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Effect of Cognitive Behavioral Therapy on Improving Sleep Quality in Older Adults With Insomnia: A Systematic Review Protocol

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ADMINISTRATIVE INFORMATION

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Review Stage at time of this submission - Piloting of the study selection process.

Conflicts of interest - None declared.

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Amendments - This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 26 May 2026 and was last updated on 26 May 2026.

INTRODUCTION

Review question / Objective The objective of this systematic review is to critically and systematically evaluate the effect of Cognitive Behavioral Therapy for Insomnia (CBT-I) on sleep quality in older adults aged 60 years and older diagnosed with insomnia, through the synthesis of the available scientific evidence derived from intervention studies. The review aims to determine the effectiveness of CBT-I as a non-pharmacological strategy to improve sleep quality and to contribute to evidence-based clinical decision-making in the care of older adults with insomnia.

The review question was formulated using the PIO framework, defined as follows: P (population): older adults aged 60 years and older diagnosed with insomnia, without comorbidities and without pharmacological treatment for insomnia; I (intervention): Cognitive Behavioral Therapy for Insomnia (CBT-I); O (outcome): improvement in sleep quality.

Based on this framework, the following review question was established: What is the effect of Cognitive Behavioral Therapy for Insomnia (CBT-I) on improving sleep quality in older adults aged 60 years and older with insomnia?

Rationale Insomnia is one of the most common sleep disorders among older adults and represents an important public health concern due to its high prevalence and its negative impact on physical, cognitive, and emotional health. In older adults, insomnia is associated with reduced quality of life, functional impairment, cognitive decline, depression, anxiety, increased risk of falls, and greater functional dependence. In addition, age-related physiological changes contribute to alterations in sleep architecture, increased nighttime awakenings, prolonged sleep latency, and reduced sleep efficiency, which may favor the development and persistence of insomnia.

Traditionally, insomnia treatment has included the use of hypnotic medications and benzodiazepines; however, in older adults these treatments present important limitations because of their adverse

effects, including daytime sleepiness, cognitive impairment, balance disturbances, dependence, and increased risk of falls and fractures. Consequently, several international clinical guidelines recommend prioritizing non-pharmacological interventions as first-line treatment for chronic insomnia in this population.
In this context, Cognitive Behavioral Therapy for Insomnia (CBT-I) has been recognized as the most effective non-pharmacological intervention for the treatment of insomnia. CBT-I integrates cognitive and behavioral strategies aimed at modifying dysfunctional thoughts, maladaptive habits, and behaviors associated with sleep disturbances. Its main components include stimulus control, sleep restriction, sleep hygiene, relaxation techniques, and cognitive restructuring.

Available scientific evidence has demonstrated that CBT-I produces significant improvements in several sleep-related outcomes, including sleep quality, sleep latency, sleep efficiency, and insomnia severity. However, published studies present substantial heterogeneity regarding intervention modalities, duration of treatment, assessment instruments, and characteristics of the studied populations. Furthermore, many studies include participants with multiple comorbidities or concurrent pharmacological treatment, making it difficult to isolate the specific effect of CBT-I on sleep quality in otherwise healthy older adults with insomnia.
Therefore, there is a need to conduct a systematic review specifically focused on adults aged 60 years and older diagnosed with insomnia, without comorbidities and without pharmacological treatment for insomnia, in order to critically synthesize the available scientific evidence regarding the effect of CBT-I on sleep quality improvement. This review may contribute to strengthening evidence-based clinical decision-making, identifying effective non-pharmacological therapeutic strategies, and supporting comprehensive care and healthy aging in the older adult population.

Condition being studied Insomnia is one of the most common sleep disorders among older adults and is characterized by difficulty initiating or maintaining sleep, as well as impairments in daytime functioning. Its prevalence increases with age and is associated with negative physical, cognitive, and emotional health outcomes, including reduced quality of life, increased risk of falls, and functional dependence.
In older adults, the pharmacological treatment of insomnia presents important limitations due to its adverse effects, such as daytime sleepiness, cognitive impairment, and risk of dependence. Therefore, international clinical guidelines recommend prioritizing non-pharmacological interventions, particularly Cognitive Behavioral Therapy for Insomnia (CBT-I), which is currently considered the first-line treatment for chronic insomnia.
CBT-I has demonstrated effectiveness in improving sleep quality and other insomnia-related outcomes; however, many studies include participants with comorbidities or concurrent pharmacological treatment. Consequently, there is a need to synthesize the available scientific evidence specifically focused on adults aged 60 years and older with insomnia, without comorbidities and without pharmacological treatment for insomnia, through a systematic review conducted with methodological rigor.

METHODS

Search strategy A systematic literature search was conducted in accordance with the PRISMA guidelines,26 up to May 17, 2026, in the following electronic databases: PubMed, Web of Science, Scopus, Cochrane Central Register of Controlled Trials (CENTRAL), SciELO, and LILACS.
Controlled vocabulary terms and keywords related to the topic of interest were used, including: insomnia, sleep initiation and maintenance disorders, cognitive behavioral therapy for insomnia (CBT-I), older adults, elderly, aged, and sleep quality. These terms were combined using Boolean operators (AND, OR) to construct the search strategy.
The primary search strategy was as follows: (insomnia OR "sleep initiation and maintenance disorders") AND ("cognitive behavioral therapy for insomnia" OR CBT-I) AND (elderly OR aged OR "older adults") AND ("sleep quality" OR "sleep efficiency" OR PSQI) NOT (depression OR dementia OR cancer OR Parkinson OR "sleep apnea").
The search strategy was adapted to the specific characteristics of each database. Terms in both English and Spanish were included in order to maximize search sensitivity.
Additionally, a gray literature search was conducted to identify unpublished or difficult-to-access studies that could be relevant to the present systematic review.

Participant or population Studies evaluating older adults aged 60 years and older diagnosed with insomnia will be included, regardless of sex, provided that participants do not present medical or psychiatric comorbidities and are not receiving pharmacological treatment for insomnia.

Intervention Studies evaluating Cognitive Behavioral Therapy for Insomnia (CBT-I) as an intervention aimed at improving sleep quality in older adults with insomnia will be included. CBT-I may include components such as stimulus control, sleep restriction, sleep hygiene, relaxation techniques, and cognitive restructuring.
The interventions may be delivered in individual, group-based, face-to-face, digital, or hybrid formats, provided that they are specifically oriented toward the treatment of insomnia through cognitive-behavioral strategies.

Comparator Due to the nature of the present systematic review and the formulation of the research question using the PIO framework, the presence of a comparator group will not be mandatory for study inclusion.

Study designs to be included Primary intervention studies evaluating the effect of Cognitive Behavioral Therapy for Insomnia (CBT-I) on sleep quality in older adults with insomnia will be included.Eligible study designs will include randomized controlled trials (RCTs), quasi-experimental studies, and pre-experimental studies, provided that they allow the assessment of changes in sleep quality following the intervention.

Eligibility criteria Eligibility criteria will be established based on the elements of the PIO framework in order to ensure a rigorous, systematic, and reproducible selection of the studies included in the present systematic review.
Studies conducted in adults aged 60 years and older, of both sexes, diagnosed with insomnia, without medical or psychiatric comorbidities and without pharmacological treatment for insomnia, will be included.
Studies evaluating Cognitive Behavioral Therapy for Insomnia (CBT-I) will be considered, regardless of the mode of delivery (individual, group-based, face-to-face, digital, or hybrid), duration, or frequency of the intervention.
Studies reporting sleep quality as the primary outcome, assessed through validated instruments, will be included. Secondary outcomes will include sleep-related variables such as sleep latency, sleep efficiency, insomnia severity, and daytime functioning.
Regarding methodological design, primary intervention studies such as randomized controlled trials, quasi-experimental studies, and pre-experimental studies that evaluate the effect of CBT-I on sleep quality will be included.
No restrictions regarding publication year, language, or country of study will be applied in order to maximize the sensitivity and comprehensiveness of the literature search.

Information sources The information search was conducted in international electronic health science databases, including PubMed, Web of Science, Scopus, Cochrane Central Register of Controlled Trials (CENTRAL), SciELO, and LILACS, using the previously defined search strategy adapted to each database.

Additionally, a gray literature search will be conducted through sources such as TESIUNAM and Google Scholar in order to identify potentially relevant non-indexed studies and minimize publication bias. Furthermore, a manual search of the reference lists of included studies and relevant reviews will be performed to identify additional evidence not retrieved through the electronic search.

Main outcome(s) The primary outcome of this review will be sleep quality in older adults with insomnia, assessed using validated instruments such as the Pittsburgh Sleep Quality Index (PSQI), the Insomnia Severity Index (ISI), or other standardized scales. This outcome was selected due to its direct clinical relevance to the well-being, functioning, and overall health of this population.
Outcome measurements will be extracted as reported in each study, prioritizing post-intervention assessments at short- and medium-term follow-up in order to estimate the effect of CBT-I on sleep quality.

Additional outcome(s) Additional outcomes will include sleep-related variables such as sleep latency, sleep efficiency, total sleep duration, nighttime awakenings, and insomnia severity, provided that these outcomes are assessed using validated instruments.
Furthermore, outcomes related to daytime functioning, daytime sleepiness, and adherence to the intervention will be included when such information is available in the included studies. These outcomes will contribute to a more comprehensive interpretation of the effect of Cognitive Behavioral Therapy for Insomnia (CBT-I) on sleep quality in older adults with insomnia.

Data management Data management will be conducted through a systematic and standardized process that will include the identification, selection, organization, and extraction of relevant information from the studies included in the present systematic review. The study selection process will be carried out in two phases: the first phase will consist of screening titles and abstracts,

and the second phase will involve full-text assessment according to the previously established eligibility criteria. This procedure will be independently performed by two reviewers, and any disagreements will be resolved through consensus.
The identified records will be organized and managed using a database created in Microsoft Excel, where duplicate studies will also be removed. Subsequently, data extraction will be performed using a standardized form designed to collect information related to the methodological characteristics of the studies, population characteristics, components of the CBT-I intervention, mode of delivery, duration of the intervention, assessment instruments, and the main outcomes related to sleep quality.
Data extraction will be independently conducted by two reviewers in order to ensure the accuracy, consistency, and reliability of the collected information. The findings will be synthesized narratively and, if methodological and statistical homogeneity among studies is sufficient, a quantitative analysis using Review Manager (RevMan) will be considered.

Quality assessment / Risk of bias analysis The methodological quality of the included studies will be independently assessed by two reviewers. For randomized controlled trials, the Cochrane Risk of Bias 2 (RoB 2) tool will be used. For quasi-experimental and pre-experimental studies, validated methodological assessment tools appropriate for non-randomized intervention studies will be employed, such as the Joanna Briggs Institute critical appraisal tools.
The assessment will consider domains related to potential sources of bias, including selection bias, performance bias, detection bias, attrition bias, and reporting bias, in order to determine the methodological quality and internal validity of the included studies.

Strategy of data synthesis Data synthesis will be conducted primarily through a qualitative approach, using a narrative synthesis of the methodological characteristics and main findings of the included studies. The results will be organized and presented in a structured manner, considering population characteristics, CBT-I intervention modality, intervention duration, assessment instruments used, and the main outcomes related to sleep quality.
Due to the potential clinical and methodological heterogeneity expected among the included studies, particularly regarding study designs, intervention modalities, and outcome measures, descriptive synthesis of the evidence will be prioritized.
However, if sufficient methodological and statistical homogeneity among studies is identified, a meta-analysis using Review Manager (RevMan) version 5.4.1 will be considered. For continuous outcomes, mean differences with 95% confidence intervals will be calculated, and heterogeneity will be assessed using the I^2 statistic and the chi-square test.
If quantitative analysis is not feasible, the results will be presented narratively and in summary tables in order to facilitate a comprehensive interpretation of the available evidence.

Subgroup analysis If the number and characteristics of the included studies allow, subgroup analyses will be conducted to explore potential sources of heterogeneity in the effect of CBT-I on sleep quality in older adults with insomnia.
The predefined subgroups will include intervention delivery modality (face-to-face, digital, or hybrid), type of intervention (individual or group-based), and intervention duration (short-, medium-, or long-term). These factors will be considered due to their potential influence on the effectiveness of CBT-I and on the magnitude of the observed outcomes.
If the available evidence is limited or substantial heterogeneity exists among the studies, subgroup analyses will not be performed and the findings will be described narratively.

Sensitivity analysis If a quantitative analysis is conducted, sensitivity analyses will be performed to assess the robustness and consistency of the obtained results.
To this end, the impact of relevant methodological decisions will be examined through the progressive exclusion of studies with high risk of bias, small sample sizes, or incomplete information. Additionally, the influence of the different methodological designs included in the review on the overall results will be evaluated.
The observed variations will be analyzed in order to determine their potential effect on the interpretation of the findings and on the strength of the synthesized evidence.

Language restriction No language restrictions will be applied.

Country(ies) involved Mexico.

Other relevant information Any additional information considered relevant to strengthen the transparency, reproducibility, and methodological

clarity of the present protocol will be incorporated into this section as the systematic review progresses.

Keywords Insomnia; Older adults; Elderly; Cognitive Behavioral Therapy for Insomnia (CBT-I); Sleep quality.

Dissemination plans The results of the present systematic review will be disseminated through publication in a peer-reviewed high-impact scientific journal in the field of health sciences. Additionally, the findings are expected to be presented at national and international academic conferences in order to promote scientific discussion and increase visibility within the specialized community.
Furthermore, the results may be shared with healthcare professionals, researchers, and decision-makers with the aim of contributing to the strengthening of evidence-based clinical practice in the management of insomnia in older adults, particularly through the use of psychoeducational interventions.

Contributions of each author

Author 1 - Katy Monserrat Moreno Cuevas - Responsible for the methodological design of the systematic review, as well as data collection, management, analysis, and interpretation; additionally responsible for the drafting, writing, and critical revision of the protocol and final manuscript.
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