Cost-utility and cost-effectiveness of blended eHealth treatment for severe anxiety disorders in secondary mental health care

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This cost-effectiveness study will compare blended cognitive behavioral treatment (bCBT) with standard face-to-face CBT (CBT-TAU) among patients with a diagnosis of an anxiety disorder referred to an outpatient specialized mental health care. The...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Anxiety disorders and symptoms
Study type	Interventional

Summary

ID

NL-OMON44051

Source
ToetsingOnline

Brief title
Health care efficiency for blended eHealth treatment for anxiety

Condition

- Anxiety disorders and symptoms

Synonym
Anxiety, Nervousness

Research involving
Human

Sponsors and support

Primary sponsor: Vrije Universiteit

Source(s) of monetary or material Support: ZonMw: Doelmatigheid

Intervention

Keyword: Anxiety, Blended cognitive behavioral treatment, 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.

Primary clinical outcomes are 1) Severity of anxiety symptoms measured with the Beck Anxiety Inventory (BAI), 2) quality-adjusted life years (QALY*s), derived from the Euro Quality of Life questionnaire (EQ-5D-3L) and health-related quality of life, tapped by the SF-36 Health Survey.

* Beck Anxiety Inventory (BAI) (Beck et al., 1988)consists of twenty-one questions about how the subject has been feeling in the last week, expressed as common symptoms of anxiety (such as numbness and tingling, sweating not due to heat, and fear of the worst happening). It is designed for an age range of 17* 80 years old. Each question has the same set of four possible answer choices, which are arranged in columns and are answered by marking the appropriate one with a cross. The BAI has a maximum score of 63. For this study, treatment response is defined as a symptom reduction of the baseline BAI symptom severity score of at least 30% and remission A score reduction of at least 30% reductie

plus a totale score <11.

* 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).

*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).

Primary cost outcomes 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.

*BDI (Beck Depression Inventory) (Beck et al., 1961) is a 21-question multiple choice self report inventory of the most widely used instruments for measuring the severity of depression and assesses presence and severity of depressive symptoms.

*BSI (Brief Symptom Inventory) (Derogatis and Melisaratos, 1983)is a 53-item, self-report symptom inventory designed to evaluate general psychopathology. It is a brief form of the SCL-90 and is designed to provide a multidimensional symptom measurement in about 10 minutes.

*PDSS (Panic Disorder Severity Scale (PDSS) (Shear et al., 1997) is one tool that can be used to assess the severity of your panic attacks. The scale is fairly simple. There are only 7 questions numbered, each one with 5 answers that can be worth a maximum of 4 points (using 0 to 4 for scoring). That leads to 28 total points possible with this scale. Any score over 9 is considered

important enough to discuss with a clinical psychologist.

*LSAS (Liebowitz Social Anxiety Scale) originally developed by Liebowitz (1987) is a short questionnaire to assess the range of social interaction and performance situations feared by a patient in order to assist in the diagnosis of social anxiety disorder. The scale features 24 items, 13 relating to performance anxiety and 11 concerning social situations and has been validated as a self-report scale (Rytwinski et al., 2009).

*PSWQ (Penn State Worry Questionnaire) (Meyer et al., 1990) is a elf-report measure to assess pathological worry in GAD patients. By adding up the value (five-point scale, range 1*5) of all 16 items (e.g., *I*m always worrying about something*) a score from 16 to 80 can be reached.

*WSAS (Work and Social Adjustment Scale) (Mundt et al., 2002) (is a simple 5-item patient self-report measure, which assesses the impact of a person*s mental health difficulties on their ability to function in terms of work, home management, social leisure, private leisure and personal or family relationships. The WSAS is used for all patients with depression or anxiety as well as phobic disorders.

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 anxiety characteristics such as age of onset, number of months with anxiety symptoms 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

*CSQ (Client Satisfaction Questionnaire-8 (CSQ-8; Larsen et al., 1979)) will be administered at week 64-72 (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 64-72. The interviews focus on the feasibility and usability of the CBT treatment provided.

Study description

Background summary

Anxiety disorders (1 year prevalence 10,1%, incidence 3,1%) are severe psychiatric disorders associated with a poor quality of life and substantial economic ramifications (Graaf R de, 2010; RIVM, 2013; Smit et al., 2006). In the Netherlands, the annual healthcare costs associated with anxiety disorders are estimated at ¤286 million, 45% (¤128 million) of which is spent on secondary mental health care, to treat patients with more severe anxiety disorders. Costs due to absenteeism in anxiety disorders are estimated at ¤998 million per year (RIVM, 2013), exceeding those of depression which are estimated at ¤467.4 million (GGZNederland, 2010; RIVM, 2013; Smit et al., 2006) In 2007, the total disease burden caused by anxiety disorders was 202,000 DALY*s in the Netherlands, being third in the top ten list of medical disorders and having a higher cost impact than depression, diabetes or lung cancer (RIVM, 2013).

For the above reasons it is of paramount importance to deliver appropriate and efficient treatment in severe anxiety disorders to decrease the public health impact of these disorders. Anxiety disorders can be treated effectively with cognitive-behavioural therapies (CBT), whether or not combined with pharmacotherapy. CBT is regarded as treatment as usual (TAU) and recommended in national and international treatment guidelines (NICE; www.ggzrichtlijnen.nl). It has been shown that anxiety disorder patients in the Netherlands have a preference for non-pharmacological treatment. In addition, compared with pharmacotherapy, patients who achieve full remission after treatment with CBT are less likely to relapse when treatment has stopped (Bruce et al., 2005). However, less than half of the patients with anxiety disorders receives appropriate treatment (Bijl et al., 2003), due to anxiety related avoidance behaviour, stigmatisation, costs, and a perceived lack of availability of appropriate treatments (Reger and Gahm, 2009).

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).

Internet based cognitive behavioural therapy programmes (iCBT) have been developed for most common anxiety disorders like panic disorder with or without agoraphobia, social phobia and generalized anxiety disorder, which have proven to be at least equally effective as face-to-face psychotherapy. Another advantage of iCBT is that it requires less therapist time and as a consequence is expected to be less costly than conventional CBT.

Studies show that anxiety treatment delivered via Internet is more effective than non-intervening and that it can be as effective as face-to-face treatment (Andersson et al., 2014; Andrews et al., 2010; Cuijpers et al., 2009; Haug et al., 2012; Lewis et al., 2012; Mayo-Wilson and Montgomery, 2013; Reger and Gahm, 2009; Spek et al., 2007). Importantly, studies investigating the cost-effectiveness of Internet-based depression and anxiety treatments suggest that these may also be more cost-effective than face-to-face treatment, but the number of studies is still scarce (e.g., (Gerhards et al., 2010; Hedman et al., 2014; Hedman et al., 2012; Lokkerbol et al., 2014; Nordgren et al., 2014; Smit et al., 2011; Tyrer et al., 2014; Warmerdam et al., 2010).

Additionally, 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, 2013).

Clinical and economical evaluations of treatment of anxiety 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 approach (Riper, 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, 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, 2013), because it is assumed that blended cognitive behavioural therapy (bCBT) and usual face-to-face CBT (CBT-TAU) 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 cost-effectiveness study, we will examine health care efficiency in a randomized controlled trial of bCBT vs. face-to-face CBT (CBT-TAU), among patients with a diagnosis of with a diagnosis of a severe anxiety disorder like panic disorder with or without agoraphobia, as social phobia or a generalized anxiety disorder. The proposed study is one of a series of projects in which we explore the potential of a *blended cognitive behavioral treatment* (bCBT) for anxiety and depression.

The study is funded through the healthcare efficiency funding program (Dutch: doelmatigheidsonderzoek) of the Netherlands Organization for Health Research and Development (ZonMw). In subprogram 2 of this funding program, ZonMw enables the investigation of health care efficiency of applied interventions.

The results of this cost-effectiveness study will provide a) insight into the

health-economical outcomes of *blended treatment*, b) indication whether blended treatment will add value when it is implemented in clinical settings, and c) insight in whether blended treatment for anxiety is advisable and feasible from the perspective of various stakeholders.

Study objective

This cost-effectiveness study will compare blended cognitive behavioral treatment (bCBT) with standard face-to-face CBT (CBT-TAU) among patients with a diagnosis of an anxiety disorder referred to an outpatient specialized mental health care. The main goal of the study is to explore the health-economic outcomes of bCBT in comparison to CBT-TAU, through cost-effectiveness analysis (CEA), cost-utility analysis (CUA) and a budget impact analysis (BIA), both from the societal and a healthcare perspective. We assume that bCBT and CBT-TAU 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 CBT-TAU. If so, this would justify further large-scale evaluations and dissemination efforts.

Study design

The study is a cost-effectiveness study, designed as a parallel-group randomized controlled trial (N = 156), in which participants are randomly allocated to either bCBT (n=78) or CBTAU (n=78). Participants are recruited in a Dutch specialized mental healthcare center (GGZInGeest, GGZ Noord-Holland-Noord, GGZAltrecht or GGZ Oost Brabant), both large scale mental health service organizations, respectively in the Noord-Holland, Utrecht and Noord- Brabant region.

Measurements are taken at four fixed 6-10-week intervals (depending on the type of anxiety treatment); at baseline (T0), week 6-10, week 12-20 and at week 78 (T1 * T3). The recruitment of participants aims to start at 27th of March 2015 (after METC consent) and the last patient follow-up measurement will be December 2017. The outcomes of our study are to be expected in 2018. For information on the sample size, see the study protocol.

Intervention

Treatments in both groups are based on CBT and exposure with response prevention (ERP) protocols for face-to-face treatment of anxiety disorders according to the Dutch multidisciplinary treatment guidelines for anxiety disorders (panic disorder with or without agoraphobia, social phobia, and generalized anxiety). CBT and ERP are the most recommended treatments for anxiety, according to these guidelines (van Balkom et al, 2013).

The protocols comprise psycho-education (explanation of the treatment rationale

and the general procedures in CBT treatment), cognitive therapy (examining relation between thoughts, emotions and behavior), a combination of exposure in vivo with response prevention (ERP; exposure to feared situations combined with prevention of avoidance behaviour and challenging accompanying catastrophic expectations, followed by cognitive restructuring). Depending on the type of disorder all of these components receive more or less attention in the therapy. In case of comorbidity (ie. depression) or when the initial CBT response is insufficient, psychotropic drugs are added; including Serotonin reuptake inhibitors (SSRI's) or as a next step serotonergic Tricyclic Antidepressants. The last part of the protocol will provide information on 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 CBT-TAU condition, patients receive on average 12-20 45-minutes sessions of face-to-face CBT, spread out over 12-20 weeks (depending on the type of anxiety disorder).

In the CBTAU condition, patients receive on average 12-20 45-minutes sessions of face-to-face CBT, spread out over 12-20 weeks (depending on the type of anxiety disorder).

Blended CBT (bCBT)

In the bCBT group, patients receive 6-10 face-to-face sessions and 6-10 internet sessions, which will be delivered over a period of 12-20 weeks. Treatment starts and ends with a face-to-face session. The online sessions are delivered through a secured 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 focuses on working with the online platform. The therapist monitors patients* online progress and provides weekly feedback prior to the next face-to-face session. Face-to-face sessions will be audio-recorded and checked, following the same procedures as in the CBT-TAU condition. Online sessions are recorded in the online treatment platform database. On completion of treatment, patients can still access the online treatment platform to re-read 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. Pharmacotherapy falls under the responsibility of a psychiatrist and is provided independently of the current study.

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.

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 a severe anxiety 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

Primary diagnosis of a bipolar, psychotic or substance abuse disorder and/or acute risk of suicide

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):	12-11-2015
Enrollment:	156
Type:	Actual

Ethics review

Approved WMO Date:	20-04-2015
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	27-10-2015

Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	12-02-2016
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	17-02-2016
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	06-09-2016
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

No registrations found.

In other registers

Register	ID
CCMO	NL51672.029.15