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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This pilot cost-effectiveness study will compare blended cognitive behavioral treatment (bCBT) with standard face-to-face CBT (CBTAU) among patients with a diagnosis of major depressive disorder (MDD), who are treated in outpatient specialized...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Mood disorders and disturbances NEC
Study type	Interventional

Summary

ID

NL-OMON41269

Source
ToetsingOnline

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

Condition

- Mood disorders and disturbances NEC

Synonym
Depression, sadness

Research involving
Human

Sponsors and support

Primary sponsor: Vrije Universiteit
Source(s) of monetary or material Support: ZonMw Doelmatigheid

Intervention

Keyword: Blended cognitive behavioral treatment, Depression, Pilot RCT cost-effectiveness, Specialized mental health care

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.

The Mini-International Neuropsychiatric Interview (MINI; Sheehan et al., 1992; Van Vliet et al., 2007) is a brief clinician-administered structured diagnostic interview for assessing the presence of DSM-IV and ICD-10 psychiatric disorders. The interview takes 45 minutes to conduct at the most, depending on the amount of disorders that are present. In this study, independent, trained research assistants, who are blind to the random allocation, will administer the MINI either over the telephone or face-to-face at the clinic (based on patient preference). At T0 and T3, the MINI will be administered in full. At T1

and T2, current state will be assessed through a focused telephone or face to face interview, in which only MINI section A & B are administered (assessing depressive disorders and dysthymic disorder). At T0, the lifetime-version is administered (which also yields current state). At T1-T3, the MINI is only focused on *current* symptoms of the participant.

The IDS-SR (Rush et al., 1986; Rush et al., 1996; Rush et al., 2000) is a self-report measure of the severity of depressive symptoms in the past week. It consists of 28 items which each have four response categories, ranging from 0 (low severity) to 3 (high severity). The total score varies between 0 and 84, with higher scores being indicative of a higher severity of depressive symptoms. For this study, treatment response is defined as a symptom reduction of the baseline IDS-SR symptom severity score of at least 50%.

The EQ-5D-3L (EuroQol Group, 1990; Lamers et al., 2006) will be administered at every assessment moment (T0-T3) to assess general well-being. The questionnaire consists of five questions that tap mobility, self-care, daily activities, pain and mood. Each item has three response categories, ranging from 0 (no problems) to 3 (severe problems). In addition to this, participants use a VAS scale to rate their health on a scale ranging from 0 (worst possible health) to 100 (best possible health). The answers on the five questions are combined in a number sequence that corresponds with the five answers, for example 03210. The total number of possible sequences is 35=243. Each sequence stands for a certain health state. On these health states, a value (utility) has been placed (Lamers et al., 2006), which in turn is used to determine the quality-adjusted life years (QALYs). This is done by calculating the QALYs gained between the

follow-up periods by weighing the length of time spent in a particular health condition by the utility score (Drummond & Sculpher, 2005).

The Short Form Health Survey (SF-36) will be used to assess health-related quality of life (Aaronson et al., 1998; Bech et al., 2003; Ware et al., 2000). This questionnaire consists of 36 questions that are scored on a 8 multi-item scales, which assess physical functioning, role limitations caused by physical health problems, bodily pain, general health perceptions, vitality, social functioning, role limitations caused by emotional problems and general mental health. The raw scores are converted to a scale ranging from 0 to 100 with higher scores being indicative of better levels of functioning. SF-36 scores will provide a second source to determine QALYS, through the application of the Brazier algorithm (Brazier, Roberts & Deverill, 2002).

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).

TiC-P is the most widely used health service receipt interview for economic evaluations in the Netherlands. The TiC-P consists of 46 questions, divided over two parts. Part 1 entails the health care uptake at relevant health care providers in the past 4 weeks, such as medication intake, and the number of contacts within the mental health care setting, with the GP and with other medical specialists. To determine the costs associated with these contacts, the care consumption is multiplied by the cost price described in the before mentioned guideline (Tan et al., 2012). Part 2 of the TiC-P entails loss of productivity in the past 4 weeks. This is measured by enquiring about the number of days absent from work and the number of days with reduced efficiency due to feeling ill. The costs of productivity losses will be based on the gender and age specific friction costs, as outlined in the Dutch guideline for costing (Tan et al., 2012).

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). This questionnaire consists of 16 questions. The total score ranges from 0 to 27, with higher scores being indicative of a higher severity of depressive symptoms.

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. Locus of control could potentially mediate treatment effect and facilitate relapse prevention (Badamgarav et al., 2003; Neumeyer-Gromen et al., 2004) The questionnaire consists of five questions, which are scored on a five-point Likert-scale, ranging from 1 (totally disagree) to 5 (totally agree). The total score ranges from 5 to 30, with higher scores being indicative of a higher level of experienced 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). The questionnaire is administered to investigate whether the blended treatment for has an effect on the quality of the work alliance.
The questionnaire consists of 12 items, which are scored on a five-point Likert-scale, ranging from 1 (seldom or never) to 5 (always). The raw scores range from 12 to 60, with higher scores being indicative of a better alliance between therapist and patient.

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. The depression scale consists of 14 questions on which a patient rates the frequency with which a thought typically occurs on a five-point Likert-scale ranging from 0 (never) to 4 (always). Scores range from 0-56 with higher scores being indicative of more frequent negative depressive cognitions.

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 CSQ consists of 8 questions with item-specific response categories. The total score ranges from 8 to 32, with higher scores being indicative of higher levels of client satisfaction.

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. We will consider the aspects that will feed the study flow

chart according to the CONSORT guidelines (Moher et al., 2010; Schulz et al., 2010), such as the losses and exclusions for each group, with reasons. In addition to this, we will pay specific attention to:

- The extent to which treatment was provided parallel to bCBT or CBTAU, such as pharmacotherapy, and the nature of this treatment.
- Therapy drop-out (number of completed sessions);
- The total number of face-to-face contacts and cancellations (amount of therapy received);
- Treatment fidelity of both patients and therapists. 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 by both the patient and the therapist. In the bCBT group time investment can be calculated based on the number of face-to-face contacts and the amount of time spent working with the online platform. In the CBTAU group time investment will be estimated based on the number of face-to-face contacts and the treatment fidelity rating.
- 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

Background summary

Depression is a highly prevalent disorder. One in five adults in the general population of the Netherlands will meet the criteria for a major depressive disorder (MDD) at one point in their life (de Graaf et al., 2012). It is estimated that about 300.000 patients per year are treated for mood disorders in the Netherlands and that this results in 5.3 million contact moments with health care professionals (Nuyen et al., 2010).
MDD is severely debilitating and associated with great functional impairments in the mental, physical, social and occupational (if applicable educational) domains. This causes considerable economic costs and increased use of services (Smit et al., 2006). The World Health Organization (WHO) estimates that depression will be the disorder with the highest disease burden in developed countries by 2030 (Mathers & Loncar, 2006; Whiteford et al., 2013).
Internet interventions, especially internet-based cognitive behavioral treatment (iCBT), are seen as an important strategy for lowering the costs of the treatment of common mental health disorders (e.g. unipolar depression and anxiety disorders). Studies show that depression treatment delivered via Internet is more effective than non-intervening and that it can be as effective as face-to-face treatment (Richards & Richardson, 2012, Andersson et al. 2014). Importantly, studies investigating the cost-effectiveness of Internet-based depression treatments suggest that these may also be more cost-effective than face-to-face treatment, albeit the number of studies is still scarce (e.g., Lokkerbol et al., 2013; Smit et al., 2011, Warmerdam et al., 2010; Gerhards et al., 2010). It should be noted that most study results are obtained among self-referred depressed individuals from the general population who participate in standalone Internet treatments (Riper et al. 2013). Clinical and economical evaluation of treatment of depression via Internet among patients in routine primary care and specialized mental health care services are still scarce.
A rather new treatment approach combines face-to-face treatment with Internet sessions into one integrated treatment. This is a so-called *blended* treatment or *hybrid* treatment approach (Riper et al., 2013).
Viewed from a cost-effectiveness perspective, blended treatment could possibly diminish the number of face-to-face contacts, increase self-management competencies of patients and thereby decrease the overall (direct) costs of depression treatment. This approach could also have a positive effect on waitlist periods, as therapists can take on more patients thereby reducing the number of patients that are waitlisted. Dutch mental health care organizations are ready to implement blended treatment, and they are motivated to do so by Dutch health policy makers and insurers (Bakker & Jansen, 2013), because it is

assumed that blended cognitive behavioral treatment (bCBT) and usual face-to-face CBT (CBTAU) are at least similarly clinically effective, and that bCBT can be offered at lesser costs. At present, however, little is known about the clinical and health-economic benefits of blended treatment.
In the current pilot cost-effectiveness study, we will provide a proof-of-concept of this blended treatment, by examining health care efficiency in a pilot randomized controlled trial of bCBT vs. face-to-face CBT (CBTAU), among patients with a diagnosis of major depressive disorder (MDD).
The proposed pilot study is one of a series of projects in which we explore the potential of a new *blended cognitive behavioral treatment* for depression (bCBT). The study is funded through the healthcare efficiency funding program (Dutch: doelmatigheidsonderzoek) of the Netherlands Organization for Health Research and Development (ZonMw). In subprogram 1 of this funding program, ZonMw enables small pilot trials to provide initial scientific assessments of new promising interventions that may have a considerable impact on the efficiency of routine healthcare practice. The development of the blended treatment protocol and intervention has been funded by the Innovation Foundation of the Netherlands Health Insurers Organizations (the umbrella organization of Dutch health insurance companies).
The results of this pilot project will provide a) a first insight into the health-economical outcomes of *blended treatment* (proof of concept), b) indication whether blended treatment will add value when it is implemented in clinical settings, and c) insight in whether blended treatment for depression is advisable and feasible from the perspective of various stakeholders and thus requires a full- blown clinical and economical randomized controlled trial of blended treatment for depression.

Study objective

This pilot cost-effectiveness study will compare blended cognitive behavioral treatment (bCBT) with standard face-to-face CBT (CBTAU) among patients with a diagnosis of major depressive disorder (MDD), who are treated in outpatient specialized mental health care. 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

The study is a pilot cost-effectiveness study, designed as a parallel-group randomized controlled trial (N = 150), in which participants are randomly

allocated to either bCBT (n=75) or CBTAU (n=75). Participants are recruited in a Dutch specialized mental healthcare center of GGZ inGeest (location De Nieuwe Valerius and Zuiderpoort), GGZ Oost Brabant (location Oss) or GGZ Noord-Holland-Noord (location Schagen/Den Helder and Hoorn).
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). The recruitment of participants aims to start at June 2014 (after METC consent) and the study ends at December 2015 (18-month study period, last patient out).
For information on the sample size, see page 14 of the study protocol.

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.

Study burden and risks

The blended CBT treatment that will be provided in this trial does not add risks to the CBT treatment as usual. The questionnaires can be considered a burden. To lessen this burden participants are exempted from partaking in the Routing Outcome Measurement (ROM).

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

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

Bipolair, psychotic or substance abuse disorder and/or a acute rise 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
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	02-09-2014
Enrollment:	150
Type:	Actual

Ethics review

Approved WMO Date:	16-06-2014
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	29-01-2015
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	29-07-2015
Application type:	Amendment
Review commission:	METC Amsterdam UMC

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

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

ID: 29413
Source: Nationaal Trial Register
Title:

In other registers

Register	ID
CCMO	NL47874.029.14

Register	ID
OMON	NL-OMON29413

Study results

Date completed: 05-03-2017

Actual enrolment: 102

Summary results

Trial ended prematurely