The (cost-) effectiveness of blended Cognitive Behavioral Therapy (bCBT) for Major Depressive Disorder in specialised mental health care: E-COMPARED trial in the Netherlands.

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Compare the clinical- and cost-effectiveness of blended cognitive behavioral treatment (bCBT) to treatment as usual (TAU) for adults with MDD in specialised ambulatory mental healthcare.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Mood disorders and disturbances NEC
Study type	Interventional

Summary

ID

NL-OMON44347

Source
ToetsingOnline

Brief title
Blended CBT for depression in specialised mental health care

Condition

- Mood disorders and disturbances NEC

Synonym
depression, mood disorder

Research involving
Human

Sponsors and support

Primary sponsor: Vrije Universiteit Medisch Centrum
Source(s) of monetary or material Support: European Community's Seventh Framework Program (EU-FP7)

Intervention

Keyword: blended CBT, ecological momentary assessment, major depressive disorder (MDD), specialised mental healthcare

Outcome measures

Primary outcome

Primary study outcome is the score on the PHQ-9/QIDS-SR, measuring the level of

depressive symptoms.

Secondary outcome

- A diagnosis of depression (and comorbid disorders), assessed with the MINI

International Neuropsychiatric Interview.

- Health-Related Quality of Life, measured with the EQ-5D-5L (EuroQol).

- Health service uptake and production loss due to illness, which produces

economic costs, measured with the Trimbos and iMTA Questionnaires on Costs

Associated with Psychiatric Illness (TiC-P).

- Patient's expectancy of treatment, measured with the Credibility and

Expectancy Questionnaire (CEQ)

- Patient*s satisfaction with the treatment, assessed with the Client

Satisfaction Questionnaire (CSQ-8)

- Satisfaction with the platform, evaluated with the System usability scale

(SUS)

- The working alliance between therapists and patient, assessed with the short

version of the Working Alliance Inventory (WAI-SF).

- The technical alliance, measured with the Technical Alliance Inventory (TAI)

- Patients' sense of mastery, measured with the Masteryscale

- Possible negative side-effect of the treatment, assessed with the 'Inventory

for the assessment of Negative Effects of Psychotherapy' (INEP)

Study description

Background summary

Internet-based CBT (iCBT) has been developed and shown effective for prevention and treatment of depression in the general population and in primary care. The next step is to find ways to deliver iCBT in routine mental health practice and to test its effectiveness in that context. As patients in mental health care have more severe and more complex symptomatology, it is assumed that so called *blended* treatment (a combination of face-to-face and online treatment) is most suitable for this population. Blended treatment may provide a (cost-) effective alternative to face-to-face treatment for patients with major depressive disorder (MDD).

Study objective

Compare the clinical- and cost-effectiveness of blended cognitive behavioral treatment (bCBT) to treatment as usual (TAU) for adults with MDD in specialised ambulatory mental healthcare.

Study design

A pragmatic randomized controlled trial (N = 150) with two parallel conditions, comparing the clinical effects and economic outcomes of TAU (N = 75) to those of bCBT (N = 75), as delivered in two treatment center locations of GGZ inGeest. Measurements are taken at baseline (T0), at month 3 (T1) and follow-up at month 6 (T2) and month 12 (T3).

Intervention

Blended cognitivive behavioral therapy (bCBT) combines individual face-to-face CBT with CBT delivered through an Internet-based treatment platform (ICT4Depression) and a mobile phone component for ecological momentary assessment (EMA). Patients receive weekly alternating face-to-face and online

sessions over a period of 18 weeks. The core components of the treatment are: (1) psycho-education, (2) cognitive restructuring, (3) behavioural activation and (4) relapse prevention.

Study burden and risks

The burden consists of having to fill out extra questionnaires. The risk is estimated to be low.

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

- Being 18 years of age or older

- Meet DSM-IV diagnostic criteria for MDD as confirmed by the MINI International Neuropsychiatric Interview version 5.0 and a score > 5 on the PHQ-9.

Exclusion criteria

- Current high risk of suicide according to the MINI Interview section C.
- Serious psychiatric co-morbidity that requires alternative treatment including substance dependence, bipolar affective disorder, psychotic illness, obsessive compulsive disorder as established at the MINI interview.
- 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 a computer or tablet with an internet connection
- Not motivated to use the mobile application of the intervention that is offered on Android mobile phones (ICT4Depression)

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	29-07-2015
Enrollment:	150
Type:	Actual

Medical products/devices used

Generic name:	ICT4Depression platform and Moodbuster application

Registration:	No

Ethics review

Approved WMO Date:	08-05-2015
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	30-07-2015
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	14-03-2016
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	03-06-2016
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	24-08-2016
Application type:	Amendment
Review commission:	METC Amsterdam UMC

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
CCMO	NL50340.029.15

Study results

Date completed: 22-07-2018

Actual enrolment: 103

Summary results
Trial is onging in other countries