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

Published: 18-01-2016
Last updated: 19-03-2025

The main aim of the ZELF-i project is to investigate the effectiveness of self-monitoring and personalized feedback as an add-on tool in the treatment of depression. By starting directly after intake, patients can make the most out of the usual...

Ethical review	Approved WMO
Status	Completed
Health condition type	Mood disorders and disturbances NEC
Study type	Interventional

Summary

ID

NL-OMON42825

Source
ToetsingOnline

Brief title
ZELF-i

Condition

- Mood disorders and disturbances NEC

Synonym
depression, depressive disorder

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Groningen
Source(s) of monetary or material Support: Ministerie van OC&W,Gratama stichting

Intervention

Keyword: depression, e-health, experience sampling method, personalized medicine

Outcome measures

Primary outcome

The primary outcome measure to determine effectiveness of the intervention will be change in depression symptom severity as measured by the self-report Inventory of Depressive Symptomatology (IDS-SR, Rush et al., 1999) across 6 time points: pre-ESM, after 4 weeks of ESM and at 4 follow-ups at 4, 8, 12, and 24 weeks (post-ESM).

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). Moreover, we will assess 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). This questionnaire has been developed by the Trimbos institute in collaboration with individuals with psychiatric problems.

Other outcome measures:

Questionnaires regarding cost-effectiveness: PRODISQ, TiC-P, en Euroqol-5D

Baseline characteristics: demographics, LEIDS-R (Cognitive Reactivity), TAS-20 (Alexithymia)

Study description

Background summary

The leading cause of disability worldwide is depression, a common mental disorder that is characterized by two core symptoms: depressed mood and/or decreased interest or pleasure in activities. A pioneer Randomized Controlled Trial (RCT) has shown that systematic self-monitoring and personalized feedback on contextualized patterns of positive affect through the Experience Sampling Method (ESM) could provide an empowering and effective add-on tool to treatment as usual (TAU). While promising, the intervention was highly labor intensive, including manual statistical analyses and an extensive face-to-face component. In addition, the intervention targeted only one of depression*s core symptoms. This project takes the next logical step: (re)examine the effectiveness of ESM-derived personalized feedback in a format that is optimized for clinical practice for two ESM variants, each targeted at one of depression*s core symptoms. We expect that the use of ESM as a self-management tool will benefit depressed patients not only by reducing depressive symptomatology, but also by increasing psychosocial functioning and enhancing patients* feelings of empowerment.

Study objective

The main aim of the ZELF-i project is to investigate the effectiveness of self-monitoring and personalized feedback as an add-on tool in the treatment of depression. By starting directly after intake, patients can make the most out of the usual waiting list period, and commence subsequent treatment programs with a kick-start.

Study design

RCT with three treatment arms: wait-list (WL), ESM *Do*-module, ESM *Think*-module. Randomization (allocation ratio 1:1:1) will be stratified according to the duration of antidepressant pharmacotherapy (new/switch vs. maintenance, i.e. receiving antidepressant or mood stabilizing medication for less vs. longer than 8 weeks prior to study entry), and current psychotherapy (yes or no).

Intervention

28 days of systematic self-monitoring (5 times per day) with weekly personalized feedback. The Do-module focuses on positive affect and activities, the Think-module focuses on negative affect and thinking patterns.

Study burden and risks

There are no risks involved in participating in the study. The burden associated with participation comprises: an instruction session and questionnaires before the ESM period (2 hours), filling in a diary using a mobile application five times a day for 28 days (~2 minutes per measurement), a debriefing session and questionnaires after the ESM period (2 hours in total), and 4 follow-up assessments (1 hour per assessment). Benefits are an increased insight in (fluctuations in) one*s own mood states and person-specific factors that may promote the increase of positive affect or reduction of negative affect. The intervention could also increase feelings of empowerment, improve (social) functioning, and help patients bridge the usual wait list in a constructive way. The burden for the control group consists of an instruction session and filling out the same questionnaires at the same time points as the intervention groups. The control group does not fill out electronic diaries, nor engage in a debriefing session after the intervention.

Contacts

Public
Universitair Medisch Centrum Groningen

Hanzeplein 1
Groningen 9713 GZ
NL
Scientific
Universitair Medisch Centrum Groningen

Hanzeplein 1
Groningen 9713 GZ
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)

Elderly (65 years and older)

Inclusion criteria

- Depression treatment is indicated by the practitioner
- Aged between 18 and 65 years
- Written informed consent

Exclusion criteria

- Crisis intervention warranted (i.e. in the case of acute suicidality)
- Presence of psychotic or manic symptoms
- 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)

Primary purpose: Treatment

Recruitment

NL

Recruitment status:	Completed
Start date (anticipated):	16-05-2016
Enrollment:	150
Type:	Actual

Ethics review

Approved WMO

Date:	18-01-2016

Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	30-03-2016
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	22-08-2017
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

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

ID: 29201
Source: NTR
Title:

In other registers

Register	ID
Other	22968 (in behandeling bij NTR)
CCMO	NL55319.042.15
OMON	NL-OMON29201