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

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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...

Ethische beoordeling	Positief advies
Status	Werving gestart
Type aandoening	-
Onderzoekstype	Observationeel onderzoek, zonder invasieve metingen

Samenvatting

ID

NL-OMON26184

Bron
NTR

Verkorte titel
SMARD WP1

Aandoening

(Remitted) Major Depressive Disorder

Ondersteuning

Primaire sponsor: Radboudumc
Overige ondersteuning: Dutch Brain Foundation (Hersenstichting)

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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.

Onderzoeksopzet

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

Onderzoeksproduct en/of interventie

None

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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

Onderzoeksopzet

Opzet

Type:	Observationeel onderzoek, zonder invasieve metingen
Onderzoeksmodel:	Anders
Toewijzing:	N.v.t. / één studie arm

Blindering:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	13-04-2017
Aantal proefpersonen:	60
Type:	Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nog niet bepaald

Toelichting
N/A

Ethische beoordeling

Positief advies

Datum:	12-08-2021
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL9658

Register	ID
Ander register	METC CMO Arnhem-Nijmegen : ABR: NL60033.091.16; METC: 2016-3009

Resultaten

Samenvatting resultaten
N/A