Therap-i: A personalized monitoring and feedback tool as an add-on to support standard treatment for depression.

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The main aim is to investigate efficacy of the Therap-i module, in addition to treatment-as-usual (TAU), in decreasing depressive symptoms in patients with MDD, who are unresponsive to protocolized psychological treatment for depression.

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

Summary

ID

NL-OMON46281

Source
ToetsingOnline

Brief title
Therap-i

Condition

- Mood disorders and disturbances NEC

Synonym
depression, major depressive disorder

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Groningen
Source(s) of monetary or material Support: Stichting tot steun VCVGZ
https://www.stichtingtotsteunvcvgz.nl

Intervention

Keyword: case-conceptualization, depression, ecological momentary assessment, treatment

Outcome measures

Primary outcome

The primary outcome measures to determine efficacy of the intervention will be the change in depressive symptom severity, as measured by the Inventory of Depressive Symptomatology self-report (IDS-SR).

Secondary outcome

Secondary outcome measures to determine efficacy of the Therap-i module are changes in i) psychological functioning as measured by the Outcome Questionnaire (OQ-45), ii) illness perception as measured by the Illness Perception Questionnaire Mental Health (IPQ-MH), iii) therapeutic alliance as measured by the Work Alliance Inventory (WAI). A descriptive outcome measure to determine efficacy of the Therap-i module are differences between the treatment arms in self-management as measured by the Questionnaire Self-Management in Recovery from Depression (Vragenlijst zelfmanagement bij herstel van depressie; QSRD).

Study description

Background summary

Major depressive disorder (MDD) is a disabling condition with debilitating consequences for those who suffer from it and their relatives. Optimizing treatments will reduce societal burden and risk for relapse, and improve an individual*s quality of life. A pioneer Randomized Controlled Trial (RCT) has shown that systematic intensive self-monitoring and personalized feedback on contextualized patterns of positive affect through Ecological Momentary

Assessment (EMA) could provide an effective add-on tool to routine clinical care. While promising, standardized EMA and feedback modules were used, focused only on positive affect, in a relatively less affected group of patients in secondary care. In this project, we will use a personalized EMA and feedback module, named Therap-i, to intensively self-monitor affect and person specific factors in daily life in patients with MDD in tertiary care. We hypothesize that this module will contribute to decreased depressive symptoms via a more precise descriptive diagnosis, tailored treatment and increased self-insight, resulting in enduring increased self-management and better functional outcomes. Objective: The main aim is to investigate efficacy of the Therap-i module, in addition to treatment-as-usual (TAU), in decreasing depressive symptoms in patients with MDD, who are unresponsive to protocolized psychological treatment for depression.

Study objective

The main aim is to investigate efficacy of the Therap-i module, in addition to treatment-as-usual (TAU), in decreasing depressive symptoms in patients with MDD, who are unresponsive to protocolized psychological treatment for depression.

Study design

A RCT with two treatment arms: TAU and TAU + Therap-i module. TAU consists of policlinic psychological treatment for patients with MDD. The Therap-i module can be added to treatment after patients have gone through a primary psychological/psychotherapeutic intervention for depression, consisting of four months of (cognitive) behavioural therapy, interpersonal therapy or brief psychodynamic therapy. Randomization (allocation ratio 1:1) will be stratified on the quantified level of treatment resistance based on the Dutch Method for Quantification of Treatment Resistance in Depression (DM-TRD (Peeters et al., 2016); cut off score >=11).

Intervention

In the Therap-i module patients will systematically self-monitor their affect and person specific factors five times a day for two months with an electronic diary. The diary items are based on patient data and case-conceptualization (CC), and discussed by the therapist, researcher and patient to reach a definitive selection. After 2, 4 and 8 weeks, patients will receive a personalized feedback report, which will be discussed by the therapist, researcher and patient.

Study burden and risks

There are no risks involved in study participation. The burden associated with

participation consists of: being formally screened for participation via telephone (experimental group (EG) and control group (CG); on average 50 minutes); taking part in a resilience interview (EG, 45 minutes) and an electronic-diary-creation session (EG; 45 minutes); filling in questionnaires at baseline (EG and CG; 43 minutes); filling out an electronic diary on a smartphone five times a day for two months during TAU (EG; 2 minutes per measurement); wearing a motion watch for two months (EG and CG); taking part in three feedback sessions wherein the personal feedback report will be discussed during a regular consult (EG; 45 minutes per session); filling out questionnaires on outcome measures 7 times (including follow-up assessments; EG and CG; 18 minutes per measurement); filling out an evaluation questionnaire and participating in a semi-structured interview at the end of the Therap-i module (EG; 30 minutes; latter only until N = 20); filling out the questionnaire on the descriptive outcome (EG and CG; 9 minutes). Benefits are increased insight in (fluctuations in) one*s own affect and person specific factors that may decrease depressive symptoms by increasing self-management and improving functional outcomes.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

- Main diagnosis is Major Depressive Disorder (MDD) according to the DSM-V
- Age between 18-65 years
- Patients have previously received a primary protocolled psychological/psychotherapeutic intervention for depression, consisting of four months of (cognitive) behavioural therapy, interpersonal therapy or brief psychodynamic therapy, which is evaluated as not effective (enough) to repeat or continue by the clinician responsible for the patient.
- Patients start or receive policlinic psychological treatment wherein they have weekly one-on-one consults with a therapist for at least 8 weeks

Exclusion criteria

- A current diagnosis of:
* MDD with psychotic features
* bipolar disorder
* substance-related and addictive disorder
* schizophrenia spectrum and other psychotic disorder
* neurocognitive disorder
- Previous treatment with Electroconvulsive Therapy
- Visual impairments that cannot be corrected
- Insufficient mastery of the Dutch language
- Inability or unwillingness to manage a smartphone

Study design

Design

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

Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	27-06-2019
Enrollment:	100
Type:	Actual

Ethics review

Approved WMO Date:	15-11-2018
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	10-04-2019
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	26-08-2019
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	07-07-2021
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	18-10-2021
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

No registrations found.

In other registers

Register	ID
Other	29302 Nederlands Trial Register (ingedient)
CCMO	NL66311.042.18