The effect of acupuncture on postpartum stress urinary incontinence
A protocol for systemic review and meta-analysis

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1. Introduction
Stress urinary incontinence, a phenomenon of urinary involuntary overflow when abdominal pressure suddenly rises,
for women with PSUI. Unfortunately, in a 15-year follow-up, long-term adherence to PFME was found to be low, with no difference between intensive and home training programs.\[^{17}\]

In summary, there is a clinically unmet need and a mandate for effective, lower cost, noninvasive treatment, especially for people living in low-income regions.

As one of the important methods of Traditional Chinese Medicine, acupuncture has been widely used in the treatment of PSUI. Currently, many studies have shown that acupuncture is effective for PSUI. There are researches suggesting that acupuncture may improve symptoms of stress urinary incontinence by facilitating the reinnervation and strengthening of pelvic floor muscles.\[^{18–20}\]

A previously published meta-analyses concluded that electroacupuncture (EA) was superior to sham EA or no intervention.\[^{21}\]

Until now, no well-established systematic review has focused exclusively on acupuncture for PSUI. Accordingly, the first systematic review and meta-analysis will be conducted to investigate the efficacy and safety of acupuncture in the treatment of PSUI.

2. Methods

2.1. Study registration

This study protocol has been funded through a protocol registry. The registry number is INPLASY202220045, any revisions to the program will be documented on the INPLASY platform (https://inplasy.com/).

2.2. Criteria for considering studies

2.2.1. Types of studies. Only randomized controlled trials (RCTs) of acupuncture for the treatment of PSUI will be included, the language of articles included by our team will be limited to Chinese and English.

2.2.2. Types of participants. Participants will include patients diagnosed with PSUI based on The International Consultation on Urological Diseases without any age and race limit.\[^{22}\]

2.2.3. Types of interventions. The interventions under consideration must involve needle insertion at acupuncture points, pain points, or trigger points, and have to be described as acupuncture. Studies evaluating the following treatments, including body acupuncture (manual acupuncture or EA), auricular acupuncture, scalp acupuncture, warm needle acupuncture, plum blossom needling, and fire needling, will be considered.

2.2.4. Types of comparator(s)/control. The inclusion of the comparator mainly included sham or placebo acupuncture intervention such as nonpenetrating, sham needle, or superficial needling at nonacupuncture points, moxibustion, massage, western medicine, pelvic floor muscle exercise, and bioelectrical stimulation therapy will also be taken into account.

2.3. Outcome measures

2.3.1. Primary outcome. The changes in pelvic floor muscle strength compared with baseline will be used as primary outcomes.

2.3.2. Secondary outcomes. The secondary outcomes will be the International Consultation on Incontinence Questionnaire-Urinary Incontinence Short Form score, the urodynamic indexes, the incontinence quality of life questionnaire, and acupuncture adverse events.

2.3.3. Search strategies. Firstly, RCTs of acupuncture treatment for PSUI were retrieved from PubMed, Web of Science, EMBASE, the Cochrane Central Register of Controlled Trials, Chinese National Knowledge Infrastructure, Chinese Biomedical Literature Database, Wanfang Database and Technology Periodical Database. We will consider articles published in English or Chinese between database initiation and December 2021. The studies will be independently retrieved by 2 researchers. According to different databases, we combine keywords and free words to conduct a comprehensive search. Medline’s search strategy is shown in Table 1.

Table 1

| NO. | Search items                                      |
|-----|--------------------------------------------------|
| #1  | Randomized controlled trial [pt]                 |
| #2  | Controlled clinical trial [pt]                   |
| #3  | Randomized [tab]                                 |
| #4  | Placebo [tab]                                    |
| #5  | Clinical trials [MeSH]                           |
| #6  | Randomly [tab]                                   |
| #7  | Trial [ti]                                       |
| #8  | #1 OR #2 OR #3 OR #4 OR #5 OR #6 OR #7          |
| #9  | Humans [MeSH]                                    |
| #10 | #8 AND #9                                       |
| #11 | postpartum [MeSH]                                |
| #12 | Postnatal OR after delivery OR after childbirth [ti, ab] |
| #13 | #11 OR #12                                      |
| #14 | Stress urinary incontinence [MeSH]               |
| #15 | (Urinary Stress Incontinence OR Incontinence, Urinary Stress OR Stress Incontinence, Urinary) [ti, ab] |
| #16 | #14 OR #15                                      |
| #17 | Acupuncture therapy [MeSH]                       |
| #18 | Acupuncture OR Electroacupuncture OR (Electroacupuncture therapy) OR (body acupuncture) OR Electro-acupuncture OR (Manual acupuncture) OR (Auricular acupuncture) OR (Acupuncture and Moxibustion) OR (warm needling) [ti, ab] |
| #19 | #17 OR #18                                      |
| #20 | #10 AND #13 AND #16 AND #19                     |

2.4. Data collection and analysis

2.4.1. Selection of studies. Two independent researchers will import the retrieved literature into NoteExpress 3.5.0 software literature management system according to the selected topic. First of all, we will delete the duplicate studies. Then, according to our established inclusion and exclusion, preliminary screening will be carried out by screening title, abstract and keywords to exclude irrelevant literature. The researchers will then read the full text and re-evaluate it. If there is any objections, it will be addressed by a third researchers. Besides, the exclusion of items and the reasons for exclusion will be recorded. The flow chart of literature screening is shown in Figure 1.

2.4.2. Data extraction and management.

1. Two researchers will conduct data extraction and data management from the database. If there is data uncertainty, it will be solved through group discussion, and further differences will be solved by contacting authors and/or third-party arbitration. The basic information which will be extracted form the final included study will include:

   1. First authors, years of publication, sources/journals, countries, and regions.
3. Subject characteristics such as sample size, age, diagnostic criteria, course of disease, severity of disease.
4. Inclusion and exclusion criteria, outcome indicators, interventions, research results, adverse reactions, and other detailed information.

2.4.3. Risk of bias (quality) assessment. The bias risk assessment included in the literature will be completed by 2 researchers through the Cochrane Collaboration's tool.[23] The project covers: random sequence generation, allocation concealment, blinding methods for patients, researchers, and outcome evaluators, incomplete result data, selective reporting, and other prejudices. The evaluation results are divided into three levels: “low bias risk,” “high bias risk,” or “unclear bias risk.” Any differences will be resolved by discussion within the group or by a third researcher.

2.4.4. Measures of treatment effect. Review Manager (RevMan 5.3) software will be applied to perform statistical analysis. For continuous results, the mean difference or standardized mean difference will be used to evaluate the measurement data. For dichotomous outcomes, a risk ratio with 95% confidence intervals will be used for analysis.

2.4.5. Dealing with missing data. As for the missing or inadequate data, the researchers will attempt to get information by contacting the corresponding author. We will exclude these studies if the missing data cannot be supplied by the corresponding author.

2.4.6. Assessment of heterogeneity. We will use RevMan 5.3 software to evaluate statistical heterogeneity by $I^2$ statistical test. The fixed-effect model will be used if $I^2 < 50\%$. $I^2 > 50\%$, there is significant heterogeneity between studies, sensitivity analysis, and subgroup analysis will be performed from clinical and methodological perspectives to find possible reasons.

2.4.7. Assessment of reporting bias. If more than 10 studies are included, the funnel plot will be used to construct the reporting bias. Otherwise, we will use the STATA 15.1 software to assess reporting bias by Egger test.
3. Discussion

PSUI is a major public health problem that significantly affects postpartum women both in physical and mental health,[8-12,25] Although surgery, medications and PFMT can reach a certain curative effect, there are shortcomings like difficult training techniques, adverse reaction of drugs and surgery.[3,13-16] Acupuncture is a treatment method with fast curative effect and small side effect, which can improve PSUI symptoms by promoting nerve reinnervation, enhancing pelvic floor muscle strength and improving muscle coordination.[18-20] Hitherto, there is still lack of valid evidence to support that acupuncture is effective for PSUI. Therefore, we need to perform a Systematic Review and Meta-analysis by including high-quality and up-to-date studies to assess the efficacy and safety of acupuncture for PSUI. We hope this study will provide robust evidence to inspire clinicians to conduct large-sample RCTs and promote the utilization of acupuncture for PSUI. Of course, there may be some potential limitations in this review. Specifically, due to the variance of acupuncture methods and the different severity of PSUI, the statistical heterogeneity may be higher. In addition, the quality of RCTs may be low, which will result in a risk of bias. The SR will be conducted and reported in strict accordance with the standards in the AMSTAR 2.0 and PRISMA. In the future, we will make further improvements and deepening of this study according to the deficiencies mentioned above and the actual changes.

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References

[1] Abrams P, Cardozo L, Fall M, et al. The standardisation of terminology in lower urinary tract function: report from the standardisation sub-committee of the International Continence Society. Urology 2003;61:37-49.
[2] Sangsawang B, Sangsawang N. Stress urinary incontinence in pregnant women: a review of prevalence, pathophysiology, and treatment. Int Urogynecol J 2013;24:901-12.
[3] Gonzales AL, Barnes KL, Qualls CR, et al. Prevalence and treatment of postpartum stress urinary incontinence: a systematic review. Female Pelvic Med Reconstr Surg 2021;27:e139-45.
[4] Mac Arthur C, Wilson D, Herbsom P, et al. Urinary incontinence persisting after childbirth: extent, delivery history, and effects in a 12-year longitudinal cohort study. BJOG 2016;123:1022-9.
[5] Dolan LM, Hilton P. Obstetric risk factors and pelvic floor dysfunction 20 years after first delivery. Int Urogynecol J 2010;21:535-44.
[6] Tahtinen RM, Cartwright R, Tsu JF, et al. Long-term impact of mode of delivery on stress urinary incontinence and urgency urinary incontinence: a systematic review and meta-analysis. Eur Urol 2016;70:148-58.
[7] Wang H, Ghoniem G. Postpartum stress urinary incontinence, is it related to vaginal delivery? J Matern Fetal Neonatal Med 2017;30:1552-5.
[8] Lin YH, Chang SD, Hsieh WC, et al. Persistent stress urinary incontinence during pregnancy and one year after delivery; its prevalence, risk factors and impact on quality of life in Taiwanese women: an observational cohort study. Taiwan J Obstet Gynecol 2018;57:340-5.
[9] Hermansen IL, O’Connell BO, Gaskin CJ. Women's explanations for urinary incontinence, their management strategies, and their quality of life during the postpartum period. J Wound Ostomy Continence Nurs 2010;37:187-92.
[10] Moore IS, James ML, Brockwell E, et al. Multidisciplinary, biopsychosocial factors contributing to return to running and running related stress urinary incontinence in postpartum women. Br J Sports Med 2021;55:1286-92.
[11] Thomaz RP, Colla C, Darski C, et al. Influence of pelvic floor muscle fatigue on stress urinary incontinence: a systematic review. Int Urogynecol J 2018;29:197-204.
[12] Jurašková M, Piler P, Kukla L, et al. Association between Stress urinary incontinence and depressive symptoms after birth: the Czech ELSPAC study. Sci Rep 2020;10:6233.
[13] Kombrich KC, Albo ME, Dmochowski RR, et al. Surgical treatment of female stress urinary incontinence: AUA/SUFU guideline. J Urol 2017;198:875-83.
[14] Wang X, Xu X, Luo J, et al. Effect of app-based audio guidance pelvic floor muscle training on treatment of stress urinary incontinence in primiparas: a randomized controlled trial. Int J Nurs Stud 2020;104:103527.
[15] Wein AJ. Re: surgery versus physiotherapy for stress urinary incontinence. J Urol 2015;193:607.
[16] Pollard ME, Morriss S, Anger JT. Outcomes of pregnancy following surgery for stress urinary incontinence: a systematic review. J Urol 2012;187:1966-70.
[17] Bo K, Kvarstein B, Nygaard I. Lower urinary tract symptoms and pelvic floor muscle exercise adherence after 15 years. Obstet Gynecol 2005;105(5 pt 1):999-1005.
[18] Liu Z, Liu Y, Xu H, et al. Effect of electroacupuncture on urinary leakage among women with stress urinary incontinence: a randomized clinical trial. JAMA 2017;317:2493-501.
[19] Wang LL, Ren ZX, Zhu JY, et al. Efficacy of electroacupuncture combined with penetrating moxibustion for postpartum stress urinary incontinence. Zhongguo Zhen Jiu 2019;39:599-603.
[20] Chen F, Zhou J, Wu W, et al. Study on the therapeutic effect of floating needle therapy combined with pressing acupoint embedding for female stress urinary incontinence after childbirth: a randomized trial. Ann Palliat Med 2021;10:7786-93.
[21] Han X, Shen H, Chen J, et al. Efficacy and safety of electrical stimulation for stress urinary incontinence in women: a systematic review and meta-analysis. Int Urogynecol J 2022;33:738-99.
[22] Abrams P, Cardozo L, Khoury S, et al. INCONTINENCE (4th Edition 2009). Paris: Health Publications Ltd, 2008. 4-5.
[23] Huggins JR, Altman DG, Gøtzsche PC, et al. The Cochrane Collaboration’s tool for assessing risk of bias in randomised trials. BMJ 2011;343:d5928.
[24] Puhan MA, Schünemann HJ, Murad MH, et al. Group A GRADE Working Group approach for rating the quality of treatment effect estimates from network meta-analysis. BMJ 2014;349:g3630.
[25] Chen L, Luo D, Chen X, et al. Development of predictive risk models of postpartum stress urinary incontinence for primiparas and multiparas. Urol Int 2020;104:824-32.

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