

Testing the effect of metacognitive therapy for insomnia

Submission date 09/07/2020	Recruitment status No longer recruiting	☐ Prospectively registered
		☐ Protocol
Registration date 13/07/2020	Overall study status Completed	☐ Statistical analysis plan
		☒ Results
Last Edited 03/10/2025	Condition category Mental and Behavioural Disorders	☐ Individual participant data

Plain English summary of protocol

Background and study aims

Insomnia is defined by the presence of long sleep latency (the time it takes to get to sleep), frequent nocturnal awakenings or prolonged periods of wakefulness during the sleep period. Insomnia has severe consequences for individuals' quality of life, and healthcare expenditures are about 160% of people without insomnia. The aim of this study is to test the effectiveness of a psychological therapy called metacognitive therapy for insomnia.

Who can participate?

Patients with insomnia

What does the study involve?

Participants receive up to 10 sessions of metacognitive therapy. Participants are assessed on insomnia severity, anxiety, depression, time spent worrying and metacognitive beliefs before treatment, after treatment and at 6 and 12 months follow-up.

What are the possible benefits and risks of participating?

There are no previously reported risks of metacognitive therapy. Participants can withdraw from the trial at any time without giving a reason. If any participants' condition deteriorates whilst being in the metacognitive therapy they are referred to psychiatric care.

Where is the study run from?

Cektos - Center for Metakognitiv Terapi (Denmark)

When is the study starting and how long is it expected to run for?

July 2020 to September 2024

Who is funding the study?

Cektos - Center for Metakognitiv Terapi (Denmark)

Who is the main contact?

Dr Pia Callesen

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Contact information

Type(s)

Scientific

Contact name

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Additional identifiers

Study information

Scientific Title

Metacognitive therapy for insomnia: a randomised controlled trial

Acronym

MCTINSOMNIA

Study objectives

The alternative hypothesis of this study states that Metacognitive Therapy (MCT) for insomnia will result in a statistically significant positive change in patient symptoms of insomnia compared to a waiting-list control group receiving no treatment for 12 weeks.

Ethics approval required

Old ethics approval format

Ethics approval(s)

1. Approved 23/11/2020, Den Videnskabsetiske Komité for Region Sjælland (Sekretariatet for Den Regionale Videnskabsetiske Komité Alléen 15 , Sorø, 4180, Denmark; +45 (0)5787 5283; rvk-sjaelland@regionsjaelland.dk), ref: SJ-872 - EMN-2020-35209
2. Approved 03/02/2021, Danish Ethics Board (Den Videnskabsetiske Komité for Region Sjælland, Alléen 15, 4180 Sorø, Denmark; +45 (0)93 56 60 00; RVK-sjaelland@regionsjaelland.dk), ref: 74316

Primary study design

Interventional

Study design

Open trial

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Insomnia

Interventions

Current interventions as of 30/08/2023:

Patients receive up to 10 sessions of MCT. Assessment is made at pre, post and finally at 6 and 12 months follow-up with primary and secondary variables.

Previous interventions:

Randomisation is achieved using a random number generator. The treatment group receive up to 10 sessions of MCT and a waiting list control group receive MCT after 12 weeks waiting time. Assessment is made at pre, post and finally at 6 and 12 months follow-up with primary and secondary variables.

Intervention Type

Behavioural

Primary outcome(s)

Insomnia severity measured using Insomnia Severity Index (ISI) before treatment, after approximately 12 weeks treatment (10 sessions) and at 6 and 12 months follow-up

Key secondary outcome(s)

Anxiety and depressive symptoms measured using hospital anxiety and depression scale (HADS) before treatment, after approximately 12 weeks treatment (10 sessions) and at 6 and 12 months follow-up

Completion date

06/09/2024

Eligibility

Key inclusion criteria

Patients suffering from insomnia as measured on the ISI

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 Years

Sex

All

Key exclusion criteria

Patients are excluded if they:

1. Suffer from severe depression, anxiety or psychosis
2. Report any suicidality
3. Have sleep disruptive medical illnesses

Date of first enrolment

22/06/2020

Date of final enrolment

01/09/2022

Locations**Countries of recruitment**

Denmark

Study participating centre

Cektos - Center for Metakognitiv Terapi

Riddergade 7, 1 sal

Næstved

Denmark

4700

Sponsor information**Organisation**

Cektos - Center for Metakognitiv Terapi

Funder(s)**Funder type**

Hospital/treatment centre

Funder Name

Cektos - Center for Metacognitiv Terapi

Results and Publications

Individual participant data (IPD) sharing plan

The data-sharing plans for the current study are unknown and will be made available at a later date.

IPD sharing plan summary

Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		25/09/2025	03/10/2025	Yes	No
Study website	Study website	11/11/2025	11/11/2025	No	Yes