Self-monitoring and personalized feedback as a tool to boost depression treatment

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We expect that patients with depressive complaints will benefit from self-monitoring and personalized feedback through the Experience Sampling Method (ESM) started shortly after intake at their mental health care organizations.

Ethische beoordeling	Positief advies
Status	Werving nog niet gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON29201

Bron
NTR

Verkorte titel
ZELF-i

Aandoening

Depression, depressie

Ondersteuning

Primaire sponsor: University Medical Center Groningen
Overige ondersteuning: - University Medical Center Groningen (sponsor)
- Gratama Stichting / Groninger Universiteitsfonds (project number: 2015-05)

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

The primary outcome measure to determine effectiveness of the intervention will be the change in depression symptom severity as measured by the self-report Inventory of Depressive Symptomatology (IDS-SR, Rush et al., 1996) across 6 time points: baseline, after 4 weeks of ESM and at 4 follow-ups at 4, 8, 12, and 24 weeks (post-ESM). Subjects will be followed prospectively to compare the effectiveness of the intervention modules mutually and to the control group, before and during TAU.

Toelichting onderzoek

Achtergrond van het onderzoek

According to the World Health Organization, the leading cause of disability worldwide is depression. There is a need for cost-effective interventions that support the mental health care sector and reinforce self-management of patients. Systematic self-monitoring and personalized feedback on behavioral patterns and associated emotions through the Experience Sampling Method (ESM) could provide such an empowering, low-cost intervention that can complement treatment as usual (TAU). With ESM, a patient gathers a multitude of prospective in-the-moment daily life assessments on affect, behavior, and context. Through aggregation of these systematically collected data, ESM can
generate information that goes beyond what has been explicitly listed by the patient. ESM has great potential for clinical practice and the individual patient, because it allows personalized feedback.

A randomized controlled trial (RCT) in 102 depressed outpatients recently established the effectiveness of ESM as a therapeutic tool (Kramer et al., 2014). They showed that add-on ESM-derived personalized feedback on positive affect and activities resulted in a significantly and clinically relevant stronger decrease in depressive symptoms compared to TAU. The ZELF-i project aims to take the necessary next steps to move this promising intervention towards implementation. First, the ESM
intervention will be optimized for clinical practice by making it easily accessible on patients' own smartphones and by reducing personnel investment through automatized personalized analyses and digital feedback reports. Second, we will (re)examine effectiveness of ESM-derived
personalized feedback in a high-quality RCT in 150 patients dealing with depressive complaints.

In the ZELF-i project, the effectiveness of personalized ESM-derived feedback will be examined with regard to two ESM variants: a "Do"-module (in Dutch: "Doe"-module) oriented at positive affect and activities, and a "Think"-module ("Denk"-module in Dutch) focused on negative affect and thinking patterns. The ultimate target of personalized ESM-derived

feedback is not merely to reduce depressive symptomatology; we hope patients will benefit from the intervention in terms of an increase in psychosocial functioning and enhanced feelings of empowerment. By having patients start directly after intake at their mental health care organizations, they can make the most out of the usual waiting list period, and hopefully commence subsequent treatment programs with a kick-start.

Doel van het onderzoek

We expect that patients with depressive complaints will benefit from self-monitoring and personalized feedback through the Experience Sampling Method (ESM) started shortly after intake at their mental health care organizations.

Onderzoeksopzet

IDS-SR, OQ-45, NEL at 6 time points: baseline, after 4 weeks of ESM and at 4 follow-ups at 4, 8, 12, and 24 weeks (post-ESM).

Adjusted TiC-P and EQ-5D at 4 time points: baseline, after 4 weeks of ESM and at 2 follow-ups at 12 and 24 weeks (post-ESM).

Onderzoeksproduct en/of interventie

A randomized controlled trial will be conducted with three treatment arms:

- ‘Do’-module (n=50): patients report ESM data via their smartphone, five times a day for 28 days, with weekly feedback (to the patient) on positive affect (PA) and activities.

- ‘Think’-module (n=50): patients report ESM data via their smartphone, five times a day for 28 days, with weekly feedback (to the patient) on NA and thinking patterns.

- Control group (n=50): patients will be on the wait list as usual, but engage in the baseline, post-ESM, and 4 follow-up assessments to make comparisons with the ESM arms possible. The control group could be considered a low-intensity self-monitoring group.

Patients will be enrolled in ZELF-i shortly after intake at their mental health care organizations. Note that patients in all three arms will be enrolled in specialist treatment upon availability; that is, treatment as usual (TAU) will not be postponed until ZELF-i finishes.

Contactpersonen

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

In order to be eligible to participate in the study, a subject must meet the following criteria:

- Depression treatment is indicated by the practitioner

- Aged between 18 and 65 years

- Written informed consent

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

Exclusion criteria (based on appraisals by the practitioner) are:

- Crisis intervention warranted (i.e. in the case of acute suicidality)

- Presence of psychotic or manic symptoms

- Incapability of following research procedures due to inadequate Dutch language proficiency, significant auditory or visual impairments, or mental retardation.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Open / niet geblindeerd
Controle:	Geneesmiddel

Deelname

Nederland

Status:	Werving nog niet gestart
(Verwachte) startdatum:	01-03-2016
Aantal proefpersonen:	150
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	01-02-2016
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 42825
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL4465
NTR-old	NTR5707
CCMO	NL55319.042.15
OMON	NL-OMON42825

Resultaten