

INPLASY PROTOCOL

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None declared.

Efficacy of brief behavioral therapy for insomnia in older adults with chronic insomnia: A systematic review and meta-regression from randomized trials

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Review question / Objective: In this study, we aimed to evaluate the efficacy of a brief 4-week behavioural therapy for insomnia (BBT-i) in improving sleep quality in older adults with chronic insomnia.

Eligibility criteria: In the current review, we included all studies conducted on determining the efficacy of BBTi among older adults. Our inclusion criteria were 1) randomized controlled trials (RCTs) and systematic reviews and meta-analyses; 2) older adults (aged 60 years and over) with chronic insomnia; 3) an experimental group that received a brief behavioural therapy intervention; 4) a control group that received standard care (or no treatment); 5) the primary outcome was related to sleep quality; and 6) the study type was a RCT to minimize the risk of bias.

INPLASY registration number: This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 18 September 2022 and was last updated on 18 September 2022 (registration number INPLASY202290086).

INTRODUCTION

Review question / Objective: In this study, we aimed to evaluate the efficacy of a brief 4-week behavioural therapy for insomnia (BBT-i) in improving sleep quality in older adults with chronic insomnia.

Condition being studied: Chronic insomnia is a highly prevalent and persistent health concern among older adults, and it has significant adverse effects on cognitive function and physical health.

METHODS

Participant or population: Adults aged 60 years and older.

Intervention: A brief 4-week behavioural therapy for insomnia (BBT-i).

Comparator: Standard of care.

Study designs to be included: RCTs.

Eligibility criteria: In the current review, we included all studies conducted on determining the efficacy of BBTi among older adults. Our inclusion criteria were 1) randomized controlled trials (RCTs) and systematic reviews and meta-analyses; 2) older adults (aged 60 years and over) with chronic insomnia; 3) an experimental group that received a brief behavioural therapy intervention; 4) a control group that received standard care (or no treatment); 5) the primary outcome was related to sleep quality; and 6) the study type was a RCT to minimize the risk of bias.

Information sources: Eight electronic databases, namely, Ovid Medline, Embase, Cochrane Library, CINAHL, Scopus, Web of Science (WoS), and ClinicalTrials, were systematically searched to identify relevant articles published through the end of March 2022 and without language restrictions. EndNote reference management software was used to manage the citations of all the selected studies for screening, and duplicate records were manually removed in EndNote. The three main concepts of older individuals, BBTi and sleep quality, and search strategy were used with search terms to retrieve relevant studies.

Main outcome(s): Outcome measures were not considered as part of the eligibility criteria. Primary outcomes 2.3.1 Subjective sleep quality, assessed by validated scales such as Pittsburgh sleep quality index (PSQI), insomnia severity index (ISI), and one-item self-reported sleep quality. The higher scores in Pittsburgh sleep quality index (PSQI) or insomnia severity index (ISI) are representing poorer sleep quality. 2.3.2

Sleep parameters such as total sleep time (TST), sleep onset latency (SOL), wake after sleep onset (WASO), and sleep efficacy (SE), as measured by actigraphy and sleep diary.

Quality assessment / Risk of bias analysis: Three reviewers (Y. C. Chen, E. N. Ku, and Lai, P. C.) also independently assessed the methodological quality of RCTs using the Cochrane Collaboration tool for assessing the risk of bias (ROB 2.0). [29] The six domains used to assess the risk of bias included random sequence generation and allocation concealment (selection bias), blinding of participants and personnel (performance bias), blinding of outcome assessment (detection bias), incomplete outcome data (attrition bias), selective reporting (reporting bias) and other bias. [30] Each individual item was rated as either a low, unclear, or high risk of bias. Any disagreements or uncertainty were resolved by discussion with the fourth reviewer (C. T. Chen) [30]. The Grading of Recommendations Assessment, Development, and Evaluation (GRADE) methodology was used to assess the certainty of evidence (CoE) regarding the major outcomes reported by each included study, including risk of bias, consistency, directness, precision, and publication bias [31]. The levels of CoE were classified as high, moderate, low and very low certainty [31].

Strategy of data synthesis: A standardized data extraction template was used to collect descriptive information (e.g., study reference, country, mean age). Review Manager 5.4.1 software (The Cochrane Collaboration, The Nordic Cochrane Centre, Copenhagen, Denmark) was used for data synthesis. For the continuous dependent variable change scores of sleep quality as well as sleep parameters measured by actigraphy and sleep diary. The effect size was defined as the difference between pre- and post-BBTi intervention. The outcome measures of sleep quality obtained from the Pittsburgh Sleep Quality Index (PSQI), insomnia severity index (ISI), and self-rated sleep quality scale (score ranged from 1 to 10)

are presented as the standardized mean differences (SMDs) between the intervention and control groups with the corresponding 95% confidence intervals (CIs). The secondary outcomes were sleep measures, including objective data (total sleep time, wake after sleep onset, sleep efficacy) obtained from actigraphy and subjective data (total sleep time, wake after sleep onset, sleep efficacy, sleep latency) obtained from sleep diaries. We combined the outcomes of four RCTs through meta-analysis with a random-effects model as variability was expected between the studies.

Subgroup analysis: Subgroup analyses were planned to explore whether the effectiveness of BBTi differed according to the types of BBTi therapy.

Sensitivity analysis: Heterogeneity was assessed using the Higgins I² statistic. Heterogeneity was considered to be reported if I² > 75%. [32] Since some studies stated that I² is not absolute measure of heterogeneity due to it does not directly inform us about the distribution of effects and quality of evidence appraisal. [33] We planned to do a random-effects meta-regression [34] using STATA statistics software (Version 17.0, Stata corporation, College Station, Texas, USA) and subgroup analyses to identify possible sources of heterogeneity. Sources of potential variability were based on covariates of country, sleep quality tools used, the types of BBTi therapy, and methodological quality of studies.

Language restriction: None.

Country(ies) involved: Taiwan, National Cheng Kung University Hospital.

Keywords: brief behavioural therapy for insomnia (BBT-i), older adults, chronic insomnia, systematic review and meta-analysis

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