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

No registrations found.

Ethical review	Positive opinion
Status	Pending
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON29201

Source
NTR

Brief title
ZELF-i

Health condition

Depression, depressie

Sponsors and support

Primary sponsor: University Medical Center Groningen
Source(s) of monetary or material Support: - University Medical Center Groningen (sponsor)
- Gratama Stichting / Groninger Universiteitsfonds (project number: 2015-05)

Intervention

Outcome measures

Primary outcome

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.

Secondary outcome

From a patient perspective, functional outcomes are at least as relevant as clinical outcomes. Therefore, we will also assess change in psychosocial functioning by means of the Outcome Questionnaire (OQ-45, Lambert et al., 1996) and the extent to which individuals regain self-esteem and take control over their own lives by means of the Dutch Empowerment questionnaire (NEL; Boevink, Kroon, & Giesen, 2010).

Cost-effectiveness will be determined by the means of the quality of life measure EQ-5D (Prieto et al., 2013) and the TiC-P questionnaire on medical costs and productivity losses (Bouwmans et al. 2013) adjusted for a psychiatric population.

Study description

Background summary

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.

Study objective

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.

Study design

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).

Intervention

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.

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Eligibility criteria

Inclusion criteria

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

Exclusion criteria

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.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-03-2016
Enrollment:	150
Type:	Anticipated

Ethics review

Positive opinion

Date:	01-02-2016
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 42825
Bron: ToetsingOnline
Titel:

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

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

Study results