# Beating the Blues - a randomized controlled clinical trial on computerized cognitive behavior therapy for mild to moderate depression in the Netherlands.

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| **Ethical review** | Approved WMO |
| **Status** | Will not start |
| **Health condition type** | Mood disorders and disturbances NEC |
| **Study type** | Interventional |

## Summary

### ID

NL-OMON36592

**Source**
ToetsingOnline

**Brief title**
Beating the Blues

### Condition

- Mood disorders and disturbances NEC

**Synonym**
depressive symptoms; melancholy

**Research involving**
Human

### Sponsors and support

**Primary sponsor:** Interhealth

**Source(s) of monetary or material Support:** Interhealth B.V.

## Intervention

**Keyword:** Beating the Blues, Cognitive behavior therapy, Internet therapy, RCT

## Outcome measures

### Primary outcome

The main study parameter is the presence/ severity of depressive symptoms as measured with the Beck Depression Inventory. Measurement takes place over time at (1) baseline, (2) post-treatment, (3) six-month follow-up and (4) twelve-month follow-up.

Other clinical and economic questionnaires will be used to back up the main study parameter (see Table 7 1 in protocol) . 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 (composed) questionnaire AFQ; (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 (3).

# Study description

### Background summary

Our general aim is to evaluate the Dutch version of Beating the Blues, a computer-based cognitive behavioural therapy for mild to moderate depressive complaints, offered in conjunction with limited therapist support. The effectiveness of Beating the Blues has been established in the UK, but not yet in the Netherlands. However, the program is currently used in Dutch practices of Mentaal Beter, as an alternative to face-to-face therapy based on cognitive-behavioural techniques. On the basis of the available literature, we hypothesize that computerized cognitive-behavioural therapy with limited therapist support is not inferior to face-to-face therapy based on cognitive-behavioural techniques.

### Study objective

The primary objective of this trial is to determine the clinical and cost effectiveness of computerized cognitive behavioural therapy with therapist support, compared to face-to face therapy based on cognitive-behavioural techniques for mild to moderate depressive symptoms. Secondary objectives include the acceptability of the two forms of treatment, as well as their influence on symptoms of anxiety. Additionally, predictors and moderators of outcome will be investigated.

### Study design

A non-inferiority randomized clinical trial will be conducted, with 374 participants randomly allocated to either computerized cognitive-behavioural therapy with limited therapist support or face-to-face therapy based on cognitive-behavioural techniques. We will make use of blocked randomization to assure an equal amount of participants in each group. Blinding is not possible - both the researcher and the participant are aware of the allocated condition, but only so after the screening and randomization. The study will be preceded by an external pilot, with 30 participants.

### Intervention

Beating the Blues consists of eight fifty-minute (inter)active modules with a cognitive-behavioural content, elucidated by several returning case studies. Each session ends with a summary and with home-work assignments. The Dutch version of Beating the Blues is offered with limited therapist support (three face-to-face contacts).

### Study burden and risks

It is unlikely that Beating the Blues or the treatment as usual will lead to serious adverse events. As such, the study poses no risk to the participants. However, the participants are asked to invest time into this study. The screening will be conducted by telephone and will take approximately 30-40 minutes. Furthermore, over a one-year period, four sets of questionnaires will be offered via the internet. It will approximately take 30-50 minutes to complete each set of questionnaires.

## 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

BDI-II-NL range 14 to 28;Duration complaints >= two months;Age range 18 to 65 ;Native Dutch speaker;Access to internet and e-mail at home

### Exclusion criteria

Other psychological treatment for complaints;Presence of suicide ideation (currently) ;Severe co-morbid disorders ;Substance abuse (alcohol/ drugs)

## Study design

### Design

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

### Recruitment

NL

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|---|---|
| Recruitment status: | Will not start |
| Start date (anticipated): | 15-06-2011 |
| Enrollment: | 404 |
| Type: | Anticipated |

## Ethics review

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| Approved WMO Date: | 19-08-2011 |
| Application type: | First submission |
| Review commission: | METIGG: Medisch Ethische Toetsingscommissie Instellingen Geestelijke Gezondheidszorg (Utrecht) |

## Study registrations

## Followed up by the following (possibly more current) registration

No registrations found.

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

ID: 22545
Source: NTR
Title:

## In other registers

| Register | ID |
|---|---|
| CCMO | NL33917.097.10 |
| OMON | NL-OMON22545 |