INPLASY

The effectiveness and safety of acupuncture for chronic prostatitis/chronic pelvic pain syndromes: a protocol for systematical review and meta-analysis

INPLASY2024110003
doi: 10.37766/inplasy2024.11.0003
Received: 1 November 2024
Published: 1 November 2024

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ADMINISTRATIVE INFORMATION

Support - Clinical Research Fund Project of Zhejiang Medical Association(2022ZYC-A32).

Review Stage at time of this submission - The review has not yet started.

Conflicts of interest - None declared.

INPLASY registration number: INPLASY2024110003

Amendments - This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 1 November 2024 and was last updated on 1 November 2024.

INTRODUCTION

Review question / Objective To evaluate the effectiveness and safety of acupuncture for chronic prostatitis/chronic pelvic pain syndrome.

P: patients who diagnosed as chronic prostatitis/chronic pelvic pain syndrome, at least kept for 3 months;

I:Acupuncture therapy (including acupuncture, electroacupuncture, or warm acupuncture) as the main intervention in the treatment group, which could be combined with other therapies.

C: Sham acupuncture only or Sham acupuncture combined with other therapies which is the same as acupuncture group.

O:NIH-Chronic Prostatitis Symptom Index (NIH-CPSI),International Prostate Symptom Score,response rate and adverse effects

S: Randomized controlled trials.

Rationale Firstly, with sham acupuncture as the control group, bias due to the placebo effect can be effectively accounted for, allowing for a comparative analysis of efficacy without actual therapeutic intervention. Secondly, adherence to the PRISMA-A guidelines promotes transparency and reproducibility in systematic reviews and meta-analysis, enhancing the objectivity of acupuncture efficacy evaluations while reducing potential biases. Lastly, There is an increasing number of Chinese randomized controlled trials (RCTs) in the literature, which further substantiates and enriches the evidence base supporting acupuncture's therapeutic benefits.

Condition being studied Chronic prostatitis/chronic pelvic pain syndrome (CP/CPPS) is a prevalent condition in the field of urology, affecting as many as 50% of men at some point in their lives. Type III CP/CPPS, the most complex and controversial form of prostatitis, poses significant challenges due to its high incidence rate, uncertain

treatment efficacy, and the long-term impact on patients' psychological well-being. This condition not only presents physical symptoms but also exerts a substantial psychological burden on those affected.

Researchers have identified a high prevalence of psycho-social problems and catastrophic distress among CP/CPPS patients, including serious mental disorders such as depression, anxiety, and stress. The debilitating nature of the pain associated with this condition further compounds the psychological impact, creating a vicious cycle that can be difficult to break.

Conventional treatment approaches, primarily relying on drugs and physical interventions, have often fallen short in providing comprehensive and lasting relief for patients with CP/CPPS. This underscores the need for a more holistic approach that addresses the intricate relationship between the physical manifestations of the disease and the psychological well-being of the patient.

METHODS

Participant or population Patients who diagnosed as chronic prostatitis/chronic pelvic pain syndrome, at least kept for 3 months.

Intervention Received acupuncture therapy combined with Drugs or without Drugs.

Comparator Sham acupuncture only or Sham acupuncture combined with other therapies which is the same as acupuncture group.

Study designs to be included All the RCT of Type III chronic prostatitis/chronic pelvic pain syndrome patients.

Eligibility criteria All the RCTs meet the standard of “PICO”mentioned above will be included. Studies were excluded based on the following criteria: (1) non-randomized controlled trials; (2) duplicate publications or incomplete information preventing full-text inclusion; (3) studies with poor methodological design, inconsistent intervention measures, or control measures; and (4) studies lacking clearly defined outcome indicators.

Information sources The following electronic databases will be searched: PubMed, Embase, Cochrane Library, Web of Science, ClinicalTrials.org,Chinese Biomedical Literature Database (CBM), Chinese National Knowledge Infrastructure (CNKI), Chinese Scientific Journal Database(VIP), and Wanfang Database(WF),J-State, the Chinese Clinical Trial Registry (ChiCTR) and International Traditional Medicine Clinical Trial Registry(ITMCTR).

Main outcome(s) Including NIH-Chronic Prostatitis Symptom Index (NIH-CPSI),International Prostate Symptom Score,response rate and adverse effects.

Data management Two reviewers(Sinian Zheng and Bangbing Chen) will independently screen and extract data from the included studies. Disagreements will be resolved through discussion or consultation with a third reviewer(Tieding Chen).Two reviewers will independently screen and extract data from the included studies. Disagreements will be resolved through discussion or consultation with a third reviewer.

Quality assessment / Risk of bias analysis The methodological quality of the randomized controlled trials (RCTs) included in this analysis will be systematically assessed utilizing the Cochrane Risk of Bias 2 (RoB 2) tool.Additionally, the quality of the evidence gathered from these studies will undergo evaluation through the application of the GRADE approach (Grading of Recommendations Assessment, Development and Evaluation).

Strategy of data synthesis The RevMan5.4 software will be used to conduct the meta analysis. Descriptive analysis or systematic narrative synthesis will be performed to summarize and explain the characteristics and findings of the included studies and provide the information in the texts and tables. For dichotomous data (e.g., effective and ineffective), we will calculate risk ratio (RR) and 95% confidence intervals (CIs). For continuous data, which will be pooled as standardized mean difference (SMD) with 95% CIs.The I^2 test was used to test heterogeneity with a significance level set at 50%. If heterogeneity was not significant ($I^2 \leq 50\%$), the fixed-effect model was used for meta-analysis. Otherwise, the random effect model was used ($I^2 \geq 50\%$).

Subgroup analysis If sufficient data are available, subgroup analyses will be conducted based on the type of acupuncture, duration of treatment, or other difference in acupuncture technique details.

Sensitivity analysis Sensitivity analyses will be conducted to evaluate the robustness of the findings, including the exclusion of studies with a high risk of bias.

Language restriction English and Chinese.

Country(ies) involved China.

Keywords Chronic prostatitis, acupuncture, sham acupuncture,chronic pelvic pain syndrome, systematic review, meta-analysis.

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