INPLASY PROTOCOL

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None declared.

Cognitive-behavioral therapy for insomnia with objective short sleep duration phenotype

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Review question / Objective: **Insomnia disorder with objective short sleep duration (ISS) phenotype is a distinct subtype from insomnia with normal sleep duration (INS) phenotype, and cognitive-behavioral therapy for insomnia (CBT-I) may have different therapeutic response. The aim of this meta-analysis was to reveal the different efficacy of ISS and INS phenotypes to CBT-I alone.**
Condition being studied: **Cognitive-behavioral therapy for insomnia (CBT-I) is the recommended first-line treatment for the insomnia disorder, with hypnotic medication suggested when CBT-I is unsuccessful. However, insomnia disorder is inherently multidimensional, and insomnia with objective short sleep duration (ISS), which is defined as patients with insomnia disorder with sleep duration less than 6 hours measured by polysomnography, is considered a distinct biobehavioral process from insomnia with objective normal sleep duration (INS) phenotype. With a proposed hallmark of physiologic hyperarousal, the ISS phenotype has been characterized as a chronic and unremitting course and linked to cardiovascular, metabolic, neurocognitive and psychiatric morbidity. In contrast, the INS phenotype is characterized as a disorder of cognitive-emotional and concomitant cortical arousal that is more likely to remit and linked to sleep misperception and psychiatric morbidity.**

INPLASY registration number: This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 13 August 2022 and was last updated on 13 August 2022 (registration number INPLASY202280046).

INTRODUCTION

Review question / Objective: **Insomnia disorder with objective short sleep duration (ISS) phenotype is a distinct subtype from insomnia with normal sleep duration (INS) phenotype, and cognitive-behavioral therapy for insomnia (CBT-I) may have**

different therapeutic response. The aim of this meta-analysis was to reveal the different efficacy of ISS and INS phenotypes to CBT-I alone.

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METHODS

Search strategy: We searched PubMed, EMBASE, and the Cochrane Library for studies that observed the efficacy of cognitive-behavioral therapy for those with the ISS and INS phenotypes through July 31, 2022 by using combination of "insomnia" AND ("cognitive-behavioral therapy" OR "CBT" OR "cognitive therapy" OR "stimulus control" OR "sleep restriction" OR "sleep hygiene" OR "relaxation therapy").

Participant or population: Adult patients with insomnia disorder diagnosed by DSM (Diagnostic and Statistical Manual of Mental Disorders) or ICD (International Classification of Diseases) criteria.

Intervention: Cognitive-behavioral therapy for insomnia (CBT-I) including a combination of two or more elements, such as stimulus control, sleep restriction therapy, sleep hygiene, cognitive therapy, relaxation therapy, or other counter-arousal techniques.

Comparator: ISS phenotype defined as less than 6 h of total sleep using polysomnography (PSG), and comparisons with the INS phenotype.

Study designs to be included: case-control study.

Eligibility criteria: Case-control study that reported results as either pre-post means and standard deviation/error, changed-scores in all groups, or effect sizes.

Information sources: PubMed, EMBASE, and the Cochrane Library.

Main outcome(s): Subjective sleep measures (sleep diaries) and objective sleep measures (polysomnography or actigraphy), Insomnia Severity Index, Dysfunctional Beliefs and Attitudes about Sleep, as well as calculated response (clinically significant improvement in insomnia symptoms by post-treatment, decline of at least 8 points in the Insomnia Severity Index or decline in sleep diary-measured total wake time of at least 25% or more) or remission (absence of clinically significant insomnia symptoms at post-treatment, Insomnia Severity Index of less than 8 or Pittsburgh Sleep Quality Index of less than 5).

Quality assessment / Risk of bias analysis: The Newcastlee Ottawa Quality Assessment Scale.

Strategy of data synthesis: The open-source R packages, including "meta", "compute.es", "metafor", and "Mad", were used to analyze the data collected. First, we computed the effect sizes of Hedge's g from each study. The post-treatment effect sizes were calculated using post-treatment data and pre-treatment data that were used as reference data, for ISS group and INS group, respectively. In the comparative analysis, the differences (mean differences

and their standard deviations) between post-treatment data and pre-treatment data were used to analyze effect sizes, and the ISS group data were used as reference data. The direction of effect size values was adjusted so that a positive value would always indicate a better efficacy in INS group compared to ISS group. Given that subjective and objective sleep measures included multiple sleep measures including sleep onset latency, wake after sleep onset, total sleep time and sleep efficiency, we aggregated the multiple effect sizes to one effect size (i.e., subjective measure or objective measure) using the Borenstein-Hedges-Higgins-Rothstein method, which had the least biased and most precise method to aggregate effect sizes.

Subgroup analysis: N/A.

Sensitivity analysis: N/A.

Country(ies) involved: China.

Keywords: Insomnia disorder; Insomnia with objective short sleep duration; ISS phenotype; Cognitive-behavioral therapy for insomnia; CBT-I

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