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Efficacy 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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Abstract

Background: This study selected the use of modified Shen-Ling baizhusan 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. The aim of this study is to evaluate the effect of modified Shen-Ling baizhusan combined with external treatment on obese patients, and to provide scientific evidence support for its clinical application.

Methods: This Meta is based on previously conducted studies and does not contain any new studies with human participants or animals performed by any of the authors.

Retrieve randomized clinical trials published before May 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. According to the inclusion and exclusion criteria, the randomized controlled trials (RCT) that met the criteria were screened. The Cochrane handbook was used for the risk assessment and the Revman 5.4 software was used for Meta analysis, the TSA 0.9 Beta software was used for sequential analysis.

Protocol and Registration: This Meta was performed according to the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) checklist. We registered the process of our review on the INPLASY website (http://inplasy.com) under registration number INPLASY202490032.

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Results: The Meta-analysis results showed that the treatment group had done much better than controlled group at increasing the effective rate. 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.

Conclusion: Based on existing research evidence, we need to improve the quality of RCT treatment for obesity using modified Shen-Ling baizhusan combined with external treatment. Meta analysis shows that the combination of modified Shen-Ling baizhusan and external treatment is superior to conventional treatment in terms of total effective rate, BMI, HDL, TC, TG, and FINS in the treatment of obesity. The TSA analysis further confirms the reliability of the above viewpoint.

Keywords: Obesity; Overweight; Shen-Ling baizhusan; External Treatment; Meta-Analysis; TSA Trial Sequential Analysis; Randomized Controlled Trial

Abbreviations

RCTs: Randomized Clinical Trials; CNKI: China National Knowledge Infrastructure; BMI:Body Mass Index; HDL: Hign Density Lipoprotein; FINS: Fasting Serum Insulin; TC: Total Cholesterol; TG: Triglycerider; RR: Relative Risk; MD: Mean Difference; SMD: Standardized Mean Difference; OR: Odds Ratio; TSA: Trial Sequential Analysis; RIS: Required Information Size

Introduction

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 [1,2]. 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 [3].

Modern medicine mainly focuses on drug therapy [4]. Due to the unsatisfactory drug treatment effects and numerous side effects in some obese patients, long-term use is not recommended.

"Spleen deficiency and dampness accumulation" is the basic pathogenesis of obesity. If the spleen is weak, the transportation and transmission are weak [5], and the essence of water and grains is slightly lost in distribution, transforming into ointment and water dampness [6]. 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 Shen-Ling baizhusan Powder is chosen [7]. Traditional Chinese medicine has advantages in treating overweight and obesity, and explores the treatment methods for obesity from the perspectives of invigorating the spleen, dispelling dampness, and promoting the three jiao. Traditional Chinese medicine decoction, dietotherapy, Tonic Diet, etc., which are taken orally, have repeatedly achieved good results in the treatment of obesity [8-10], while massage, catgut embedding, acupuncture and moxibustion, ear points and other treatment methods in the external treatment have also shown unique advantages in the treatment of obesity. Clinical practice and basic research have found that the combination of traditional Chinese medicine and external treatment for obesity has many effective approaches, longterm therapeutic effects, improved body condition, and reduced complications.

This study systematically evaluates the efficacy and safety of modified Shen-Ling baizhusan combined with topical treatment for obesity, providing evidence-based medicine for the treatment of obesity.

Materials and 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 May 30, 2024. There are no language restrictions. We use randomized controlled clinical trials and metaanalysis 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.

Inclusion 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) ≥ 28 kg/m², male waist circumference \geq 85cm, female waist circumference \geq 80cm [11]. 3) The intervention measures of the experimental group are the combination of modified Shen-Ling baizhusan 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.

Exclusion criteria

We excluded the following characteristics of clinical studies: 1) Other traditional Chinese medicine formulas; (2) Systematic review and independent descriptive research; (3) Empirical case reports; (4) Unable to obtain data information; (5) Animal experiments and conference papers; (6) Unable to obtain complete text or incomplete data.

Data extraction

Two reviewers independently search and extract data, and screen based on inclusion and exclusion criteria. For studies that meet the inclusion criteria, the data is independently extracted by two reviewers. Retrieved the following data: title, author, publication date, sample size, diagnostic criteria, baseline data, intervention measures, course of treatment, follow-up time, outcome evaluation indicators, and outcomes. Any differences were discussed with third parties. The corresponding author reviewed the final data.

Quality assessment

The quality evaluation tool is Bias Risk Assessment Tool developed by Cochrane Collaboration Network.

Evaluation items are as follows: how random sequences are generated; whether distribution is hidden; whether researchers and subjects are blinded; whether study outcomes are blinded; whether outcome data remain intact; selective reporting; and whether there are other biases. The judgment of low risk, unknown risk, and high risk were given one by one according to the performance of the included literature in the above evaluation items. When two researchers disagree, a third-party researcher steps in to assess.

Statistical analyses

RevMan 5.4.1 was used for data analysis and odds ratio (OR) or relative risk (RR) was used for the dichotomous variable and mean difference (MD) or standardized mean difference (SMD) was used for continuous variables and 95% CI was used to test the effect [12].

The heterogeneity was analyzed by using the Q value test and I² test. If P > 0.1 and I² ≤50%, no heterogeneity was judged, and the fixed effect model was used for meta-analysis. P > 0.1, I² >50% indicate heterogeneity; random effect model is used for meta-analysis; and the source of heterogeneity is found through sensitivity analysis or subgroup analysis (a sufficient number of studies are included). If the heterogeneity cannot be solved, the meta-analysis will be abandoned and descriptive analysis will be used.

For the primary outcome, trial sequential analyses were performed by TSA 0.9 [13] with type I error α = 0.05 and type II error β = 0.1, aiming at examining and minimizing the impact of type 1 errors due to sparse data and repeated significance testing following updates with new trials.

Results

Study characteristics

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-

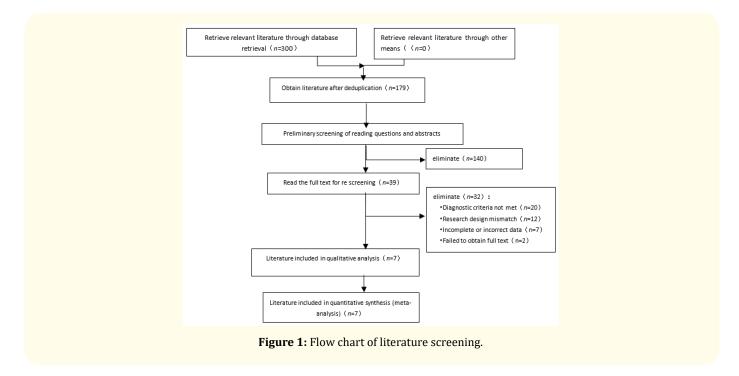
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text review. A total of 32 studies were exempted for the following reasons: 20 articles did not meet the diagnostic criteria, and 12

articles did not meet the research design. Among the 7 studies included, 616 patients were used for this meta-analysis, as shown in Figure 1.



Characteristics of included studies

Finally, 7 articles were included, including 616 patients. Among them, 6 articles reported total effective rate, 7 articles reported

BMI, 5 articles reported FINS, 5 articles reported TG, 5 articles reported TC, and 4 articles reported HDL.Please refer to Table 1 for details.

	Example count (T/C)	Intervention me	Course of	Outcome indica-	
Inclusion in research		Т	С	treatment (days)	tors
Bianyuying 202318]	15/15	Acupuncture and Medicine Combination Group	Metformin group	93	123456
Hanlulu 2022 [19]	22/23	Acupuncture and Medicine Combination Group	Acupuncture group	14	23456
Huangxiaojie 2019 [22]	130/130	Acupuncture and Medicine Combination Group	Acupuncture group	28	123456
Linchenjuan 2020 [20]	30/30	Acupuncture and Medicine Combination Group	Buried line group	93	12345
Sujian 2015 [17]	40/40	Acupuncture and Medicine Combination Group	Acupuncture group	93	126
Wangchenye 2016 [16]	49/35	Acupuncture and Medicine Combination Group	Metformin group	93	123456

	-			-	
Wennuan	29/28	Acupuncture and Medicine	Buried line group	93	123456
2023 [21]		Combination Group			

Table 1: Basic characteristics of the included studies.

Outcome measure: 1) Total effective rate, 2) BMI, 3) TG, 4) TC, 5) HDL, 6) FINS.

Risk of bias included in the study

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. The risk of deviation assessment is shown in Figure 2.

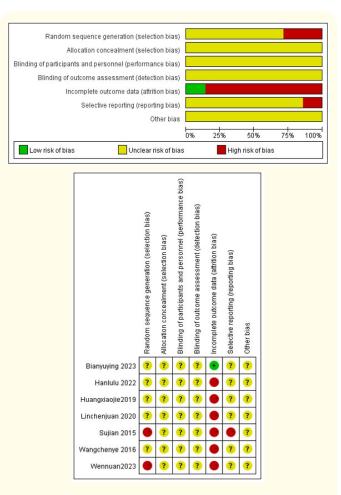
Inclusion in research quality evaluation

According to the Jadad scoring criteria, two researchers conducted a quality evaluation of the included literature. The results showed that out of 7 articles, two scored 4 points, while the remaining 5 scored 3 points, all of which were of medium quality. Please refer to Table 2 for details.

Meta-analysis results

Total effective rate

There were a total of 6 studies [16-18,20-22] discussing the total effective rate of Shen-Ling baizhusan combined with external



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Figure 2: Example of bias risk ratio.

Inclusion in research	Random method	Blind method	Allocation concealment	Integrity of result data	Selective reporting of research results	Other sources of bias
Bianyuying 2023 [18]	Unclear	Unclear	Unclear	Complete data	Non selective reporting	Unclear
Hanlulu 2022 [19]	Unclear	Unclear	Unclear	Complete data	Non selective reporting	Unclear
Huangxiaojie 2019 [22]	Unclear	Unclear	Unclear	Complete data	Non selective reporting	Unclear
Linchenjuan 2020 [20]	Unclear	Unclear	Unclear	Complete data	Selective reporting	Unclear
Sujian 2015 [17]	Random number table method	Unclear	Unclear	Complete data	Non selective reporting	Unclear

						81
Wangchenye 2016 [16]	Unclear	Unclear	Unclear	Complete data	Non selective reporting	Unclear
Wennuan 2023 [21]	Random number table method	Unclear	Unclear	Complete data	Non selective reporting	Unclear

Table 2: Includes the quality evaluation of the study.

treatment for 571 obese patients, including 278 cases in the control group and 293 cases in the experimental group. The study showed no significant heterogeneity in statistical analysis (P = 0.82, I² = 0%) and was analyzed using a fixed effects model. The meta-analysis results showed that there was a statistically significant qualitative difference between the modified combination of Shen-Ling baizhusan and the control group [OR = 4.11, 95% CI (2.49, 6.77), P<0.001], indicating that the modified combination of Shen-Ling baizhusan and external treatment can improve the treatment efficiency of obese patients (Figure 3).

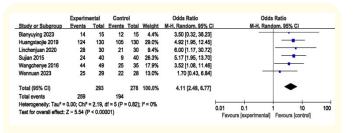


Figure 3: Meta analysis of Total efficiency.

analysis: There is no significant clinical heterogeneity, and the high heterogeneity may be related to the incomplete consistency of different measurement instruments and methods used in the study. The meta-analysis results indicate that the combination of modified Shen-Ling baizhusan and external treatment has a certain therapeutic effect on improving obese patients, but no benefits have been found to gradually increase with the course of treatment (Figure 4).

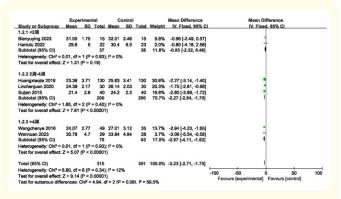


Figure 4: Meta analysis of BMI.

BMI

There are seven articles [16-22] reporting research on body mass index (BMI), including 616 individuals with obesity, including 301 in the control group and 315 in the experimental group. There is significant heterogeneity between studies (P = 0.34, I² = 12%), and a fixed effects model is used for comprehensive treatment and evaluation. The meta-analysis results showed statistically significant differences between the two groups [WMD = -2.23, 95% CI (-2.71, -1.75), P<0.0001]. Due to significant heterogeneity, further analysis of the sources of heterogeneity is needed. 1) Sensitivity analysis: Excluding the included RCTs one by one, after excluding one study (Hanlulu 2022) [19], there was a significant qualitative decrease (I² = 7%), resulting in [WMD = -0.77, 95% CI (-0.95, -0.59), P = 0.91]. Analyze the reasons, which may be related to small sample size or imprecise experimental design; 2) Subgroup

TG

A total of 5 articles [18-22] reported research on TG, involving 247 obese patients, including 131 in the control group and 116 in the experimental group. There is significant heterogeneity between the studies (P = 0.0005, I² = 83%), and the meta-analysis results using a random effects model showed statistically significant differences between the two groups [WMD = -0.08, 95% CI (-0.29, 0.13), P = 0.47]. Due to significant heterogeneity, further analysis of the sources of heterogeneity is needed. 1) Sensitivity analysis: Excluding each included RCT, heterogeneity decreased (I² = 0%) after excluding a single study (Bianyuying 2023) [18], resulting in [WMD = -0.17, 95% CI (-0.27, -0.07), P = 0.91]. Analyze the reasons, which may be related to the small sample size; 2) Subgroup analysis:

No significant clinical heterogeneity was found, suggesting that the use of equipment and technology in different laboratories may result in significant heterogeneity. Based on all data analysis, the meta-analysis results indicate that the combination of modified Shen-Ling baizhusan Powder and acupoint stimulation can effectively alleviate symptoms in obese patients (Figure 5).

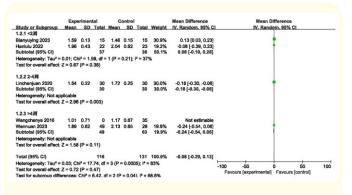


Figure 5: Meta analysis of TG.

TC

A total of 5 articles [16,18-21] reported research on TC, including 276 obese patients, including 131 in the control group and 145 in the experimental group. There is significant heterogeneity between the studies (P = 0.02, I^2 = 65%), and using a random effects model analysis, meta-analysis results showed statistically significant differences between the two groups [WMD = -0.29, 95% CI (-0.53, -0.05), P = 0.02]. Heterogeneity is high, analyze the reasons for heterogeneity. 1) Sensitivity analysis: Excluding the included RCTs one by one, excluding the included RCTs one by one. After excluding one study (Bianyuying 2023) [18], there was a significant qualitative decrease ($I^2 = 43\%$), resulting in [WMD = -0.39, 95% CI (-0.60, -0.18), P = 0.16]. Analyze the reasons, which may be related to the small sample size; 2) 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 baizhusan and external treatment has a certain therapeutic effect on obesity, and no benefits have been found with the increase of treatment course (Figure 6).

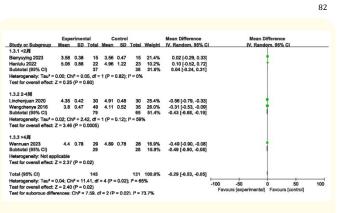


Figure 6: Meta analysis of TC.

HDL

Four studies [16,19-21] reported on the research results of HDL, including 246 obese patients, including 116 in the control group and 130 in the experimental group. There is significant heterogeneity between the studies (P<0.0001, $I^2 = 91\%$), and the meta-analysis results using a random effects model showed statistically significant differences between the two groups [WMD = 0.16, 95% CI (0.10, 0.22), P<0.0001]. Due to significant heterogeneity, further analysis of the sources of heterogeneity is needed. 1) Sensitivity analysis: Excluding the included RCTs one by one, heterogeneity decreased ($I^2 = 67\%$) after excluding one study (Wangchengye 2016) [16], resulting in [WMD = 0.03, 95% CI (-0.12, 0.19), P = 0.05]. Analyze the reasons, which may be caused by insufficient experimental design; 2) Subgroup analysis: No significant clinical heterogeneity was found, and widespread heterogeneity is likely due to differences in testing equipment and techniques used by different laboratories. The meta-analysis results indicate that the combination of modified Shen-Ling baizhusan and external treatment has a significant improvement effect on the health status of obese patients, and no benefits have been found to gradually increase with the course of treatment (Figure 7).

FINS

Five studies [16-18,21-22] have reported information on FINS, including 511 obese patients, 248 control group, and 263 experimental group. There is significant heterogeneity between the studies (P = 0.009, $I^2 = 70\%$), and using a random effects model

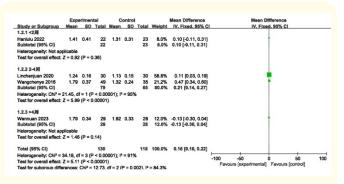


Figure 7: Meta analysis of HDL.

analysis, the meta-analysis results showed statistically significant differences between the two groups [WMD = -2.02, 95% CI (-3.49, -0.55), P = 0.007]. Due to significant heterogeneity, further analysis of the sources of heterogeneity is needed. 1) Sensitivity analysis: All included studies were gradually excluded (Bianyuying 2023) [18], which reduced heterogeneity to 31%, resulting in [WMD = -2.48, 95% CI (-3.21, -1.76), P = 0.91]. Analyze the reasons, which may be caused by a small sample size or inadequate design; 2) Subgroup analysis: No significant clinical heterogeneity was found, and it is considered that the high heterogeneity may be caused by different laboratories using different measurement equipment and methods. The meta-analysis results indicate that the combination of modified Shen-Ling baizhusan and external treatment can effectively alleviate weight problems, and no benefits have been found to gradually increase with the course of treatment (Figure 8).

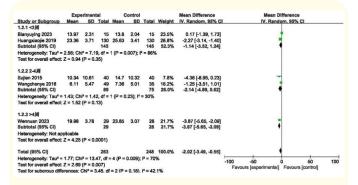


Figure 8: Meta analysis of FINS.

TSA analysis results

TSA analysis based on total effective efficiency

The T-test of TSA trial sequential analysis was used to evaluate whether the combined use Shen-Ling baizhusan and external treatment has a significant effect on weight loss. The study found that RIS reached 336, which is less than 616, but the Z-value has exceeded the boundaries of traditional and TSA. This means that although the accumulated amount of data did not meet expectations, there is no need for excessive experimentation and accurate results can be obtained in advance (Figure 9).

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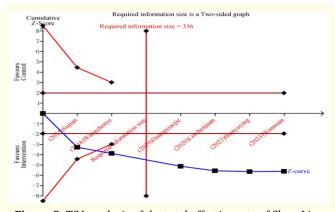


Figure 9: TSA analysis of the total effective rate of Shen-Ling baizhusan , plus and minus combined with external therapy in the treatment of obesity.

TSA analysis based on BMI

TSA conducted a study on the effects of clinical BMI and the combination of modified Shen-Ling baizhusan powder and external treatment on weight loss. TSA adopts a fixed effects model. Due to the first information section exceeding 100% of the RIS boundary, the results cannot be presented. This result indicates that conclusive evidence has been established and no further trial is needed (Figure 10).

Discussion

Excessive accumulation or abnormal distribution of adipose tissue in the body can lead to obesity. With the excessive consumption

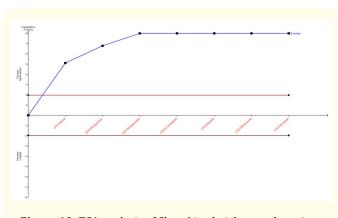


Figure 10: TSA analysis of Shen-Ling baizhusan plus minus combined with external therapy in the treatment of obesity BMI.

of high calorie food and the reduction of exercise, the incidence rate of obesity has shown a straight upward trend [14]. The high mortality, high incidence rate and high economic cost of obesity have aroused widespread concern in the medical community. In traditional Chinese medicine, the treatment principle for obesity is to strengthen the spleen, dispel dampness, and promote the circulation of the three jiao. Shen-Ling baizhusan comes from the "Tai Ping Hui Min He Ji Ju Fang" and is composed of ten herbs, including ginseng, stir fried Atractylodes macrocephala, yam, Poria cocos, lotus seeds, stir fried white hyacinth beans, platycodon grandiflorus, stir fried Coix seed, sand seed (lower part), licorice, etc. It is a classic formula for tonifying qi, strengthening spleen, removing dampness and stopping diarrhea. External treatment includes acupuncture, acupuncture and moxibustion, intradermal acupuncture, acupoint catgut embedding, electroacupuncture, etc. Acupuncture can stimulate the meridians, guide them, regulate the flow of qi and blood, and balance the yin and yang of qi and blood. Traditional Chinese Medicine (TCM) comprehensive therapy is a method of solving diseases based on more than one TCM therapy used by patients under the guidance of the holistic view of TCM. The combination of internal and external treatment has been effective in reducing body mass, improving body condition, and reducing complications in overweight and obese patients.

The results of this study indicate that the combination of modified Shen-Ling baizhusan and external treatment can effectively treat obesity with fewer adverse reactions, and the therapeutic effect (including total effective rate, BMI, TG, TC, HDL, FINS) is significantly better than conventional treatment. The results of sequence analysis indicate that the results of this meta-analysis are robust, and therefore may have implications for evidence-based clinical practice.

Innovation of this study: Prior to the proposal, the information found through the database did not include a systematic evaluation of the combined use of modified Shen-Ling baizhusan and external treatment for obesity. Therefore, this research topic is novel and can compensate for the shortcomings in the field of evidencebased medicine. Use TSA analysis method to calculate the amount of data required for clinical trials. This result further confirms the advantages of the combination of modified Shen-Ling baizhusan and external treatment in the treatment of obesity, making its results credible. The combination of meta-analysis and TSA analysis methods provides dual evidence that the combination of modified Shen-Ling baizhusan and external treatment has a significant therapeutic effect on obesity.

Limitations of this study: This study compared the combination of modified Shen-Ling baizhusan powder and external treatment with conventional treatment, which includes Western medicine and lifestyle intervention, which may introduce heterogeneity. In addition, all included studies were sourced from research databases in China. No relevant research has been found in the English database, and only one sector representing the global population may bring bias. In the literature screening process of this study, several articles were excluded because the authors were unable to obtain key data, which may have biased the results. In addition, the quality of the studies included in this study is relatively low, and in some cases, the sample size is small, which further reduces the certainty of the conclusions.

Future prospects: Future clinical research should use homogeneous outcome indicators and gradually establish a core set of outcome indicators, including indicators directly related to patient interests. We need higher quality research with high completeness, standardized reporting, and reduced bias.

Conclusion

According to current analysis, compared with the control group, the combination of modified Shen-Ling baizhusan and external

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treatment provides better clinical efficacy for obesity treatment at sufficient power, with fewer adverse reactions and significantly better results (including total effective rate, BMI, TG, TC, HDL, FINS). However, due to the small number of studies included in the meta-analysis and the high risk of bias in the included trials, this benefit should be carefully considered, indicating the need for further research.

Due to the persistence and difficult to cure nature of obesity, it has caused significant negative impacts on the mental health of patients. The high cost, serious side effects, and potential risks of Western medicine make clinical practice more inclined to use a combination of traditional Chinese and Western medicine to address this issue [15]. External treatment is a traditional Chinese medicine characteristic therapy, widely used in practical medical practice due to its advantages of no obvious pain, high efficiency and less side effects, and cost-effectiveness.

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Data Availability Statement

The original contributions presented in the study are included in the article/Supplementary Material, further inquiries can be directed to the corresponding authors.

Author contributions

HYQ, MK, and WFF: study concept and design; MK, ZXY and GLQ: protocol design. MK, WFF, and ZXY: literature retrieval and data extraction. MK, ZXY and GLQ: statistical analysis.MK and ZXY: interpretation of data and drafting of the manuscript. MK and HYQ: Quality assessment; ZXY and GLQ: adjust the article layout. MK,WFF and GLQ: critical revision of the manuscript. ZXY: technical support. All authors take responsibility for the integrity of the data and the accuracy of data analysis. WFF, ZXY and GLQ contributed equally to this work.

Disclosure

The funders had not been involved in the design, execution, or writing the study.

Conflict of Interest

The authors declare that the research was conducted in the absence of any commercial or financial relationships that could be construed as a potential conflict of interest.

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