

# Effect of Warm-Needling Acupuncture in Overweight and Obese Adults: Protocol for a Systematic Review and Meta-Analysis

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## Protocol

**Keywords:** warm-needling acupuncture, overweight, obesity, systematic review, protocol

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# Abstract

**Background:** Overweight and obesity are chronic metabolic diseases characterized by abnormal or excessive fat accumulation that presents a risk to health. Warm-needling acupuncture (WNA), which combines the characteristics of acupuncture and moxibustion, has been commonly used to manage obesity with reasonable weight control in recent years. Therefore, our objective is to systematically appraise the efficacy and safety of WNA for overweight and obesity.

**Methods:** Cochrane Central Register of Controlled Trials (CENTRAL), MEDLINE (via PubMed), Excerpt Medica Database (EMBASE), ALT HealthWatch, [Cumulative Index to Nursing and Allied Health Literature \(CINAHL\)](#), Allied and Complementary Medicine Database (AMED), the Chinese Biomedical Literature Database (CBM), Wanfang Data, and grey literature (trial registries, conference proceedings and academic degree dissertations) will be searched for the identification of articles. All randomized controlled trials (RCTs) involving WNA independently or as an adjunct to other active therapies, compared with the same therapies alone, will be included. The principal outcome will be the difference in BMI from baseline to the end of studies. Secondary outcomes include the change of weight, waist circumference, percentage of body fat, serum lipid before and after treatment. The severity and incidence of adverse events will be measured as the safety assessment. Study selection, data extraction, and assessment of risk of bias will be performed independently by two reviewers. A third reviewer will resolve and determine disagreements. The Review Manager software (V.5.3.5) and Stata software (V.14.0) will be used for data synthesis. Furthermore, the quality of the evidence for the results will be described according to the Grading of Recommendations Assessment, Development and Evaluation system (GRADE) with GRADEprofiler software (V.3.6.1).

**Discussion:** This is the first systematic review to evaluate the effect of WNA in the management of obesity. This program will provide a high-quality synthesis of the current evidence to identify whether WNA is an effective therapeutic approach for overweight and obesity.

**Systematic review registration:** PROSPERO CRD42019146380.

## Background

Overweight and obesity, which defined as abnormal or excessive fat accumulation, are the major risk factors to human health [1]. According to a latest survey among 195 countries, more than 603.7 million adults were obese in 2015 [2]. In the USA, obesity has affected 35% men and 40% women [3], the incidence of severely obese may increase continuously [4, 5]. Carrying excess weight can substantially increase people's risk of developing diabetes, hypertension, cardiovascular diseases, obstructive sleep apnea syndrome and all-cause mortality [6–9]. The latest research found that obesity and related conditions seem to increase the morbidity of novel coronavirus (COVID-19) pneumonia [10]. 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 [11]. Within China, the prevalence of obesity has risen dramatically in recent years and the obese population ranks first worldwide [12, 13].

Overweight and obesity, as well as their related noncommunicable diseases, are largely preventable and reversible. The current mainstream weight-reduction measures primarily include the lifestyle modification (e.g., reducing the number of calories consumed from fats and sugars, and engaging in regular physical activity), anti-obesity drugs and bariatric surgery [14, 15]. The lifestyle modification therapies are often accompanied with the long treatment duration and poor compliance of patients, which lead to the weight regain easily [16, 17]. For the pharmacological treatments, five anti-obesity drugs (orlistat, lorcaserin, naltrexone/bupropion, phentermine/topiramate, and liraglutide) have been approved by the US Food and Drug Administration (FDA) [18], but these drugs are imperfect due to undesirable adverse effects and limited effects [19, 20]. Bariatric surgery may be the only long-term weight control therapy for the patient with morbid obesity but is hindered by heavily cost and possible postoperative complications [21, 22]. Thus, a safe and long-term effective treatment modality for obesity is needed to achieve reasonable weight control, slow down the progress of obesity, prevent weight regain and avoid the obesity complications.

In traditional Chinese medicine (TCM) theory, obesity is associated with some dysfunctional organs, including spleen, stomach, liver and kidney. Once the Qi circulation and balance between Ying and Yang are disturbed, the body will abnormally accumulate a series of pathological products, including phlegm, dampness and stagnant blood and then result in obesity [23]. Acupuncture and moxibustion have been widely used to manage obesity amongst Asian countries, especially in China, due to validated efficacy and few adverse effects [15]. Although the mechanism of acupuncture remains unclear, some studies have shown that acupuncture can reduce weight through regulating the activity of catecholamine neurotransmitters, remodeling white adipose tissues to brown adipose tissue, inducing autophagy signaling pathway and inhibiting appetite [24, 25]. Meanwhile, moxibustion, which is often administered with acupuncture in clinical practice, also plays an essential role in weight-reducing by warming meridians and facilitating lipid conversion [23, 26].

Warm-needling acupuncture (WNA) is a specialized form of acupuncture therapy, that is, an ignited moxa will be placed on the handle of the needle after insertion, so that the thermal effect can be transmitted into the acupoints through the needle [27]. WNA combines the characteristics of both acupuncture and moxibustion therapy, and its therapeutic effect on obesity may be better than other acupuncture schemes [28]. The recent studies have shown that WNA could obviously down-regulate the levels of TC and LDL-C in obesity model animal, which mainly activate the ABCA1-LXR $\alpha$  signaling pathway, and to inhibit the expression of IL-1 $\beta$  and TNF- $\alpha$ , thus promoting the process of reverse cholesterol transport [24, 29]. Therefore, WNA has the potential to be an effective supplementary treatment option for obesity.

Although there are an increasing number of clinical studies regarding WNA for obesity published over the last few years, the efficacy of WNA remains controversial from the perspective of evidence-based medicine. In addition, the sample sizes of published clinical trials are relatively small, and the test power

of a single trial is insufficient. Considering no relevant systematic review or study protocol for WNA published, this review will retrospectively examine the current trials to identify whether WNA is effective and safe in weight management, and whether it produces better weight loss or lipid-lowering effects than other active therapies. We hope this review will guide the physicians to make evidence-based decisions in clinical practice and benefit the amelioration of the therapeutic tactics for overweight and obesity.

## Methods/design

### Study registration

The protocol for this review was registered on PROSPERO (CRD42019146380) and is available on the PROSPERO.com (<https://www.crd.york.ac.uk/prospero/>). This protocol is reported in compliance with the Preferred Reporting Items for Systematic Reviews and Meta-Analyses Protocols (PRISMA-P) statement guidelines [30] (Additional file 1). The review will be conducted in accordance with the PRISMA guidelines and follows the recommendations of the Cochrane Handbook for Systematic Reviews of Interventions [31, 32]. If we refine the procedures described in this protocol, we will update the record in the PROSPERO and disclose them in the final report.

### Eligibility criteria

#### *Inclusion criteria*

**Type of studies** 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.

**Type of participant** 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.

**Type of interventions** The experimental group should be treated with 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.

**Type of comparators** 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, electroacupuncture, 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.

**Type of outcome measurements** According to the 2013 American College of Cardiology guidelines, the main purpose of obesity management is to reduce the body weight to a reasonable level [33]. BMI is a simple index of weight-for-height that is commonly used to classify overweight and obesity in adults. Therefore, 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 ( $\text{kg}/\text{m}^2$ ).

The secondary outcomes include the change of 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.

### ***Exclusion criteria***

The exclusion criteria are as follows: (1) trials including participants who are not appropriate to receive WNA, such as pregnant or lactating women, and those were diagnosed with secondary obesity (e.g., caused by drugs such as glucocorticoids and pituitary disease) or with additional severe diseases; (2) quasi-randomized trials and case reports; (3) only providing the information of effective rate and not providing the data of BMI from baseline to the end of studies; (4) studies involving WNA but without control arm.

### **Databases and search strategy**

We will search all RCTs for warming acupuncture on weight management, electronically and manually, regardless of publication status. 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). 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, and full search strategy for PubMed is shown in Additional file 2. 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 (Additional file 3). 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.

### **Study selection**

In the study selection process, search results will be imported from the original databases to Endnote X9 and repetitive studies will be deleted by the software. Two trained reviewers (JY and LC) will independently screen all retrieval researches, read the title, abstract and keywords to determine which

studies meet the inclusion criteria. Where a study is potentially eligible, the full text will be obtained and checked independently by two reviewers (JY and LC). Studies excluded after reading the full text will be recorded and explained. Any disagreement will be resolved by consensus. Further arguments will be arbitrated by a third reviewer (LZ).

### **Data extraction**

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 (JY and LC) 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 (LZ). For publications with insufficient or ambiguous data, we will attempt to obtain information from the corresponding authors by e-mail or telephone.

### **Assessment of risk of bias**

Two independent reviewers (HZ and JY) 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) [31]. 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 (YL). In the process of data synthesis, studies with unclear or high risk of bias will be given less weight.

### **Data analysis**

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. If the standard deviation for changes from baseline to the end of studies were not reported, but the pre- and post- measurements were reported, the following formula will be used to calculate:

$$SD_{\text{change}} = \sqrt{(SD_{\text{pre}})^2 + (SD_{\text{post}})^2 - 2 \times r \times SD_{\text{pre}} \times SD_{\text{post}}}$$

and the correlation coefficient ( $r$ ) is assumed to be 0.4 [15]. 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.

### **Subgroup analysis**

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

### **Sensitivity analysis**

Multiple sensitivity analysis for primary outcome will be performed to assess the robustness of the findings and to detect if any particular study accounted for a large proportion of heterogeneity. These will be based on different statistical model, different sample size and different methodological quality. The meta-analysis will be repeated, and more inferior quality studies will be excluded.

### **Reporting bias**

We will use funnel plot to visually inspect reported bias and the effects of small-scale studies. If a sufficient number of included studies (more than 10 trials) are available, the funnel plot will be used to assess the reported bias. If the funnel plot is found to be asymmetrical, analyze the causes using Harbord test. This method is an upgraded method of Egger's regression, which has a higher test power for the dichotomous outcome data with low heterogeneity, and more accurate in combination with the visually inspect of funnel plot. All eligible trials, regardless of the quality of their methodologies, will be included.

### **Grading the quality of evidence**

The two reviewers (HZ and LC) will independently appraise the strength of the body of evidence by GRADE system [34]. In this process, direct evidence from RCTs starts at high quality and can be downgraded based on the risk of bias, indirectness, imprecision, inconsistency (or heterogeneity), and/or publication bias to levels of moderate, low, and very low quality. A summary of results table will be generated by GRADEprofiler software (V.3.6.1) and disclosed in the final publication. Any discrepancy will be arbitrated by a third reviewer (YL).

## Discussion

With the development of complementary and alternative medicine, acupuncture and moxibustion have been widely applied in obesity treatment worldwide and relative systematic reviews have been reported [15]. WNA is regarded as an upgraded acupuncture treatment modality that combines technical advantages of both acupuncture and moxibustion therapy. Some clinical studies suggest that WNA is effective in obesity treatment, and has no significant adverse effects [27–29]. The recent study has revealed that WNA could increase the levels of blood adrenaline and norepinephrine, activate cell membrane adrenaline cyclase, increase intracellular cyclic adenosine phosphate, thus generate a lipolysis effect [35].

The primary aim of this study is to compare the effect size between warm-needling acupuncture and no treatment, so as to appraise the effect of warm-needling acupuncture in overweight and obese adults. Besides, we will also analyze the subgroups by comparing the efficacy differences between warm-needling acupuncture and other acupuncture methods or any other active approaches to help further in the optimization of obesity treatment regimen.

Nevertheless, this study will also have some limitations. Due to the language barrier, the Japanese and Korean databases with the background of TCM research will not be retrieved, for which publication bias may exist. Another limitation is that different forms of WNA, different degree of obesity severity, small number of participants and diverse courses in included trials may increase the statistical heterogeneity.

To the best of our knowledge, this will be the first systematic review to comprehensively synthesize the current evidence regarding the efficacy and safety of WNA for obesity. We hope that our results will assist physicians, patients and health policymakers to make evidence-based decisions in clinical practice. Moreover, our results will also benefit the development of evidence-based guidelines, and further clinical RCTs in the field will be designed based on this systematic review.

## Abbreviations

WNA = Warm-needling acupuncture, CENTRAL = Cochrane Central Register of Controlled Trials, EMBASE = Excerpt Medica Database, CINAHL = [Cumulative Index to Nursing and Allied Health Literature](#), AMED = Allied and Complementary Medicine Database, CBM = China Biomedical Literature Database, VIP = Chinese Science and Technology Periodical Database, CNKI = China National Knowledge Infrastructure, COVID-19 = the novel coronavirus pneumonia, BMI = body index mass, WC = waist circumference, HC = hip circumference, WHR = waist-to-hip ratio, BFP = percentage of body fat, STRICTA = the Standards for Reporting Interventions in Controlled Trials of Acupuncture

## Declarations

## Acknowledgements

Not applicable.

### **Authors' contributions**

LZ and YL conceived and designed the review protocol. JY and LC drafted the original manuscript. HZ revised this manuscript. All authors have reviewed and approved the publication of this manuscript.

### **Funding**

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### **Availability of data and materials**

Not applicable.

### **Ethics approval and consent to participate**

On account of the data are not individualized, formal ethical approval is not necessary. The findings of this study will be published in a peer-reviewed publication or disseminated at scientific conferences.

### **Consent for publication**

Not applicable.

### **Competing interests**

None declared.

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