

Beating the Blues.

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On the basis of the available literature, we hypothesize that the clinical and cost effectiveness of computerized cognitive-behavioural therapy with limited therapist support is not inferior (by an amount of $\Delta = 0.2$) to face-to-face therapy...

Ethische beoordeling	Positief advies
Status	Werving tijdelijk gestopt
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON22545

Bron

NTR

Verkorte titel

BtB

Aandoening

(Sub)clinical depression, anxiety symptoms

Ondersteuning

Primaire sponsor: Interhealth

Grotekerksplein 4
3311 CC Dordrecht
T: 0880104300
www.interhealth.nl

Overige ondersteuning: Interhealth (www.interhealth.nl).

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

The main study parameter is the presence/ severity of depressive symptoms as measured with the Beck Depression Inventory (BDI-II-NL). Other clinical and economic questionnaires (CORE-34, PHQ-9, BADS, DAS, WSAS, EQ-5D/VAS, TiC-P) will be used to back up the main study parameter. More specifically, they will be used to answer the research questions about (cost) effectiveness.

Toelichting onderzoek

Achtergrond van het onderzoek

This study compares computerized cognitive behavioural therapy with limited therapist support to face-to-face therapy based on cognitive behavioural techniques in a (non-inferiority) randomized trial. The study will focus will be on clinical and cost effectiveness.

Doel van het onderzoek

On the basis of the available literature, we hypothesize that the clinical and cost effectiveness of computerized cognitive-behavioural therapy with limited therapist support is not inferior (by an amount of $\Delta = 0.2$) to face-to-face therapy based on cognitive behavioural techniques.

Onderzoeksopzet

1. Baseline;
2. Mid-treatment;
3. Post-treatment;
4. Six-month follow-up;
5. Twelve-month follow-up.

Onderzoeksproduct en/of interventie

The CCBT program that is going to be used in this study is Beating the Blues (BtB). BtB is based on cognitive-behavioural techniques and consists of an introductory video and eight computerized sessions, lasting around fifty minutes. The sessions are (inter)active and based on cognitive behavioural techniques, clarified with the help of animations and case-studies. Each session ends with a summary and several homework assignments. Furthermore, both the therapist and the client receive a progress report after each session. The complete program minimally takes eight weeks. The client is encouraged to go through one session each week, and to schedule all of the sessions in his or her diary beforehand. During the BtB program, the therapists meet their client three times in face-to-face sessions of 45 minutes

each:

1. Before the program - for an intake;
2. After the fourth session - for motivation and support;
3. After the program - for an evaluation.

The alternative to CCBT in this study is face-to-face therapy based on cognitive-behavioural techniques. The face-to-face therapy lasts minimally eight and maximally sixteen weeks, with eight to nine sessions of 45 minutes each. The client is supposed to do home work assignments after each session. In order to ensure that the therapists indeed do apply cognitive-behavioural techniques, a random selection of five percent of the sessions will be video-taped. These videos will be analyzed for their cognitive-behavioural content by independent therapists.

Contactpersonen

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen

(Inclusiecriteria)

All clients of Mentaal Beter in the age range of 18 to 65 with a score between 14 and 28 on the BDI-II-NL (Van der Does, 2002) will be asked to participate in the study. The minimal duration of the depressive complaints needs to be at least two months. The participants also need to be native Dutch speakers and to have access to internet and e-mail at home.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

These participants will only be asked to participate in the study when they receive no other psychological treatment for their depressive complaints. Furthermore, the presence of suicide ideation, severe co-morbid diagnoses (in particular current psychosis and organic mental disorders) and substance abuse are not allowed.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blinding:	Open / niet geblindeerd
Controle:	Geneesmiddel

Deelname

Nederland	
Status:	Werving tijdelijk gestopt
(Verwachte) startdatum:	01-06-2011
Aantal proefpersonen:	374
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum: 25-11-2010
Soort: Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 36592
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL2503
NTR-old	NTR2621
CCMO	NL33917.097.10
ISRCTN	ISRCTN wordt niet meer aangevraagd.
OMON	NL-OMON36592

Resultaten

Samenvatting resultaten

N/A