ISRCTN85892563 https://doi.org/10.1186/ISRCTN85892563

Testing the effect of metacognitive therapy for insomnia

Submission date
09/07/2020

Recruitment status
No longer recruiting

Registration date
13/07/2020

Overall study status
Completed

Last Edited
03/10/2025

Condition category
Mental and Behavioural Disorders

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[X] Results
[ ] 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
pia.callesen@cektos.dk

Contact information

Type(s)
Scientific

Contact name
Dr Pia Callesen

ORCID ID
https://orcid.org/0000-0001-5087-7095

Contact details
Oxford Alle 66
Copenhagen
Denmark
2300
+45 (0)22684281
pia.callesen@cektos.dk

Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
Nil known

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

Study design
Open trial

Primary study design
Interventional

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
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Study website	Study website	11/11/2025	11/11/2025	No	Yes