INPLASY

Non-Pharmacological Intervention Effects on Middle-aged Women with Menopausal Symptoms: A Systematic Literature Review and Meta-Analysis

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Yu, HJ; Kim, JY.

Corresponding author:
Heajin Yu

heajinyu@syu.ac.kr

Author Affiliation:
Sahmyook University.

ADMINISTRATIVE INFORMATION

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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 23 July 2025 and was last updated on 23 July 2025.

INTRODUCTION

Review question / Objective What are the general characteristics of studies related to non-pharmacological intervention programs for middle-aged women experiencing menopausal symptoms, both domestically and internationally?

What types of non-pharmacological intervention programs are provided to middle-aged women experiencing menopausal symptoms, both domestically and internationally?

What is the overall effectiveness of non-pharmacological intervention programs for middle-aged women experiencing menopausal symptoms, both domestically and internationally?

Condition being studied Middle-aged women experience not only physical changes such as aging and menopause but also significant psychological shifts including symptoms of depression and anxiety. This period of life is often marked by major transitional events, such as the evolving maternal role due to children becoming independent, and is considered a critical turning point in a woman's life (Kwon & Jeon, 2013). Menopause, in particular, is a natural biological process during which a woman's ovaries gradually reduce hormone production, eventually leading to the permanent cessation of menstruation. These changes typically begin in the late 40s and progress gradually over time (Lee, 2020). In the case of Korean women, the average onset of menopause has been reported to occur around the age of 51 and is clinically defined as the point when a woman has experienced the absence of menstruation for 12 consecutive months (Shin & Lee, 2020).

The primary causes of menopause are the decline in ovarian function and the subsequent decrease in estrogen levels. As the ovaries become less active and produce less estrogen, not only the reproductive system but also other vital organs such as the heart, brain, and bones are significantly affected (Shin & Lee, 2020). The menopausal experience among middle-aged

women varies widely and can be influenced by multiple factors such as genetic predisposition, smoking habits, irregular lifestyle patterns, stress, medical treatments, and the presence of chronic illnesses like hypertension and diabetes. These factors can accelerate the decline in ovarian function and exacerbate menopausal symptoms (Bang, 2019; Santoro, Epperson, & Matthews, 2015).

As women enter menopause, they undergo a range of physiological and psychological changes triggered by hormonal fluctuations. These transitions may serve as a significant life inflection point. Common physical symptoms include decreased skin elasticity, reduced libido, headaches, cardiovascular issues, hot flashes, sleep disturbances, and facial flushing (Bang, 2019; Santoro et al., 2015). Psychological symptoms frequently include increased irritability and depressive manifestations such as feelings of worthlessness, fatigue, lack of motivation, and diminished concentration (Jang & Cha, 2003; Kanter et al., 2013; Vivian-Taylor & Hickey, 2014).

Treatment strategies for menopausal symptoms can be broadly categorized into pharmacological and non-pharmacological interventions. Among these, non-pharmacological interventions are increasingly emphasized due to their lower risk of adverse side effects and relatively safer profiles when compared to hormone or drug therapy. As such, it is essential to explore non-pharmacological interventions as a priority when addressing the various symptoms experienced by menopausal women (Jang & Cha, 2003).

Several types of non-pharmacological interventions have been explored. These include physical activity programs such as dance and movement therapies (Jeong & Sung, 2011), art- or music-based interventions (Pyeon, 2010), counseling and relationship enhancement programs (Byun & Kim, 2007), and cognitive-based strategies such as cognitive training or stimulation interventions (Kim, 2020). Despite the increasing number of studies in this domain, there remains a need for a comprehensive and systematic synthesis of the evidence related to the effectiveness of such interventions, particularly in terms of both physical and psychological outcomes.

A systematic and integrated review of existing non-pharmacological interventions is warranted to objectively assess their effectiveness and provide a robust evidence base for the selection and implementation of appropriate interventions for women experiencing menopausal symptoms. Through evidence synthesis, healthcare providers can develop well-informed strategies for clinical practice and improve health outcomes for this population.

METHODS

Participant or population P (Population): Middle-aged women aged 40 to 65 years undergoing menopause.

Intervention I (Intervention): Non-pharmacological interventions.

Comparator C (Comparison): Individuals who did not receive the intervention or received a sham (placebo) intervention.

Study designs to be included Randomized Controlled Trials.

Eligibility criteria Studies will be excluded if they meet any of the following criteria:
Studies involving pharmacological or hormone replacement therapies as the primary intervention.
Observational studies, qualitative research, case reports, editorials, or review articles.
Studies not reporting relevant outcome measures or lacking sufficient data for effect size calculation.
Studies involving populations outside the specified age range or unrelated to menopausal symptoms.

Information sources The process of conducting the systematic review will follow the procedures outlined in the Cochrane Handbook, including topic selection, formulation of key research questions (PICO-SD), literature search and selection (using PubMed, CINAHL, EMBASE, CENTRAL, KISS, and RISS), critical appraisal of the included studies, meta-analysis, evaluation of the results, and publication.

Main outcome(s) Studies reporting physical or psychological outcomes related to menopausal symptoms (e.g., hot flashes, sleep disturbances, depressive symptoms, anxiety, quality of life).

Quality assessment / Risk of bias analysis The risk of bias of the included studies will be assessed using the Cochrane Risk of Bias (RoB) tool, as recommended for systematic reviews of randomized controlled trials.

Strategy of data synthesis Quantitative data synthesis will be conducted using meta-analysis if a sufficient number of studies with comparable outcomes are identified. Effect sizes will be

calculated using standardized mean differences (SMD) or mean differences (MD) with 95% confidence intervals (CIs), depending on the measurement scales used across studies. A random-effects model will be applied to account for potential heterogeneity among studies.

Statistical heterogeneity will be assessed using the Chi-squared (χ^2) test and quantified with the I^2 statistic. An I^2 value of 25%, 50%, and 75% will be interpreted as low, moderate, and high heterogeneity, respectively. Where substantial heterogeneity is detected, subgroup analyses will be performed based on intervention type, duration, outcome type (physical vs. psychological), and study quality.

If meta-analysis is not feasible due to significant heterogeneity or limited data, a narrative synthesis will be provided, summarizing the characteristics and findings of the included studies in a structured format.

Subgroup analysis Subgroup analyses will be conducted to explore potential sources of heterogeneity and to identify whether the effectiveness of non-pharmacological interventions varies by study or participant characteristics. Planned subgroup analyses may include the following factors:

Type of Intervention: (e.g., physical activity-based, mind-body, cognitive-behavioral, arts-based, or lifestyle modification programs)

Type of Outcome: (e.g., physical symptoms such as hot flashes and sleep disturbances vs. psychological outcomes such as depression and anxiety)

Intervention Duration or Frequency: (e.g., ≤8 weeks vs. >8 weeks)

Menopausal Stage: (e.g., perimenopausal vs. postmenopausal women)

Geographic Region or Country: (e.g., Asia vs. Western countries)

Study Quality/Risk of Bias: (e.g., low vs. high risk of bias).

Sensitivity analysis Sensitivity analyses will be conducted to examine the robustness of the meta-analysis results. This will involve excluding studies with a high risk of bias, studies with small sample sizes, or those with missing or imputed data. Additionally, analyses will be repeated using different statistical models (e.g., fixed-effects vs. random-effects) to assess the consistency of the findings. The impact of each individual study on the overall effect size will also be evaluated by conducting a leave-one-out analysis, in which the meta-analysis is repeated while omitting one study at a time.

Country(ies) involved Korea.

Keywords Non-pharmacological intervention, menopause, middle-aged.

Contributions of each author

Author 1 - Heajin Yu.
Email: heajinyu@syu.ac.kr
Author 2 - Jihyun Kim.
Email: hyu2861@gmail.com