

# The effectiveness of blended treatment for depression: combining face-to-face and online therapy

No registrations found.

<b>Ethical review</b>	Not applicable
<b>Status</b>	Pending
<b>Health condition type</b>	-
<b>Study type</b>	Interventional

## Summary

### ID

NL-OMON25452

### Source

Nationaal Trial Register

### Health condition

Depression, major depressive disorder.

## Sponsors and support

**Primary sponsor:** VU University Amsterdam, GGZ inGeest

**Source(s) of monetary or material Support:** European Community's Seventh Framework Program (EU-FP7)

## Intervention

## Outcome measures

### Primary outcome

Level of depressive symptoms (PHQ-9)

### Secondary outcome

Depressive Symptomatology (QIDS)

Diagnosis of depression and comorbid disorders (M.I.N.I.)  
Health-related quality of life (EQ-5D)  
Patients' treatment preference  
Patients' expectancy (CEQ)  
Patients' satisfaction (CSQ-8, SUS)  
Working alliance (WAI, WAI-online therapy)  
Costs-effectiveness of bCBT (using TiC-P)

## Study description

### Background summary

In this study, a randomized controlled trial will be conducted comparing blended Cognitive Behavioural Therapy (bCBT) to treatment as usual (TAU), among patients referred to specialised mental healthcare with a diagnosis of major depressive disorder (MDD) in The Netherlands. The study is part of a large European project ("European Comparative Effectiveness Research on Internet-Based Depression Treatment" (E-COMPARED); [www.ecompared.eu](http://www.ecompared.eu)), carrying out comparable trials in eight countries.

### Study objective

Blended depression treatment is as effective as regular treatment, but the blended treatment is more cost-effective.

### Study design

Baseline, 3, 6 and 12 months

### Intervention

Blended Cognitive Behavioural Therapy (bCBT): combines individual face-to-face CBT with CBT delivered through an Internet-based treatment platform (ICT4Depression). This platform is connected to a mobile phone application which will be used for the monitoring of patients' mood state (ecological momentary assessment: EMA) and automated feedback and motivational messages (ecological momentary intervention: EMI). Eighteen alternating face-to-face and online sessions will be delivered over a period of 18-20 weeks.

Treatment as usual (TAU): the routine care that subjects receive when they are treated for depression in specialised mental healthcare.

## Contacts

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## Eligibility criteria

### **Inclusion criteria**

- Being 18 years of age or older.
- Meet DSM-IV diagnostic criteria for MDD as confirmed by the telephone administered MINI International Neuropsychiatric Interview version 5.0 and a score of 5 or higher on the PHQ-9 screening questionnaire.
- Provide signed informed consent.

### **Exclusion criteria**

- Having current high risk for suicide according to the M.I.N.I. Interview section C.
- Having serious psychiatric co-morbidity as established in the M.I.N.I. interview, i.e. bipolar affective disorder, psychotic illness, substance dependence and obsessive compulsive disorder.
- Currently receiving psychological treatment for depression in primary or specialised mental health care.
- Being unable to comprehend the spoken and written Dutch language.
- Not having access to an internet connection.
- Not willing to carry an Android smartphone during the duration of treatment.

## Study design

### Design

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

### Recruitment

NL	
Recruitment status:	Pending
Start date (anticipated):	01-03-2015
Enrollment:	150
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 NL4838

NTR-old NTR4962

Other Grant agreement nr for Collaborative Project, funded by EU-FP7 : 603098

## Study results