Beating the Blues.

No registrations found.

Ethical review	Positive opinion
Status	Suspended
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON22545

Source
NTR

Brief title
BtB

Health condition

(Sub)clinical depression, anxiety symptoms

Sponsors and support

Primary sponsor: Interhealth
Grotekerksplein 4
3311 CC Dordrecht
T: 0880104300
www.interhealth.nl
Source(s) of monetary or material Support: Interhealth (www.interhealth.nl).

Intervention

Outcome measures

Primary outcome

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.

Secondary outcome

The secondary study parameters are:

1. Client acceptability ratings, as measured with the AQ (long and short versions);

2. Presence/ severity of anxiety symptoms, as measured with the anxiety subscale of the CORE-34 and with the GAD-7.

Age, sex, social economic status and ethnical background will be used as prognostic factors.

Study description

Background summary

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.

Study objective

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.

Study design

1. Baseline;

2. Mid-treatment;

3. Post-treatment;

4. Six-month follow-up;

5. Twelve-month follow-up.

Intervention

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.

Contacts

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Eligibility criteria

Inclusion criteria

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.

Exclusion criteria

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.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active

Recruitment

NL

Recruitment status:	Suspended
Start date (anticipated):	01-06-2011
Enrollment:	374
Type:	Anticipated

Ethics review

Positive opinion

Date:	25-11-2010
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 36592
Bron: ToetsingOnline
Titel:

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

No registrations found.

In other registers

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

Study results

Summary results
N/A