# INPLASY PROTOCOL

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

**Conflicts of interest:**
**None declared.**

# The efficacy and safety of acupuncture in the treatment of erectile dysfunction: a protocol for systematic review and meta-analysis

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**Review question / Objective:** **1. Type of studies. Only RCTs will be included. 2. Type of participants. Patients over 18 years of age who are diagnosed with ED. ED must be diagnosed by clinical and/or instrumental methods. The diagnosis will be based on the Diagnostic and Statistical Manual of Mental Disorders Third Edition (DSM)-III, DSM-III-R, DSM-IV, International Statistical Classification of Diseases and Related Health Problems (ICD)-10 criteria or any other described criteria. 3. Type of interventions. The types of acupuncture in the intervention group include: manual acupuncture, electric acupuncture, scalp acupuncture, ear acupuncture, moxibustion, and fire needling. 4. Type of comparators. Control measures can include: placebo/sham acupuncture or other interventions (such as drugs, physical therapy). 5. Types of outcome measures. The main result will be an improvement in sexual activity. This will be assessed through validated questionnaires such as the International Index of Erectile Function (IIEF).Secondary outcome measures include Quality of Life (QOL), Improvement in anxiety or depression scales, and the rate of adverse effects (AEs).**

**INPLASY registration number:** This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 07 April 2021 and was last updated on 07 April 2021 (registration number INPLASY202140040).

## INTRODUCTION

**Review question / Objective:** **1. Type of studies. Only RCTs will be included. 2. Type of participants. Patients over 18 years of age who are diagnosed with ED. ED must be diagnosed by clinical and/or instrumental methods. The diagnosis will be based on the Diagnostic and Statistical Manual of Mental Disorders Third Edition (DSM)-III, DSM-III-R, DSM-IV, International Statistical Classification of Diseases and**

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**Condition being studied:** Erectile dysfunction (ED) can negatively affect men's mental health, interpersonal relationships, and overall well-being. Erectile dysfunction has affected more than 150 million men worldwide, and this number will reach approximately 322 million by 2025. Although PDE5-Is is a landmark in the treatment of erectile dysfunction, it may have side effects such as penile pain, cardiovascular dysfunction, and deafness. Some studies have shown that acupuncture may have a positive effect on the pathophysiology of ED. Therefore, we will select all RCTs related to evaluate the efficacy and safety of acupuncture treatment of ED.

## METHODS

**Search strategy:** (((((((((Erectile Dysfunction[MeSH Terms]) OR (Dysfunction, Erectile)) OR (Male Sexual Impotence)) OR (Impotence, Male Sexual)) OR (Sexual Impotence, Male)) OR (Male Impotence)) OR (Impotence, Male)) OR (Impotence)) AND ((((((((((((((((Acupuncture [MeSH Terms]) OR (Pharmacopuncture)) OR (Acupuncture Therapy)) OR (Electroacupuncture)) OR (Manual Acupuncture)) OR (Dry Needle)) OR ((Moxibustion[MeSH Terms]) OR (moxibustion))) OR (Acupuncture, Ear[MeSH Terms])) OR (acupuncture, Ear)) OR (ear acupuncture)) OR (Auricular Acupuncture)) OR (Ear Acupuncture)) OR (Acupuncture, Auricular)) OR (acupuncture, Auricular)) OR (auricular acupuncture)) OR (Warm Acupuncture)) OR (Elongated Needle))) AND (randomized controlled trial[Publication Type] OR randomized[Title/Abstract] OR placebo[Title/Abstract]).

**Participant or population:** Patients over 18 years of age who are diagnosed with ED. ED must be diagnosed by clinical and/or instrumental methods. The diagnosis will be based on the Diagnostic and Statistical Manual of Mental Disorders Third Edition (DSM)-III, DSM-III-R, DSM-IV, International Statistical Classification of Diseases and Related Health Problems (ICD)-10 criteria or any other described criteria.

**Intervention:** The types of acupuncture in the intervention group include: manual acupuncture, electric acupuncture, scalp acupuncture, ear acupuncture, moxibustion, and fire needling.

**Comparator:** Control measures can include: placebo/sham acupuncture or other interventions (such as drugs, physical therapy).

**Study designs to be included:** Only RCTs will be included.

**Eligibility criteria:** 1. Type of studies. Only RCTs will be included. 2. Type of participants. Patients over 18 years of age who are diagnosed with ED. ED must be diagnosed by clinical and/or instrumental methods. The diagnosis will be based on the Diagnostic and Statistical Manual of Mental Disorders Third Edition (DSM)-III, DSM-III-R, DSM-IV, International Statistical Classification of Diseases and Related Health Problems (ICD)-10 criteria or any other described criteria. 3. Type of interventions. The types of acupuncture in the intervention group include: manual acupuncture, electric acupuncture, scalp acupuncture, ear acupuncture, moxibustion, and fire needling. 4. Type of comparators. Control measures can include: placebo/sham acupuncture or other interventions (such as drugs, physical

therapy). 5. Types of outcome measures. The main result will be an improvement in sexual activity. This will be assessed through validated questionnaires such as the International Index of Erectile Function (IIEF).Secondary outcome measures include Quality of Life (QOL), Improvement in anxiety or depression scales, and the rate of adverse effects (AEs).

**Information sources:** This study will systematically search 7 digital databases including China National Knowledge Infrastructure (CNKI), Wanfang, VIP, China Biology Medicine (CBM), Cochrane Library, PubMed and Embase for RCTs without language restrictions. Two researchers will independently read the title, abstract, and full text to screen for studies that can be included in the meta-analysis. If there is any dispute, the third party will be required to reach a consensus.

**Main outcome(s):** The main result will be an improvement in sexual activity. This will be assessed through validated questionnaires such as the International Index of Erectile Function (IIEF).

**Additional outcome(s):** Secondary outcome measures include Quality of Life (QOL), Improvement in anxiety or depression scales, and the rate of adverse effects (AEs).

**Data management:** Two authors will independently select the trials included in the review according to the inclusion/exclusion criteria. Any disagreement will be resolved by discussion. We will perform data extraction using a Microsoft Excel spreadsheet. Information extracted from each included article will include first author, publication year, sample size, characteristics of participants, type of treatments, and outcome measures. If the necessary data are not available in the trial reports, further information will be sought by contacting corresponding author.

**Quality assessment / Risk of bias analysis:** The risk of bias in the included literature will be assessed according to the Cochrane Collaboration's tool for assessing risk of bias. We will assess the risk of bias from the following seven items: random sequence generation, allocation concealment, blinding of participants and personnel, blinding of outcome assessment, incomplete outcome data, selective reporting and other sources of bias. The risk of bias graph and the risk of bias summary will be generated by Review Manager (RevMan) V.5.3 software. Any disagreement should be solved in consultation with a third reviewer.

**Strategy of data synthesis:** Fixed effects models will be used if the I2 value is <50%. Otherwise, we will remove low-quality studies and use sensitivity analysis to investigate which study has the most significant impact on heterogeneity. If quantitative synthesis is not possible, we will make a qualitative description.

**Subgroup analysis:** If there is significant heterogeneity between the study results, we will perform a subgroup analysis to investigate differences in gender, age, types of acupuncture interventions styles, etc.

**Sensitivity analysis:** Sensitivity analysis will be conducted to explore the effects of trial risk of bias on important outcomes. Several factors in the meta-analysis process will be taken into consideration, such as low-quality research, small sample research, etc. In addition, we will give the results of the sensitivity analysis in the summary table. The results of the sensitivity analysis will discuss the risk of bias in the meta-analysis.

**Language:** Without language restrictions.

**Country(ies) involved:** China.

**Keywords:** acupuncture, erectile dysfunction, complementary therapy, efficacy, TCM, impotence.

**Contributions of each author:**

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