Blended versus face-to-face Cognitive Behavioral Therapy for major depression in specialized mental health care – a pilot randomized controlled trial examining health care efficiency

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

Samenvatting

ID

NL-OMON29413

Bron
NTR

Verkorte titel
Health care efficiency of blended CBT for depression – a pilot RCT

Aandoening

Marjor Depressive Disorder (MDD)

Ondersteuning

Primaire sponsor: Perfomers VU University Amsterdam, GGZ inGeest
Overige ondersteuning: ZonMw

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

The health-economic analyses combine clinical outcomes with cost estimates. Measures of these primary variables are described in this section.

Clinical outcomes:
Primary clinical outcomes are 1) recovery from Depression as assessed by the Mini-International Neuropsychiatric Interview (MINI), 2) changes in Depressive symptom severity as measured by the Inventory of Depressive Symptomatology – Self Report (IDS-SR), 3) quality-adjusted life years (QALY's), derived from the Euro Quality of Life questionnaire (EQ-5D-3L) and 4) health-related quality of life, tapped by the SF-36 Health Survey.

Cost outcomes:
Cost estimates include 1) the costs of offering the treatments and 2) Patients' out-of-pocket costs (non-medical), such as the costs of travelling to the health services and the patients' time costs of travelling, waiting and receiving treatment, which are determined with the standard cost prices as listed in the pertinent Dutch guideline for economic evaluation (Tan et al., 2012). Furthermore, 3) Costs stemming from health care uptake, including costs of medication, and 4) Costs stemming from productivity losses due to absenteeism and lesser efficiency while at work (presenteeism) are assessed with The Trimbos/iMTA questionnaire for Costs associated with Psychiatric Illness (TiC-P; Hakkaart – van Roijen et al., 2002).

Toelichting onderzoek

Doel van het onderzoek

The main goal of the study is to explore the health-economic outcomes of bCBT in comparison to CBTAU, through cost-effectiveness analysis (CEA), cost-utility analysis (CUA) and a budget impact analysis (BIA), both from the societal and the health-care perspective. In this proof-of-concept pilot, we assume that bCBT and CBTAU are similarly clinically effective, but that bCBT can be offered at lesser costs. Hence, we expect health-economic outcomes of bCBT to be favorable in comparison to those of CBTAU. If so, this would justify further large-scale evaluations and dissemination efforts.

Onderzoeksopzet

Measurements are taken at four fixed 10-week intervals (see Figure 1); at baseline (T0), week 10, week 20 and at week 30 (T1 – T3).

Onderzoeksproduct en/of interventie

Treatment in both groups is based on a CBT protocol for face-to-face treatment of depression by Bockting and Huibers (2011). CBT is one of the most recommended treatments for depression, according to the multidisciplinary guidelines for depression (Spijker et al., 2012). The protocol comprises psycho-education (explanation of the treatment rationale and the general procedures in CBT treatment), behavioral activation (establishing a balance between compulsory and pleasant activities & building a day structure), cognitive therapy (examining automatic negative thoughts and dysfunctional assumptions) and relapse prevention (identifying and adopting techniques/strategies to prevent depressive symptoms to re-occur). In accordance with standard treatment procedures parallel treatment (such as medication and/or social skills training) is allowed in both conditions, if the practitioner deems this warranted.

Face-to-face CBT (CBTAU)
In the CBTAU condition, patients receive on average 20 45-minutes sessions of face-to-face CBT, spread out over 20 weeks. Sessions will be audio-recorded, if agreed upon by patients and therapists. A randomly selected sample (max. 30%) of these session-recordings will be checked for therapist's treatment integrity by independent raters.

Blended CBT
In the bCBT group, patients receive 10 face-to-face sessions and 10 internet sessions, which will be delivered over a period of 10 weeks (one face-to-face session and one online session per week). Treatment starts and ends with a face-to-face session. The online sessions are delivered through a secure web-based online treatment platform (Minddistrict; www.minddistrict.com). Patients access this platform with a personalized login. The website offers information that repeats and extends the contents of the face-to-face sessions. In addition, patients use the website to complete homework exercises, such as monitoring their activities, feelings, thoughts and behavior. The first online session focusses on working with the online platform. The therapist monitors patients' online progress and weekly provides feedback before the next face-to-face session. Face-to-face sessions will be audio-recorded and checked, following the same procedures as in the CBTAU condition. Online sessions are recorded in the online treatment platform database. On completion of treatment, patients can still access the online treatment platform to reread information and look up homework exercises, such as the relapse prevention plan.

The same medication regimes will be administered for both conditions throughout the study. The pharmacotherapy falls under the responsibility of a psychiatrist and is provided independently of the current study. Patients in both treatment conditions will be monitored throughout the study. The therapists will get monthly feedback of the mood ratings (QIDS-SR) of their patients. When necessary, additional treatments are allowed for all patients at any point of time during the study. If the assessments indicate signs of relapse or suicidal ideation, the investigator will contact the therapist immediately.

Contactpersonen

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

Diagnosis of major depressive disorder Age>18 years Sufficient command of the Dutch Language Access to the Internet, an e-mail adress and a personal computer (PC) or tablet computer Willing to be randomised to one of the two treatment conditions Signed informed consent form

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

Bipolar, psychotic or substance abuse disorder and/or a acute risk of suicide (as signaled by the answer yes to questions 4 or 5 or 3+6 in section C of the MINI plus diagnostic interview).

Onderzoeksopzet

Opzet

Type: Interventie onderzoek

Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Open / niet geblindeerd
Controle:	Geneesmiddel

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	01-09-2014
Aantal proefpersonen:	150
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	18-06-2014
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 41269
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL4408
NTR-old	NTR4650
CCMO	NL47874.029.14
OMON	NL-OMON41269

Resultaten