The treatment of depressive disorders with online psychological treatment supported by a clinician

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

Samenvatting

ID

NL-OMON28356

Bron
Nationaal Trial Register

Verkorte titel
BLENDING

Aandoening

Depressive disorders, depression, depressive symptoms, major depressive disorder, depressieve stoornissen, depressieve klachten

Ondersteuning

Primaire sponsor: University Medical Center Groningen
Overige ondersteuning: ZonMw

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Reduction in symptoms of depression from baseline to the 3 months follow-up

Toelichting onderzoek

Achtergrond van het onderzoek

Depression is a common mental disorder that has a high disease and high economic burden. The majority of patients with mental health problems are treated by general practitioners (GPs). Guidelines recommend a stepped care approach for the treatment of these patients. This means that structured non-pharmacological interventions of low-intensity (e.g. brief psychological treatments) are recommended before starting antidepressants. However the dissemination of this approach is limited and it has been estimated that 70% of the cases are primarily treated with antidepressants. Time constraints and lack of familiarity with psychological treatments are probably key to this problem. In this randomized controlled trial we will study the effectiveness of an e-prescription for a blended care approach in the psychological treatment of participants with depression or depressive symptoms in the general

practice compared to the intention to start an antidepressant. The e-prescription will be a prescription to an online self-management program based on the principles of behavioral activation blended with a few face-to- face or telephonic contacts with a GP or POH-GGZ (mental health worker of the general practice).

Objective:

The primary objective is to evaluate if a blended behavioral activation intervention reduces depressive symptoms on the short term. Secondary objectives are to assess this additional value on long term outcomes, and to assess its effectiveness on percentage response, remission, treatment satisfaction, general health status, functional impairment and daily

activities.

The second aim of this study is to examine the real-time experience of cognitions, emotions as

well as behaviors during treatment by ecological momentary assessment (EMA). Compared to more conventional questionnaires, EMA has the advantage to reduce memory distortions. It also gives insight into actual experiences during treatment.

Study design

Pragmatic investigator blinded monocenter 1:1 randomized controlled trial

Study population:

Adult participants with a depressive disorder or depressive symptoms.

Intervention:

E-prescription of an online self-management program (one module per week spread over 5-10

weeks), blended with a few face-to- face or telephonic contacts with the GP or POH-GGZ.

Main study parameters/endpoints:

The main endpoint is the reduction in depressive symptoms as assessed by the Hamilton Depression Rating Scale-17 (HRSD-17) from baseline to three months after intervention. Secondary endpoints are the reduction on depressive symptoms using the HRSD-17 at 12 months, percentage response (50% reduction in symptoms on HRSD-17), remission (HRSD-17 score below 7) at three and twelve months of follow-up, antidepressant use, effect on general health status, treatment satisfaction, functional impairment and daily activities as well

as cost-effectiveness.

In addition to conventional questionnaires, we will capture real-time momentary ratings of cognitions and moods with so-called Ecological Momentary Assessment (EMA) in a sub-group of 60 participants. Specifically, using a smart phone application, auditory cue signals will be sent to participants' mobile smartphones. Thereupon, participants will be asked to rate

their momentary states of mood and distress, positive and negative affect as well as activity levels. Momentary states will be rated on visual analogue scales.

Doel van het onderzoek

The main aim is to evaluate the effectiveness of a blended behavioral activation intervention or the offering of psychological care using an e-health program blended with support offered by the mental health worker of the general practice (in Dutch POH-GGz). In a randomized controlled trial, we will examine whether such blended treatment has additional value compared to care as usual which frequently constitutes antidepressants alone.

Onderzoeksopzet

Baseline, three months, six months and twelve months

Onderzoeksproduct en/of interventie

Intervention:

The intervention under study is a prescription to an online self-management program blended with a few direct contacts (face-to-face or telephonic) with a GP or POH-GGZ. This program will focus on depressive symptoms and it will be based on the principles of behavioral activation. The program will consist of six to eight modules with a recommended frequency of 1-2 times a week over 6-10 weeks in well-structured sessions with GP at two, four and six weeks (or delegated to POH-GGZ). All participating GPs will receive training on the use of the e-prescription.

Comparator: Care as usual, with medical therapy or other as therapy.
Initiation of an antidepressant: the intention to start with antidepressant medication logically

following the eligibility criteria. Consultations with GP will be arranged at two, four and six weeks (or delegated to POH-GGZ) and a prescription for antidepressant medication will be handed out. During the treatment the dose of the medication is allowed to be adjusted if necessary according to the GP.

Contactpersonen

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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

- Adult patients, i.e. aged 18 or over;

- Patients presenting to the GP with depressive disorder or depressive symptoms;

- Patients with depressive symptoms or a depressive disorder for whom the GP or general practice mental health worker consider a second step in the treatment of depression after the first step of psycho-education and day-structuring exercises have yielded insufficient improvement.
- Patients for whom a GP wants to intensify the current therapy with medications, psychological therapy (GGz) or other

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

- Severe depression requiring referral to specialized mental health service according to current guideline, e.g. acute suicidality

- Severe mental illness (current/past: schizophrenia, psychotic episode, bipolar disorder, depression with psychotic features)

• Anxiety disorder or obsessive compulsive disorder as primary diagnosis

- Current substance abuse (e.g. alcohol, drugs)

- Currently receiving psychological treatment for depression (e-mental health intervention or face-to- face psychological treatment)
- Insufficient command of the Dutch language

- No informed consent given

- No internet available or grossly insufficient computer skills

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Enkelblind
Controle:	Geneesmiddel

Deelname

Nederland

Status:	Werving nog niet gestart
(Verwachte) startdatum:	01-09-2014
Aantal proefpersonen:	302
Type:	Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nog niet bepaald

Ethische beoordeling

Positief advies

Datum:	25-08-2014
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL4606
NTR-old	NTR4757
CCMO	NL80-83910-98-12010

Resultaten