Is your mood influenced when you monitor your mood using your smartphone?

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Mood monitoring using smartphones has no clinically relevant effect on low mood.

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

Samenvatting

ID

NL-OMON24975

Bron
NTR

Verkorte titel
MoodMonitor

Aandoening

Low mood, depressive symptoms, stemming, depressie

Ondersteuning

Primaire sponsor: VU Medical Centre, Department of Psychiatry
Overige ondersteuning: VU Medical Centre, Department of Psychiatry;
Vrije Universiteit Amsterdam, Section Clinical Psychology;
EU

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

The primary outcome measure of this study is retrospectively measured low mood. We will use the Center for Epidemiologic Studies Depression scale (CES-D), which will be administered online at baseline, after week 6 and after week 12. Change in mood over time will also be analysed within group 1 using the monitoring data.

Toelichting onderzoek

Achtergrond van het onderzoek

Rationale

Mood can be assessed in the moment and place it is experienced, which is called ecological momentary assessment (EMA). EMA may be a valid method for assessing mood, and recently it has become possible to use smartphones to conduct EMA. EMA may not only measure, but also influence an individual's mood. From a clinical perspective, this would be especially relevant among individuals who experience low mood, a depressive symptom. It is, however, unknown whether EMA has an effect on low mood, and if there is, in which direction.

Objectives

The primary objective is to investigate whether EMA of mood, self-administered by individuals who experience low mood, has an effect on retrospectively self-reported low mood over time. A secondary objective is a longitudinal analysis of EMA data.

Study design

This study is a randomised controlled trial among participants who experience low mood. The trial consists of three groups: group 1 self-administers EMA of mood, group 2 self-administers daily assessment of other variables (active placebo, see below), group 3 does neither (control). All groups receive a retrospective self-report questionnaire (CES-D) at baseline (T0), six weeks after baseline (T6) and 12 weeks after baseline (T12).

Study population

We aim to recruit 120 participants who experience low mood among the general population. Low mood is defined as a mild to moderate score on the PHQ-9 (total score 5 to 15).

Main study parameters/endpoints

The primary outcome measure is retrospectively self-reported mood, measured with the CES-D.

Doel van het onderzoek

Mood monitoring using smartphones has no clinically relevant effect on low mood.

Onderzoeksopzet

There are 3 time points:

T0 - Baseline assessment

T6 - Assessment at week 6

T12 - Assessment at week 12

Onderzoeksproduct en/of interventie

It is unknown whether monitoring one's mood can be considered an intervention. That is what this study will find out. Nevertheless, we provide a description of the monitoring here. Participants in group 1 will install an application on their smartphones, which allows them to monitor their mood. Every day, the participant receives one notification at a random time point between ten o'clock in the morning and ten o'clock in the evening. This notification directs the participant to the question 'How is your mood right now?', which the participant can enter on a visual analogue scale from 1 (worst) to 10 (best). The notification remains accessible until the next notification is sent. The measurement will be time stamped, i.e. the system saves the exact time when the participant rates his/her mood (not when the notification was sent). During week 1 and week 12, the participant rates his/her mood 3 times a day in order to measure mood fluctuations during the day.

Participants in group 2 will also install an application on their smartphones, which works the same as the mood monitoring app, but presents the following question each day: “How energetic do you feel right now?”.

Participants in group 3 do not monitor anything. They complete online questionnaires, just as groups 1 and 2.

Contactpersonen

Publiek

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

Applicants are eligible for participation when they:

- Are 18 years of age or older

- Have mild to moderate depression symptoms as defined by a PHQ-9 score of 5 to 15

- Own a smartphone with Android version 4.0 or later.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

See inclusion.

Onderzoeksopzet

Opzet

Type:	Observationeel onderzoek, zonder invasieve metingen
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Enkelblind
Controle:	Placebo

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	12-04-2016
Aantal proefpersonen:	120
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	12-04-2016
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	NL5507

Register	ID
NTR-old	NTR5803
Ander register	METc VUmc : Protocol 15.333

Resultaten