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

Gepubliceerd: 06-10-2020 Laatst bijgewerkt: 19-03-2025

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.

Ethische beoordeling	Positief advies
Status	Werving gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON22668

Bron
Nationaal Trial Register

Verkorte titel
EINSTEIN

Aandoening

Unipolar depression, insomnia disorder

Ondersteuning

Primaire sponsor: Amsterdam UMC (locatie VUmc)
Overige ondersteuning: ZonMw

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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).

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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.

Onderzoeksopzet

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

Onderzoeksproduct en/of interventie

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.

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

- 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.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

- 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.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek

Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Enkelblind
Controle:	Geneesmiddel

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	01-09-2020
Aantal proefpersonen:	175
Type:	Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nog niet bepaald

Ethische beoordeling

Positief advies

Datum:	06-10-2020
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 50166
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

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

Resultaten