

INPLASY PROTOCOL

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None declared.

INTRODUCTION

Review question / Objective: What is the efficacy and safety of external treatment of Traditional Chinese medicine(ET-TCM) for overweight or simple obesity? What is the current state of the available evidence? What is the level of evidence?

The effect of external treatment of traditional Chinese medicine in overweight or simple obese patients: An umbrella review of meta-analyses of randomized controlled trials

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Review question / Objective: What is the efficacy and safety of external treatment of Traditional Chinese medicine(ET-TCM) for overweight or simple obesity? What is the current state of the available evidence? What is the level of evidence?

Information sources: Eight electronic databases (PubMed, Embase, Web of science, Cochrane library, CNKI, VIP, Wan Fang, CBM) and references included in the studies were used to supplement.eight lectronic database(PubMed, Embase, Web of science, Cochrane library, CNKI, VIP, Wan Fang, CBM) and references for inclusion in the literature to supplement.

INPLASY registration number: This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 29 March 2023 and was last updated on 29 March 2023 (registration number INPLASY202330119).

Condition being studied: Obesity(5B81) is a chronic complex disease defined by excessive adiposity that can impair health and overweight is a condition characterized by excessive adiposity in the 11th edition of the International classification of disease (ICD 11). Obesity and overweight can be assessed by the body mass index (BMI), a proxy for obesity calculated as weight (kg)/height squared

(m²). Simple obesity accounts for the most part of the obese population about 99%. Simple obesity, caused solely by genetic and lifestyle behavioral factors rather than triggered by disease, therapeutic drugs or surgery, may be related to factors such as genetics, diet and exercise habits.

Overweight is an influential factor in obesity, which is a risk factor for many chronic metabolic diseases such as diabetes, hypertension, and cardiovascular disease. Obesity can impair a person's physical and mental health and lower the quality of life. The number of overweight and obese people is numerous and increasing. The World Obesity Federation predicts that the obese population will account for 24% of the global population and 51% of the overweight population in 2035. It is high time that effective interventions should be taken before serious public health problems and economic losses occur.

ET-TCM are defined as all therapeutic techniques and methods applied outside the body or from outside the body including a diversity of therapies such as acupuncture, moxibustion, tui na, ear acupressure, etc. ET-TCM are potential therapies to improve overweight and obesity conditions. However, there are many different types of ET-TCM methods used to intervene in overweight and simple obesity, and it is still a problem to be solved to choose the appropriate therapy for different obese people (such as children). So the purpose of this study was to summarize and present the available evidence of ET-TCM for overweight and obesity and to synthesize the evidence qualitatively or quantitatively.

METHODS

Search strategy: A total of eight databases including PubMed, Embase, Web of science, Cochrane library, CNKI, VIP, Wan Fang, CBM will be searched up to march 2023. Searches will be performed using Mesh terms and free terms, and the search strategy will be adjusted to the the specific situation of each databases. The search terms mainly included overweight, obesity, acupuncture, electro acupuncture, point

embedding therapy, auriculotherapy, Massage, moxibustion, cupping, acupoint application, gua sha, bloodletting, Chinese medicine fumigation and washing, external therapies of traditional Chinese medicine, systematic review, meta-analysis. The details are shown in the Appendix.

Participant or population: Overweight or simple obese patients, with clear diagnostic criteria, not limited to BMI criteria. Patients diagnosed by internationally recognized diagnostic criteria for overweight and obesity will be included. Patients with obesity co-morbidities or complications will be excluded. BMI is the most commonly diagnostic criterion for overweight and simple obesity, in addition to body fat rate, waist circumference, weight, waist-hip ratio, etc.

Intervention: One of the ET-TCM alone or combined with usual care. ET-TCM include acupuncture therapy (body acupuncture, electroacupuncture, warm acupuncture, abdominal acupuncture), auricular acupuncture or auricular pressure, acupuncture point embedding, cupping therapy, tui na therapy, moxibustion therapy, acupuncture point application, and gua sha therapy. Specific definitions of each therapy will be given in Table 1.

Comparator: No treatment or waiting list, placebo, or usual care. In this umbrella review, usual care refers to lifestyle interventions (diet, exercise, behavioral lifestyle intervention) and Pharmacotherapy (orlistat, lorcaserin, Naltrexone-Bupropion, Liraglutide, Phentermine-Topiramate, Smeaglutide, Metformin).

Study designs to be included: Only systematic reviews and/or meta-analyses will be included.

Eligibility criteria: If there is very high overlap (>15%), we will select the most recent and comprehensive review (i.e., the review that included the most randomized controlled trials).

Information sources: Eight electronic databases (PubMed, Embase, Web of science, Cochrane library, CNKI, VIP, Wan Fang, CBM) and references included in the studies were used to supplement.eight lectronic database(PubMed, Embase, Web of science, Cochrane library, CNKI, VIP, Wan Fang, CBM) and references for inclusion in the literature to supplement.

Main outcome(s): BMI, waist circumference, body fat rate, and weight.

Additional outcome(s): Hip circumference, waist-hip ratio, quality of life, and adverse effects.

Quality assessment / Risk of bias analysis: AMSTAR 2 with 16 domains will be used to evaluate the methodological quality of the included studies by two researchers independently. The GRADE online tool was applied to evaluate the certainty of evidence. Training will be conducted prior to the evaluation to reach consensus on the same issues, and if there is disagreement a third person will be approached to negotiate a decision.

Strategy of data synthesis: The characteristics of included ET-TCM studies will be qualitatively summarized. MD or SMD and 95%CI for continuous variables, and RR or OR and 95%CI for dichotomous variables are summarized using random-effect model by R3.5.0 software. If different systematic reviews or meta-studies of the same therapy are conducted, the Corrected Covered Area (CCA) will be used to calculate the degree of overlap of the original study. CCA15% is considered moderate, high, and very high overlap. If there is very high overlap (>15%), we will select the most recent and comprehensive review (i.e., the review that included the most randomized controlled trials). We will use I² to assess the between-study statistical heterogeneity. If I²<25% is considered small , 25≤I² < 50% is moderate, and I²≥50% is high. We will use the Egger test to assess publication bias. In addition, excessive significant findings (ESF) were estimated to evaluate whether

the results of some meta-analyses were over-reported.

Subgroup analysis: People (overweight or simple obesity, if available).

Sensitivity analysis: Sensitivity analysis will be performed on primary outcomes with excessive heterogeneity to explore the stability of the results.

Country(ies) involved: China.

Keywords: overweight, simple obesity, external treatment of Traditional Chinese medicine, acupuncture, umbrella review.

Contributions of each author:

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Author 2 - You-zhu Su.

Author 3 - Jian-ping Liu.

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