

# INPLASY PROTOCOL

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## Conflicts of interest:

None declared.

## Effect of Acupuncture on Mammary Gland Hyperplasia (MGH): a Bayesian network meta-analysis

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**Review question / Objective:** This review aims at conducting a network meta-analysis to assess the potential therapeutic effectiveness and safety of acupuncture therapy for the treatment of MGH.

**Condition being studied:** MGH is a benign breast disease caused by excessive growth of mammary duct epithelial cells and interstitial fibers. Its prevalence rate among women of childbearing age is about 13.5-42%, accounting for 99.3% of the total number of patients with breast related diseases, and its possibility of developing breast cancer can reach 5-10%. Breast hyperplasia can cause clinical symptoms such as breast pain, breast lump, nipple pigmentation and mood fluctuation, which brings severe physical and mental burden to patients. Modern medicine believes that the pathogenesis of MGH is related to sexual hormone disorder secondary to hypothalamus pituitary ovary axis dysfunction. At present, the treatment options of MGH are limited and not completely effective. The commonly used drugs in clinical practice, such as tamoxifen, danazol and goserelin, are expensive, which may lead to breast pain, swelling and increase of interstitial fibrous nodules, and the long-term use of MGH has huge side effects. The clinical guidelines recommend that the use time should be 2 to 6 months. Therefore, it is necessary to seek a treatment method of MGH that is effective, stable and safe.

**INPLASY registration number:** This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 14 September 2022 and was last updated on 14 September 2022 (registration number INPLASY202290058).

## INTRODUCTION

**Review question / Objective:** This review aims at conducting a network meta-

analysis to assess the potential therapeutic effectiveness and safety of acupuncture therapy for the treatment of MGH.

**Rationale:** Relevant evidence shows that acupuncture can inhibit estrogen secretion, thereby slowing down cell proliferation and promoting cell apoptosis. And effectively improve the blood circulation of breast tissue, so as to relieve breast pain, stop its progress, and finally reverse the disease change.

**Condition being studied:** MGH is a benign breast disease caused by excessive growth of mammary duct epithelial cells and interstitial fibers. Its prevalence rate among women of childbearing age is about 13.5-42%, accounting for 99.3% of the total number of patients with breast related diseases, and its possibility of developing breast cancer can reach 5-10%. Breast hyperplasia can cause clinical symptoms such as breast pain, breast lump, nipple pigmentation and mood fluctuation, which brings severe physical and mental burden to patients. Modern medicine believes that the pathogenesis of MGH is related to sexual hormone disorder secondary to hypothalamus pituitary ovary axis dysfunction. At present, the treatment options of MGH are limited and not completely effective. The commonly used drugs in clinical practice, such as tamoxifen, danazol and goserelin, are expensive, which may lead to breast pain, swelling and increase of interstitial fibrous nodules, and the long-term use of MGH has huge side effects. The clinical guidelines recommend that the use time should be 2 to 6 months. Therefore, it is necessary to seek a treatment method of MGH that is effective, stable and safe.

## METHODS

**Search strategy:** We will search the following electronic bibliographic databases: PubMed, Cochrane Library, EMBASE, Chinese National Knowledge Infrastructure, Chinese Biomedical Literature Database, Wanfang Database, the Chongqing VIP Chinese Science and Technology Periodical Database. All of them will be searched from inception to June 2022. The retrieval mode used will be a combination of free words and medical subject headings terms, including

“fibrocystic breast disease,” “fibrocystic disease of breast,” “breast hyperplastic disease,” “hyperplasia of mammary glands,” “mammary glands hyperplasia,” “cyclo mastopathy,” “acupuncture,” “acupuncture therapy,” “electroacupuncture,” “auriculotherapy,” “acupoint,” “acupoint injection,” “acupoint catgut embedding,” “moxibustion,” “needle,” “warm needle,” “temperature needle” “randomized controlled trial,” “randomized controlled,” “randomized, controlled,” “clinical trial.”

**Participant or population:** All patients, who are over 18, have MGH (as diagnosed using any authoritative diagnostic criteria) regardless of age, sex, race, duration of disease, weight, or education.

**Intervention:** ACU treatments include moxibustion, catgut embedding, electro-ACU, transcutaneous electrical acupoint stimulation, auricular ACU, scalp ACU, warm needling, manual ACU, acupoint injection, regardless of needling techniques and stimulation method.

**Comparator:** The control group is treated with sham-ACU, placebo, pharmacotherapy, which is recommended in international or domestic authorized clinical guidelines, or no treatment. When studies combine ACU treatments with other active therapy, both the experimental and the control groups are required to use the same active therapy.

**Study designs to be included:** All the randomized controlled trials which is stated the “randomization” phrase will be included, regardless of allocation concealment, or used of blinding. The language will be restricted in Chinese or English.

**Eligibility criteria:** Diagnostic criteria for MGH.

**Information sources:** PubMed, Cochrane Library, EMBASE, Chinese National Knowledge Infrastructure, Chinese Biomedical Literature Database, Wanfang Database, the Chongqing VIP Chinese

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Science and Technology Periodical Database.

**Main outcome(s):** Main outcome: efficiency. Secondary outcome: (1) Digital scoring scale: the most painful day of breast pain before and after treatment. (2) Breast lump size score: compare the size of the target lump before and after treatment. (3) Estradiol level: Compare the estradiol level before and after treatment. (4) Progesterone level: compare the progesterone level before and after treatment.

**Quality assessment / Risk of bias analysis:** The assessment will be conducted by 2 reviewers with the risk-of-bias assessment method from Cochrane Reviewer's Handbook 5.0.24. The main contents comprise 7 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 studies will be evaluated as being of "low risk of bias," "high risk of bias," or "unclear risk of bias."

**Strategy of data synthesis:** STATA 16.0 software will be used to through the GeMTC package will be used to perform NMA to synthesize direct and indirect evidence.

**Subgroup analysis:** If necessary, subgroup analysis will be conducted according to the following factors: duration or dose of ACU, duration of disease, treatment time and intervention type of control group.

**Sensitivity analysis:** When significant heterogeneity exists, sensitivity analysis will be conducted according to the following aspects: sample size, heterogeneity quality, methodological elements and research characteristics. If heterogeneity decreases after excluding low-quality or small sample studies, we must draw conclusions more cautiously.

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

**Keywords:** MGH; Acupuncture and moxibustion; NMA; Total efficiency.

**Contributions of each author:**

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