INPLASY

Combined Effects of Herbal Medicine and Lifestyle Modification on Childhood Simple Obesity: A Systematic Review and Meta-Analysis

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ADMINISTRATIVE INFORMATION

Support - None.

Review Stage at time of this submission - The review has not yet started.

Conflicts of interest - None declared.

INPLASY registration number: INPLASY202560096

Amendments - This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 24 June 2025 and was last updated on 24 June 2025.

INTRODUCTION

Review question / Objective This study investigates whether the combination of herbal medicine and lifestyle modification provides enhanced benefits in treating childhood simple obesity.

Rationale For childhood simple obesity, Deng(2024) conducted a meta-analysis on the effectiveness of lifestyle interventions, and Cui(2025) included several studies that combined acupuncture and moxibustion with lifestyle interventions. To the best of our knowledge, no systematic review or meta-analysis has yet been identified that evaluates the combined effects of herbal medicine and lifestyle modification for childhood obesity. This study therefore aims to evaluate whether the combined intervention produces a synergistic effect in treating childhood obesity and to provide evidence to inform future clinical treatment strategies.

Condition being studied Childhood simple obesity is a complex, multifactorial condition influenced by genetic, behavioral, and environmental factors, and it is associated with significant short- and long-term health risks, including insulin resistance, dyslipidemia, and psychosocial problems. Lifestyle interventions (including dietary changes, physical activity and so on) remains the cornerstone of treatment and is recommended as the first-line approach in most clinical guidelines. However, in real-world, the effectiveness of lifestyle interventions alone is often limited due to poor adherence, insufficient support systems, and individual variability in response. These limitations pose significant challenges to achieving sustained weight loss and metabolic improvement, particularly in pediatric populations.

Herbal medicine has shown promising efficacy in managing childhood obesity, and its combination with lifestyle interventions is being explored to enhance treatment outcomes. This study aims to compare lifestyle interventions alone with lifestyle

interventions combined with herbal medicine in terms of BMI reduction, lipid profile improvement and overall safety. A systematic review and meta-analysis of existing studies will be conducted to provide evidence-based insights into the clinical benefits of integrating herbal medicine with lifestyle interventions for the treatment of childhood obesity.

METHODS

Search strategy We will search electronically on English databases, Chinese databases, Korean databases and Japanese database. We used the search terms "simple obesity" and "herbal medicine" which were adapted to suit the language specifications of each database.

Participant or population
[Inclusion Criteria]
Patients diagnosed with childhood simple obesity according to the diagnostic criteria outlined in Pediatrics or relevant clinical guidelines.

[Exclusion Criteria]
Patients younger than 2 years or older than 18 years.
Patients with secondary obesity due to genetic metabolic disorders, endocrine diseases, hypothyroidism, Cushing's syndrome, or other relevant conditions.
Patients with severe cardiac, hepatic, pulmonary, renal, hematologic, infectious, psychiatric disorders, or other serious systemic conditions.
Patients who have taken any weight loss medications within the past 3 months.

Intervention The experimental group received the comparative intervention combined with oral herbal medicine.

Comparator The control group received lifestyle intervention including diet and exercise therapy.

Study designs to be included All the randomized controlled trials (RCTs) were included.

Eligibility criteria All randomized controlled trials (RCTs) on the efficacy of lifestyle intervention combined with oral herbal medicine in the treatment of simple obesity in children were included. Non-RCTs, RCT protocol, animal studies, case reports, thesis, survey and reviews were excluded.

Information sources We will electronically search 12 following databases. Three English databases (MEDLINE via PubMed, EMBASE, the Cochrane Central Register of Controlled Trials), three Chinese databases(China National Knowledge Infrastructure, Wanfang database, and VIP), five Korean databases (such as Oriental Medicine Advanced Searching Integrated System, Korean studies Information Service System, Korea Citation Index, Research Information Sharing Service, and Korean Medical database), and one Japanese databases(Citation Information by the National Institute of Informatics) without any language restrictions.

Main outcome(s)
1)Body mass index (BMI)
2)Lipid profile (e.g., LDL-C, TC) in peripheral blood.

Additional outcome(s)
1)Total effective rate
2)Adverse events.

Quality assessment / Risk of bias analysis Quality assessment will be performed using Risk of bias (Rob2) tool from the Cochrane Handbook for Systematic Reviews of Interventions. The tool includes bias arising from the randomization process, bias due to deviations from intended interventions, bias due to missing outcome data, bias in the measurement of the outcome, and bias in the selection of reported results.

Strategy of data synthesis The data will be synthesized using Review Manager 5.4 software. Dichotomous outcomes will be summarized using Risk Ratios (RR) with 95% Confidence Intervals (CI). Continuous outcomes will be presented as the standard mean difference (SMD) or mean difference (MD) with 95% CI. Heterogeneity was evaluated using the Higgins I2 index, with I2 ≥ 50% indicating potential heterogeneity, and I2 ≥ 75% indicating significant heterogeneity.

Subgroup analysis If the meta-analysis shows significant heterogeneity, subgroup analyses will be conducted. Subgroup analyses will also be performed based on the compositions of herbal medicines, both with and without conventional treatment, provided that a sufficient amount of data is available.

Sensitivity analysis A sensitivity analysis was performed by excluding one study at a time to assess the robustness of the meta-analysis results.

Language restriction No language restriction.

Country(ies) involved Republic of Korea.

Keywords childhood; simple obesity; lifestyle intervention; herbal medicine.

Dissemination plans childhood; simple obesity; lifestyle intervention; herbal medicine.

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