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

Testing the effect of metacognitive therapy for insomnia

Submission date	Recruitment status	[ ] Prospectively registered
09/07/2020	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
13/07/2020	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
11/09/2024	Mental and Behavioural Disorders	[X] Record updated in last year

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

Study website
https://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

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
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

Secondary study design
Non randomised study

Study setting(s)
Other

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use contact details to request a participant information sheet

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 measure
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

Secondary outcome measures

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

Overall study start date
01/07/2020

Completion date
06/09/2024

Eligibility

Key inclusion criteria
Patients suffering from insomnia as measured on the ISI

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
26

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

Sponsor details
Riddergade 7, 1 sal
Næstved
Denmark
4700
+45 (0)55734849
info@cektos.dk

Sponsor type
Hospital/treatment centre

Website
www.cektos.dk

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Cektos - Center for Metacognitiv Terapi

Results and Publications

Publication and dissemination plan
Planned publication in a high impact peer-reviewed journal. All documents are available on request.

Intention to publish date
31/12/2025

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