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

Submission date
08/02/2022

Recruitment status
No longer recruiting

Registration date
05/04/2022

Overall study status
Completed

Last Edited
28/10/2024

Condition category
Mental and Behavioural Disorders

[X] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[X] 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 of 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 of GPS. 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?
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Contact information

Type(s)
Principal Investigator

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
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

Secondary study design
Randomised parallel trial

Study setting(s)
GP practice

Study type(s)
Prevention

Participant information sheet

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 measure

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

Secondary outcome measures
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

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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

Overall study start date
01/01/2020

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

Age group
Adult

Lower age limit
18 Years

Upper age limit
75 Years

Sex
Both

Target number of participants
206

Total final enrolment
134

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
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Sponsor type
Government

Funder(s)

Funder type
Government

Funder Name
Instituto de Salud Carlos III

Alternative Name(s)
SaludISCIII, InstitutodeSaludCarlosIII, Instituto de Salud Carlos III | Madrid, Spain, Carlos III Institute of Health, Institute of Health Carlos III, Carlos III Health Institute, ISCIII

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
Spain

Results and Publications

Publication and dissemination plan
Planned publication of the results of this study in peer-reviewed journals. Findings will also be presented at national and international scientific meetings. The results will be made available open access.

Intention to publish date
31/05/2025

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study will be stored in a publically 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?
Participant information sheet	in Spanish		15/02/2022	No	Yes
Protocol file	in Spanish		15/02/2022	No	No
Protocol article		26/10/2024	28/10/2024	Yes	No