

# INPLASY

## The Effectiveness of Cognitive Behavioral Therapy on Depression and Sleep Problems for Climacteric Women: A Systematic Review and Meta-Analysis

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### ADMINISTRATIVE INFORMATION

**Support** - N/A.

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

**Conflicts of interest** - None declared.

**INPLASY registration number:** INPLASY202410033

**Amendments** - This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 09 January 2024 and was last updated on 09 January 2024.

### INTRODUCTION

**Review question / Objective** The specific purposes of this study, which involves conducting a meta-analysis on the effects of cognitive-behavioral interventions applied to perimenopausal women with symptoms of depression and sleep disorders, are as follows:

- 1) To establish the overall features of cognitive-behavioral interventions identified in the search process.
- 2) To evaluate the effect size of the impact of cognitive-behavioral interventions in mitigating depressive symptoms.
- 3) To measure the effect size of the effect of cognitive-behavioral interventions on issues related to sleep.

The review encompassed RCTs that satisfied the following conditions: 1) studies concentrating on women in the perimenopausal stage within the age

range of 40 to 65 years; 2) studies encompassing assessments related to depression; 3) studies involving assessments related to sleep disorders; 4) Randomized Controlled Trials (RCTs); 5) and studies that were published in the English language.

**Rationale** Women in their middle years undergoing perimenopause encounter a range of physical and psychological alterations attributed to hormonal changes. The prominent symptoms among menopausal women are depressive symptoms and sleep-related problems.

**Condition being studied** One of the prominent psychological symptoms among menopausal women is depression. Menopausal women often experience depressive disorders due to changes in female hormones as well as social role changes, such as their children becoming independent and

the death of elderly family members. Symptoms of depression include lethargy, feelings of worthlessness, low self-esteem, weight gain or loss, impaired memory, reduced concentration, and sleep difficulties, all of which have a significant impact on a person's life and can cause a great deal of distress. Also, depression signifies an emotional state characterized by concerns, feelings of failure, loss, helplessness, and worthlessness, which are the results of negative perceptions about oneself.

Menopausal women may also experience difficulty falling asleep, tossing and turning during sleep, poor sleep quality, fatigue, and daytime sleepiness due to symptoms such as hot flashes and palpitations. It is a well-known fact that sleep disturbances and difficulties have a serious negative impact on both physical and mental health. The prevalence of insomnia in menopausal women is approximately 15%, and persistent sleep disturbances can increase the risk of various cardiovascular diseases, stroke, diabetes, and metabolic syndrome, and in severe cases, it can lead to death. In addition, inability to sleep prevents restoration from fatigue, resulting in daytime tiredness and drowsiness.

## METHODS

**Participant or population** Menopausal women.

**Intervention** Cognitive Behavioral Therapy.

**Comparator** Control group(waitlist, usual care, no treatment).

**Study designs to be included** Randomized Controlled Trial.

**Eligibility criteria** The review encompassed RCTs that satisfied the following conditions: 1) studies concentrating on women in the perimenopausal stage within the age range of 40 to 65 years; 2) studies encompassing assessments related to depression; 3) studies involving assessments related to sleep disorders; 4) Randomized Controlled Trials (RCTs); 5) and studies that were published in the English language.

**Information sources** To identify relevant and qualified research articles, a comprehensive search was conducted using databases: Cumulative Index to Nursing and Allied Health Literature (CINAHL), PubMed, EMBASE, and Cochrane Central Register of Controlled Trials (CENTRAL). The search terms included a variety of relevant terms such as "climacteric," "menopause," "depression," "emotional depression," "depressive symptoms,"

"sleep disorder," "sleep-related problem," "cognitive behavioral therapy," "psychological intervention," "therapy," "counseling" and "program." To enhance the comprehensiveness of the search, the search terms were expanded or "exploded," incorporating controlled vocabularies in addition to including free-text terms.

**Main outcome(s)** Upon reviewing nine studies that satisfied our inclusion criteria and involved a total of 923 participants, it was noted that four of these studies incorporated diverse cognitive-behavioral strategies. The combined effect size for depressive symptoms was found to be 3.55 (95% confidence interval: -5.48, -1.61;  $p < 0.05$ ), and for sleep quality, it was 0.78 (95% confidence interval: -1.32, -0.25;  $p = 0.004$ ).

### Quality assessment / Risk of bias analysis

Revision Manager 5.3 software (Risk of Bias Assessment Tool) was used to check quality assessment. All nine Randomized Controlled Trials (RCTs) (100%) provided a sufficient description of their randomization sequences. Allocation concealment was adequately demonstrated in eight out of nine studies (88%), with one study (11%) considered ambiguous due to a lack of a clear description. In two of the nine investigations (22%), it was not feasible to implement blinding for participants, staff, or outcomes. In one study (11%), the blinding of study personnel was considered ambiguous due to insufficient detail. Among the five studies (55%) evaluated for attrition bias, none showed frequent missing data. However, in the remaining four studies (44%), no information was provided regarding either the attrition rate or the reasons for missing data. Finally, none of the studies (100%) assessed for selective reporting demonstrated selective reporting bias.

**Strategy of data synthesis** Revision Manager 5.3 software was used to determine effect sizes, assessing the impact of psychological therapies on depressive symptoms and sleep quality. The overall effect size was established using Standardized Mean Differences (SMD), 95% confidence intervals, and weighted mean difference calculations. A fixed-effect model was applied due to the homogeneity of the data, indicating a shared real treatment effect. Statistical tests, such as Q-test and Higgins' I<sup>2</sup> Cochran's statistics, were employed to quantify statistical heterogeneity comprehensively. Forest plots were employed for visual assessment of effect sizes, confidence intervals, and their overlap before applying statistical techniques.

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**Subgroup analysis** We conducted subgroup analyses based on the heterogeneity observed in the dependent variable. The analyses were carried out according to the types of scales (whether the Pittsburgh Sleep Quality Index was used), the form of intervention (individual vs. group), and the average number of intervention applications (5.5 times or more vs. less than 5.5 times). In the subgroup analysis based on the type of scale, when measuring the quality of sleep with the Pittsburgh Sleep Quality Index, the effect size was statistically significant at -2.8 (95% CI: -3.71, -2.06), indicating a significantly larger effect compared to measurements with other types of sleep scales ( $P < 0.001$ ,  $I^2 = 0\%$ ), and the heterogeneity was low. In the subgroup analysis based on the form of intervention, for the quality of sleep, group intervention showed a statistically significant effect size of -2.73 (95% CI: -3.69, -1.78) compared to individual intervention ( $P < 0.001$ ,  $I^2 = 0\%$ ), and the heterogeneity was low. In the analysis based on the number of intervention applications, when the average application frequency was 5.5 times or more, the effect size was -0.88 (95% CI: -1.27, -0.48), which was statistically significant ( $P < 0.001$ ,  $I^2 = 27\%$ ), and the heterogeneity was low. However, when the intervention application frequency was less than 5.5 times, statistical significance was achieved ( $P < 0.009$ ,  $I^2 = 62\%$ ), but the heterogeneity was moderate. Overall, the findings suggest that the type of scale, form of intervention, and the number of intervention applications may influence the effectiveness and heterogeneity of the outcomes in the study.

**Sensitivity analysis** Not Applicable in our study ("A sensitivity analysis is a repeat of the primary analysis or meta-analysis, substituting alternative decisions or ranges of values for decisions that were arbitrary or unclear"-Cochrane Handbook).

**Country(ies) involved** South Korea.

**Keywords** Menopuase;Cognitive Behavioral Therapy; Depression;Sleep Difficulty.

#### **Contributions of each author**

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