Smartphone based Monitoring and cognition Modification Against Recurrence of 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-OMON47013

Source
ToetsingOnline

Brief title
SMARD

Condition

- Mood disorders and disturbances NEC

Synonym
Major Depressive Disorder, recurrent type

Research involving
Human

Sponsors and support

Primary sponsor: Radboud Universitair Medisch Centrum
Source(s) of monetary or material Support: Hersenstichting

Intervention

Keyword: Cognitive training, Major Depressive Disorder, MRI, Neuroimaging, recurrent type, Smartphone

Outcome measures

Primary outcome

A. Saturation of ideas obtained in the focus-groups;

B, E. SCID-+ve recurrences of depression during follow-up;

C, D. Changes in PASAT, Visual Probe and Recall/Evaluation task (RET)

performance

Secondary outcome

B, E. Changes in ESM-based symptom-networks;

C, D. Drop-out/noncompliance (<80% of training sessions) of CCT, ABM or

MBT-tasks; Change in rumination-scores; Change in executive neuropsychological

functioning; Changes in brain network-connectivity and associated parameters;

E. Association of change in PASAT/PVT/RET performance, negative biases and

executive functioning with future recurrences of depression during follow-up

Study description

Background summary

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 1. Impending recurrence is identified too late and 2. Preventive strategies do not address underlying, ethiopathophysiological risk-factors like cognitive reactivity, tendency to ruminate, insufficient cognitive control over one*s thoughts and rumination or negative attentional biases. The Smartphone based Monitoring and cognition Modification Against Recurrence of Depression (SMARD) study (funded by the Hersenstichting) will develop a second generation recurrence prevention

program, which will address 1. Earlier recognition by Smartphone application measuring individual*s behavioural changes with a background app and occasional intensive experience sampling method (ESM) data-collection with diaries 10 times/day for 6 days; and 2. Cognitive control training (CCT), Attentional Bias Modification (ABM) training or Memory Bias Training (MBT) applied for 3 weeks when patients with recurrent MDD (i.e. having a vulnerability to experience recurrences) are in stable remission. We have the expectation that the total SMARD second generation recurrence prevention program will reduce recurrence-rates with 30%.

Study objective

In the current protocol we describe 2 work packages in which we aim to perform:
A. >=2 focus-groups to gauge acceptability of the smartphone-app (WP1);
B. follow-up remitted patients with recurrent MDD for 1.5 year while the background app (BeHapp) is obtaining data, to start to develop algorithms to identify impending recurrence, which will be cheked with a repetition of ESM-data (WP1);
C. test the effects of smartphone based CCT, ABM and MBT training by a smartphone app, in a sham-CCT/ABM/MBT training controlled randomised controlled trial (WP2);
D. additional measurements (neuropsychology, MRI); and
E. successive follow-up over 1 year (WP2).

Primary objectives are:
A. to set up at least 2 focus groups (16-24 participants) to determine the acceptability and/or need of modifications/explanation of BeHapp;
B. To gather BeHapp-data and ESM-data for 50-60 remitted patients with recurrent MDD in association with follow-up data of prospective recurrences;
C. To validate three cognitive training modules (CCT, ABM and MBT) versus sham training in 120 remitted patients with recurrent-MDD;
D. To assess the effects of CCT/ABM/MBT training to evoke changes in cognitive dysfunctions (executive and emotional) and brain network function;
E. To gather BeHapp-data and ESM-data for 50-60 remitted patients with recurrent MDD in association with follow-up data of prospective recurrences in these patients treated with CCT/ABM/MBT or sham.

Study design

A. Focus groups;
B. Cohort-study;
C, D, E. Randomised controlled trial with secondary prospective follow-up (cohort)

Intervention

A&B. none;
C, D, E. CCT (21 sessions of the Paced Auditory Serial Addition Task (PASAT); 1/day), sham CCT (21 sessions of the Peripheral Visual Training (PVT), ABM (42 sessions 2/day; positive bias training) or sham ABM (42 sessions 2/day; no bias training), or MBT (21 days, 8 prompts/day; in 5x participants will be asked to recall, evaluate and describe a recent positive event) or sham MBT (21 days, 8 prompts/day; in 5x participants will be asked to describe and evaluate their current location).

Study burden and risks

Overall, the participation in the most intensive parts (C, D) consists of undergoing neuropsychological and MRI test-sessions, a randomly assigned CCT/ABM/MBT training during three weeks. During the follow-up (B, E), the burden of the investigation is a 3-monthly telephone interview and in some cases repeated ESM.
We consider the risk of moderate harm in this study to be low, while the risk of low harm is expected to be low-moderate. Therefore, the overall risk classification of this study is *negligible risk*.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

In order to be eligible to participate in this study, a patient must meet all of the following criteria:
- recurrent MDD diagnoses (assessed using the Structured Clinical Interview for Diagnostic and Statistical Manual of Mental Disorders, fourth edition (DSM-IV) (SCID) [First 1996])
- at least 3 previous MDD-episodes (as assessed with the SCID-interview)
- a 17-item Hamilton Depression Rating Scale (HDRS17) <=10 [Hamilton 1967], not fulfilling the criteria for a current MDD episode (as assessed with the SCID-interview)
- having a stable remission (>=8 weeks)
- age 18-65 years
- in possession of smartphone and experienced in use thereof
For the focus-groups in WP1, assessment of unipolarity, number of recurrences and non-depressed state will be assessed by history only (no SCID/HDRS17) as more thorough assessments are not proportional to the aim of the focus-groups.

Exclusion criteria

For both WPs:
- diagnosis of bipolar, primary psychotic or borderline personality disorder or strong suspicion of this type of disorder
- primary diagnosis of substance use or anxiety disorder with secondary MDD (comorbid secondary anxiety disorder allowed for participation)
- electroconvulsive therapy within two months before inclusion
- average alcohol intake of >3 units/day
- daily use of benzodiazepines (>=5mg diazepam or equivalent)
- Incompatible smartphone to install BeHapp ;Additional exclusion-criteria for WP2:
- ongoing psychotherapy during the CCT/ABM training
- previous CCT/ABM ;For the add-on MRI-part of WP2, standard MRI exclusion criteria will apply:
- Metal objects in the body
- Claustrophobia
- A history of head trauma or neurological disease, severe general physical illness

Study design

Design

Study phase:	2
Study type:	Interventional
Masking:	Double blinded (masking used)
Control:	Uncontrolled
Primary purpose:	Prevention

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	13-04-2017
Enrollment:	224
Type:	Actual

Ethics review

Approved WMO Date:	23-01-2017
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	16-05-2018
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	08-10-2018
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	16-11-2020
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)

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	NL60033.091.16