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

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

Ethische beoordeling	Niet van toepassing
Status	Werving gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON27262

Bron
Nationaal Trial Register

Aandoening

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

Angststoornis; paniekstoornis; sociale fobie; gegeneraliseerde angststoornis

Ondersteuning

Primaire sponsor: Altrecht Anxiety Center
Overige ondersteuning: ZonMW, The Netherlands Organization for Health Research and Development

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Primary outcome measure: presence and severity of anxiety symptoms measured with the Beck Anxiety Inventory (BAI).

Toelichting onderzoek

Achtergrond van het onderzoek

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).

Doel van het onderzoek

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

Onderzoeksopzet

T0 = 0 weeks

T1 = 8 weeks after baseline

T2 = 16 weeks after baseline

T3 = 52 weeks after end of treatment

Onderzoeksproduct en/of interventie

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.

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Enkelblind
Controle:	Geneesmiddel

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	01-12-2014
Aantal proefpersonen:	156
Type:	Verwachte startdatum

Ethische beoordeling

Niet van toepassing

Soort:	Niet van toepassing

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL4774
NTR-old	NTR4912
Ander register	ZonMw : 837002505

Resultaten