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

No registrations found.

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

Summary

ID

NL-OMON29413

Source
Nationaal Trial Register

Brief title
Health care efficiency of blended CBT for depression – a pilot RCT

Health condition

Marjor Depressive Disorder (MDD)

Sponsors and support

Primary sponsor: Perfomers VU University Amsterdam, GGZ inGeest
Source(s) of monetary or material Support: ZonMw

Intervention

Outcome measures

Primary outcome

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).

Secondary outcome

To further evaluate bCBT compared to CBTAU, a number of explorative measures are administered.

The Quick Inventory of Depressive Symptomatology (QIDS-SR; Rush et al., 2003), a shortened version of the IDS-SR, will be administered monthly during the study period to more closely monitor the depressive symptom change trajectory (at weeks 4, 8, 12, 16, 24, 28).

The five item version of The Mastery Scale (Pearlin, & Schooler, 1987) is administered at every assessment moment (T0-T3) to assess changes in locus of control.

The 12-item version of the Work Alliance Inventory (WAV-12, Reynolds et al., 1995; Andrusyna et al., 2001; Stinckens et al., 2009) is used to let patients rate the quality of the work alliance between patient and therapist at T1 (week 10). T
The depression scale of the Cognition Checklist (Beck et al., 1987) will be used to assess the frequency of automatic thoughts relevant to depression, at T0-T3. Demographic characteristics such as age, sex, education, employment and marital status will be collected with a general demographic questionnaire. Additional questions are asked concerning clinical

depression characteristics such as age of onset, number of months depressed in past 4 years, duration of current episode, medical illnesses and treatment status. In addition, patients indicate their treatment preference (BCBT / CBTAU). Finally, participants are asked about their computer use: number of hours spent behind a computer and reasons for use. Patient evaluations The Client Satisfaction Questionnaire-8 (CSQ-8; Larsen et al., 1979) will be administered at week 30 (T3).

The System Usability Scale (SUS, Brooke, 1996) will be administered at week 20 amongst the participants randomized to the bCBT group. The SUS consists of 10 questions with 5 response options, ranging from 0 (strongly disagree) to 4 (strongly agree).The total scores are converted to a scale ranging from 0 to 100. Higher scores are indicative of higher usability of the online platform that is used for the Internet sessions in the blended therapy.

Process data Data for process analyses are obtained from the administration of the participating mental health care institutions and through usage statistics of the online platform.

In order to measure treatment fidelity of therapists face-to-face sessions are audio-taped in both treatment groups (when a patient has provided consent for this). A randomly selected sample of these session-recordings will be checked for therapist's treatment integrity by independent raters. In the bCBT condition the raters also include a random selection of the written feedback therapists have provided on the online sessions. The sessions recordings also provide insight in the extent to which patients complied with making their homework exercises.

Time investment will be discussed in more detail in qualitative interviews for which we will invite a random selection of 10 patients per treatment group after week 30. The interviews focus on the feasibility and usability of the CBT treatment provided.

Study description

Study objective

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.

Study design

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).

Intervention

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.

Contacts

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Eligibility criteria

Inclusion criteria

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

Exclusion criteria

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).

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-09-2014
Enrollment:	150
Type:	Anticipated

Ethics review

Positive opinion

Date:	18-06-2014
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 41269
Bron: ToetsingOnline
Titel:

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL4408
NTR-old	NTR4650

Register	ID
CCMO	NL47874.029.14
OMON	NL-OMON41269

Study results