INPLASY PROTOCOL

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Conflicts of interest:
None declared.

Herbal medicine using pattern-identification for the treatment of obesity : a systematic review and meta-analysis

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Review question / Objective: **The aim of this systematic review and meta-analysis is to evaluate effectiveness and safety of Herbal medicine using pattern-identification on obesity.**
Condition being studied: **Herbal medicine based on pattern identification is widely used in Korean medicine to make more effective treatment. Depending on patient's symptoms and signs, obese patient's are classified to several pattern. Proper herbal medicine using pattern identification has been suggested to be able to reduce the body weight more effectively with decreasing adverse events.**

INPLASY registration number: This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 02 August 2021 and was last updated on 02 August 2021 (registration number INPLASY202180006).

INTRODUCTION

Review question / Objective: **The aim of this systematic review and meta-analysis is to evaluate effectiveness and safety of Herbal medicine using pattern-identification on obesity.**

Rationale: **Herbal medicine has been known to be effective on obesity. Herbal medicine using pattern identification is common, however there has been no systematic review about herbal medicine focused on pattern identification for obesity.**

Condition being studied: Herbal medicine based on pattern identification is widely used in Korean medicine to make more effective treatment. Depending on patient's symptoms and signs, obese patient's are classified to several pattern. Proper herbal medicine using pattern identification has been suggested to be able to reduce the body weight more effectively with decreasing adverse events.

METHODS

Search strategy: Randomized controlled trials about herbal medicine using pattern identification for obesity will be searched through multiple electronic databases, manual search, and contact to author.

Participant or population: Obese participants with body mass index(BMI) over 25kg/m2 will be included. Participants under 18 years will be excluded. Participants with complications or secondary obesity will also be excluded.

Intervention: Randomized controlled trials that investigated the effects of herbal medicine using pattern identification will be included. There will be no limits on forms of herbal medicine such as decoctions, capsules, tablets, pills, powders, and extracts. Studies involving herbal medicine combined with other therapy as experimental intervention will be excluded.

Comparator: Control interventions will be include placebo, no treatment, other medication and managing habits containing dietary education or exercise.

Study designs to be included: Randomized controlled trials with parallel-group designs will be included.

Eligibility criteria: Randomized controlled trials with cross-over designs will be excluded. We excluded non-RCTs containing mechanism studies, non-controlled studies, case reports, feasibility studies, and reviews.

Information sources: A search will be performed from inception to August 2021 in following databases: MEDLINE, Cochrane Central Register of Controlled Trials, EMBASE, China National Knowledge Infrastructure(CNKI), CiNii, KoreaMed, Korean Studies Information Service System(KISS), Science-on, and Oriental Medicine Advanced Searching Intergrated System(OASIS). The searches will be conducted with each electronic database;s supported language.

Main outcome(s): The primary outcome will be body weight reduction and BMI reduction.

Additional outcome(s): The additional outcomes will be include waist circumference(WC), hip circumference(HC), waist-hip ratio(WHR), and adverse events.

Quality assessment / Risk of bias analysis: Two reviewers will extract the following data: study design, sample size, characteristics of participants, intervention and comparators, treatment duration, outcomes, adverse events, and information for assessment of study quality. If it is necessary, the contact with original authors via email will be followed to obtain missing data. Risk of bias assessment will be conducted using “risk of bias” tool from Cochrane Collaboration. The tool consists of seven domains: sequence generation, allocation concealment, blinding of participants and personnel, Blinding of outcome assessors, incomplete outcome data, selective outcome reporting and other bias. Two reviewers will independently assess the risk of bias. If there are any disagreements or discrepancies, a third researcher will make final decision.

Strategy of data synthesis: The Review Manager software for Windows (RevMan ver.5.3.; Copenhagen; The Nordic Cochrane Center, The Cochrane Collaboration, 2014) will be used for data synthesis. Meta-analysis and evaluating risk ratio or standard mean difference will be conducted. To calculate the pooled estimates of the effect size, a random effect model with 95% confidence will be selected. The heterogeneity will be

evaluated using Chi-squared and I-squared test: 0% to 40% indicate unimportant heterogeneity, 30% to 60% present moderate heterogeneity, 50% to 90% mean substantial heterogeneity, and 60% to 100% indicated considerable heterogeneity.

Subgroup analysis: If the necessary data will be available, subgroup analysis will be conducted according to differences in intervention characteristics.

Sensitivity analysis: Sensitivity analysis will be performed, if needed.

Country(ies) involved: Republic of Korea (South Korea).

Keywords: Obesity, Herbal medicine, Pattern identification, systematic review, meta-analysis.

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