# INPLASY PROTOCOL

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

# Do all these conservative therapies effective for vocal nodules? : A systematic review and meta-analysis of randomized controlled trials

Wang, XC[1]; Zhou, J[2]; Ren, QW[3]; Zhou, Li[4]; He, XN[5]; He, XY[6].

**Review question / Objective:** **P: Patients with vocal nodules, regardless of age, sexual and races. I: Conservative therapies including: acupuncture, TEN, traditonal chinese medicine and western medicine, voice therapy, vocal hygenie. C: no medical treatment (placebo only, no intervention or routine care). O: VHI index, Jitter, Shimmer, MHR, Total efficiency; whether the therapies are effective. S: Randomized controlled trials.**
**Condition being studied:** **The vocal nodule is one of the benign vocal fold pathologies, which is more prevalent in voice professionals, such as teachers, singers, and lawyers. With increasing life quality and job requirements, the growing prevalence of vocal nodule (VN) is becoming a rising problem for people who take their voice as a lifeline. The key to treating vocal nodules is to improve the quality of life in voice professions towards the high burden of voice use. As less-invasive alternative voice treatments, it is not surprising to find a rising number of international dysphonic patients looking for conservative therapies rather than surgery.**

**INPLASY registration number:** This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 04 June 2022 and was last updated on 04 June 2022 (registration number INPLASY202260012).

## INTRODUCTION

**Review question / Objective:** **P: Patients with vocal nodules, regardless of age, sexual and races. I: Conservative therapies including: acupuncture, TEN, traditonal chinese medicine and western medicine, voice therapy, vocal hygenie. C: no medical treatment (placebo only, no intervention or routine care). O: VHI index, Jitter, Shimmer, MHR, Total efficiency; whether the therapies are effective. S: Randomized controlled trials.**

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and lawyers. With increasing life quality and job requirements, the growing prevalence of vocal nodule (VN) is becoming a rising problem for people who take their voice as a lifeline. The key to treating vocal nodules is to improve the quality of life in voice professions towards the high burden of voice use. As less-invasive alternative voice treatments, it is not surprising to find a rising number of international dysphonic patients looking for conservative therapies rather than surgery.

## METHODS

**Participant or population:** Patients with vocal nodules, regardless of age, sexual and races.

**Intervention:** Conservative therapies including: acupuncture, TEN, traditonal chinese medicine and western medicine, voice therapy, vocal hygenie.

**Comparator:** No medical treatment (placebo only, no intervention or routine care).

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

**Eligibility criteria:** P: Patients with vocal nodules, regardless of age, sexual and races.I: Conservative therapies including: acupuncture, TEN, traditonal chinese medicine and western medicine, voice therapy, vocal hygenie.C: no medical treatment (placebo only, no intervention or routine care)O: VHI index, Jitter, Shimmer, MHR, Total efficiency; whether the therapies are effective.S: Randomized controlled trials.

**Information sources:** Online databases including: Embase, Pubmed, Web of Science, Sinomed, China National Knowledge Internet (CNKI), China Science Periodical Database (CSPD), China Science and Technology Journal Database.

**Main outcome(s):** VHI index, Jitter, Shimmer, MHR, Total efficiency; whether the therapies are effective.

**Quality assessment / Risk of bias analysis:** Using the Review manager 5.4 software to assess the quality of randomized controlled studies, accroding to Corchrane tool (risk of bias, ROB).

**Strategy of data synthesis:** According to the Cochrane Collaboration's tool for assessing risk of bias provided by Cochrane Handbook for Systematic Reviews of Interventions, we will assess from 7 dimensions: random sequence generation, allocation concealment, blinding of patients, blinding of testers, blinding of outcome evaluators, outcome data incompletion, and selective reporting of 7 dimensions for evaluation. The results of the assessment will be divided into 3 levels: low risk, unclear, and high risk. The assessment will be conducted independently by 2 trained research members, and the inconsistencies will be resolved through intragroup discussions, contacting authors to determine details with the third-party arbitrator.The enumeration data are expressed as relative risk, the measurement data adopt mean difference, and each effect amount is expressed in 95% confidence interval. Subset of trials will be analysed where there has been appropriate treatment of missing values (eg, multiple imputations). A sensitivity analysis may not be needed if the subset differs only from the entire set or is very small. Prior to statistical analysis, the chi-squared test will be used to determine the homogeneity of the study. If the resulting P value exceeds .1, it indicates significant heterogeneity of the test. The cause of the heterogeneity will be analyzed and a subgroup analysis will be performed. And the variance τ2 fromthe random-effects model will be provided. When more than 10 studies are included, the symmetry of the funnel plot will be first used to determine whether there is a publication bias. If the image is unclear, Egger test will be performed for quantitative analysis using STATA 12.0 software. Then, using the Review manager

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5.4 software to compute the data synthesis carefully. When there is no statistical heterogeneity among the results, a fixed-effects model will be used for meta-analysis. When there is statistical heterogeneity among the results, the heterogeneity source will be further analyzed and a random-effects model will be used for meta-analysis after excluding the effects of significant clinical heterogeneity. When there is significant clinical heterogeneity, we will use subgroup analysis or sensitivity analysis, or only descriptive analysis.

**Subgroup analysis:** The following subgroup analysis will be performed to assess the heterogeneity of the research Clinical consideration ? Different conservative therapies? Different aspects of treatments' efficiency ? Tests with unclear or high risks of bias?

**Sensitivity analysis:** Sensitivity analysis. Sensitivity analysis is an important method primarily used to assess the robustness and reliability of the combined results of meta-analysis. It is a commonly used sensitivity analysis method to combine the effect size after eliminating each of the included studies, or after changing the inclusion or exclusion criteria or eliminating certain types of studies. For possible low-quality studies, sensitivity analysis is required.

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

**Keywords:** Vocal Nodlues; Hoarseness; Conservative Therapies; Acupuncture; Transcutaneous Electrical Nerve Stimulation; Medicine; Meta-analysis; Review.

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