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Corresponding author:

Yuejuan Xu

1650927031@qq.com

Author Affiliation:

Children's Hospital of Wujiang District, Children's Hospital of Soochow University. The effects of cognitive behavioral therapy for insomnia in sleep apnea patients with co-morbid insomnia: a systematic review and meta-analysis

Xu, YJ1; Tan, X2; Xu, LN3; Yu, XM4; Hao, CL5.

ADMINISTRATIVE INFORMATION

Support - N/A.

Review Stage at time of this submission - Completed but not published.

Conflicts of interest - None declared.

INPLASY registration number: INPLASY202410024

Amendments - This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 07 January 2024 and was last updated on 07 January 2024.

INTRODUCTION

Review question / Objective To assess the effectiveness of cognitive behavioral therapy (CBTi) for insomnia in individuals who have both sleep apnea and co-morbid insomnia (COMISA).

Condition being studied Insomnia is a prevalent clinical symptom that is defined by recurrent difficulties in sleep start, sleep maintenance, or early morning awakenings from sleep. Patients frequently have mood issues, difficulty concentrating, weariness, and other daytime impairments. Chronic insomnia (regular nocturnal and daytime symptoms lasting at least 3 months) affects around 6-10% of the general population and is frequently associated with decreased quality of life, higher risk of mental disorders, decreased productivity, and increased medical economic

burden. Obstructive sleep apnea (OSA) is another prevalent sleep problem. It is defined by recurrent upper airway closure (apnea) or narrowing (hypopnea) during sleep, which causes momentary hypoxia and carbon dioxide retention. Eventually, sympathetic nerve activity rises, airflow recovers to normal, and the cortex commonly wakes up from fragmented sleep. It's important to remember that OSA and insomnia frequently coexist. The cooccurrence of sleep apnea and insomnia was originally recorded in 1973 by Guilleminault and associates. (COMISA). Additionally, individuals with COMISA experienced more significant impairments to their quality of life, their ability to function throughout the day, and their emotional and cognitive abilities as compared to those with insomnia or OSA alone. In comparison to patients with OSA alone, Krakow and colleagues found that COMISA patients had higher rates of emotional and cognitive issues, such as anxiety, depression,

irritability, and impaired attention. Furthermore, there are significant social and financial costs associated with COMISA. It is crucial to investigate suitable COMISA therapy as a result.

METHODS

Search strategy Two independent investigators systematically searched MEDLINE, EMBASE, Cochrane Library and the ClinicalTrials.gov to identify relevant studies published until December 31, 2023. "Cognitive behavioral therapy for insomnia" and "co-morbid insomnia and sleep apnea" were the keywords for search.

Participant or population Patients ≥18 years of age diagnosed with COMISA.

Intervention CBTi.

Comparator Corresponding control.

Study designs to be included RCTs.

Eligibility criteria We established the following inclusion standards: (1) RCT study design; (2) limited language availability to English; (3) Participants: individuals diagnosed with COMISA who are at least 18 years old; (4) CBTi as the intervention and the associated control; (5) our outcomes, which include three patient-evaluated outcomes as well as objective and subjective sleep maintenance and onset outcomes. Polysomnography (PSG) was used to quantify the objective outcomes, which comprised total sleep time (TST), wake after sleep onset (WASO), sleep onset latency (SOL), and sleep efficiency (SE). Subjective outcomes, such as subjective wake after sleep onset (sWASO), subjective sleep efficiency (sSE), and subjective sleep onset latency (sSOL), were examined using the patient-reported electronic morning sleep diary. The Pittsburgh sleep quality index (PSQI), Epworth sleepiness scale (ESS), and insomnia severity index (ISI) score were among the patient evaluation findings. All of the above-mentioned results were not required to be provided by the included RCTs.We established the following exclusion standards: (1) research type: case reviews, case reports, cohort studies, and retrospective studies; (2) control: active control, which compares an experimental treatment to a proven, successful treatment rather than a placebo.

Information sources Two separate researchers conducted a thorough search of ClinicalTrials.gov, MEDLINE, EMBASE, the Cochrane Library, and other databases to find pertinent research

published up until December 31, 2023. For MEDLINE, the following search strategy was used: (cognitive behavioral therapy for insomnia [Title/ Abstract]) AND (co-morbid insomnia and sleep apnea [Title/Abstract]); for EMBASE, `cognitive behavioral therapy for insomnia'/exp AND `comorbid insomnia and sleep apnea'/exp;" for Cochrane Library, "cognitive behavioral therapy for insomnia" in Title Abstract Keyword AND "comorbid insomnia and sleep apnea" for ClinicalTrials.gov. To guarantee a more thorough search, the reference lists of RCTs, pertinent systematic reviews, and meta-analyses were additionally independently and personally reviewed. Two independent investigators systematically searched MEDLINE, EMBASE, Cochrane Library and the ClinicalTrials.gov to identify relevant studies published until December 31, 2023. The following search strategy was employed: (cognitive behavioral therapy for insomnia [Title/Abstract]) AND (co-morbid insomnia and sleep apnea[Title/Abstract]) for MEDLINE; 'cognitive behavioral therapy for insomnia'/exp AND `co-morbid insomnia and sleep apnea'/exp for EMBASE; "cognitive behavioral therapy for insomnia" in Title Abstract Keyword AND "co-morbid insomnia and sleep apnea" in Title Abstract Keyword for Cochrane Library; "cognitive behavioral therapy for insomnia | comorbid insomnia and sleep apnea" for ClinicalTrials.gov. Additionally, the reference lists of RCTs, relevant systematic reviews and metaanalyses were also screened independently and manually to ensure a more comprehensive search.

Main outcome(s) Polysomnography (PSG) was used to assess objective outcomes such as sleep efficiency (SE), wake after sleep onset (WASO), sleep onset latency (SOL), and total sleep time (TST).

Additional outcome(s) Subjective outcomes were assessed using a patient-reported electronic morning sleep diary, which comprised subjective sleep efficiency (sSE), subjective sleep onset latency (sSOL), and subjective wake after sleep onset(sWASO).

Quality assessment / Risk of bias analysis Review Manager 5.3 was used to assess the risk of bias plot. The risk of bias for RCTs was evaluated using the universal criteria of the Cochrane Collaboration, which included biases related to reporting, attrition, performance, detection, and selection. There were three categories for bias criteria: "low," "high," and "unclear."

Strategy of data synthesis Direct evidence was subjected to pairwise meta-analysis using Review Manager 5.3 software. A random effect model was used to assess and compute the mean difference (MD) with 95% confidence interval [CI] for each outcome.

Subgroup analysis N/A.

Sensitivity analysis The stability of the combined data was also investigated using sensitivity analysis.

Country(ies) involved China.

Keywords insomnia, COMISA, cognitive behavioral therapy for insomnia, systematic review.

Contributions of each author

Author 1 - Yuejuan Xu.

Email: 1650927031@qq.com

Author 2 - Xin Tan.

Email: 862968596@qq.com

Author 3 - Lina Xu.

Email: xulina163@163.com Author 4 - Xingmei Yu.

Email: yxm19870720@126.com Author 5 - Chuangli Hao. Email: hcl_md@163.com