

fficacy and Safety of Shen-Ling baizhusan combined with external treatment for obesity: A systematic review and meta-analysis with trial sequential analysis

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ADMINISTRATIVE INFORMATION

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

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 7 September 2024 and was last updated on 7 September 2024.

INTRODUCTION

Review question / Objective This study selected the use of modified Shen-Ling-Bai-Zhu-San combined with external treatment as the research objective of a randomized controlled trial (RCT) on obese patients in the experimental group, and conducted meta-analysis. The effectiveness of the TSA method was further verified through sequential analysis of the experiment.

Condition being studied Obesity is a response to environmental stimuli, genetic susceptibility, and abnormalities, exhibiting a series of specific physiological indicators and clinical manifestations, accompanied by significant structural changes in the body. The status and acceptance of obesity as a disease are crucial for determining its treatment and developing broad intervention measures, and preventing overweight and obesity should be an important component of healthcare .

"Spleen deficiency and dampness accumulation" is the basic pathogenesis of obesity. If the spleen is weak, the transportation and transmission are weak, and the essence of water and grains is slightly lost in distribution, transforming into ointment and water dampness. Dampness and turbidity block the body, causing stagnation of qi and blockage of the three jiao. Therefore, Jianpi Qushi Tongsanjiao is a commonly used treatment for obesity, so Shenling Baizhu Powder is chosen ..

METHODS

Search strategy We searched seven databases, including PubMed, Embase, Cochrane, Web of Science, China National Knowledge Infrastructure, Chinese Biomedical Medical Database, and Wanfang Database, from database establishment until December 31, 2024. There are no language restrictions. We use randomized controlled clinical trials and meta-analysis of Chinese medicine, "obesity", "overweight", "Chinese medicine", "external treatment", "acupuncture", "acupuncture

and moxibustion", "acupoint catgut embedding", and "abdominal acupuncture" as keywords. Two authors processed the searches independently, and we also searched the references of the original and review studies manually for trials.

Participant or population A total 7 literatures were included, involving 616 patients.

Intervention Shen-Ling baizhusan combined with external treatment for obesity.

Comparator Shen-Ling baizhusan treatment for obesity.

Study designs to be included The main outcomes include total effective rate and BMI. Secondary outcomes include TG、TC、FINS、HDL-C.

Eligibility criteria 1) The original data are clinical randomized controlled trials published in Chinese or English. 2) The research subjects are cases included in the literature, regardless of patient gender, race, region, etc., aged 16 years or above; Clearly diagnosed as "obese" or "overweight". Body mass index (BMI) $\geq 28\text{kg/m}^2$, male waist circumference $\geq 85\text{cm}$, female waist circumference $\geq 80\text{cm}$. 3) The intervention measures of the experimental group are the combination of modified Shen-Ling-Bai-Zhu-San and external treatment, with external treatment methods (such as acupuncture, moxibustion, electroacupuncture, acupoint embedding, acupoint application, scraping and cupping, ear acupuncture, etc.). The experimental group can be used in combination with the same Western medicine as the control group. The form of traditional Chinese medicine is not limited and can take the form of decoctions, granules, capsules, tablets, powders, etc. 4) The intervention for the control group is routine treatment for obesity, including Western medicine or placebo, exercise, dietary management, and unrestricted use of Western medicine. 5) The original data is complete and extractable. 6) The main outcomes include total effective rate and BMI. Secondary outcomes include TG、TC、FINS、HDL-C.

Information sources Retrieve randomized clinical trials published before December 31, 2024, on the treatment of obesity with modified *Atractylodes macrocephala* combined with external treatment, from the following Chinese and English databases: China National Knowledge Infrastructure (CNKI), Wanfang Database, China Science and Technology Journal Database (VIP), China Biomedical

Literature Database (CBM), PubMed, Cochrane Library, Web of Science, and Scopus.

Main outcome(s) A total 7 literatures were included, involving 616 patients. The Meta-analysis results showed that the treatment group had done much better than controlled group at increasing the effective rate [OR=4.11, 95% CI (2.49, 6.77), $P < 0.001$], decreasing BMI [WMD=-2.23, 95% CI (-2.71, -1.75), $P < 0.0001$] and TG [WMD=-0.08, 95% CI (-0.29, 0.13), $P = 0.47$], decreasing TC [WMD=-0.29, 95% CI (-0.53, -0.05), $P = 0.02$] and HDL [WMD=0.16, 95% CI (0.10, 0.22), $P < 0.0001$], FINS [WMD=-2.02, 95% CI (-3.49, -0.55), $P = 0.007$]. The sequential analysis showed that the effective rate of the treatment group was higher than that of the controlled group with the possibility of false positive and more trials needed to be included for validation, but it confirmed the treatment group was more effective in total effective rate and BMI than the controlled group.

Quality assessment / Risk of bias analysis We evaluated the bias risk of 7 randomized controlled trials using the Cochrane bias risk tool. Among the 7 articles, 3 discussed random methods and all used the method of random sequence. In addition, the four articles only mentioned the word "random" and did not provide a detailed explanation of its precise randomization methods. There is no literature explaining the hidden method of random allocation; There is no literature on the specific steps and practical methods of blinding; There is no literature describing whether there are research individuals who have withdrawn or lost follow-up. But the research results are consistent with the research design they set. Display the deviation risk map by using Revman 5.4 software.

Strategy of data synthesis Through our preliminary search, a total of 179 potential corresponding studies have been identified. After removing duplicate records, we identified 39 studies out of 179 for full-text review. A total of 32 studies were exempted for the following reasons: 20 articles did not meet the diagnostic criteria, and 12 articles did not meet the research design. Among the 7 studies included, 616 patients were used for this meta-analysis.

Subgroup analysis No significant evidence was found to suggest clinical differences. The high heterogeneity may be due to the use of different measuring devices. The meta-analysis results indicate that the combination of modified Shen-Ling-Bai-Zhu-San and external treatment has a certain therapeutic effect on obesity, and no

benefits have been found with the increase of treatment course.

Sensitivity analysis Excluding the included RCTs one by one, excluding the included RCTs one by one. After excluding one study (Bianyuying 2023) , there was a significant qualitative decrease, resulting in [WMD=-0.39, 95% CI (-0.60, -0.18), P=0.16].

Country(ies) involved China.

Keywords Obesity; Overweight; Shen-Ling-Bai-Zhu-San; external treatment; Meta-analysis; TSA trial sequential analysis; randomized controlledtrial.

Contributions of each author

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