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

No registrations found.

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

Summary

ID

NL-OMON24975

Source
NTR

Brief title
MoodMonitor

Health condition

Low mood, depressive symptoms, stemming, depressie

Sponsors and support

Primary sponsor: VU Medical Centre, Department of Psychiatry
Source(s) of monetary or material Support: VU Medical Centre, Department of Psychiatry;
Vrije Universiteit Amsterdam, Section Clinical Psychology;
EU

Intervention

Outcome measures

Primary outcome

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.

Secondary outcome

We will investigate the participants' experience with the monitoring application by assessing fidelity to the measurements, usability of the application and the qualitative experience. Fidelity will be measured by tracking the amount of responses. We will regard a response rate of 80% or more as high fidelity. Usability is assessed using the System Usability Scale (SUS). At the end of the study, we will interview ten randomly selected participants by telephone to obtain qualitative information about their experience with tracking their mood and any influence that could have had on them.

Study description

Background summary

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.

Study objective

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

Study design

There are 3 time points:

T0 - Baseline assessment

T6 - Assessment at week 6

T12 - Assessment at week 12

Intervention

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.

Contacts

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Eligibility criteria

Inclusion criteria

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.

Exclusion criteria

See inclusion.

Study design

Design

Study type:	Observational non invasive
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)
Control:	Placebo

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	12-04-2016
Enrollment:	120
Type:	Anticipated

Ethics review

Positive opinion

Date:	12-04-2016
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	NL5507
NTR-old	NTR5803
Other	METc VUmc : Protocol 15.333

Study results