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

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Ethical review	Approved WMO
Status	Recruiting
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON50166

Source
ToetsingOnline

Brief title
EINSTEIN

Condition

- Other condition
- Sleep disorders and disturbances

Synonym
depression, insomnia, mood disorder, sleeping problems

Health condition

depressieve stemmingstoornis

Research involving
Human

Sponsors and support

Primary sponsor: Vrije Universiteit Medisch Centrum
Source(s) of monetary or material Support: ZonMw (Doelmatigheidsonderzoek Open Ronde 2020)

Intervention

Keyword: CBT-I, depression, e-Health, insomnia

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 treated in specialized mental healthcare has not yet been performed. We hypothesize that addition of i-Sleep to usual care will result in a significant improvement in depression treatment outcomes and quality of life as well as a decrease in healthcare and societal costs, compared to usual care alone.

Study objective

The current project aims to assess both the effectiveness and cost-effectiveness of an internet-based insomnia intervention (i-Sleep) in addition 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 design

This study is a multi-centre randomized controlled trial with randomisation at the patient level with 12 months of follow-up.

Intervention

i-Sleep is a guided, internet-based cognitive behavioural therapy for insomnia, which will be added to usual care for depression in specialized mental healthcare. The i-Sleep program consists of 5 online sessions: 1) psycho-education on sleep, sleep disorders and sleep hygiene, 2) sleep restriction and stimulus control training, 3) rumination and relaxation techniques, 4) cognitive restructuring, 5) relapse prevention. The i-Sleep module is offered prior to the start of usual care for depression, in a blended format.

Study burden and risks

The sole burden of participating in this trial will be adhering to the program, i.e. completing assignments and questionnaires. There are no known serious risks associated with the investigational treatment, although patients may experience side effect of the treatment due to sleep restriction, e.g. fatigue, daytime sleepiness, loss of motivation/energy and headaches.

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

• 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 abovementioned 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
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	12-11-2020
Enrollment:	175
Type:	Actual

Ethics review

Approved WMO Date:	04-09-2020
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	25-10-2021
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

ID: 22668
Source: Nationaal Trial Register
Title:

In other registers

Register	ID
CCMO	NL73477.029.20
OMON	NL-OMON22668