Digital cognitive behavioral therapy for inSomNia symptOms in pRegnant womEn with psychiatric vulnerability: a prospective cohort study

Published: 06-09-2021
Last updated: 16-11-2024

1. Provide evidence for the clinical effectiveness of dCBT-I for the treatment of insomnia symptoms in pregnant woman with psychiatric vulnerability. 2. Provide evidence for the effectiveness of insomnia treatment and the positive effects on mental...

Ethical review	Approved WMO
Status	Completed
Health condition type	Sleep disorders and disturbances
Study type	Interventional

Summary

ID

NL-OMON55999

Source
ToetsingOnline

Brief title
SNORE

Condition

- Sleep disorders and disturbances

Synonym
difficulty sleeping, insomnia

Research involving
Human

Sponsors and support

Primary sponsor: OLVG

Source(s) of monetary or material Support: ? het betreft zorgonderzoek met reeds bestaande middelen die geen extra geld kosten.

Intervention

Keyword: Digital Cognitive Behavioural Therapy, Insomnia, Pregnancy, Psychiatric vulnerability

Outcome measures

Primary outcome

The main study parameter is the change on Insomnia Severity Index score (ISI)

after the intervention.

Secondary outcome

- Objective sleep (Actiwatch)

- Depression symptoms (HADS)

- Anxiety symptoms (HADS)

- Sleep medication use

Study description

Background summary

Insomnia symptoms are highly prevalent during pregnancy with an overall prevalence of 38,2 percent. Research has shown that insomnia during pregnancy is associated with an increased risk of preterm birth, perinatal depression, suicidality, and anxiety disorders. Prenatal stress, anxiety and depression also influence fetal development, birth outcome and child development. Cognitive behavioral therapy for insomnia (CBT-I) has been proven effective in pregnancy for insomnia symptoms with also a positive effect on depressive- and anxiety symptoms. Unfortunately, there is limited access to CBT-I-trained clinicians, resulting in a lack of treatment of insomnia or treatment with off label medication. Digital CBT-I (dCBT-I), has been developed to grant easy access to insomnia treatment, is widely used and proven effective in the general population. Results for the use in pregnant women are promising, but up until now psychiatrically vulnerable women have been excluded in previous studies. Hence, there is an utmost urgency to gain more knowledge on the

effectiveness of insomnia interventions during pregnancy for women with known psychiatric vulnerability and to implement effective programs in standard gynecological care to improve maternal-fetal outcome.

Study objective

1. Provide evidence for the clinical effectiveness of dCBT-I for the treatment of insomnia symptoms in pregnant woman with psychiatric vulnerability.
2. Provide evidence for the effectiveness of insomnia treatment and the positive effects on mental health for pregnant women who already struggle with psychiatric vulnerability.

Study design

a prospective cohort design. N=76

Intervention

CBT-I is a form of evidence-based psychotherapy with a focus on behaviour, thoughts, emotions and their corelation regarding sleep. The digital intervention consists of six modules with explanatory text, videos, figures and exercises. Patients will be asked to finish the modules within seven weeks. However, there will be a possibility of extending this period if needed. This extension beyond seven weeks will be documented. Patients can access their intervention from several digital devices such as mobile phones, tablets and personal computers. It works in every main browser available to date. Patients are free to choose when and where they want to complete the module. The intervention is self-guided, so patients will not receive any feedback from a health-care professional.

Study burden and risks

Risks: Patients will not be exposed to additional risks due to this treatment. Patients and treating physicians are free to treat psychiatric symptoms to their best knowledge. No restrictions are given to the patients participating in this trial.
Patients who do not want to participate in this trial will receive care-as-usual from the psychiatrist of the POP outpatient center and their general practitioner and/or other caregiver.

Burden: Time: Filling in questionnaires (3 x 30 min), completing the online module (6 sessions of 1-2 hours).
Sleepwatch and sleep diary: patients have to wear a watch-sized actimeter on their wrist two times: at baseline (T0) for 7 days and after treatment (T1) for 7 days. So 14 days in total. Patients fill in a sleep diary simultaneously that will take 2 minutes every day.

Benefits: An easy to use, patient friendly low intensive treatment to develop coping skills for insomnia problems.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Inclusion criteria

Being 18 years of age or older
Being a pregnant woman in the first trimester up to week 25 of the pregnancy
Report sleeping problems with ISI score above cut-off
Being able to understand and complete the self-help dCBT-I in Dutch

Exclusion criteria

Patients who have insufficient Dutch language skills
Active psychosis
drug dependence or abuse

Shift- work
Use of sleep medication (benzodiazepines)
Untreated sleep apnea

Study design

Design

Study type:	Interventional
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Completed
Start date (anticipated):	13-02-2022
Enrollment:	76
Type:	Actual

Ethics review

Approved WMO

Date:	07-09-2021
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)

Approved WMO

Date:	21-04-2022
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)

Approved WMO

Date:	24-10-2022
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	03-05-2023
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	25-05-2023
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	14-09-2023
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)

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	NL78328.100.21

Study results

Date completed: 15-10-2024

Summary results
Trial ended prematurely