INPLASY PROTOCOL

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None declared.

Clinical Evidence for Acupuncture Related to the Improvement of Female Stress Urinary Incontinence: A systematic Review and Meta-Analysis

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Review question / Objective: **The purpose of this systematic review is to evaluate the effect of acupuncture on SUI and the quality of life-based on the latest literature.**
Condition being studied: **At least 25% of adult females in the world have urinary incontinence in some measure, of which more than half are stress urinary incontinence (SUI). SUI seriously affects the mental health of patients, but also leads to perineal rash, urinary tract infection, and other harms. The American Urological Association recommends pelvic floor muscle training (PFMT) as a conservative treatment for patients with mild to moderate SUI, but the cost of treatment is the main obstacle to its wide use of it. Acupuncture is one of the traditional therapies in ancient China, which is simple and cheap. Some systematic reviews and meta-analyses provide evidence for acupuncture in the treatment of SUI. Due to the quality of the study, these research results are not very reliable.**

INPLASY registration number: This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 23 May 2022 and was last updated on 23 May 2022 (registration number INPLASY202250135).

INTRODUCTION

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mild to moderate SUI, but the cost of treatment is the main obstacle to its wide use of it. Acupuncture is one of the traditional therapies in ancient China, which is simple and cheap. Some systematic reviews and meta-analyses provide evidence for acupuncture in the treatment of SUI. Due to the quality of the study, these research results are not very reliable.

METHODS

Search strategy: The combinations of Medical Subject Headings(MeSH) and non-MeSH terms were adopted. The search strategy includes three elements: clinical conditions (stress urinary incontinence), intervention methods (acupuncture, manual acupuncture, electroacupuncture, warm acupuncture, or fire needle), and study types (randomized controlled trials).

Participant or population: Adult female diagnosed as SUI.

Intervention: Reasonable intervention measures are acupuncture (body acupuncture, manual acupuncture, electroacupuncture, fire needle, and warm acupuncture or their combination).

Comparator: Control measures can consider sham acupuncture and PFMT.

Study designs to be included: Randomized controlled trial(RCT).

Eligibility criteria: Inclusion criteria: Intervention measures are acupuncture (body acupuncture, manual acupuncture, electroacupuncture, fire needle, and warm acupuncture or their combination), which can be included regardless of acupoint combination, acupuncture manipulation, and stimulation amount.Exclusion criteria:patients who have received surgical treatment for SUI, two types of acupuncture (such as different acupuncture techniques, stimulation amount, acupuncture manipulation, etc.), acupuncture and another kind of traditional Chinese medicine therapy (such as Chinese Medicinal Herbs, moxibustion, and tuina).

Information sources: Five English-language databases (PubMed, Embase, Scopus, Ovid, and Cochrane Library) and four Chinese-language databases (CNKI, VIP, WanFang, and SinoMed) were searched for randomized controlled trials from the establishment of the database to May 17, 2022. The combinations of Medical Subject Headings(MeSH) and non-MeSH terms were adopted. The search strategy includes three elements: clinical conditions (stress urinary incontinence), intervention methods (acupuncture, manual acupuncture, electroacupuncture, warm acupuncture, or fire needle), and study types (randomized controlled trials).Five English-language databases (PubMed ,EmBASE, Scopus,Ovid and Cochrane Library) and four Chinese-language databases (CNKI, VIP, WanFang, and SinoMed) were searched for randomized controlled trials from the establishment of the database to May 17, 2022. The combinations of Medical Subject Headings(MeSH) and non-MeSH terms were adopted. The search strategy includes three elements: clinical conditions (stress urinary incontinence), intervention methods (acupuncture, manual acupuncture, electroacupuncture, warm acupuncture, or fire needle), and study types (randomized controlled trials).

Main outcome(s): Urine leakage measured by the 1-hour pad test, the mean 24-hour incontinence episodes frequency(24-hour IEF), the mean 72-hour incontinence episode frequency (72-hour IEF).

Additional outcome(s): International Consultation in Incontinence questionnaire Short Form (ICIQ-SF) score.

Data management: Data extraction was performed independently by two researchers. Basic characteristics were extracted from each included study: participants (sample size, age, weight, course of disease), intervention measures (treatment details), outcome indicators (type, results), and methodological characteristics. If necessary, any missing information will be obtained by contacting the corresponding author.

Quality assessment / Risk of bias analysis: Two evaluators complete the quality assessment independently. If there is any difference between them, discuss and solve it with another evaluator. The risk of bias in the included studies was evaluated with the Cochrane Collaboration Recommendations assessment tool. Seven domains were assessed as low-risk, high-risk, or unclear-risk including random sequence generation, allocation concealment, blinding of participants and personnel, blinding of outcomes assessors, incomplete outcome data, selective reporting, and other biases. Besides, the Grading of Recommendations Assessment, Development, and Evaluation (GRADE) was performed to assess the quality of evidence as high, moderate, low, or very low quality.

Strategy of data synthesis: Considering the diversity of interventions and the potential heterogeneity of included studies, meta-analyses were used for RCTs with available data by a random-effect model. The difference was statistically significant ($P < 0.05$). All outcome measures were continuous variables, and the standardized mean difference (SMD) was calculated by a 95% confidence interval (CI). Subgroup analysis was performed according to different intervention types. When there is more than one control group in the study (such as acupuncture, PFMT, acupuncture + PFMT), the results are compared in pairs. For non-normal distribution data, if the literature report indicators are median, P25 and p75, use the method provided by McGrath s; For median, maximum and minimum values, use the method provided by Hozo sp. Heterogeneity analysis was assessed by I2. If the I2 > 50%, it is considered that there is the heterogeneity, and further sensitivity analysis is carried out to verify the robustness of the results and explore the source of heterogeneity. When there are at least 10 studies, publication bias can be detected by funnel plots and egger test.

Subgroup analysis: Subgroup analysis was performed according to different intervention types.

Sensitivity analysis: Heterogeneity analysis was assessed by I2. If the I2 > 50%, it is considered that there is the heterogeneity, and further sensitivity analysis is carried out to verify the robustness of the results and explore the source of heterogeneity.

Country(ies) involved: China.

Keywords: Stress urinary incontinence, Acupuncture, Meta-analysis.

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