

The impact of cognitive behavioural therapy delivered by GPs and nurses on sleep quality

Submission date 08/02/2022	Recruitment status No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered
		<input checked="" type="checkbox"/> Protocol
Registration date 05/04/2022	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
Last Edited 28/10/2024	Condition category Mental and Behavioural Disorders	<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> Record updated in last year

Plain English summary of protocol

Background and study aims

Insomnia is a type of sleep disorder that involves an inability to initiate and/or maintain sleep with several daytime consequences, such as extreme tiredness (fatigue), mood disturbances, poor concentration, and memory problems. This study is based on Cognitive Behavioural Therapy (a type of therapy that changes behaviour) for insomnia delivered by a nurse or GP in clinical practice,

Participants will be offered a face-to-face cognitive behavioral therapy of 4 sessions of 20 minutes proven (through previous research) to improve sleep. The aim of this study is to see whether those people who receive this cognitive behavioral therapy will improve the quality of their sleep in comparison to those people who do not receive this treatment.

Who can participate?

Men and women aged 18 to 75 years old who complain of insomnia.

What does the study involve?

Participants are randomly allocated into one of two groups. Those in the first group receive the Cognitive Behavioural Therapy intervention, delivered by a nurse or GP. The Cognitive Behavioural Therapy intervention consists of 4 sessions, and receive a sleep hygiene brochure and a sleep diary, if participants take medication for sleep they will be asked to reduce medication if the quality of sleep improves by the intervention.

Both groups complete the quality of sleep and quality of life questionnaire at the first visit (0 months), follow-up visit (6 months) and final visit (12 months).

What are the possible benefits and risks of participating?

CBT is likely to be both interesting and helpful to participants.

There are no notable risks associated with participating in this study.

Where is the study run from?

The study is run by the management of Majorca Primary Care (Spain)

When is the study starting and how long is it expected to run for?
January 2020 to December 2024

Who is funding the study?
Instituto de salud Carlos III (Spain)

Who is the main contact?
1. Isabel Torrens, isabel.torrensdarder@ibsalut.es
2. Susana Gonzalez, susana.gonzaleztorrente@ibsalut.es

Contact information

Type(s)
Principal investigator

Contact name
Mrs Isabel Torrens

ORCID ID
<https://orcid.org/0000-0003-3949-7635>

Contact details
C/ Riu Sil 25
Calvià
Spain
07180
+34 971 694 654
isabel.torrensdarder@ibsalut.es

Type(s)
Scientific

Contact name
Mrs Susana Gonzalez

Contact details
C/Reina Esclaramunda n 9
Palma
Spain
07005
+34 971175893
susana.gonzaleztorrente@ibsalut.es

Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Protocol serial number
PI19/00029

Study information

Scientific Title

To analyse the effectiveness of cognitive behavioural therapy in primary care delivered by GPs and nurses on the reduction of sleep quality at 12 months in patients with chronic insomnia

Study objectives

The cognitive behavioural therapy (CBT) intervention will reduce:

1. Self-reported sleep latency
 2. Self-reported sleep duration
 3. Self-reported sleep efficiency
 4. Self-reported sleep severity
 5. Benzodiazepine consumption
- all at 12 months relative to the usual care group

Ethics approval required

Old ethics approval format

Ethics approval(s)

Approved 28/07/2021, Balearic Island Ethics Committee (C. de Jesús, 38 A, CP07010 Palma, Spain; +34971 17 73 78; ceic_ib@caib.es), ref: IB 4604/21 PI

Study design

Multicenter parallel group superiority interventional randomized controlled trial

Primary study design

Interventional

Study type(s)

Prevention

Health condition(s) or problem(s) studied

Insomnia

Interventions

Participants are randomised to the intervention or control group (treatment as usual) using computer-generated randomisation.

The CBT intervention is delivered face-to-face by nurses and GPs with the active participation of the patient for the treatment of persistent insomnia. It consists of 5 individual sessions (3 face-to-face and 2 by telephone) of 20 minutes and an optional session to withdraw long-term benzodiazepine users. The therapeutic objectives are agreed upon between the professional and the patient and patient participation includes homework tasks to improve the sleep quality. The intervention includes a 4-hour training session in CBT. Professionals will have support teaching material and a workbook for the patient.

Session 1: To identify the knowledge that the patient has about insomnia and establish the goals that he wants to achieve. Interactive dialogue between professional and patient about their

beliefs about insomnia. The CBT intervention and relaxation technique is delivered by primary health care (PHC) professionals; a sleep diary and sleep hygiene brochure were also given to the patient. Review of routines and times; work-at-home routines and times.

Session 2: Where are my difficulties, how are my routines and my times? Objective: Find out where the sleep difficulties, routines, and times are. Content: Review of the sleep diary to establish the baseline of sleep characteristics. Modification of sleep habits is established by PHC professionals. Practice the relaxation technique during the visit.

Session 3: Follow-up session (telephone). At 3 months; The quality and efficiency of the sleep will be evaluated by the Pittsburgh sleep quality index and sleep hygiene habits and identify what has been achieved and reflect on what has not been achieved.

Session 4: What have I achieved? Objective: to assess what was achieved in the intervention period. Content: Review the sleep diary, identify what has been achieved and reflect on what has not been achieved and the guidelines to follow in the future through a structured interview. The sleep diary is delivered to complete before the next visit at 4 months.

Optional: Benzodiazepine withdrawal. At the end of the CBT and those patients who are regularly consuming hypnotics for insomnia, they will be offered the possibility of carrying out a brief intervention to stop consumption. If they accept, a structured interview will be conducted with the following contents: consequences of prolonged consumption, concepts of dependency and withdrawal syndrome, how to withdraw the medication through a gradual withdrawal pattern. The patient will receive a structured intervention by GP along with written reinforcement information and a tailored stepped dose reduction schedule.

Session 5: Follow-up session (telephone). At 6 months; The quality and efficiency of the sleep will be evaluated by the Pittsburgh sleep quality index and sleep hygiene habits and identify what has been achieved and reflect on what has not been achieved.

During the sessions, the health professional is available to the patient to consult any doubts or difficulties that may arise. The patient will receive a work manual, sleep hygiene brochures, and a sleep diary. The relevant information that occurred in each session is recorded in the electronic clinical record of the patient.

Intervention Type

Behavioural

Primary outcome(s)

Self-reported sleep latency measured using the Pittsburgh sleep quality index at baseline and follow-up (12 months)

Key secondary outcome(s)

Current secondary outcome measures as of 27/08/2024:

1. Self-reported sleep duration measured using the Pittsburgh sleep quality index at baseline and follow-up (12 months)
2. Self-reported sleep efficacy measured using the Pittsburgh sleep quality index at baseline and follow-up (12 months)
3. Self-reported sleep severity (PSQI total score) measured using the Pittsburgh Sleep Quality Index at baseline and follow-up
4. The use of hypnotic and antidepressant medications (self-reported and measured by The

Spanish-language version of the Severity of Dependency Scale) will be used to measure the use of benzodiazepines at 12 months

5. EuroQol Quality of life 5d at baseline at 12 months

6. Direct healthcare expenditures: These will be calculated based on costs related to medications, healthcare visits (PCPs, PCNs, hospital and community emergency services, and hospital specialists), diagnostic and therapeutic procedures, and inpatient care

7. Indirect costs: These will be calculated based on costs associated with work absences

Previous secondary outcome measures:

1. Self-reported sleep duration measured using the Pittsburgh sleep quality index at baseline and follow-up (12 months)

2. Self-reported sleep efficacy measured using the Pittsburgh sleep quality index at baseline and follow-up (12 months)

3. Self-reported sleep severity measured using the Pittsburgh sleep quality index at baseline and follow-up (12 months)

4. Number of defined daily doses of benzodiazepines in the last 6 months by the e-prescription system (12 months)

5. EuroQol Quality of life 5d at baseline at 12 months

Completion date

31/12/2024

Eligibility

Key inclusion criteria

1. 18 to 75 years old

2. Fulfils diagnostic criteria for insomnia disorder by the Diagnostic and Statistical Manual of Mental Disorder DSM-5

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Upper age limit

75 years

Sex

All

Total final enrolment

Key exclusion criteria

1. In treatment with CBT-i or other psychological therapies for the treatment of insomnia
2. Insomnia secondary to sleep apnea; work shift; severe mental disorder (psychosis, bipolar disorders, depression higher); history of attempted autolysis; alcohol or drug abuse in the past year; Other sleep disturbances such as restless legs syndrome or parasomnias
3. Neurodegenerative diseases, oncological diseases with poor prognosis, acute or chronic pain secondary to diseases rheumatic and chronic decompensated diseases that produce insomnia

Date of first enrolment

24/11/2022

Date of final enrolment

20/12/2023

Locations

Countries of recruitment

Spain

Study participating centre

Son Serra-La Vileta health care center

Carrer Massanella 22 B

Palma

Spain

07013

Study participating centre

Santa Ponsa Health care center

C/ Riu Sil 25

Calvià

Spain

07180

Sponsor information

Organisation

Management Primary care Majorca

Funder(s)

Funder type

Government

Funder Name

Instituto de Salud Carlos III

Alternative Name(s)

SaludISCI, InstitutodeSaludCarlosIII, Instituto de Salud Carlos III | Madrid, Spain, Carlos III Institute of Health, Institute of Health Carlos III, Carlos III Health Institute, La misión del Instituto de Salud Carlos III (ISCI), ISCI

Funding Body Type

Government organisation

Funding Body Subtype

National government

Location

Spain

Results and Publications

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study will be stored in a publicly available repository (<https://zenodo.org/>)

IPD sharing plan summary

Stored in publicly available repository

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article		26/10/2024	28/10/2024	Yes	No
Participant information sheet	in Spanish		15/02/2022	No	Yes
Protocol file	in Spanish		15/02/2022	No	No