INPLASY PROTOCOL

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None declared.

Efficacy and safety of warm-needling acupuncture for obesity: a protocol for systematic review and meta-analysis

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Review question / Objective: **Whether WNA is effective and safe in weight management, and whether it produces better weight loss or lipid-lowering effects than other active therapies.**
Condition being studied: **Overweight and obesity, which defined as abnormal or excessive fat accumulation, are the major risk factors to human health. According to a latest survey among 195 countries, more than 603.7 million adults were obese in 2015. In the USA, obesity has affected 35% men and 40% women, the incidence of severely obese may increase continuously. Carrying excess weight can substantially increase people's risk of developing diabetes, hypertension, cardiovascular diseases, obstructive sleep apnea syndrome and all-cause mortality. The latest research found that obesity and related conditions seem to increase the morbidity of novel coronavirus (COVID-19) pneumonia. As a result, approximate 9.5 billion dollars has been provided by the U.S. National Institutes of Health to obesity prevention and medication research over the last decade. Within China, the prevalence of obesity has risen dramatically in recent years and the obese population ranks first worldwide.**

INPLASY registration number: This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 18 March 2023 and was last updated on 18 March 2023 (registration number INPLASY202330069).

INTRODUCTION

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METHODS

Search strategy: Electronic databases include CENTRAL, MEDLINE (via PubMed), EMBASE, CINAHL, AMED, Alt Healthwatch, CBM, Wanfang Data, Chinese Science and Technology Periodical Database (VIP) and China National Knowledge Infrastructure (CNKI). Any relevant ongoing or unpublished clinical studies will be acquired from the International Clinical Trials Registry Platform (ICTRP), NIH clinical registry Clinical Trials.gov, and the Chinese clinical registry. The reference lists of selected studies and published systematic reviews will be screened for additional studies. Manually search for the grey literature, including conference proceedings. We will also consult experts in the field to obtain possible studies and most up-to-date clinical data that are not available through the previously mentioned searching. The key search terms will be developed from Medical Subject Headings (MeSH) and free text terms, such as obesity OR overweight AND warm-needling acupuncture OR warming acupuncture OR warming needle AND randomized. The search strategy will be adapted to different databases demands.

Participant or population: Patients diagnosed with overweight or obese and age were greater than 18 years will be included, diagnosed according to World Health Organization (WHO) recommended criteria. All eligible study participants will be included in this review regardless of their ethnic background or gender.

Intervention: The experimental group should be treated with Warm-needling acupuncture (WNA), that is, an ignited moxa will be placed on the handle of the needle after insertion, and the acupoints selected according to TCM nomenclature. WNA combined with other treatments will also be included, such as moxibustion, massage, cupping, and drugs or Chinese herbs. The types of moxa used and duration of treatment will be unlimited.

Comparator: The control group will include patients treated with control interventions, such as no treatment, anti-obesity drugs, lifestyle modification, simple acupuncture (e.g., manual acupuncture, electro-acupuncture, acupoint catgut embedding and auriculotherapy), simple moxibustion, cupping therapy, Chinese herb medicine and any other active therapies. In addition, studies that have intervention groups comparing WNA plus one or more therapies with the same therapies alone will also be included.

Study designs to be included: All RCTs applying WNA independently or as an adjunct to other active therapies targeting overweight and obesity will be included. Completed and ongoing trials will be included. Owing to the language restriction of our researchers, we will limit the language of search literature to Chinese and English. If the study was designed as a cross-over trial, only the first phase results will be analyzed in order to eliminate carry-over effects.

Eligibility criteria: The review will include all the RCTs utilizing WNA independently or as an adjunct to other active therapies targeting overweight and obesity, without language restrictions. Ongoing and completed studies will be included. However, animal studies, quasi-RCTs, case reports and crossover trials will be excluded.

Information sources: Electronic databases include CENTRAL, MEDLINE (via PubMed), EMBASE, CINAHL, AMED, Alt Healthwatch, CBM, Wanfang Data, Chinese Science and Technology Periodical Database (VIP) and China National Knowledge Infrastructure (CNKI). Any relevant ongoing or unpublished clinical studies will be acquired from the International Clinical Trials Registry Platform (ICTRP), NIH clinical registry Clinical Trials.gov, and the Chinese clinical registry.

Main outcome(s): Our principal outcome will be the difference in BMI from baseline to the end of studies. It is defined as a person's weight in kilograms divided by the square of his height in meters (kg/m2).

Additional outcome(s): The secondary outcomes include the change of body weight, percentage of body fat, waist circumference (WC), hip circumference (HC), waist-to-hip ratio (WHR), serum lipid (such as cholesterol, triglyceride, high-density lipoprotein cholesterol and low-density lipoprotein cholesterol) before and after treatment, the incidence and severity of adverse events (e.g., hematomas, dizziness or local pain) will also be measured as secondary outcomes for safety assessment.

Data management: A pilot extraction will be done before the review is conducted to achieve consistency (at least 80%) between those collecting data. The following data will be extracted from the eligible studies by two reviewers independently using a self-designed data acquisition form, which includes the following items: (1) details of the study (publication year, nationality, journal, study design); (2) patient demographics (sample size, age, sex, height, weight, BMI); (3) intervention (duration, frequency, types of warm-needling acupuncture, types of comparators); (4) weight-related outcomes (the difference in BMI, the change of weight, percentage of body fat, WC, HC, WHR and serum lipid); (5) main conclusion, adverse reactions and a list of the Standards for Reporting Interventions in Controlled Trials of Acupuncture (STRICTA). Any discrepancy noticed in the process of data extraction will be resolved through discussion and the suggestion of a third reviewer. For publications with insufficient or ambiguous data, we will attempt to obtain information from the corresponding authors by e-mail or telephone.

Quality assessment / Risk of bias analysis: Two independent reviewers will use the Cochrane Collaboration's bias risk assessment tool to assess the risk of bias for all included studies. The assessments include potential selection bias (random sequence generation and allocation concealment), performance bias (blinding of investigators and participants), detection bias (blinding of outcome assessors), attrition bias (incomplete outcome data), reporting bias (selective reporting) and possible other sources of bias (funding bias). Our systematic review uses L, U, and H as the key to these assessments, where L (low) indicates a lower risk, U (unclear) indicates an uncertain risk, and H (high) indicates a higher risk. If inconsistent results appear, the final decisions will be made by the third reviewer. In the process of data synthesis, studies with unclear or high risk of bias will be given less weight.

Strategy of data synthesis: Data analysis and quantitative data synthesis will be performed using RevMan software (V.5.3.5) and Stata software (V.14.0). For continuous data, we will use the standardized mean difference (SMD) along with its 95% confidence intervals (CIs) to measure the therapeutic effect, whereas dichotomous data will be presented as relative risk (RR) with 95% CIs for analysis. Statistical heterogeneity between studies will be assessed using the I^2 test. The study is not considered to have large heterogeneity if the I^2 test is less than 50%, and a fixed-effects model will be used for data synthesis. Otherwise, a random-effects model will be used. When the statistical heterogeneity is identified, we will search for possible causes from the clinical and methodological perspective, then provide a subgroup analysis or descriptive analysis to explore the possible causes of heterogeneity. To explore whether the

evidence in our meta-analysis is reliable and conclusive, a Trial Sequence Analysis (TSA) will be performed. TSA software (version 0.9.5.10) will be used to maintain an overall 5% risk of type I error and 80% power.

Subgroup analysis: Subgroup analysis will be employed to explain heterogeneity if possible. In the present study, the heterogeneity will significant with respect to the subjects, WNA types, comparators, treatment courses, etc. Therefore, subgroup analysis will be employed according to various comparators, the forms of WNA, the initial BMI of patients, diverse treatment courses or frequency, different outcomes, and so on.

Sensitivity analysis: Sensitivity analysis will be performed by excluding studies with high risk of bias and changing the statistical model.

Country(ies) involved: China.

Keywords: Warm-needling acupuncture, Obesity, Systematic review, Trial sequential analysis, Protocol.

Contributions of each author:
Author 1 - Chenxi Liao - Conceptualization, Methodology and Writing-Original Draft.
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