# INPLASY PROTOCOL

To cite: Wang et al. Are all conservative therapies effective for vocal nodules? Protocol for a systematic review and meta analysis. Inplasy protocol 202260012. doi: 10.37766/inplasy2022.6.0012

Received: 04 June 2022

Published: 04 June 2022

**Corresponding author:**
**Xiaocen Wang**

**wangxiaocen@stu.cdutcm.edu.cn**

**Author Affiliation:**
**Hospital of Chengdu University of Traditional Chinese Medicine.**

**Support:** **The subject is jointly funded.**

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

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

# Are all conservative therapies effective for vocal nodules? Protocol for a systematic review and meta analysis

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

**Review question / Objective:** **Population: Patients with VNs, regardless of age, sex, and race. Intervention: Conservative therapies, including acupuncture, TENS, TCM, WM, voice therapy, and vocal hygiene. Comparison: No medical treatment (placebo only, no intervention or routine care). Outcomes: Voice Handicap Index (VHI), jitter, shimmer, harmonic-to-noise ratio (HNR), and speech efficiency score (SES). Study design: Systematic review of 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 03 September 2022 (registration number INPLASY202260012).

## INTRODUCTION

**Review question / Objective:** **Population: Patients with VNs, regardless of age, sex, and race. Intervention: Conservative therapies, including acupuncture, TENS, TCM, WM, voice therapy, and vocal hygiene. Comparison: No medical treatment (placebo only, no intervention or routine care). Outcomes: Voice Handicap Index (VHI), jitter, shimmer, harmonic-to-noise ratio (HNR), and speech efficiency score (SES). Study design: Systematic review of 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.

## METHODS

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

**Intervention:** Conservative therapies, including acupuncture, transcutaneous electrical nerve stimulation (TENS), traditional Chinese medicine (TCM), Western medicine (WM), voice therapy, and vocal hygiene.

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

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

**Eligibility criteria:** This study will only include randomized controlled trials (RCTs) that examined adults diagnosed with VNs, and will not include studies that examined other miscellaneous benign lesions of the larynx. To be eligible, study must have randomized participants into a conservative therapy group or no medical treatment group (placebo only, no intervention or routine care). We will include non-English language studies and unpublished trials, but will not include any cluster RCT, crossover RCT, n of 1 RCT, or pragmatic controlled trial (PCTs), given the functional nature of this disease. Population: Patients with VNs, regardless of age, sex, and race. PICOS framework: Intervention: Conservative therapies, including acupuncture, TENS, TCM, WM, voice therapy, and vocal hygiene. Comparison: No medical treatment (placebo only, no intervention or routine care). Outcomes: Voice Handicap Index (VHI), jitter, shimmer, harmonic-to-noise ratio (HNR), and speech efficiency score (SES). Study design: Systematic review of randomized controlled trials.

**Information sources:** Electronic searches: We will utilize a comprehensive search strategy, with help from the Information Specialist at Cochrane Gut. We will search the following databases for publications that appeared from database inception (or the date indicated below) to the date of the search for identification of eligible studies written in English or Chinese: Web of Science (via Ovid); Cochrane Central Register of Controlled Trials (CENTRAL, via Ovid); Pubmed (via Ovid, from 1964); Embase (via Ovid, from 1974); China National Knowledge Internet (CNKI, via Ovid); China Science Periodical Database (CSPD, via Ovid); and the China Science and Technology Journal Database (via Ovid). We will also search the following clinical trial registries: ClinicalTrials.gov (www.clinicaltrials.gov); World Health Organization International Clinical Trials Registry Platform (ICTRP; http://www.who.int/trial); and the Chinese Clinical Trial Registry Platform (http://www.chictr.org.cn/addproject2.aspx). Searching other resources: We will review all references cited in review articles on this subject and all references cited in each eligible manuscript. We will also contact experts in the field to identify additional studies. We will attempt to obtain a copy of all full articles for each reference to identify potentially eligible trials; if this is not possible, we will attempt to contact the authors for additional information.

**Main outcome(s):** Effectiveness based on measurements of the voice handicap index (VHI), jitter, shimmer, and harmonic noise ratio (HNR), and speech efficiency score (SES).

**Quality assessment / Risk of bias analysis:** We will use the Cochrane Collaboration RoB 2 version 6.0 from the Cochrane Handbook to assess the risk of bias. Summary assessments of low, medium, or high risk of bias will be determined after considering the RoB 2 mandatory domains. We will present data on the risk of bias for each study in a table, and will consider this assessment when interpreting the results. We will not exclude studies based on assessment of the risk of bias. If a meta-analysis is considered appropriate, we will include the risk of bias in our GRADE assessment of study limitations.

**Strategy of data synthesis:** Enumeration data will be expressed as relative risk (RR), measurement data as mean difference, and each effect will be expressed with a 95% confidence interval (CI). Dichotomous outcomes will be evaluated by RR values and corresponding 95% CIs. Some trials may have missing data, in which case we will contact the study authors to obtain additional relevant information. When a subset differs only from the entire set or the difference is very small, sensitivity analysis may not be necessary. In addition, we will split the placebo group in half to avoid unit of analysis errors when analyzing multi-arm trials with a single placebo group and two treatment groups with different doses.

**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.

**Contributions of each author:**

Author 1 - Xiaocen Wang.
Email: wangxiaocen@stu.cdutcm.edu.cn
Author 2 - QuanWei Ren.
Author 3 - Jing Zhou.
Author 4 - Li Zhou.
Author 5 - Xinning He.
Author 6 - Xinyi He.