

INPLASY PROTOCOL

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The authors have no conflicts
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Acupoint Catgut Embedding for Obesity: a Protocol of Systematic Review

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Review question / Objective: Obesity is a chronic metabolic disease in which patients are overweight due to the excessive accumulation of fat in the body. As a subtype of acupuncture, catgut embedding at acupoints has increased in clinical application for obesity. The aim of this study is to evaluate the effectiveness and safety of acupoint catgut embedding therapy for simple obesity.

Condition being studied: Obesity.

Information sources: Electronic searches of the Cochrane Library, PubMed, Springer Medline, EMBASE, Web of Science, CNKI, WANFANG, CBM and VIP databases will be performed. The Chinese Clinical Trial Registry Centre (<http://www.chictr.org.cn/>) and the WHO International Clinical Trials Registry Platform (ICTRP) (<https://clinicaltrials.gov/>) will also be searched for ongoing trials. All of the databases will be searched from the available date of inception to August 2020. The key words used will be catgut embedding, catgut implantation, thread implantation, thread embedding, simple obesity, obesity, weight loss, weight control, weight reduction, adiposity, adiposis and over-weight.

INPLASY registration number: This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 11 November 2020 and was last updated on 11 November 2020 (registration number INPLASY2020110045).

INTRODUCTION

Review question / Objective: Obesity is a chronic metabolic disease in which patients are overweight due to the

excessive accumulation of fat in the body. As a subtype of acupuncture, catgut embedding at acupoints has increased in clinical application for obesity. The aim of this study is to evaluate the effectiveness

and safety of acupoint catgut embedding therapy for simple obesity.

Condition being studied: Obesity.

METHODS

Participant or population: The participants in the RCTs must meet the acknowledged diagnostic and inclusion criteria and have a clear diagnosis of simple obesity. Patient characteristics such as gender and race will not be restricted.

Intervention: 1. Clinical trials in which the treatment group used acupoint catgut embedding as the sole treatment will be included (studies that used diet or exercise therapy in the control group will be allowed). 2. Trials involving combinations of acupoint catgut embedding and other acupuncture therapies will be excluded, as will studies comparing different forms of acupoint catgut embedding. 3. The materials used for acupoint catgut embedding will not be considered.

Comparator: Clinical trials that used other types of acupuncture, drugs, lifestyle modifications (diet or exercise therapy), placebo, or waitlists as control interventions will be included.

Study designs to be included: This review will be limited to RCTs involving a treatment course longer than three months and comparing acupoint catgut embedding with other interventions; language and blinding will not be restricted.

Eligibility criteria: All the RCTs or quasi-RCTs of acupoint catgut embedding for patients with obesity will be included. Review articles, case reports, conference abstracts, cross-sectional studies, and all observational studies will be excluded.

Information sources: Electronic searches of the Cochrane Library, PubMed, Springer Medline, EMBASE, Web of Science, CNKI, WANFANG, CBM and VIP databases will be performed. The Chinese Clinical Trial Registry Centre (<http://www.chictr.org.cn/>) and the WHO International Clinical Trials

Registry Platform (ICTRP) (<https://clinicaltrials.gov/>) will also be searched for ongoing trials. All of the databases will be searched from the available date of inception to August 2020. The key words used will be catgut embedding, catgut implantation, thread implantation, thread embedding, simple obesity, obesity, weight loss, weight control, weight reduction, adiposity, adiposis and over-weight.

Main outcome(s): The primary outcomes will consist of the improvement rate and reduction in body weight.

Additional outcome(s): BMI, waist circumference (WC), fat percentage (F %) and adverse effects.

Data management: Two reviewers will independently complete this step. A standard data extraction form will be used to record the following information: (1) general information on the study (author name(s) and contact information, research location and year of publication); (2) patient characteristics (age, gender and race) and diagnostic and improvement criteria for obesity; (3) risk of bias assessment; (4) experimental intervention details and control interventions; the revised Standard for Reporting Interventions in Clinical Trials of Acupuncture (STRICTA) will be used in conjunction with CONSORT to extract the details; (5) outcome data, adverse effects and follow-up. NoteExpress software will be used to help the reviewers manage data and identify duplicate publications. When two or more reports describe a single trial, only one publication will be included.

Quality assessment / Risk of bias analysis: The risk of bias in the included studies will be assessed according to the Cochrane Collaboration Risk of Bias Tool. The methodology will be evaluated according to the following domains: random sequence generation, allocation concealment, blinding of participants and personnel, blinding of outcome assessment, incomplete outcome data, selective reporting and other bias. Two reviewers will categorise each trial as low risk, high risk

or unclear risk. A third reviewer will assist in resolving the disagreements.

Author 7 - Dan Wei.
Author 8 - Zhongyu Zhou.

Strategy of data synthesis: RevMan (V.5.3) will be used to calculate the RR for dichotomous data and the MD for continuous variables. The estimated value and 95% CI of each effect will be calculated. If the research results are not significantly different ($I^2 < 50\%$), a fixed effect model will be used for the meta-analysis. If the research results are significantly different ($I^2 > 50\%$), a meta-analysis will be performed using a random effects model after further analysis of the heterogeneity of the sources. If the data are not suitable to quantitatively combine, text will be provided to summarise the findings of the included publications. For trials reporting only pre- and postintervention values, the mean changes will be obtained by subtracting the pre-measurements from the postmeasurements. Accordingly, the standard deviation (s.d.) for changes will be estimated.

Subgroup analysis: The basis of the subgroup will be the type of control group and the frequency of treatment.

Sensibility analysis: If the test for heterogeneity remains at a value of $p < 0.1$ after subgroup analysis, a sensitivity analysis will be performed. The low quality studies will be excluded, and the meta-analysis will be performed again.

Language: English and Chinese.

Country(ies) involved: China.

Keywords: Acupoint Catgut Embedding; Obesity; acupuncture; Systematic Review; Study Protocol.

Contributions of each author:

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Author 2 - Xia Chen.

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