Smartphone based Monitoring and cognition Modification Against Recurrence of Depression (SMARD) – Workpackage 1

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON26184

Source
Nationaal Trial Register

Brief title
SMARD WP1

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. Focus-groups BEHAPP acceptability – saturation of ideas obtained in the focus-groups

2. BEHAPP and prediction of prospective recurrence during an observational follow-up of 1.5 years

Secondary outcome

1. BEHAPP and prediction of recurrence during follow-up related to residual symptoms (HDRS17) and changes in baseline ESM-based symptom-networks (daily positive and negative affect measurement) across a six-day period

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. The Smartphone based Monitoring and cognition Modification Against Recurrence of Depression (SMARD) study will develop building blocks for a second generation recurrence prevention program, which will address 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.

AIMS:
The aim is to measure early changes in behavior, indicative of an imminent depressive episode by using continuous and passive monitoring of behavioral data (e.g., GPS, social media use, etc.) with the BEHAPP smartphone application (https://behapp.org/). The following objectives will be addressed:

1. Create focus-groups (≥2), which will assess the acceptability of the BEHAPP app.

2. To gather BEHAPP data and ESM data for 1.5 years in remitted patients with recurrent MDD and associate this data with follow-up data of prospective recurrences.

3. Develop an algorithm to identify recurrence.

DESIGN:
1. Focus groups to assess acceptability of BEHAPP use.
2. A prospective cohort design with a 1.5 years follow-up period.

METHODS:
Participants: Sixty Remitted participants (18 - 65 yrs.) 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. Of these, 10 will participate in the initial focus-groups.

Measurements: Participants of the prospective cohort will complete a set of baseline questionnaires (IDS-SR, SHAPS, RRS-NL, LEIDS-R, DAS, APL, UCL, JTV-SR, IRS, WHOQOL, NEO-FFI, DART) 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. During a subsequent 1.5 years follow-up, participants will receive questionnaires every three months (IDS-SR, SHAPS, RRS-NL, APL, IRS, WHOQOL) and will be called every three months to assess recurrence-status of depression (using the SCID-I and HDRS). 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. For analyses, data will be combined with ≥50 additional subjects from SMARD WP 2.

Study objective

1. 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).

2. The algorithm will be able to identify the (impending) prospective recurrence within two-weeks before it actually starts.

Study design

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

Intervention

None

Contacts

Public
Radboudumc & Donders Institute for Brain, Cognition and Behavior, Radboud University
Henricus G. Ruhe

+31 6 51508197
Scientific

Radboudumc & Donders Institute for Brain, Cognition and Behavior, Radboud University
Henricus G. Ruhe

+31 6 51508197

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. Incompatible smartphone to install BEHAPP

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other
Allocation:	N/A: single arm study
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	13-04-2017
Enrollment:	60
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Undecided

Plan description
N/A

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	NL9658
Other	METC CMO Arnhem-Nijmegen : ABR: NL60033.091.16; METC: 2016-3009

Study results

Summary results
N/A