

# Effectiveness and cost-effectiveness of internet-based treatment of insomnia in depressed patients treated at a mental healthcare outpatient clinic.

No registrations found.

<b>Ethical review</b>	Positive opinion
<b>Status</b>	Recruiting
<b>Health condition type</b>	-
<b>Study type</b>	Interventional

## Summary

### ID

NL-OMON22668

### Source

Nationaal Trial Register

### Brief title

EINSTEIN

### Health condition

Unipolar depression, insomnia disorder

## Sponsors and support

**Primary sponsor:** Amsterdam UMC (locatie VUmc)

**Source(s) of monetary or material Support:** ZonMw

## Intervention

## Outcome measures

### Primary outcome

The main study parameter is the change in depressive symptoms within patients at 3, 6, 9

and 12 months of follow-up, as well as the difference between intervention and control groups. This will be assessed with the Patient Health Questionnaire-9 (PHQ-9).

## **Secondary outcome**

Secondary outcomes are insomnia severity (Insomnia Severity Index, ISI), daily functioning (Work and Social Adjustment Scale, WSAS), general quality of life (EuroQol 5-level version, EQ-5D-5L), lost productivity costs (adapted version of the iMTA Productivity Cost Questionnaire, iPCQ) and healthcare, patient and family costs (adapted version of the iMTA Medical Cost Questionnaire, iMCQ).

# **Study description**

## **Background summary**

Patients with unipolar depression often simultaneously meet the DSM-5 criteria for insomnia disorder. These patients have significantly lower quality of life and worse treatment outcomes than depressive patients without insomnia. While cognitive behavioral therapy for insomnia (CBT-I) is the treatment option of first choice, insomnia is currently, if recognized accurately, often treated pharmacologically. A pilot study has already shown that the online CBT-I intervention i-Sleep could potentially serve as a relatively easily accessible addition to the usual care for depression. However, a randomized controlled trial evaluating the effectiveness and cost-effectiveness of adding i-Sleep to usual care among depressed patients has not yet been performed. The current project aims to assess both the effectiveness and cost-effectiveness of an internet-based insomnia intervention (i-Sleep) prior to usual care for depression, compared to usual care alone, in depressive patients with comorbid insomnia treated at a specialized mental healthcare outpatient clinic. Furthermore, a process evaluation of implementing i-Sleep in daily clinical practice will take place.

## **Study objective**

We hypothesize that addition of i-Sleep to usual care for depression improves patient outcomes and reduces societal costs as compared to usual care alone.

## **Study design**

Repeated assessments will take place at baseline (prior to the start of treatment) and at 3, 6, 9, and 12 months of follow-up.

## **Intervention**

A guided, internet-based cognitive behavioral therapy program for insomnia (i-Sleep). This online CBT-I program consists of five sessions, containing information and exercises on sleep.

## Contacts

### **Public**

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Savannah Ikelaar

06-46415557

### **Scientific**

GGZ inGeest  
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## Eligibility criteria

### **Inclusion criteria**

- 18 years or older with a maximum age of 75 years,
- Scheduled for treatment of unipolar depression according to the DSM-5 criteria at one of the participating specialized mental healthcare outpatient clinics,
- Fulfilling the DSM-5 criteria for insomnia disorder.

### **Exclusion criteria**

- Insufficient command of the Dutch language,
- Working night shifts,
- Sleep-related conditions other than insomnia, e.g. sleep apnoea,
- No daily access to an internet-connected computer.
- Presence of a mental health crisis situation.

## Study design

### **Design**

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial

Masking:	Single blinded (masking used)
Control:	Active

## Recruitment

NL	
Recruitment status:	Recruiting
Start date (anticipated):	01-09-2020
Enrollment:	175
Type:	Anticipated

## IPD sharing statement

**Plan to share IPD:** Undecided

## Ethics review

Positive opinion	
Date:	06-10-2020
Application type:	First submission

## Study registrations

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

ID: 50166  
Bron: ToetsingOnline  
Titel:

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

No registrations found.

## In other registers

Register	ID
NTR-new	NL8955
CCMO	NL73477.029.20
OMON	NL-OMON50166

## Study results