INPLASY PROTOCOL

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Corresponding author:
Yaoguang Guo

guoyaoguang@cdutcm.edu.cn

Author Affiliation:
Hospital of Chengdu University of T.C.M

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Review Stage at time of this submission: **Formal screening of search results against eligibility criteria.**

Conflicts of interest:
None.

Acupuncture and related therapies for stress urinary incontinence: a protocol for systematic review and network meta-analysis

Yang, J[1]; Cheng, Y[2]; Zhao, L[3]; Chen, J[4]; Zheng, Q[5]; Xu, G[6]; Guo, Y[7]; Liang, F[8].

Review question / Objective: **In recent years, a large number of RCTs and meta-analyses have shown that acupuncture has certain effects in the treatment of stress urinary incontinence. However, due to the diversity of acupuncture methods, its relative effectiveness has not yet been studied and explained. Therefore, based on the NMA analysis method, this study will compare the differences in the efficacy of multi-acupuncture in the treatment of stress urinary incontinence, in order to provide a reference for clinical treatment.**
Condition being studied: **Stress urinary incontinence is a common health condition that may decrease quality of life. It involves the involuntary loss of urine due to physical activity such as coughing, laughing, or sneezing. The pathophysiology of stress urinary incontinence involves a weakening of muscular support at the urethrovesical junction, which causes hypermobility of the urethra during times of increased intraabdominal pressure. A number of risk factors areassociated with stress urinary incontinence, with 2 of the most common being parity and obesity. Recently the treatments of stress urinary incontinence include pharmacological approaches, pelvic exercises and surgery. However, the pharmacological approaches and surgery can carry some side effects, acupuncture has obvious advantage with it.**

INPLASY registration number: This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 14 May 2020 and was last updated on 14 May 2020 (registration number INPLASY202050061).

INTRODUCTION

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METHODS

Participant or population: All cases included in the trial will be patients with stress urinary incontinence, regardless of age, race, duration of disease, weight, mode of delivery, or education.

Intervention: We will consider acupuncture and related therapies (acupoint-based therapy), regardless of needling techniques and stimulation method including moxibustion, catgut embedding, electro-acupuncture, transcutaneous electrical acupoint stimulation, acupoint injection, medium-frequency electric stimulation, et.al.

Comparator: Treatments in the comparison groups can be sham-acupuncture, placebo, pharmacotherapy or rehabilitation exercise therapy. Studies compared different types of acupuncture and related therapies will be included.

Study designs to be included: The review will include randomised controlled trials (RCT) that were reported in English or Chinese.

Eligibility criteria: 1.Types of studies We will include randomized controlled trials (RCTs) reporting in English or Chinese without any regional restrictions. The first period of randomized cross-over trials will be also included. We will exclude Non-RCTs reviews, animal experimental studies, case report, expert experience, conference article and duplicated publications. 2. Types of participants Participants diagnosed with SUI will be included, regardless of age, race, duration of disease, weight, mode of delivery, or education. 3.Types of interventions We will define acupuncture as acupoint-based therapies(e.g. moxibustion, catgut embedding, electro-acupuncture, transcutaneous electrical acupoint stimulation, auricular acupuncture , scalp acupuncture, warm needling, manual acupuncture, acupoint injection, medium-frequency electric stimulation and so on), regardless of needling techniques and stimulation method. We will rule out interventions without stimulating the acupoint. 4. Types of control groups Treatments in the comparison groups can be sham-acupuncture, placebo, pharmacotherapy or rehabilitation exercise therapy. Studies compared different type of acupuncture methods will be included.

Information sources: The following databases will be searched from their inception to March 2020: Cochrane Library, MEDLINE, EMBASE, Ovid, Chinese National Knowledge Infrastructure (CNKI), Wanfang Database, the Chongqing VIP, Chinese Science and Technology Periodical Database (VIP), Chinese Biomedical Literature Database(CBM), World Health Organization Clinical Trials Registry, ClinicalTrials.gov, and reference lists of articles to identify additional studies.

Main outcome(s): 1.Cure: number of women with self-reported continence. 2. Improvement: number of women with self-reported improvement in SUI (cured or improved).

Quality assessment / Risk of bias analysis: Two reviewers(Ying Cheng and Guixing Xu) will appraise the quality of the included trials using the risk of bias tool developed by the Cochrane Collaboration. We will

appraise each study in terms of selection bias (random sequence generation and allocation concealment), performance bias (blinding of participants and personnel), detection bias (blinding of outcome assessment), attrition bias (incomplete outcome data), selective reporting bias and other bias. Particularly, we will use the Grades Profiler as the Grading of Recommendation, Assessment, Development, and Evaluation (GRADE) system to grading the quality of the evidence.

Strategy of data synthesis: Efficacy data will be synthesized and statistically analyzed in R3.5.1. Dichotomous data will be investigated by using a risk ratio with 95% CIs. For continuous outcomes, data will be analyzed by using a standard mean difference (SMD) with 95% CIs or a weighted mean difference (WMD). The WMD will be used for the same scale or the same assessment instrument; SMD will be used for different assessment tools. A consistency examination will be taken using the Z test. We will calculate the P-value to find out whether there are inconsistencies among the comparison of direct and indirect. If the $p > 0.05$, there is no statistical significance, so the comparison of direct and indirect is consistency; on the contrary, inconsistency is considered. Pragmatic trials, with patient's treatments, shift between modalities and dosages according to treatment response, are investigated in a narrative synthesis. Other data synthesis will be conducted (http://www.r-project.org) . We defined Sham interventions and placebo as inert control. Network meta-analysis including both direct and indirect evidence was performed by using a Bayes method. SMDs and RRs of network meta-analysis were also computed along with their 95% CIs. The reliability of the result of network meta-analysis mainly depends on the transitivity of the evidence. The transitivity was usually defined as the similarity level in effect modifiers (eg, study design, the severity of illness at baseline, treatment dose, and study quality). We will assess the transitivity of the network largely in the consistency between direct and indirect analysis. Consistency of the network meta-analysis will be estimated by the Z test to explore the difference between direct and indirect estimates. The contribution of different designs to the final effect size of the network meta-analysis will be evaluated by net-heat plots.

Subgroup analysis: If sufficient evidence is available, we will conduct subgroup analyses based on duration of disease, mode of delivery, and so on.

Sensibility analysis: If it is necessary, sensitivity analysis or meta-regression and subgroup analysis will be used to explore possible sources of heterogeneity.

Country(ies) involved: China and England.

Keywords: acupuncture, network meta-analysis, stress urinary incontinence, systematic review.

Contributions of each author:
Author 1 - Jiao Yang - Jiao Yang will perform the literature search, screened the potentially eligible studies.
Author 2 - Ying Cheng - Ying Cheng will perform the literature search, screened the potentially eligible studies.
Author 3 - Ling Zhao - Ling Zhao will evaluate the data from each included study.
Author 4 - Jiao Chen - Jiao Chen will evaluate the data from each included study.
Author 5 - Qianhua Zheng - Qianhua Zheng will evaluate the data from each included study.
Author 6 - Guixing Xu - Guixing Xu will perform the literature search, screened the potentially eligible studies.
Author 7 - Yaoguang Guo - Yaoguang Guo produced the idea to this study and he will responsible for making the final version of this paper and critically revise this manuscript, including important intellectual contents and the grammatical mistakes existed in our original study.