

Disrupting the rhythm of depression using e-mental health.

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It is hypothesized that adding an e-mental health self management intervention (E-Self CT), based on cognitive therapy to Care As Usual (CAU) is clinically superior to CAU alone, for preventing relapse/recurrence in depressive disorder. In addition...

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

Samenvatting

ID

NL-OMON26980

Bron

Nationaal Trial Register

Verkorte titel

Disrupting the rhythm of depression using e-mental health.

Aandoening

Depressive Disorder, E-mental health, Prevention, Relapse, Online Cognitive behavior therapy, Cognitive behavior therapy

Ondersteuning

Primaire sponsor: University of Groningen

Clinical Psychology
Grote Kruisstraat 2/1
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Overige ondersteuning: ZON-MW, The Netherlands Organization for Health Research and Development

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Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Cumulative person-time based incidence of depression relapse/recurrence over 24 months using DSM-IV-TR criteria as assessed by the Structural Clinical Interview for DSM-IV Axis I Disorders (SCID) based on the DSM-IV-TR.

Given the results of previous studies, differential response dependent on number of previous depressive episodes will be examined explicit.

Toelichting onderzoek

Achtergrond van het onderzoek

Rationale:

Major depressive disorder (MDD) is projected to rank second on a list of 15 major diseases in terms of burden in 2030. The major contribution of MDD to disability and health care costs is largely due to its highly recurrent nature. Accordingly, efforts to reduce the disabling effects of this chronic condition should shift to preventing recurrence, especially in patients at high risk of recurrence. Given its high prevalence and the fact that interventions are necessary during the remitted phase of this life long disease, new approaches are needed to prevent relapse in depression and monitor relapse and recurrence as part of a disease management program focused on all stages of MDD. The best established effective and available psychological intervention is cognitive therapy. However, it is costly and not available for all patients. Therefore, we will compare the effectiveness and cost-effectiveness of E-mental health self management CT (E-Self CT) accompanied by SMS based tele-monitoring of depressive symptomatology in addition to care as usual (CAU) versus CAU alone.

Objective:

To study the (cost) efficiency of E-Self CT in preventing relapse for people in remission of recurrent depression. This hasn't been studied before. Alongside the (cost) efficiency we also study the usefulness of the intervention and for which people in particular E-Self CT is an adequate intervention.

Study design:

In this study a total of 268 people will participate. This is a randomised controlled clinical trial of two parallel groups comparing (1) E-Self CT in addition to CAU versus (2) CAU alone, with follow-up measurements every 3 months during this two-year study. Randomisation will be stratified for number of previous episodes, type of care as usual and employment status, because these are potential prognostic ally important variables.

Study population:

Remitted patients presenting with at least two previous depressive episodes in the past five years. Participants need to be able to read in Dutch and have access to the internet. We recruit in primary care (at general practitioners) secondary care (at GGZ institutions) and via media.

Intervention:

When participants are selected (after randomisation) into the intervention group, they will be invited to start with the 8 modules of internet based Preventive Cognitive Training (PCT). In addition to the PCT the mood of participants in the E-Self CT will be monitored with, among other things, text messages and, when needed, questionnaires to detect possible re-occurring depressive symptoms.

Doel van het onderzoek

It is hypothesized that adding an e-mental health self management intervention (E-Self CT), based on cognitive therapy to Care As Usual (CAU) is clinically superior to CAU alone, for preventing relapse/recurrence in depressive disorder. In addition, we expect that the intervention dominates the comparator condition in terms of cost-effectiveness.

Onderzoeksopzet

1. Primary outcome: Cumulative person-time based incidence of depression relapse/recurrence over 24 months using DSM-IV-TR criteria as assessed by the Structural Clinical Interview for DSM-IV Axis I Disorders (SCID, telephonic version) based on the DSM-IV-TR after 3, 12 and 24 months;
2. Implicit measures: Before start, after 3, 12 and 24 months;
3. Secondary outcomes: Before start, after 6 weeks, 3, 6, 9, 12, 15, 18, 21, 24 months.

Onderzoeksproduct en/of interventie

When participants are selected into the intervention group, after randomization, they will

receive E-Self CT in addition to CAU, (for example care of a general practitioner, secondary care or no care at all) and this will be compared to CAU alone. The e-mental health intervention consists of an online version of an effective face to face Preventive Cognitive Therapy (PCT), therapist support and monitoring of mood. The internet PCT consists of 8 modules with complementary homework assignments. Every session has a fixed structure.

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

Participant with a recurrent MDD (DSM-IV-TR) who suffered through at least two previous depressive episodes in the past five years. These participants have to be in remission according to DSM-IV criteria for longer than eight weeks and no longer than two years, and have to have a current score of

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

1. Current mania or hypomania or a history of bipolar illness;

2. Psychotic disorder (current and previous);
3. Alcohol or drug misuse;
4. A predominant anxiety disorder for which treatment is obtained.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blinding:	Enkelblind
Controle:	Actieve controle groep

Deelname

Nederland	
Status:	Werving gestart
(Verwachte) startdatum:	01-01-2010
Aantal proefpersonen:	268
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies	
Datum:	10-09-2010
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	NL2395
NTR-old	NTR2503
Ander register	ABR : 30613
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Resultaten

Samenvatting resultaten

N/A