through different mechanisms, making one strategy more effective for some persons than others. Positive fantasizing, a core component of Preventive Cognitive Therapy that has been shown effective in lowering relapse risk, focuses on enhancing positive attitudes by future-related thinking. Mindfulness, that in the context of Mindfulness Based Cognitive Therapy was effective in lowering relapse risk, in contrast does not cultivate any particular belief but rather changes individuals* attitudes towards their thoughts. Whether these techniques have dissociable mechanisms of affecting PC, are differentially effective in individuals at risk for depressive relapse vs. healthy controls and to which extent effectiveness of these techniques for lowering relapse risk depends on individual PC characteristic, is unknown. Unraveling the underlying differential mechanisms instead of accepting its

evidence-based effectiveness allows further theorizing about what interventions are most useful for which individuals in reducing depressive relapse. To examine these issues, this protocol presents three different studies, investigating the working mechanisms by which specific techniques affect PC.

Study objective

The main objective of study 1 is to test whether psychological and psychophysiological indices of PC are differentially affected by fantasizing vs. mindfulness in a cross-over design in 50 remitted MDD patients vulnerable for depressive relapse. The main objective of study 2 is to test whether mechanisms of change, by which fantasizing and mindfulness affect PC, differ between remitted MDD patients vs. healthy controls (HC). The main objective of study 3 is to explore the value of individual characteristics associated with the effectiveness of interventions in reducing PC (i.e. what works for whom) in a mixed group of both remitted MDD patients and HC.

Study design

A cross-over design will be used comparing measures before and during both a mindfulness- and a positive fantasizing intervention period in individuals who remitted from two major depressive episodes (i.e. remitted MDD patients) and a HC group. After checking for eligibility of the participants, participants will fill-out several questionnaires about their personal characteristics, experiences and expectations. These questionnaires will be used to study individual characteristics that could serve as treatment markers predicting the effectivity of interventions. Furthermore, diary measures of thought patterns (experience sampling method [ESM]), behavioural measures (using the Sustained Attention to Response Task [SART]), actigraphy, (neuro)physiological measures (impedance cardiography [ICG], electrocardiography [ECG] and electroencephalogram [EEG]) and measures of depressive mood (self-report questionnaires) will be performed during the week before (pre-) the interventions and the week during (peri-) performance of the interventions. In-between pre-and peri-intervention measures, there is a one month wash-out period. The order of the interventions will be counterbalanced across participants. Pre- and peri-intervention measures will be compared to study intervention effects in remitted MDD patients (study 1), remitted MDD patients vs. healthy controls (study 2) and in relation with individual characteristics (study 3).

Intervention

All participants will receive two interventions, a mindfulness intervention and a positive fantasizing intervention. For both interventions, participants will first receive a professional training from an expert to get familiar with the technique. After the professional training, participants will perform one

exercise for 5-10 minutes per day, using the intervention technique guided by an application on their smartphone.

Study burden and risks

First, screening interviews take place to assess current and past psychopathology and relevant other health issues, and participants are asked to fill-out questionnaires to check for their eligibility for participation. This screening session will take approximately 120 minutes. After checking for eligibility and study inclusion, included participants will fill-out several questionnaires (at home) about their personality, characteristics, feelings, childhood experiences and expectations about the study and the two interventions. Filling out these questionnaires will take approximately 65 minutes. Next, four measurement blocks of one week, namely pre-intervention measurement #1, peri-intervention measurement #1, pre-intervention measurement #2 and peri-intervention measurement #2, will be performed. The same measures will be performed in all blocks, which allows to compare pre- and peri-intervention measures. During the peri-intervention blocks, the participants will practice daily with either mindfulness or fantasizing for 10 minutes per day. The order of the interventions will be pseudo-randomized. In between peri-intervention measurement #1 and pre-intervention measurements #2, a washout period of one month with no measurements or exercises will take place.

Participants will be instructed about the measurements at the UMCG or online and start the measurements from home.

In 'MINDCOG full', pre-and peri-measurements include one week daily ambulatory ESM questions (10x5 min per day for 7 days), daily performance of a short behavioural task (2x5 min per day for 7 days), ambulatory actigraphy measurements, followed by 24-hours at-home ICG/ECG measurements, questionnaires about depressive symptoms and EEG measures while performing an attention task and an emotion regulation task in the lab on the 7th day (2,5 hours).

In 'MINDCOG online', pre-and peri-measurements include one week daily ambulatory ESM questions (10x5 min per day for 7 days), daily performance of a short behavioural task (2x5 min per day for 7 days) and questionnaires about depressive symptoms (50 min). These measurements will be performed from home.

At the start of the peri-intervention measurements, participants will receive a professional training (2 hours) about the respective intervention. The training will be followed by performing short exercises at home using an application on their smartphone (one exercise of 10 min per day, for 6 days) while performing measurements.

In total, in 'MINDCOG full' the measurements include four times 2,5 hours in the lab and 60 minutes daily measures using the mobile application, for four weeks. In 'MINDCOG online' the measurements include 60 minutes daily measures

using the mobile application for four weeks in total and four times filling out questionnaires about depressive symptoms which takes around 50 min each time.

All measurements are non-invasive and therefore bear no risk for the participants. No disadvantages regarding interventions or measurements are known or expected. Participants may benefit from participation in the study as the interventions may reduce their negative, ruminative thought patterns. In 'MINDCOG full', participants will receive a compensation of ¤80,- (¤20,- per experimental lab visit) and a personal report with their personal data including their rumination reports (as obtained via ESM). Participants will be compensated for travel expenses incurred for the lab visits. In 'MINDCOG online', participants will receive a compensation of ¤40,- (¤20,- per measurement period) and a personal report with their personal data.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)

Inclusion criteria

All participants will be between 18 and 60 years of age. Participating patients will have experienced at least two major depressive episodes (experienced in the past ten years) and are in (partial or complete) remission from a depressive episode (for more than 2 months).

Exclusion criteria

Participants should not have any current DSM-5 diagnoses, should currently not use anti-depressant medication (i.e. >4 weeks) have not received protocolized preventive cognitive therapy for their last episode or have recent (daily practice) experiences with mindfulness. Healthy participants should furthermore show no life-time psychopathology.

Study design

Design

Study type:	Interventional
Intervention model:	Crossover
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Prevention

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	19-06-2020
Enrollment:	100
Type:	Actual

Ethics review

Approved WMO Date:	12-02-2020
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	18-11-2020
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	09-05-2022
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	19-11-2024
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

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

No registrations found.

In other registers

Register	ID
CCMO	NL71566.042.19