

# INPLASY PROTOCOL

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**Support:** Chengdu University of TCM

**Review Stage at time of this submission:** Piloting of the study selection process.

**Conflicts of interest:** No

## The maintenance effect of acupuncture on the side effects of breast cancer endocrine therapy: a systematic review and meta-analysis

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**Review question / Objective:** Is acupuncture effective for hot flashes and arthralgia after endocrine therapy of breast cancer, and how long can the effect be maintained? Which points are more common?

**Condition being studied:** This review includes randomized controlled trials of acupuncture for endocrine therapy-related symptoms of breast cancer and drug therapy, sham acupuncture, and non-therapy. All participants were diagnosed with hot flashes or arthralgia after endocrine therapy for breast cancer and received acupuncture treatment. Our review is limited to acupuncture manipulation, emphasizing transdermal and manipulation of qi, thus excluding auricular point, finger pressure and laser acupuncture tests. The main result of our review is the duration of improvement and maintenance of patients' overall symptoms. There are no restrictions on language and date.

**INPLASY registration number:** This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 04 April 2020 and was last updated on 04 April 2020 (registration number INPLASY202040024).

## INTRODUCTION

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## METHODS

**Participant or population:** Women with breast cancer have hot flashes and arthralgia after endocrine therapy. (as diagnosed using any recognized diagnostic criteria).

**Intervention:** Acupuncture or electroacupuncture.

**Comparator:** Medication, sham acupuncture, or no treatment.

**Study designs to be included:** Randomized controlled trials.

**Eligibility criteria:** 1.non-randomized trials; 2. non-clinical trials; 2. articles not in English or Chinese; 3. articles which data analysis did not fulfill protocol criteria.

**Information sources:** PubMed, Embase, the Cochrane Library, Web of Science, China National Knowledge Infrastructure(CNKI), Chinese Scientific Journal Database(VIP), and WanFang Data, Chinese Clinical Trial Register (ChiCTR) were all searched. European Medicines Agency (EMA), WHO International Clinical Trials Registry Platform There were no restrictions on language.

**Main outcome(s):** The overall effect and duration of acupuncture on hot flashes and arthralgia in breast cancer patients after endocrine therapy.

**Quality assessment / Risk of bias analysis:** The Risks of bias will be assessed according to the Cochrane Handbook Version 5.1.0. by 2 reviewers. The following factors were assessed: 1. Randomization sequence generation: was the allocation sequence adequately generated? 2. Treatment allocation concealment: was the allocated treatment adequately concealed from study participants and clinicians and other healthcare or research staff at the enrolment stage? 3. Blinding: were the personnel assessing outcomes and analyzing data sufficiently blinded to the intervention allocation throughout the trial?

4. Completeness of outcome data: were participant exclusions, attrition, and incomplete outcome data adequately addressed in the published report? 5. Selective outcome reporting: is there evidence of selective outcome reporting and might this have affected the study results? 6. Other sources of bias: was the trial apparently free of any other problems that could produce a high risk of bias? Disagreements were solved by discussion until a consensus was reached.

**Strategy of data synthesis:** Data analysis will be performed with Review Manager 5.3 software provided by the Cochrane Collaboration. Effective Rate was calculated by relative risk, and the HAMA score will be calculated by mean difference. Heterogeneity is recognized as significant when  $I^2 \geq 50\%$ . A fixed-effect model will be performed when there is no significant heterogeneity, otherwise, a random-effects model will be performed.

**Subgroup analysis:** If a sufficient number of studies are identified for inclusion, Subgroup analyses of patients with mild, moderate, and severe breast cancer will be performed.

**Sensibility analysis:** sensitivity analysis will also be employed to explore possible factors that may lead to heterogeneity, such as intervention measures (electroacupuncture and manual acupuncture), control measures, length of treatment or quality of articles, etc. If quantitative synthesis is not appropriate, we will conduct a narrative synthesis.

**Countries involved:** China

**Keywords:** Acupuncture, breast cancer, endocrine therapy, systematic review.

**Contributions of each author:**

Author 1 - Data curation; Author 2 - Formal analysis; Author 3 - Investigation; Author 4 - Methodology; Author 5 - Project administration; Author 6 - Software; Author 7 - Supervision.