Smartphone based Monitoring and cognition Modification Against Recurrence of Depression (SMARD) – Workpackage 2

No registrations found.

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

Summary

ID

NL-OMON27513

Source
Nationaal Trial Register

Brief title
SMARD WP2

Health condition

(Remitted) Major Depressive Disorder

Sponsors and support

Primary sponsor: Radboudumc
Source(s) of monetary or material Support: Dutch Brain Foundation (Hersenstichting)

Intervention

Outcome measures

Primary outcome

1. Changes in attention (PASAT), peripheral attention (PVT), attentional bias and memory bias

task performance
2. SCID positive recurrences of MDD during an observational follow-up of 1.5 years

Secondary outcome

1. Validation of three cognitive training modules:
• Change in rumination scores (RRS)
• Changes in executive neuropsychological functioning
• Changes in brain network-connectivity and associated parameters
• Drop-out / compliance of CCT, ABT, MBT tasks
2. BEHAPP data to be used for identification and prediction of prospective recurrence during an observational follow-up of 1.5 years
3. Changes in ESM-based symptom-networks (daily positive and negative affect measurement) and residual symptoms (HDRS17)

Study description

Background summary

BACKGROUND:
Despite high prevalence of MDD and 50-80% recurrence rate of Major Depressive Disorder (MDD), recurrence prevention programs for MDD have limited efficacy. This might be caused by the fact that impending recurrence is identified too late and preventive strategies do not address underlying, ethiopathophysiological risk-factors like tendency to ruminate or negative attentional biases. Especially patients who have ≥3 episodes have an increased vulnerability to experience a recurrence. Before a new recurrence, patients often do not recognize early symptoms, impeding rapid early interventions against recurrence. The Smartphone based Monitoring and cognition Modification Against Recurrence of Depression (SMARD) study will develop building blocks for a second generation recurrence prevention program containing: earlier recognition by smartphone application measuring an individual's behavioral changes with a background app (BEHAPP) and intensive experience sampling method (ESM) data-collection with diaries (SMARD WP 1), and three-week training modules (Cognitive Control, Attention Bias, and Memory Bias Training) (SMARD WP 2), in patients with recurrent MDD who are currently in stable remission.

AIMS:
1. To validate three cognitive training modules (Cognitive Control Training (CCT), Attention Bias Training (ABT) and Memory Bias Training (MBT)) versus sham training in remitted patients with recurrent-MDD.

2. To assess the effects of the 3 training modules (CCT, ABT and MBT) to evoke changes in cognitive dysfunctions (executive and emotional) and brain network functioning.

3. To gather BEHAPP data and ESM data for remitted patients with recurrent MDD who also

completed CCT/ABM/MBT or sham-CCT/ABM/MBT and associate this data with follow-up data of prospective recurrences (contributing to SMARD WP 1).

4. To associate changes in cognitive functioning with 1.5 year risk of recurrence.

DESIGN:
A double-blind randomized, sham-controlled study of 3 weeks with a secondary observational follow-up of 1.5 years.

METHODS:
Participants: One hundred twenty Remitted participants (18 - 65 years) with recurrent-MDD who are in stable remission (HDRS ≤10 for ≥8 weeks) and have vulnerability for recurrence (≥3 episodes); who are either using antidepressant maintenance therapy or not and regularly using a smartphone.

Measurements: Participants will complete a set of baseline questionnaires (IDS-SR, SHAPS, RRS-NL, LEIDS-R, DAS, APL, UCL, JTV-SR, IRS, WHOQOL, NEO-FFI, DART, STAI trait, STAI state) and an Experience Sampling Method (ESM) period (6 days) via their smartphone, during which their positive and negative affect is assessed at 10 random multiple timepoints during the day. Participants will then complete baseline assessments of the PASAT, PVT, attention bias and memory bias tasks, and will be invited for a baseline (pre-training) MRI scan (including a resting state scan, DTI scan, T1 anatomical scan, Emotion regulation task, Stroop task, Harriri task). MRI is an optional add-on. Following this, participants follow a three-week training of the cognitive training modules (CCT, ABT, MBT) or corresponding (active) sham-trainings. After finishing training, participants will complete post-training questionnaires (IDS-SR, SHAPS, RRS-NL, LEIDS-R, DAS, APL, UCL, IRS, STAI trait, STAI state) and reassessments of the PASAT, PVT, attention bias and memory bias tasks. Participants, from who a baseline MRI scan is obtained, are invited for a (post-training) MRI scan (including a resting state scan, DTI scan, T1 anatomical scan, Emotion regulation task, Stroop task, Harriri task). During a subsequent 1.5 years follow-up, participants will receive questionnaires every three months (IDS-SR, SHAPS, RRS-NL, APL, IRS, STAI trait, STAI state, (WHOQOL)) and will be called every three months to assess recurrence-status of depression (using the SCID-I and HDRS). In addition, alike SMARD WP 1, in the background, behavioural data will be passively gathered using the BEHAPP smartphone application. BEHAPP is a smartphone application enabling longitudinal, 24/7 measures of an individual's behavior (https://behapp.org/). BEHAPP passively monitors behavior 'in the background'. A diversity of social communication and exploratory behavioral endpoint features are extracted from continuously collected smartphone sensor information such as GPS, text-messages, phone, social media (e.g., Facebook, Twitter, WhatsApp), Wi-Fi, access (social density) signals.

Study objective

1. There will be a significant improvement in cognitive control, attention bias and memory bias performance after completion of the selected training module in the active vs. control training.

2. Rumination and depressive symptom severity will moderate improvement (pre vs. post

assessment) on the cognitive control, attention bias and memory tasks.

3. Changes in cognitive control, attention bias, and memory bias performance will be related to recurrence-rates during follow-up.

4. A specific AI algorithm on multidimensional BEHAPP data will be able to identify a recurrence from the period preceding it (distinguishing data-patterns during remission from six weeks of a depressive episode; analyzed together with data from SMARD WP 1).

5. More rigid dynamic functional connectivity patterns of brain states (at baseline and/or after training) will be related to future recurrences during follow-up.

Study design

1. Baseline
2. Post-training
3. Follow-up every 3 months for 1.5 years

Intervention

Participants are randomized to a CCT (21 sessions of the Paced Auditory Serial Addition Task (PASAT); 1/day) or sham CCT (21 sessions of the Peripheral Visual Training (PVT); 1/day), ABT positive bias training (42 sessions; 2/day) or sham ABT (42 sessions 2/day; no bias training), MBT (21 days; 8 prompts/day) or sham MBT (21 days; 8 prompts/day). Randomization will be done based on a minimization procedure for use of antidepressants and residual symptoms to obtain comparable antidepressant use and mean HDRS 17 scores between groups.

Contacts

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Eligibility criteria

Inclusion criteria

1. Age 18-65 years
2. Recurrent MDD diagnoses (according to DSM-IV and SCID)
3. At least 3 previous MDD-episodes (assessed with the SCID-interview)
4. In stable remission: does not meet criteria for a current MDD episode (SCID-interview) ≥8 weeks and a Hamilton Depression Rating Scale score ≤10
5. In possession of smartphone and experienced in use thereof

Exclusion criteria

1. Diagnosis of bipolar, primary psychotic or borderline personality disorder or strong suspicion of this type of disorder
2. Primary diagnosis of substance use or anxiety disorder with secondary MDD
3. Electroconvulsive therapy within two months before inclusion
4. Average alcohol intake of >3 units/day
5. Daily use of benzodiazepines (≥5mg diazepam or equivalent)
6. Ongoing psychotherapy during the CCT/ABT/MBT training
7. Previous CCT/AB/MBT training

For the optional add-on MRI-part, standard MRI exclusion criteria will apply.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Placebo

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-01-2019
Enrollment:	120

Type:	Anticipated

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Positive opinion Date:	12-08-2021
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	NL9659
Other	METC CMO Arnhem-Nijmegen : Source ID: ABR: NL60033.091.16; METC: 2016-3009

Study results