Disrupting the rhythm of depression using e-mental health.

No registrations found.

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

Summary

ID

NL-OMON26980

Source
NTR

Brief title
Disrupting the rhythm of depression using e-mental health.

Health condition

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

Sponsors and support

Primary sponsor: University of Groningen
Clinical Psychology
Grote Kruisstraat 2/1
9712 TS Groningen
Source(s) of monetary or material Support: ZON-MW, The Netherlands Organization for Health Research and Development
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Intervention

Outcome measures

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) 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.

Secondary outcome

1. Number of relapse/recurrence;

2. Severity: Symptom severity as measured with the Inventory of Depressive Symptomatology (IDS-R);

3. Economic evaluation:

A. Balance between costs and health outcomes with the Quality Adjusted Life Years (QALY) measured with the EQ-5D;

B. Cost data stemming from production losses due to absenteeism and working less efficiently while at work will be collected with the TIC-P.

4. Treatment outcome for participants with co-morbidity with concurrent somatic illnesses assessed by the Health Survey Inquiry and additional questions concerning somatic illnesses;

5. Examining differential predictors of treatment outcome;

6. Mediators.

Study description

Background summary

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.

Study objective

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.

Study design

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.

Intervention

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.

Contacts

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Eligibility criteria

Inclusion criteria

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

Exclusion criteria

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.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)
Control:	Active

Recruitment

NL
Recruitment status:	Recruiting
Start date (anticipated):	01-01-2010
Enrollment:	268
Type:	Anticipated

Ethics review

Positive opinion
Date: 10-09-2010
Application type: First submission

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
NTR-new	NL2395
NTR-old	NTR2503
Other	ABR : 30613
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Study results

Summary results
N/A