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

No registrations found.

Ethical review	Not applicable
Status	Recruiting
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON27262

Source
Nationaal Trial Register

Health condition

Anxiety disorder; panic disorder; social phobia, generalized anxiety disorder

Angststoornis; paniekstoornis; sociale fobie; gegeneraliseerde angststoornis

Sponsors and support

Primary sponsor: Altrecht Anxiety Center
Source(s) of monetary or material Support: ZonMW, The Netherlands Organization for Health Research and Development

Intervention

Outcome measures

Primary outcome

Primary outcome measure: presence and severity of anxiety symptoms measured with the

Beck Anxiety Inventory (BAI).

Secondary outcome

Secondary outcome measures: (i) presence and severity of depressive symptoms measured with the Beck Depression Inventory, general psychopathology (Brief Symptom Inventory). Patient satisfaction, quality of life and degree of daily functioning will be measured with the Psychiatric Care Satisfaction Questionnaire (PCSQ) the European Quality of life 5-dimension (EQ-5D) and the Work and Social adjustment Scale(WSAS).

Economic outcome measures include: direct and indirect healthcare costs as measured by the Trimbos/iMTA questionnaire for Costs associated with Psychiatric Illness (TIC-P) including productivity losses costs as measured by the iMTA Productivity Cost Questionnaire iPCQ.

Study description

Background summary

Background:

In the Netherlands, treatment of patients with anxiety disorders in secondary mental health care costs €128 million per year.The costs due to absenteeism are €998 million per year.

Treatment as usual (TAU) for anxiety disorders entails cognitive behavioural therapy (CBT). Internet based CBT (iCBT) can increase availability, has proven to be at least equally effective and requires less therapist time. Blended eHealth is a combination treatment, in which regular face-to-face CBT contacts are partially replaced by iCBT and is applied in secondary mental health care.

Objective:

To investigate the efficacy and cost-effectiveness of blended eHealth treatment versus TAU for patients with anxiety disorders in secondary mental health care. We hypothesize that blended eHealth treatment is evenly effective, but more cost-effective than TAU.

Design:

In a multicenter, randomized controlled clinical trial blended eHealth treatment is compared to TAU. Measurements: baseline (T0), 8 weeks (T1: mid-treatment), 16 weeks (T2: post-

treatment), 52 weeks after treatment (T3: follow-up).

Population:

Patients over 18 years of age with severe anxiety disorders (DSM-IV: panic disorder with or without agoraphobia, generalized anxiety disorder or social phobia) referred for outpatient treatment in the secondary mental health services.

Interventions:

Blended eHealth is protocolled and contains max. 16 sessions, of which 8 face-to-face CBT and 8 iCBT sessions. TAU includes max. 16 regular face-to-face CBT sessions.

Outcomes:

Primary: Anxiety (BAI). Secondary: quality of life (EQ-5D), Depression (BDI), general psychopathology (BSI) and disease-specific symptoms. Economic: The direct and indirect costs of care and due to absenteeism (TIC-p).

Sample-size:

Inclusion of 78 patients per condition (total n = 156). The sample size in this equivalence study is based on an applied equivalence limit difference ES of 0.4 with a 80% power that both treatments are similar

Analysis:

The differential efficacy is analysed in an intention to treat analysis. The cost-effectiveness and utility analysis is conducted from both a healthcare and social perspective and contains incremental cost-utility and cost-effectiveness ratios. A Markov model will estimate the long-term economic outcome and the budget impact.

Time schedule:

36 months: preparation (3), inclusion (18), follow-up (12) and analysing and reporting (3).

Study objective

Blended eHealth treatment is evenly effective and more cost-effective than treatment as usual.

Study design

T0 = 0 weeks

T1 = 8 weeks after baseline

T2 = 16 weeks after baseline

T3 = 52 weeks after end of treatment

Intervention

Blended eHealth is a combination treatment, in which regular face-to-face CBT contacts are partially replaced by internet based CBT (iCBT). This blended treatment is applied in secondary mental health care as fewer patients drop out of treatment when there is some face-to-face contact with a therapist, in contrast to primary care. The iCBT modules in blended eHealth resemble conventional CBT modules of weekly sessions (up to 16); both consisting of 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. The iCBT sessions include video’s and text boxes where patients receive therapy information and can provide feedback and track
registration of their assignments. Once an exercise is completed, the therapist receives a message or an alert and can provide feedback, if necessary.

The control group will receive care as usual. The usual standard care CBT interventions for anxiety disorders in secondary mental health care entails face-to-face sessions with a therapist and usually consist of 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 Tricyclic Antidepressant Clomipramine.

Contacts

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Eligibility criteria

Inclusion criteria

Inclusion criteria are:

1. Being 18 years or older

2. Primary diagnosis of a severe anxiety disorder; i) panic disorder with or without agoraphobia, ii) social phobia, iii) generalized
anxiety disorder according to the DSM-IV classification criteria, as assessed by a Structural Clinical for DSM-IV for axis-I disorders (SCID-I) after psychiatric intake by a psychiatrist or clinical psychologist.

3. Referred for ambulatory secondary mental health care services

Exclusion criteria

Exclusion criteria are:

1. No access to internet or personal computer

2. Not able to speak or read the Dutch language

3. Illiteracy

4. Refusal to participate

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):	01-12-2014
Enrollment:	156
Type:	Anticipated

Ethics review

Not applicable

Application type:	Not applicable

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	NL4774
NTR-old	NTR4912
Other	ZonMw : 837002505

Study results