Predicting and Understanding Depression Prevention Techniques: a mechanistic cross-over trial of mindfulness vs. fantasizing to reduce vulnerability for depression

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON22588

Source
NTR

Brief title
MINDCOG

Health condition

major depressive disorder

Sponsors and support

Primary sponsor: University Medical Center Groningen
Source(s) of monetary or material Support: Nationale Wetenschapsagenda - Idea Generator (NWA.1228.191.473)

Intervention

Outcome measures

Primary outcome

Main endpoint: Pre- and peri-intervention changes between-groups (MDD vs. HC) and within-subjects (mindfulness vs. fantasizing) in 1) self-reported measures of PC measured with ESM and the SART; 2) HR, HRV and PEP during reported PC and sleep; 3) EEG characteristics during PC measured with the SART.

Main endpoint: Correlations between individual differences in pre-intervention measures of personal characteristics (i.e. pre-intervention main parameters) and the efficacy of mindfulness vs. fantasizing (i.e. changes in pre- and peri-intervention main parameters).

Secondary outcome

Secondary parameters concern: i) measures of depressive symptoms and other factors that are potent in being influenced by the interventions (measured 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]; see 6.3.5 Pre- and peri-intervention measurements materials [T1-T4]); ii) actigraphy measures reflecting sleep patterns and iii) indices of PC as measured with self-report questions, EEG and ICG/ECG (see 6.3.5 Pre- and peri-intervention measurements materials [T1-T4]). These parameters are measured pre- and peri-interventions and will be compared to study intervention effects.

Study description

Background summary

Rationale:
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]). Targeting those maladaptive thought processes in the remitted phase 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 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, and to which extent effectiveness of these techniques for lowering relapse risk depends on individual PC characteristics, 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.

Objective:
Our aim is to provide detailed and mechanistic insight in how thinking-targeted psychotherapeutic interventions affect PC. The main objectives are to i) test whether psychological and psychophysiological indices of PC are differentially affected by fantasizing vs. mindfulness in remitted MDD patients and healthy controls (HC) in a cross-over design, and to ii) identify individual characteristics that may predict effectiveness of interventions in reducing PC (i.e. what works for whom).

Study design:
A cross-over design will be used including comparing pre-and peri-intervention measures before and during both a mindfulness intervention and a positive fantasizing intervention 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 potent as treatment markers predicting the effectivity of interventions. Furthermore, diary measures of thought patterns (experience sampling method [ESM]), behavioural measures, 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.
Study population: In total 50 remitted MDD patients and 50 HC participants will be included. HC will be matched to the remitted MDD patients by age, sex and education level. All participants will be between 18 and 60 years of age. Remitted MDD patients will have experienced at least two major depressive episodes (experienced in the past ten years), are in (partial or complete) remission from a depressive episode (for > 2 months), are currently (i.e. >4 weeks) free of anti-depressant medication and have not received protocolized preventive cognitive therapy for their last episode or have recent (i.e. daily practice) experiences with mindfulness.

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.
Main study parameters/endpoints: The main study parameters concern: i) indices of PC measured with self-report questionnaires, behavioural tasks, ICG/ECG and EEG, and ii)

measures of potential individual treatment markers (questionnaires about individual characteristics and pre-intervention characteristics). Pre-intervention measurements and changes herein during mindfulness and fantasizing will be investigated between-groups (MDD vs. HC), within-subjects (mindfulness vs. fantasizing) and between-subjects in relationship with individual treatment markers.
Nature and extent of the burden and risks associated with participation, benefit and group relatedness: 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.
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 (2,5 hours). 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, the measurements include four times 2,5 hours in the lab and 60 minutes daily measures using the mobile application, for four weeks.
In between pre-and peri-intervention measurement 1 and pre-and peri-intervention measurement 2, a washout period of one month with no measurements or exercises will take place. The order of the interventions will be pseudo-randomized.
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. Furthermore, 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). See Figure 1. for an overview of the measurements.

Study objective

I. Test whether psychological and psychophysiological indices of PC are differentially affected by fantasizing vs. mindfulness in remitted MDD patients and HC: Pre-and peri-intervention changes will be examined using within-subject and between-group comparisons of self-reported PC and ICG/ECG and EEG characteristics before and during both interventions (mindfulness vs. fantasizing; n=100) and between groups (MDD vs. HC; n=50 per group). It is hypothesized that the interventions differentially affect the main study parameters (i.e. self-

reported PC and ICG/ECG and EEG characteristics) in HC and MDD patients.

II. Identify individual characteristics that may predict effectiveness of the interventions in reducing PC: Main objective II will be examined by studying the relation between treatment effectiveness (pre- and peri-intervention changes in self-reported PC and ICG/ECG and EEG characteristics) and individual characteristics measured with the main parameters as described above (e.g. personality, cognitive reactivity, pre-intervention (neuro)physiological characteristics) using correlational and linear regression analysis within-subjects (n=100). It is hypothesized that individual differences in personal characteristics can be used as individual markers predicting treatment effectiveness.

Study design

T1, T2, T3, T4

Intervention

mindfulness training, positive fantasizing training

Contacts

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Eligibility criteria

Inclusion criteria

In order to be eligible to participate in this study, a participant must meet all the following criteria:
- Participants should be between 18 and 60 years old. They should not exceed 60 years of age in order to avoid aging related pathology in information processing (Salthouse, 2010);
- Participants should display normal intelligence (IQ>85, as assessed with the Dutch Adult

Reading Test (DART; Schmand et al., 1991) and/or having finished an education on at least vocational level).
In order to be eligible to participate in the patient group of the study, a patient participant must additionally meet all the following criteria:
- Participating patients should be in (partial or complete) remission from an Major Depressive episode for more than two months, criteria defined by the Diagnostic Statistical Manual, version 5;
- Patients should have experienced at least two depressive episodes, criteria defined by the Diagnostic Statistical Manual, version 5, experienced in past ten years;
- Patients should score 21 or lower on the Inventory of Depressive Symptomatology (IDS-SR30), indicative of the absence of clinically relevant depressive symptoms (Rush et al., 2000).

Exclusion criteria

A potential participant who meets any of the following criteria will be excluded from participation in this study:
- Participants with any current DSM-5 diagnoses as objectified with the SCID-I;
- Daily use of anti-depressant medication, benzodiazepines, methylphenidate, beta blockers or other medication potentially influencing ICG/ECG currently or in the last four weeks;
- Participants who recently (defined as their last episode, or as one year prior to inclusion in case the last episode was more than a year before inclusion) received the preventive cognitive therapy including the positive fantasizing technique and/or have recent experiences (defined as daily practice in mindfulness in the past two years for at least two weeks) with mindfulness, meditation or mindful yoga. This will be done to prevent overestimation of true effects of mindfulness and/or positive fantasizing;
- Participants who participate in another clinical intervention study at the moment of inclusion in the study.
A potential participant for the HC group who meets any of the following criteria will be excluded from participation of this study:
- Presence of symptoms of depression according to the IDS-SR30 (score < 13);
- Any life-time psychopathology of any disorder as objectified with the SCID-I.

Study design

Design

Study type:	Interventional
Intervention model:	Crossover
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)

Control:	Active

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-01-2021
Enrollment:	100
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Positive opinion

Date:	12-02-2021
Application type:	First submission

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
NTR-new	NL9260
Other	METC UMCG : 2019/537; NL71566.042.19

Study results