INPLASY PROTOCOL

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Corresponding author:
Pan Cheng

760689498@qq.com

Author Affiliation:
Jiangxi University of Traditional Chinese Medicine

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The authors report no conflicts of interest in this work.

The Acupuncture-related therapy for Post-Stroke Urinary Incontinence: A protocol for systematic review and network meta-analysis

Cheng, P[1]; Xiao, YY[2]; Jiao, L[3].

Review question / Objective: **A large number of clinical trials have shown that acupuncture is beneficial to post-stroke urinary incontinence, and various acupuncture methods have been widely used in clinical practice. However, the comparison of the efficacy and safety of these acupuncture methods is unclear. Clinicians are puzzled when choosing the best treatment for post-stroke incontinence. The purpose of this paper is to collect conclusive evidence and provide a reliable reference for the development of acupuncture treatment guidelines for post-stroke incontinence.**

INPLASY registration number: This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 01 September 2020 and was last updated on 01 September 2020 (registration number INPLASY202090003).

INTRODUCTION

Review question / Objective: **A large number of clinical trials have shown that acupuncture is beneficial to post-stroke urinary incontinence, and various acupuncture methods have been widely used in clinical practice. However, the comparison of the efficacy and safety of these acupuncture methods is unclear. Clinicians are puzzled when choosing the best treatment for post-stroke**

incontinence. The purpose of this paper is to collect conclusive evidence and provide a reliable reference for the development of acupuncture treatment guidelines for post-stroke incontinence.

Rationale: Acupuncture affects both the autonomic and somatic nervous systems of the muscles that control urination and the UI.

Condition being studied: Post-stroke urinary incontinence (PSUI) is a common clinical problem. The prevalence of post-stroke incontinence has varied across countries in the last 20 years, but it is generally accepted that incontinence is one of the most common complications after stroke. Currently, modern medical treatments for post-stroke incontinence include pelvic floor exercise (PFME), behavioral regulation therapy (including timed urination, need-based urination, bladder training, urination habit), support devices, drug therapy, various electrical stimulation, surgical therapy, etc. Bladder training and behavior regulation therapy alone are difficult to adhere to for a long time and the efficacy is not reliable. Catheter placement is easy to cause urinary tract infection, and drug therapy inevitably has side effects, while electrical stimulation and surgical therapy are invasive procedures, expensive medical costs, and may be accompanied by pain, infection and other complications, which are poorly accepted by patients. In general, modern medical treatment of post-stroke incontinence is not ideal, so it is necessary to find an effective, low-cost, non-invasive treatment. As a treasure of Traditional Chinese medicine, acupuncture and moxibustion has its unique advantages. Many reports have confirmed the efficacy of acupuncture and moxibustion in the treatment of post-stroke incontinence.

METHODS

Search strategy: We will search the following databases from their inception to August 2020: PubMed, Embase, the Cochrane Library, the Chinese National Knowledge Infrastructure (CNKI), Chinese Biomedical Literature Database (CBM), Wanfang Database, Chinese Science and Technology Periodical Database . we will also search grey literature from World Health Organization Clinical Trials Registry, ClinicalTrials.gov and Chinese clinical registry. Reference lists of articles will be retrieved as additional studies. The following search headings (MeSH) will be used:"Urinary Incontinence ","Incontinence, Urinary" "incontinence*", "urinary*","Stroke", "Cerebrovascular Accident"," Apoplexy","CVA (Cerebrovascular Accident) ", "Cerebrovascular Apoplexy","Brain Vascular Accident","Acupuncture Therapy","Acupuncture","Acupuncture, Ear","Acupuncture ","acupoin*","body acupuncture","electroacupuncture ","electro-acupuncture"," moxibustion* ","auriculotherapy","needle","scalp acupuncture","acupoint injection ","catgut embed-ding","transcutaneous electrical acupoint stimulation","warm needling","manual acupuncture","medium-frequency electric stimulation","therapeutic use""random allocation", "random* ","clinical trial","clinical trials as topic","trial","clinical".

Participant or population: Participants diagnosed with PSUI will be included, regardless of age, race, duration of disease, weight, mode of delivery, or education.

Intervention: The treatment group will receive acupuncture and related therapies, eg(e.g., moxibustion, catgut embed-ding, electro-acupuncture, transcutaneous electrical acupoint stimulation, auricular acupuncture, scalp acupuncture, warm needling, manual acupuncture, acupoint injection, medium-frequency electric stimulation, other combined therapy and so on),regardless of needle material, needling techniques and stimulation method. Treatments in the comparison groups can be conventional therapy , sham-acupuncture, placebo, pharmacotherapy or rehabilitation exercise therapy. Studies

compared different type of acupuncture methods will be included.

Comparator: Participants diagnosed with PSUI will be included, regardless of age, race, duration of disease, weight, mode of delivery, or education.

Study designs to be included: We will include reports of randomized controlled trials (RCTS) conducted in English or Chinese.

Eligibility criteria: We will include all randomized controlled trials (RCTs) reporting of acupuncture for post-stroke incontinence, without language or geography restriction. We will exclude Non-RCTs reviews, non-controlled trials, animal studies, case reports, expert experience, conference articles, and duplicate publications and reviews.

Information sources: We will search the following databases from their inception to August 2020: PubMed, Embase, the Cochrane Library, the Chinese National Knowledge Infrastructure (CNKI), Chinese Biomedical Literature Database (CBM), Wanfang Database, Chinese Science and Technology Periodical Database . we will also search grey literature from World Health Organization Clinical Trials Registry, ClinicalTrials.gov and Chinese clinical registry. Reference lists of articles will be retrieved as additional studies.

Main outcome(s): (1) Number of participants continent after treatment. (2)Number of incontinent episodes (indicated by bladder charts, total and mean number of episodes) (3) Perception of improvement or cure (as reported by participant or carer).

Additional outcome(s): (1)International Consultation on Incontinence Questionnaire Urinary Incontinence—Short Form (ICIQ-UI SF) 36; (2) Barthel Activities of Daily Living Index (Barthel ADL Index) 37 ; (3)Adverse events(e.g., skin or tissue damage, pain or discomfort, vascular, visceral or nerve injury, voiding dysfunction).

Data management: Two reviewers will independently extract parameters from applicable studies including identification information (publication year and first author), general information (country, study type, number of centers, sample size), participants (age, sex, weight, original disease), interventions (type of acupuncture, frequency/session/duration), comparator (if there is any, details of the treatment including name, dosage, frequency and course),outcomes (data and time points for each measurement, safety).

Quality assessment / Risk of bias analysis: Assessment of quality in included studies. The quality of the studies will be assessed according to the Cochrane risk of bias assessment tool.[26]The main contents include: sequence generation, allocation concealment, blinding (or masks), incomplete data assessment, selective outcome reporting and other sources of bias. Then, the risk of bias for included studies will be classified as “low”, “unclear” and “high” risk of bias. The above content evaluation will be performed by 2 researchers, and any differences will be resolved through discussions or consultation with the third reviewer. The Grading of Recommendations Assessment, Development, and Evaluation (GRADE) system will be used to grading the quality of the evidence for main outcomes.Evidence quality will be graded as “high”, “moderate”, “low” or “very low” according to the GRADE rating standards.

Strategy of data synthesis: 1.Pairwise meta-analysis. Traditional pairwise meta analysis will be performed to compare treatments with direct evidence. Continuous outcomes will be calculated as standardized mean differences (SMDs) with 95% confidence interval(95% CI), and dichotomous outcomes will be calculated as OR with95%CI.The heterogeneity of each pairwise comparison will be tested by I2test. If I2.05 indicate good consistency, otherwise, all inconsistencies will be reported (P<.05). The contribution of

different designs to the final effect size estimated by the network meta-analysis will be evaluated by using net-heat plots.The different acupuncture methods will be ranked by using P-score that measures the extent of certainty that a treatment is better than a control.100% of the P-score indicates a treatment to be the best, while 0% of a P-score indicates a treatment to be the worst.

Subgroup analysis: If there are significant heterogeneities in the included studies, the STATA software will be used for subgroup analysis and meta-regression analysis according to the characteristics of the test subjects, sample size, different acupuncture intervention methods, quality of included trials, etc.

Sensibility analysis: We will evaluate the robustness of the meta-analysis results through sensitivity analysis, and exclude such as small-sample trials and low-quality trials to explore the impact of trial quality on efficacy estimates. In addition, we will conduct a second meta-analysis based on the results of the sensitivity analysis, summarize in tables and discuss.

Language: We will include reports of randomized controlled trials (RCTS) conducted in English or Chinese.

Country(ies) involved: China.

Other relevant information: We have no other relevant information.

Keywords: acupuncture, network meta-analysis, Post-Stroke Urinary incontinence, systematic review.

Dissemination plans: we have no dissemination plans.

Contributions of each author:
Author 1 - Pan Cheng - Author 1 drafted the manuscript.
Author 2 - Yuanyi Xiao - Author 2 provided statistical expertise.
Author 3 - Lin Jiao - Author 3 gives financial and guidance.