SOUTH BAYLO UNIVERSITY

Effectiveness of Acupuncture in Treating Subjective Tinnitus: A Systematic Review and Meta-Analysis

by

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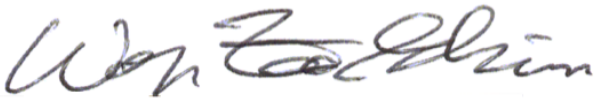

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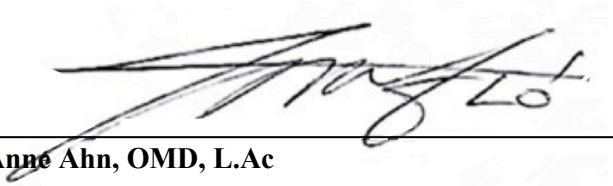

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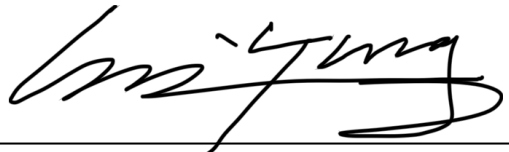

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ABSTRACT

Background: Tinnitus, which is characterized by the perception of sound with no external acoustic signal, affects approximately 15% of the population. While most individuals with tinnitus are not severely impaired, around 2.4% experience significant distress. [1] Despite numerous therapies, no definitive cure exists. Acupuncture and Oriental medicine (AOM) practice has gained attention as a potential treatment, but evidence remains conflicting.

Methods: We conducted a systematic review and meta-analysis (SR & MA) of randomized controlled trials (RCTs) evaluating the therapeutic effect of acupuncture to treat with subjective tinnitus. Databases including studies from Cochrane library, PubMed, EMBASE, KTKP, OASIS, Wan fang Data, Google Scholar and other electronic references, and this search were up to April 2025. The PRISMA guidelines and PICO framework were followed, and risk of bias was assessed by using the Cochrane tool. The outcome of Visual analog scale (VAS) and Tinnitus Handicap Inventory (THI) were collected, assessed and review by software Revman5.4.1.

Results: From total studies of 3617, 6 RCTs studies, 375 participants were selected on this systematic review and meta-analysis based on the established criteria. This study shows Acupuncture treatment has significant improvement for subjective tinnitus with VAS score [MD -4.85 (-4.96, -4.74), 95% CI, $P < 0.00001$] $I^2 = 95\%$, and THI score [MD -29.23 (-32.67, -25.8), 95% CI, $P < 0.00001$] $I^2 = 91\%$. However, there are some limitations are noted.

Conclusion: Acupuncture and Oriental medicine (AOM) treatment effectively and safely reduce the symptoms of patient with subjective tinnitus.

Keyword: Subjective tinnitus, Acupuncture, Randomized controlled trials (RCTs), Systematic review and Meta-analysis (SR & MA)

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I. INTRODUCTION

Tinnitus is a prevalent symptom associated with various conditions and diseases; both otological and non-otological. It affects over 70 million people in Europe and over 50 million people in the United States. A large majority of people with tinnitus have experienced the symptoms for at least 3 to 6 months, and their condition has an unknown etiology [2].

Tinnitus, originating from the Latin word ‘tinnire’ (‘to ring’), is a perception of sound in proximity to the head with the absence of an external source [3]. It may be described as buzzing, ringing, roaring, whistling or hissing and can be variable and complex. Tinnitus may be intermittent, continuous or pulsatile, with the latter being at best annoying and often quite distressing. Most cases are associated with hearing loss induced by exposure to a prolonged noise environment or by ageing. While the prevalence of tinnitus in people with normal hearing is 26.6%, it increases to 35.1% in people with hearing loss. The incidence of tinnitus is not related with age or sex. The problem is categorized into two types: objective and subjective. Objective tinnitus is recordable and mostly has a vascular or muscular origin. Subjective tinnitus is more common and cannot be heard by the examiner. The 5-year incidence rate of subjective type is about 5.7% [4]. The pathophysiological mechanism of tinnitus is still unclear, as the cochlear pathology and somatic modifications are all probable mechanisms. Currently, no treatments have been proven capable of eliminating tinnitus itself, but there are still treatment options. Intratympanic dexamethasone injection (ITDI) is one of the potential treatment options [5], and psychological interventions that reduce anxiety and

depression associated with tinnitus are reported by patients to be beneficial, despite the tinnitus sensation itself normally still being persistent [6]. However, these medicines have multiple side effects [7], so tinnitus treatment has always been a medical challenge.

Acupuncture, as a complementary or alternative medicine therapy, has been reported in many research articles can alleviate the symptoms and signs of subjective tinnitus for numerous patients. Study has been found stimulation of acupuncture at certain points leads to alterations in the release of neurotransmitters, such as serotonin, oxytocin and endorphins, through the central nervous system (CNS). When further check with functional MRI, it has shown positive changes in blood circulation in different parts of the brain with acupuncture stimulation [8].

Many studies have been conducted to evaluate the efficacy of Acupuncture and Oriental Medicine (AOM) treat with subjective tinnitus. While some studies report positive effects on tinnitus loudness and quality of life, but other studies highlight methodological weaknesses and inconsistent outcomes. And the results are still inconsistent and sometimes contradictory. Thus, we conduct this study synthesizes recent evidence findings from RCTs to assess the efficacy, safety and mechanisms of AOM in managing subjective tinnitus.

OBJECTIVES

This study appraises critical evidence from relevant studies and presents a comprehensive evaluation of the therapeutic value of acupuncture, including the efficacy of acupuncture in treating subjective tinnitus.

The detail objectives for this study are:

1 Conduct a thorough systematic review of current research on Acupuncture and Oriental Medicine (AOM) treatment on subjective tinnitus, analyzing and evaluating the findings.

2 Use a rigorous each method to select reliable random control trials study on Acupuncture and Oriental Medicine (AOM) treatment on subjective tinnitus that provide outcome data.

3 Organize the detail of each intervention method, participant characteristics, treatment period, result, adverse effect, etc. Extract the data and table into this Subjective Review and Meta-Analysis.

4 Evaluate the efficacy and safety on Acupuncture and Oriental Medicine (AOM) treatment on subjective tinnitus on an evidence-based medicine perspective by comprehensively exam the result in to this study.

LITERATURE REVIEW

Tinnitus from Western Medicine Perspective

Sound waves travel through the ear canal and into the middle ear, where they cause the eardrum to vibrate. The vibrations travel to the ossicles, or tiny bones in the middle ear, which send them to the cochlea, a spiral cavity in the inner ear. The cochlea is filled with fluid called endolymph that moves in response to the vibrations. This movement stimulates hair cells in a structure called the organ of Corti, which are tiny sensors that convert the vibrations into electrical impulses. The impulses travel along the auditory nerve, also known as the vestibulocochlear nerve (CN VIII), to the brain's auditory cortex for interpretation. The brain then translates the information into sound [9].

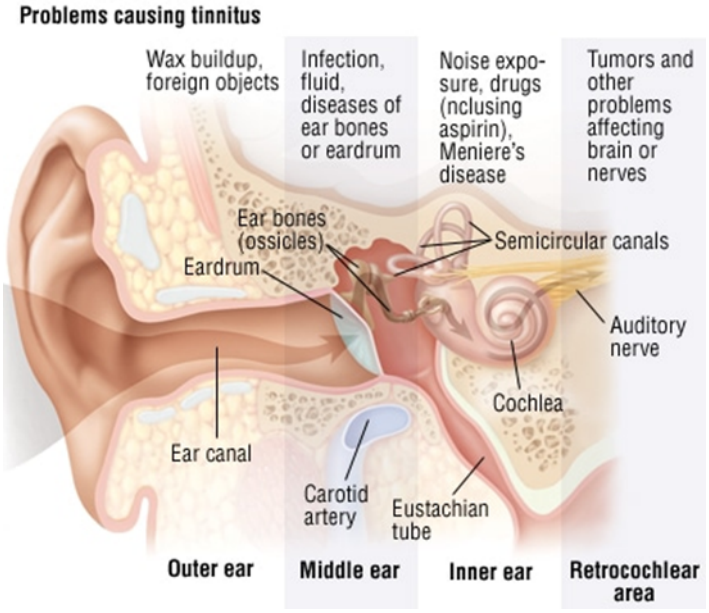

Figure 1. Problem of tinnitus

Tinnitus can occur anywhere along the auditory pathway, from the outer ear to the brain's auditory cortex. It is a symptom that something is wrong with the auditory system, which can include the cochlea, auditory nerve, and areas of the brain that process sound.

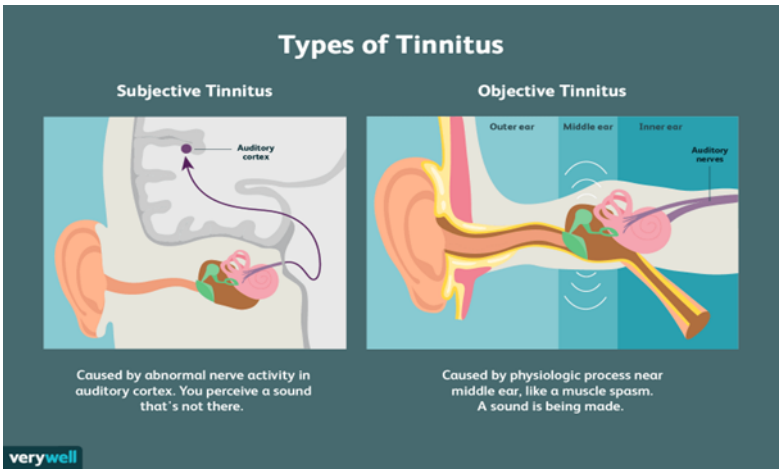

Figure 2. Types of Tinnitus

Tinnitus can be divided into subjective tinnitus and objective tinnitus [10]. Subjective tinnitus is only the patient can hear the noise, which is usually non-rhythmic and caused by an abnormality in the auditory pathway. Common causes include loud noises, aging, Meniere's disease, migraines, and drugs. Tinnitus retraining therapy (TRT), which combines sound therapy and counseling, can be an effective treatment for subjective tinnitus. Objective tinnitus is defined as a person can hear the noise, which is often rhythmic and caused by an actual noise produced near the ear. This can be because of conditions that affect mechanical structures near the ears, such as high blood pressure or muscle contractions. Sometimes, an examiner can use a stethoscope to hear the noise.

Causes, Symptoms, Diagnosis, Treatment in Western Medicine approach.

The cause of subjective tinnitus may be because of various reason, which include

Hearing loss, Cochlear Damage or Dysfunction, Neurological Factors, Vascular & Circulatory Issues, Temporomandibular Joint (TMJ) & Musculoskeletal Disorders, Medications, Metabolic & Autoimmune Disorders, Psychological & Stress-Related Factors, Other Causes [11]. The detail of each is list following:

Hearing Loss (Most Common Cause)

Age-related hearing loss (Presbycusis) – Degeneration of hair cells in the inner ear.

Noise-induced hearing loss – Exposure to loud noises (concerts, machinery, headphones) damaging cochlear hair cells.

Sudden sensorineural hearing loss (SSNHL)–Rapid hearing loss, often idiopathic, sometimes linked to viral infections or vascular issues.

Cochlear Damage or Dysfunction

Inner ear hair cell damage–These cells convert sound waves into neural signals; when damaged, they can send false signals to the brain.

Endolymphatic hydrops (Ménières's disease)–Fluid imbalance in the inner ear causing tinnitus, vertigo, and hearing loss.

Neurological Factors

Auditory nerve dysfunction – Issues with the vestibulocochlear nerve (e.g., acoustic neuroma/vestibular schwannoma).

Central auditory pathway changes–Brain rewiring (neuroplasticity) because of hearing loss, leading to phantom sounds.

Vascular & Circulatory Issues

Hypertension (high blood pressure)–Increased blood flow can cause pulsatile or non-pulsatile tinnitus.

Atherosclerosis–Narrowed arteries near the ear creating turbulent blood flow.

Venous hum – Abnormal blood flow in jugular veins or near the ear.

Temporomandibular Joint (TMJ) & Musculoskeletal Disorders

Jaw misalignment or clenching – Can affect ear structures or muscles, leading to tinnitus.

Cervical spine issues (e.g., whiplash, neck tension) – Nerve or muscle dysfunction referring signals to the auditory system.

Medications (Ototoxic Drugs)

NSAIDs (e.g., aspirin, ibuprofen)–High doses can cause temporary tinnitus.

Antibiotics (e.g., aminoglycosides, erythromycin) – Can damage inner ear cells.

Loop diuretics (e.g., furosemide)–May cause fluid imbalances in the cochlea.

Chemotherapy drugs (e.g., cisplatin) – Often ototoxic.

Antidepressants (e.g., SSRIs, SNRIs)–Rarely may worsen tinnitus.

Metabolic & Autoimmune Disorders

Hypothyroidism or hyperthyroidism–Thyroid dysfunction can contribute.

Diabetes–May affect blood flow to the inner ear.

Autoimmune inner ear disease (AIED) – Immune system attacks inner ear structures.

Psychological & Stress-Related Factors

Chronic stress or anxiety–Can heighten tinnitus perception via increased neural sensitivity.

Depression–May worsen the distress associated with tinnitus.

Other Causes

Earwax blockage–Pressure changes in the ear canal can trigger tinnitus.

Eustachian tube dysfunction – Fluid or pressure imbalance in the middle ear.

Post-viral infections (e.g., after COVID-19, flu, or cold) – May trigger or worse tinnitus.

Symptoms: include both primary symptoms and secondary symptoms.

Primary Symptoms:

1 Phantom Sounds–Perception of noises such as

Ringing (most common), Buzzing, Hissing, Whistling, Roaring, Clicking, Humming.

2 Variable Pitch & Volume–Sounds may be high-pitched (common with hearing loss) or low-pitched, and volume can fluctuate.

3 Intermittent or Constant–Some experience occasional tinnitus, while others have it continuously.

4 Unilateral or Bilateral–Can occur in one ear (unilateral) or both (bilateral).

Associated Symptoms (May Worsen Distress):

Hearing Loss (often accompanies tinnitus, especially age-related or noise-induced)

Hyperacusis (increased sensitivity to normal environmental sounds)

Ear Fullness/Pressure (sometimes linked to conditions like Meniere's disease)

Difficulty Concentrating (because of persistent noise)

Sleep Disturbances (tinnitus may be more noticeable in quiet environments)

Anxiety/Depression (chronic tinnitus can lead to emotional distress)

Triggers/Aggravating Factors:

Exposure to loud noise, stress or fatigue, Earwax blockage, Ototoxic medications (e.g., high-dose aspirin, certain antibiotics), caffeine, alcohol, or nicotine (varies by individual).

Diagnosis

Detailed Medical History [12]

Onset & Duration: Sudden vs. gradual, acute (<6 months) or chronic (>6 months).

Characteristics: Pitch (high/low), laterality (unilateral/bilateral), constant vs. intermittent, pulsatile (suggests vascular etiology).

Aggravating/Alleviating Factors: Noise exposure, stress, jaw movement (TMJ involvement).

Associated Symptoms**:** Hearing loss, ear fullness (Ménières's disease). Vertigo (vestibular disorders). Otalgia, discharge (otitis media, infection).

Risk Factors: Noise exposure, ototoxic medications (e.g., NSAIDs, aminoglycosides), head/neck trauma, and cardiovascular disease.

Physical Examination [13]

Otoscopy: Rule out cerumen impaction, otitis externa/media, eardrum perforation. Auscultation (for pulsatile tinnitus). Carotid bruit (atherosclerosis). Venous hum (jugular vein anomalies). Neurologic Exam: Cranial nerve assessment (e.g., facial nerve for vestibular schwannoma). TMJ/Temporal Palpation: Tenderness suggests temporomandibular joint dysfunction.

Hearing Evaluation [14]

Pure-Tone Audiometry: Identifies sensorineural or conductive hearing loss.

Tinnitus Pitch & Loudness Matching: Helps characterize tinnitus but have limited diagnostic value.

Speech Audiometry: Assesses speech discrimination (poor scores may suggest retrocochlear pathology).

Additional Tests [12]

Unilateral Tinnitus + Asymmetric Hearing Loss:

MRI with Gadolinium: Rule out vestibular schwannoma (acoustic neuroma).

Auditory Brainstem Response (ABR): If MRI is contraindicated.

Pulsatile Tinnitus:

CT Angiography/MRA/MRV: Evaluate vascular causes (e.g., arteriovenous malformation, venous sinus stenosis).

Temporal Bone CT: For suspected glomus tumor or otosclerosis.

Sudden Sensorineural Hearing Loss (SSNHL):

Urgent audiometry + MRI if unilateral (rule out retrocochlear lesion).

Questionnaires & Functional Assessment

Tinnitus Handicap Inventory (THI) or Tinnitus Functional Index (TFI): Quantifies impact on quality of life.

Psychiatric Screening: Anxiety/depression (common comorbidities).

Differential Diagnosis [15]

Otologic: Noise-induced hearing loss, presbycusis, Ménières's disease.

Neurologic: Vestibular schwannoma, multiple sclerosis.

Vascular: Carotid stenosis, dural arteriovenous fistula.

Musculoskeletal: TMJ dysfunction, cervical spine issues.

Metabolic: Thyroid dysfunction, vitamin B12 deficiency.

Specialist regard to key symptoms

ENT (Otolaryngologist): Unilateral/pulsatile tinnitus, asymmetric hearing loss, associated vertigo.

Audiologist: Hearing rehabilitation (hearing aids, sound therapy).

Neurologist/Neurosurgeon: Suspected central causes (e.g., MS, AVM).

Treatment

Medical Interventions [16]**:**

Hearing Aids**:** Effective for those with hearing loss, amplifying external sounds to mask tinnitus.

Medications**:** Off-label use of antidepressants (e.g., amitriptyline) or anti-anxiety drugs (e.g., benzodiazepines) for comorbid conditions; caution because of side effects/dependence.

Treat Underlying Conditions: Address issues like ear infections, vascular disorders, or TMJ dysfunction.

Sound Therapy:

Masking Devices: Wearable noise generators or smartphone apps producing white noise, nature sounds, or customized tones.

Tinnitus Retraining Therapy (TRT): Combines directive counseling with sound enrichment to promote habituation.

Hearing Aids with Masking Features: Integrate amplification and sound generation.

Psychological and Behavioral Approaches:

Cognitive-Behavioral Therapy (CBT): Helps reframe negative thoughts and reduce emotional distress.

Mindfulness and Stress Reduction**:** Techniques like meditation, yoga, or biofeedback to lower stress exacerbating tinnitus.

Lifestyle Modifications**:**

Avoid Triggers: Limit caffeine, alcohol, nicotine, and loud noise exposure.

Sleep Hygiene: Improve sleep quality to reduce tinnitus perception.

Diet and Exercise: Balanced diet and regular physical activity for overall well-being.

Alternative Therapies:

Acupuncture: Mixed evidence; some report temporary relief.

Supplements: Ginkgo biloba, zinc, or magnesium often tried, though efficacy is unproven.

Emerging Therapies

Neuromodulation: Techniques like Transcranial Magnetic Stimulation (TMS) or bimodal stimulation (combining sound with electrical pulses) show promise in clinical trials.

Cochlear Implants: For severe hearing loss, may reduce tinnitus perception by restoring auditory input.

Support and Counseling

Support Groups: Peer-led groups (e.g., American Tinnitus Association) for shared experiences.

Counseling: Audiologists or psychologists provide coping strategies and emotional support.

Individualized Approach

Treatment plans should be personalized, often combining multiple strategies. Regular follow-ups adjust interventions based on progress.

<u>Subjective tinnitus from Acupuncture and Oriental Medicine (AOM) perspective</u>

Causes:

In Acupuncture and Oriental Medicine (AOM), subjective tinnitus is viewed as a manifestation of imbalances in the body's Qi, blood, and organ systems, particularly the Kidneys, Liver, Gallbladder, Heart, and Spleen. Diagnosis involves assessing symptoms and disease patterns, tongue appearance, pulse quality, and lifestyle factors to identify underlying patterns. The disease pattern includes Kidney Deficiencies, Liver Imbalances, Heart Fire, Phlegm-Dampness Obstruction, Blood/Qi Deficiency, External Pathogens, Emotional Factors [17] [18].

Kidney Deficiencies- Kidney Yin Deficiency and Kidney Yang Deficiency, External Pathogens

Kidney Yin Deficiency:

Pathology: Inadequate nourishing Yin leads to "deficiency-fire" disturbing the ears.

Symptoms: Tinnitus (high-pitched, gradual onset), dizziness, night sweats, lower back pain, red tongue with little coating.

Treatment: Nourish Yin (e.g., Liu Wei Di Huang Wan).

Kidney Yang Deficiency:

Pathology: Weakness in warming and ascending Qi to the ears.

Symptoms: Tinnitus (low-pitched, chronic), cold limbs, frequent urination, pale tongue.

Treatment: Tonify Yang (e.g., Jin Gui Shen Qi Wan).

Liver Imbalances- Liver Fire Rising and Liver Yang Rising

Liver Fire Rising:

Pathology: Stagnant Liver Qi transforming into fire that ascends.

Symptoms: Sudden loud tinnitus, irritability, red face, bitter taste (may involve Gallbladder Fire).

Treatment: Clear Liver Fire (e.g., Long Dan Xie Gan Tang).

Liver Yang Rising:

Pathology: Often from Kidney Yin Deficiency failing to control Liver Yang.

Symptoms: Tinnitus with headaches, hypertension, taut pulse.

Treatment: Subdue Yang and nourish Yin (e.g., Tian Ma Gou Teng Yin).

Heart Fire

Pathology: Emotional stress generating Heart Fire disturbing the upper orifices.

Symptoms: Tinnitus with palpitations, insomnia, red tongue tip.

Treatment: Clear Heart Fire (e.g., Dao Chi San).

Phlegm-Dampness Obstruction

Phlegm-Fire Harassing the Upper Body:

Pathology: Spleen dysfunction leading to phlegm accumulation, combining with heat.

Symptoms: Tinnitus with muffled sensation, dizziness, obesity, greasy tongue coating.

Treatment: Resolve phlegm and clear heat (e.g., Wen Dan Tang).

Blood/Qi Deficiency

Blood Deficiency:

Pathology: Insufficient Blood to nourish the ears (linked to Spleen/Liver).

Symptoms: Tinnitus worsened by fatigue, pale complexion, thin pulse.

Treatment: Tonify Blood (e.g., Si Wu Tang).

Qi Deficiency:

Pathology: Weak Spleen/Lungs failing to lift Qi to the head.

Symptoms: Mild tinnitus, fatigue, poor appetite.

Treatment: Strengthen Qi (e.g., Bu Zhong Yi Qi Tang).

External Pathogens

Wind-Heat Invasion:

Pathology: External Wind-Heat blocking ear meridians (acute cases).

Symptoms: Sudden tinnitus post-cold/flu, fever, floating pulse.

Treatment: Expel Wind-Heat (e.g., Yin Qiao San).

Emotional Factors [19]

Chronic stress or anger causing Liver Qi stagnation, which may progress to Fire or Yang Rising.

Daily dietary factors [20]

Lower incidence of tinnitus has linked with particular food intake daily.

Differentiation and Treatment Principles

Deficiency vs. Excess:

Deficiency (Kidney/Liver Yin, Blood/Qi): Chronic, improves with rest.

Excess (Liver Fire, Phlegm): Sudden, loud, aggravated by stress.

Holistic Approach: Herbal formulas, acupuncture, dietary adjustments, and stress management.

Thus, Western medicine treatment on subjective tinnitus are targets of physiological causes (e.g., hearing loss, vascular issues) with sound therapy, CBT, or hearing aids. And Acupuncture and Oriental Medicine (AOM) focuses on systemic imbalances and use personalized herbal and acupuncture regimens. Each one has its own benefits.

II. MATERIALS AND METHODS

2.1 Materials

2.1.1 Literature Search and Selection Material (PICO)

The PICO (population, intervention, comparison, outcomes) applied to Acupuncture and Oriental Medicine (AOM) research article with study design of Randomized Controlled Trial only, and topic with "effectiveness of Acupuncture and Oriental Medicine (AOM) treatment on primary Tinnitus". The detail is a list on the following table:

Table 1. PICO elements and keywords

Component	Description
Population	Adults (>18 years) with subjective tinnitus (idiopathic or primary)
Intervention	Acupuncture (manual, electro-, scalp, or warm acupuncture) ± conventional therapy
Comparison	Sham acupuncture, medication, sound therapy, or no treatment
Outcomes	Tinnitus severity (VAS, THI), clinical efficacy rate, adverse events, etc.
Study design	Randomized Controlled Trial only

2.1.2 Data source and search method

This study is aimed at Systematic Review and Meta- Analysis on evidence base study on effectiveness of Acupuncture treatment on primary, subjective, idiopathic tinnitus. For

this Systematic Review and Meta- Analysis, only randomized controlled trial study will be considered. The following databases were searched to identify relevant studies from January 1st, 2000 to April 1st, 2025. The study includes language with English, Korean and Chinese.

- English databases: Cochrane library, PubMed, EMBASE
- Korean databases: Korean Traditional Knowledge Portal (KTKP), Oriental Medicine Advanced Searching Integrated System (OASIS)
- Chinese databases: Wan fang Data
- Other: Google Scholar and other electronic references

2.1.3 Searching keywords.

The language of study is restricted to English only. The keywords include any combination include, “Acupuncture and Oriental Medicine (AOM)”, “Traditional Chinese Medicine (TCM)”, “Oriental Medicine (OM)”, “Traditional Korean Medicine (TKM)”, “Chinese Medicine”, “Japanese Medicine (Kampo)”, “Acupuncture”, “Acupuncture treatment”, “Randomized controlled trial”, “Subjective Tinnitus”, “Primary tinnitus”, “Idiopathic tinnitus” and son on. The study selected has to have at least one outcome of variables: 1) VAS, 2) THI, 3) THS, 4) effective rate, 5) adverse effect, etc.

2.1.4. Selection of Materials

The research papers include in the study we searched are specifically on randomized

controlled trials (RCTs), with human trial only.

Inclusion criteria:

1 Study Design: Randomized controlled trials (RCTs) comparing acupuncture (alone or combined) with control interventions (sham, medication, no treatment).

2 Population: Adults (>18 years) diagnosed with subjective tinnitus (idiopathic or primary).

3 Intervention: Manual acupuncture, electroacupuncture, scalp acupuncture.

4 Outcomes: At least:

Tinnitus severity (Visual Analog Scale [VAS] or Tinnitus Handicap Inventory [THI]).

Clinical efficacy rate (as defined by included studies).

Adverse effect.

Language: English

Exclusion criteria:

1 non-RCTs (e.g., case reports, observational studies).

2 Studies on objective or secondary tinnitus (e.g., because of Meniere's disease, tumors).

3 Trials without a control group or with unclear outcome measures.

4 Duplicate publications or studies with insufficient data.

5 Animal studies, reviews, or non-peer-reviewed articles.

6 Inaccessible publish and data.

2.1.5. Data Extraction

We used the PICO method to extract data for systematic review and meta-analysis of these studies. Follow the guideline of P-I-C-O, the data were extracted by following order:

Table 2. Guideline of P-I-C-O

Data Item	Description
Study Characteristics	Author, year, country, study design, sample size, follow-up duration.
Participant Details	Age, gender, tinnitus duration, baseline severity (VAS/THI).
Intervention	Acupuncture type (e.g., manual, electro-), frequency/duration, and acupoints used.
Control	Type of control (sham, medication, sound therapy), dosage/duration.
Outcomes	Post-treatment VAS/THI scores, clinical efficacy rate, adverse events.
Adverse events and others	Any concern and side effects during the treatment

2.1.6. Conversion of the data

The Mean value, median difference, standard mean deviation, standard error, odds ratio, relative risk of the extracted data. Quantitative results of the same concept were derived by checking the basic values of Meta-analysis. The mean difference and 95% CI (confidence interval) value of the change, values of the intervention group, and the control group are used as default value and entered Cochrane Collaboration's Review

Manager 5.4.1 (RevMan 5.4.1).

2.1.7. Data Analysis

The characteristics of the RCTs on primary tinnitus included in this review were: analyzed and summarized by the order of Author and Year, Sample Size and Subject Data, Research Methods, P-Values and Outcomes.

2.2 Methods

2.2.1 Meta-Analysis

The outcome used for this analysis includes visual analog scale (VAS), Tinnitus Handicap Inventory (THI), Tinnitus Severity Index (TSI), Pure Tone Audiometry (PTA), Speech Discrimination Scores, loudness and annoyance of tinnitus, Tinnitus Loudness Severity. The outcome of 6 studies was shown on a forest plot. All the data in the review were continuous, and end-point scores were expressed as SMDs for different scales with associated 95% CI.

2.2.2. Forest plot

In this SR-MA, the forest plot was used to visually summarize and compare the results of the clinical studies under examination. The forest plot serves as a graphical representation of the effect sizes of individual studies and the overall combined effect. Each square within the plot denotes the effect size of a single study, with its size being proportional to the study's weight in the analysis. Including horizontal lines intersecting the squares illustrates the confidence intervals, while a diamond positioned at the base of the plot signifies the overall effect estimate. This visual aid facilitates the assessment of

variation among the study results, evaluation of result consistency, and determination of the overall intervention efficacy. The forest plot aids in the identification of potential publication bias or heterogeneity among the studies encompassed.

2.2.3. Assessment of risk of bias

RoB software provided by RevMan 5.4.1 and the Cochrane Risk of Bias Assessment Tool were used to evaluate the risk of bias. The Cochrane Risk of Bias Assessment Tool comprises seven qualitative elements: random sequence generation (selection bias), allocation concealment (selection bias), blinding of participants and personnel (performance bias), blinding of outcome assessment (detection bias), incomplete outcome data reporting (attrition bias), selective outcome reporting (reporting bias), and other bias. Also, the funnel plot was used to assess the potential reporting bias.

2.2.4. Data Analysis

The data collected from the studies were presented as a mean difference with a 95% confidence interval (CI). The frequency of adverse events was presented as a risk ratio (RR) with a 95% CI. In addition, Higgin's I^2 statistics were used to quantify heterogeneity. Heterogeneity was interpreted according to the I^2 value. The formula for calculating the I^2 value is shown in Appendix I, and the criteria for heterogeneity analysis are:

$0\% \leq I^2 \leq 40\%$: heterogeneity may not be significant.

$30\% \leq I^2 \leq 60\%$: there may be moderate heterogeneity.

$50\% \leq I^2 \leq 90\%$: may be substantially heterogeneous.

$75\% \leq I^2 \leq 100\%$: significant heterogeneity.

2.2.5. Safety and Adverse Effects

The safety and adverse effects of the intervention were identified using the evidence from the studies.

III. RESULTS

3.1. Study Inclusion

Under our review, 3617 studies were initially selected. These include: 198 studies collected from PubMed, 1640 studies collected from Google Scholar, 1283 studies collected from Korean Traditional Knowledge Portal (KTKP), 124 studies collected from Oriental Medicine Advanced Searching Integrated System (OASIS), 315 studies collected from Wan Fang Data, 57 studies collected from Cochrane Library. However, 2858 studies were removed because of either duplicate, or not related to Acupuncture, Subjective Tinnitus. Then 759 studies undergoing screened by title and abstract, 624 studies are excluded due to not design with RCT method. The rest of 135 studies selected for screened for eligibility, 79 studies were excluded due to for either protocol, case report, other systemic review and meta-analysis, herb studies. 56 full-text studies have been reviewed for us; 50 studies were excluded due to reason that could not get the full text and data. Finally, 6 RCT studies meet all criteria were chosen for this Systemic review and Meta-Analysis. The detail of Data-selection for showing the following diagram in Figure 1:

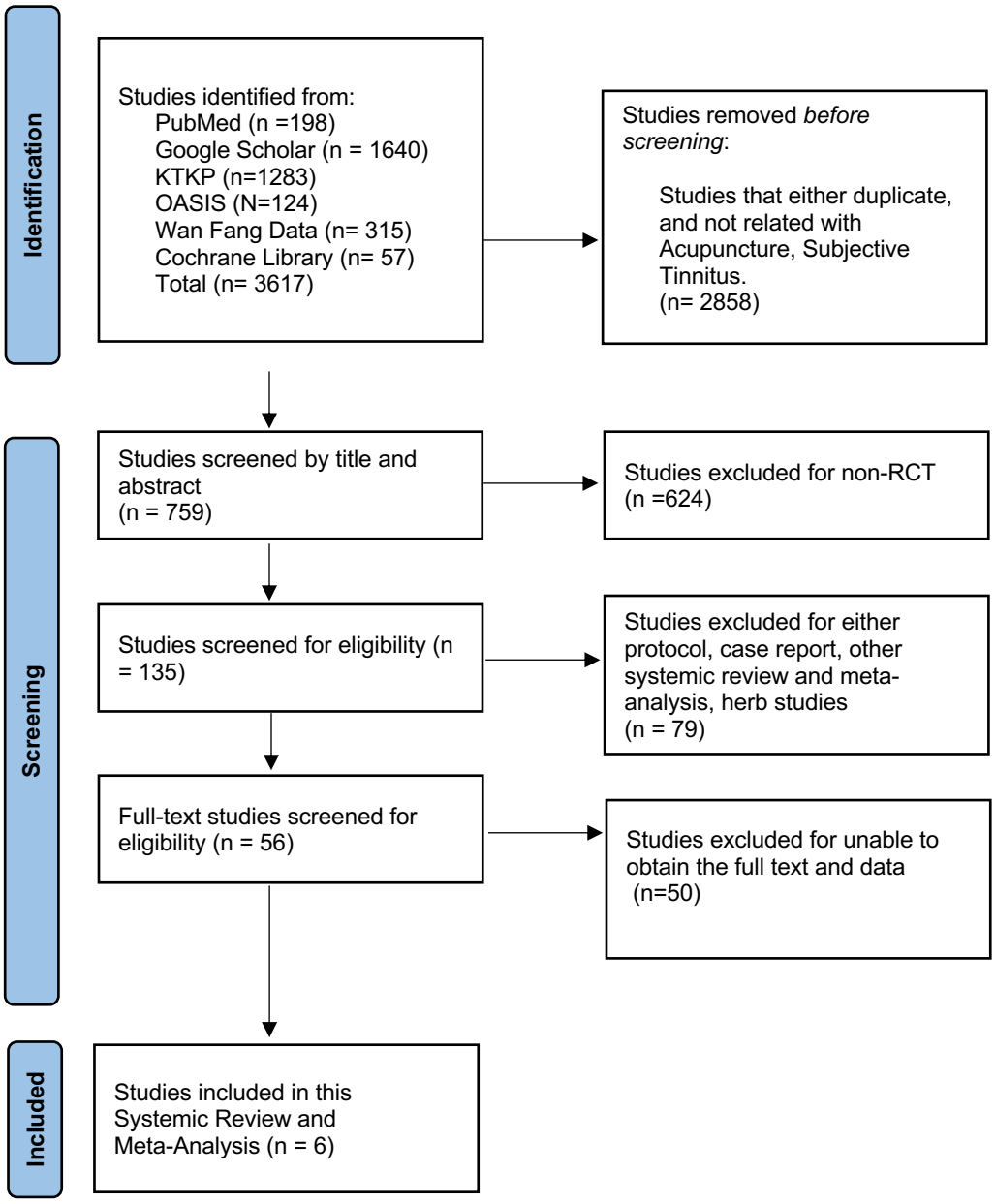

Figure 3. PRISMA Flowchart of Study Selection

3.2 Meta-analysis of Multi-arm Trial

One study is a 3-arm parallel randomized controlled trial and was split into a two-arm randomized controlled trial, which is the Manual Acupuncture group vs Tens unit control group.

Table 3. Data Items Being Extracted from the Selected Literature

Data Component	Data Item
Literature Information	Kuzucu et al. 2020 [21]
Eligibility	Inclusion or Exclusion: Six inclusion criteria and Five exclusion criteria
Methods	A two-arm parallel randomized controlled trial Frequency and period of trial: 2 times per week for 5 weeks. Period of follow-up: 3 months
Participants	Sample size: 105 Experimental group: (n=53. 19 males and 34 females) Control group: (n=52. 17 males and 35 females) Age, Gender, Hearing issues, Hearing loss grade.
Interventions	Acupuncture Group vs. Sham Acupuncture Group Method of intervention: Acupuncture Group: 11 acupuncture points (TE 21, SI 19, GB 2, TE 22, ST 7, TE 17, and GB 20 on the affected side, and TE 5, KI 3 on both sides) Sham Acupuncture Group: false needles were used, and no stimulation was applied.
Outcomes	THI, VAS, PTA, Speech Discrimination Scores
Results	VAS Baseline: 7.26 ± 0.98 vs 6.98 ± 1.12 Five weeks: 2.06 ± 1.09 vs 6.75 ± 1.19 Post-treatment: 3.66 ± 1.38 vs 6.84 ± 1.18 THI: Baseline: 61.11 ± 12.70 vs 59.25 ± 13.10 Five weeks: 30.83 ± 15.90 vs 59.01 ± 13.35 Post-treatment: 40.26 ± 16.56 vs 60.71 ± 13.90
Adverse events	None

Data Component	Data Item
Literature information	Naderinabi et al. 2018 [22]
Eligibility	Inclusion or Exclusion: 5 inclusion and 8 exclusions
Methods	A two-arm parallel randomized controlled trial Frequency and period of trial: 3 times per week for 5 weeks. Period of follow-up: 3 weeks
Participants	Sample size: 88 Experimental group: (n=44. 26 males and 18 females) Control group: (n=44. 27 males and 17f females) Age, Gender, Hearing issues, Hearing loss grade.
Interventions	Acupuncture Group vs. Sham Acupuncture Group Method of intervention: Acupuncture Group: GB2, GB20, SJ21, SI19, SJ17, SJ3, SJ5, LI4, and SI6 Sham Acupuncture Group: fake needles, next to the acupuncture points.
Outcomes	VAS, TSI, PTA, IA, SRT and SDS
Results	VAS Baseline: 9.56±0.43 vs 9.54±0.45 Three weeks: 2.88±0.33 vs 7.86±0.23 Post-treatment: 2.25±0.27 vs 7.81±0.23 TSI Baseline: 43.84±2.81 vs 43.52±2.94 Three weeks: 24.82±1.04 vs 33.16±1.24 Post-treatment: 23.11±1.03 vs 33.13±1.29
Adverse events	None

Data Component	Data Item
Literature information	Kim et al. 2020 [23]
Eligibility	Inclusion or Exclusion: 4 inclusion and 8 exclusions
Methods	A three-arm parallel randomized controlled trial Frequency and period of trial: 2 times per week for 5 weeks. Period of follow-up: 4 weeks
Participants	Sample size: 30 Manual Acupuncture group: (n=15) Tens (n=15) Age, Gender, Duration, Bilateral tinnitus, Somatosensory tinnitus
Interventions	Manual Acupuncture Group vs Tens group Method of intervention: Manual Acupuncture group: 11 acupoints (TE21, SI19, GB2, TE22, ST7, TE17, and GB20 on the affected side and GB20, TE05, and KI3 on both sides) Tens group: A pair of electrodes was attached to the tender point of the sternomastoid muscle and mastoid process (C2 dermatome) on the affected side, and the other pair of electrodes was placed at the trigger point of the masseter muscle and the temporomandibular joint in front of the tragus.
Outcomes	THI, VAS, loudness and annoyance of tinnitus, PTA, SD, Adverse event
Results	THI Baseline: 41.73 ± 23.84 vs 49.47 ± 22.90 Five weeks: −11.33 ± 12.23 vs −1.02 ± 12.21 Post-treatment: −8.67 ± 10.55 vs −5.60 ± 12.26 VAS Baseline: 5.70 ± 1.95 vs 6.76 ± 1.74 Five weeks: −1.03 ± 2.00 vs −1.35 ± 1.56 Post-treatment: −0.75 ± 1.70 ±1.03 vs −1.04 ± 1.58
Adverse events	In the MA group, two mild cases were reported, one participant had transient ear numbness near the acupoint, and one had vertigo.

Data Component	Data Item
Literature information	Doi et al. 2016 [24]
Eligibility	Inclusion or Exclusion: 4 inclusion and 5 exclusions
Methods	A two-arm parallel randomized controlled trial Frequency and period of trial: 2 times per week for 5 weeks. Period of follow-up: no follow up
Participants	Sample size: 46 Experimental group: (n=22. 8 males and 14 females) Control group: (n=24. 10 males and 14 females) Age, Gender, Hearing assessment, Hearing grade.
Interventions	Acupuncture Group vs. Sham Acupuncture Group Method of intervention: Acupuncture Group: Electrostimulation. bilaterally in the vestibulocochlear line, located 1.5 cm above the ear apex in a horizontal line segment corresponding to 4 cm. Sham Acupuncture Group: No treatment.
Outcomes	VAS, THI
Results	VAS Baseline: 8 [7–9] vs 8 [7.5–9.5] Five weeks: 4 [3–6] vs 8 [8–10] THI Baseline: 56 [44–65.5] vs 58 [48–76] Five weeks: 28 [8–55.5] vs 68 [46–76]
Adverse events	None

Data Component	Data Item
Literature information	Mehrdad et al. 2011 [25]
Eligibility	Inclusion or Exclusion: 3 inclusion and 3 exclusions
Methods	A two-arm parallel randomized controlled trial Frequency and period of trial: 3 times per week for 5 weeks. Period of follow-up: no follow up
Participants	Sample size: 54 Experimental group: (n=27) Control group: (n=27) Age, Gender, Hearing assessments
Interventions	treatment vs Control group Method of intervention: Treatment Group: TE17, GB2, SI19, TE21, and several secondary (accessory) acupoints were also added depends on diagnosis pattern. Control Group: fake needles
Outcomes	TSI, Tinnitus Loudness Severity
Results	TSI Baseline: 46.9 ± 7.9 vs 46.6 ± 7.6 Five weeks: 31.7 ± 11.1 vs 42.9 ± 10.4 VAS Baseline: 8.9 ± 1.3 vs 8.7 ± 1.1 Five weeks: 5.3 ± 3 vs 7.5 ± 2.2
Adverse events	None

Data Component	Data Item
Literature information	Maura et al. 2016 [26]
Eligibility	Inclusion or Exclusion: 5 inclusion and 5 exclusions
Methods	A two-arm parallel randomized controlled trial Frequency and period of trial: 2 times per week for 6 weeks. Period of follow-up: no follow up
Participants	Sample size: 52 Experimental group: (n=27) Control group: (n=25) Age, Gender, Duration of tinnitus, Location, Type of tinnitus, Use of psychotropic. Years of education.
Interventions	Treatment vs Control group Method of intervention: Treatment Group: DU20, TE17, GB8, SI19, GB2, TE21, CV23, GB20, TE2, TE5, SI2, GB43, GB41. Also, DU4, KD3, UL23, BL1, BL18, and CV4 are added as needed based on the TCM etiological diagnosis of tinnitus. Control Group: stimulated non-acupuncture points according to a computer-generated list of random numbers.
Outcomes	SPECT measurements, THI, VAS, BDI and HAS
Results	THI Baseline: 48 ± 19.45 vs 54 ± 18.42 Six weeks: 33.19 ± 17.53 vs 48.96 ± 22.23 VAS Baseline: 6.22 ± 2.36 vs 7.67 ± 2.12 Six weeks: 5.72 ± 2.48 vs 6.76 ± 2.44
Adverse events	None

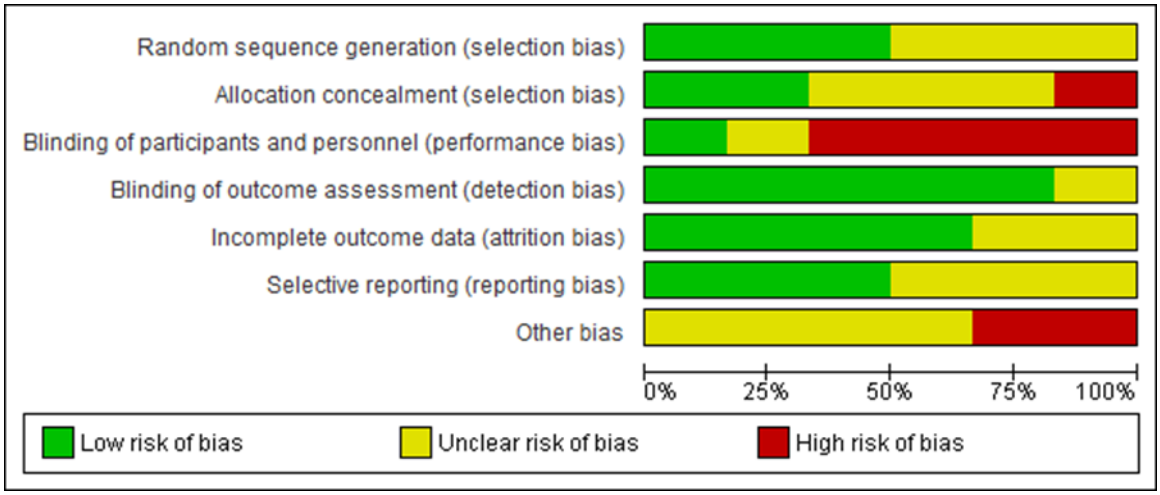

Figure 4. Risk of Bias Distribution Graph

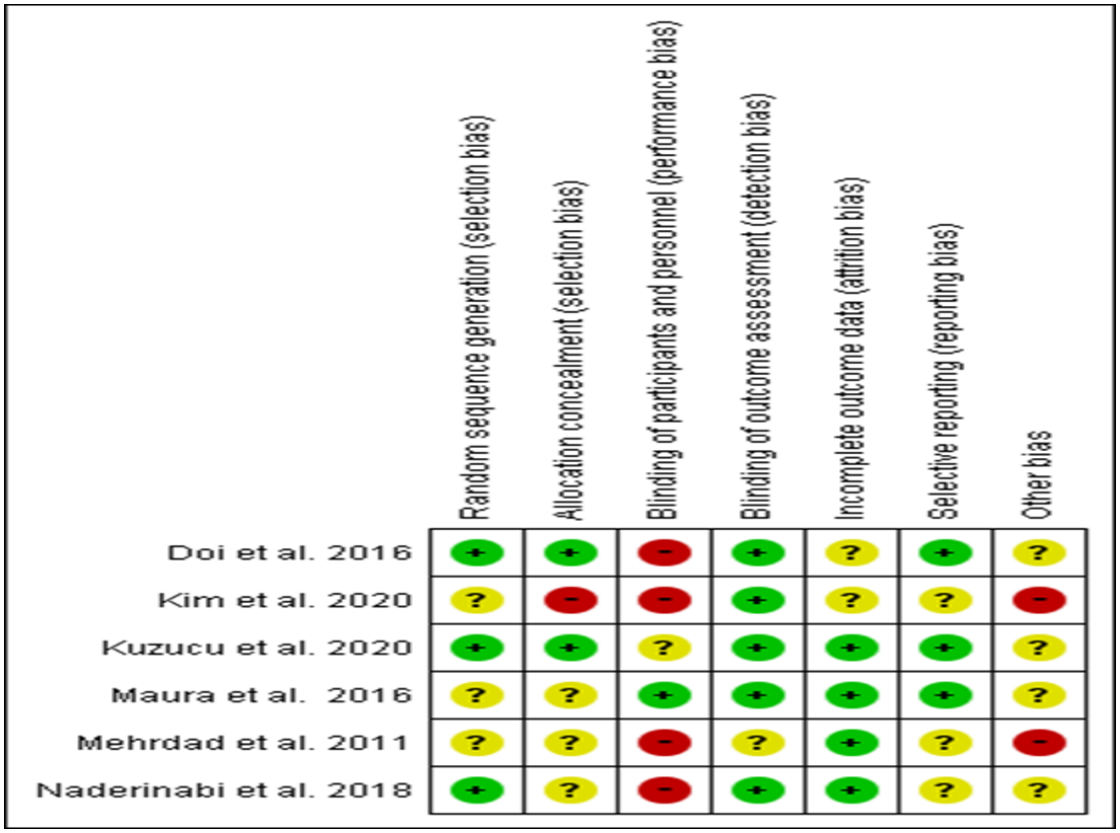

Figure 5. Risk of Bias Summary

3.3 Risk of Bias.

We evaluate the 6 RCT studies for this SR-MA. The software RevMan 5.4.1 was used to evaluate to type of risk of bias according to the criteria. The summary of the comprehensive qualitative evaluation is shown in figure. Based on the figure, the most of concern of bias came from Randomization sequence and other bias. High risk of concern under Blinding of participants/personnel.

Most of the studies conducted the randomization sequence using computer-generated random numbers or simple randomization methods. However, 3 of 6 studies cannot detail randomization methods. (Kim et al. 2020, Maura et al. 2016, Mehrdad et al, 2011).

Under the section of Allocation Concealment, one study has risk of Open-label designs, this led to increased risk of bias. (Kim et al. 2020). Other studies' sequence was well concealed, and participants and outcome assessors were blinded.

Under the section on Blinding of participants/personnel, 4 of 6 studies show a high risk of bias. All have shown concern for no blinding of participants. (Doi et al. 2016, Kim et al. 2020, Mehrdad et al. 2011, Naderinabi et al. 2018).

Also, one study has concern of the smaller sample size and heterogeneous protocols and outcomes (Kim et al. 2020). Another has concern of risk on significant difference occur at baseline (P=0.005). (Naderinabi et al. 2018).

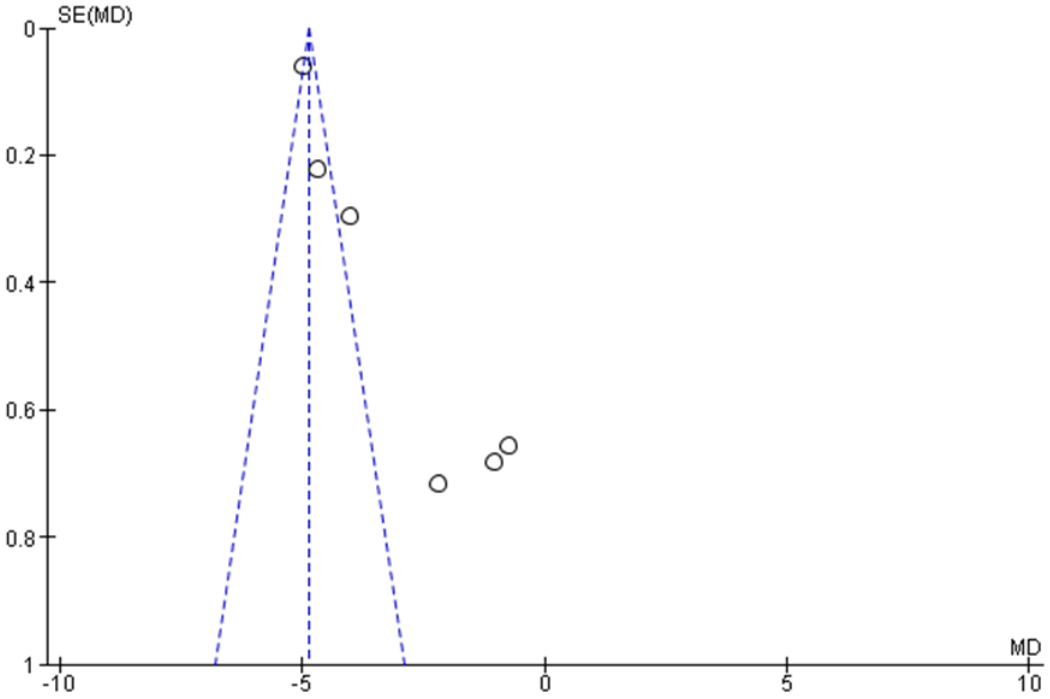

Figure 6. Funnel Plot of the included studies in terms of VAS

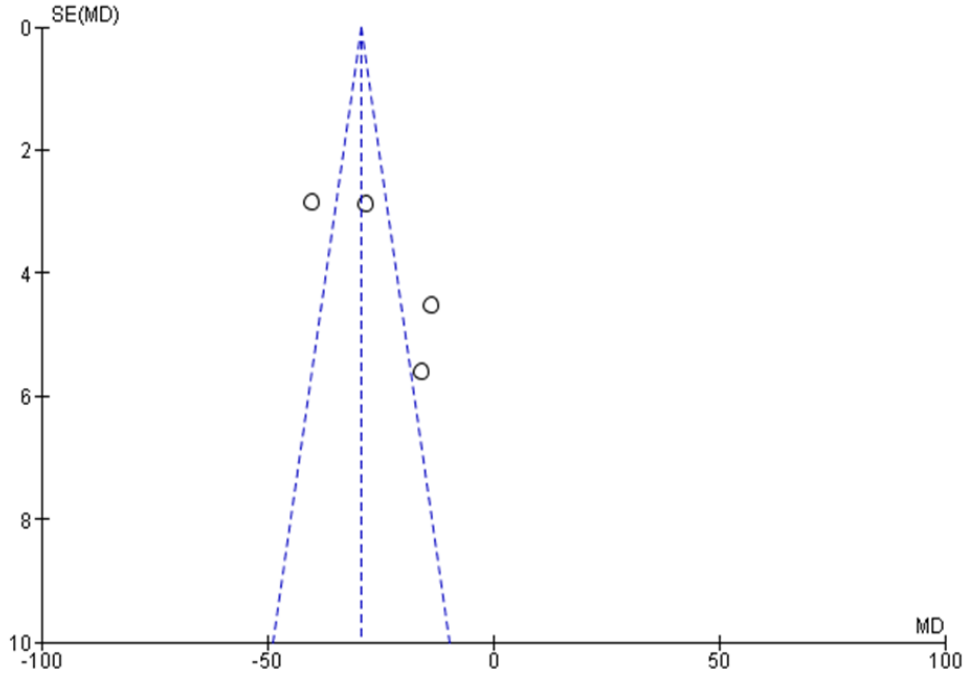

Figure 7. Funnel Plot of the included studies in terms of THI

3.4 Publication bias

Funnel plots are used to detect publication bias for SR-MA. The central line represents the combined effect size, and studies should be symmetrically distributed around this line if there is no publication bias. Larger studies appear near the top of the plot, close to the central line, while smaller studies are spread out at the bottom. Asymmetry in the plot suggests potential publication bias or heterogeneity.

Based on the figure of VAS, it showed symmetrically at top 3 studies, and more shift toward the right for smaller studies group. This raise of concerns about the possibility of bias under small size study group.

Based on the figure of THI, it showed more concentrate on the 95% CI on the top. However, couple result showed lower part still appeared asymmetry and might be also the smaller size of studies and potential bias.

3.5 Adverse event

One study (Kim et al. 2020) reported 2 mild adverse effects during the treatment. One participant had transient ear numbness near the acupoint, and one participant had vertigo.

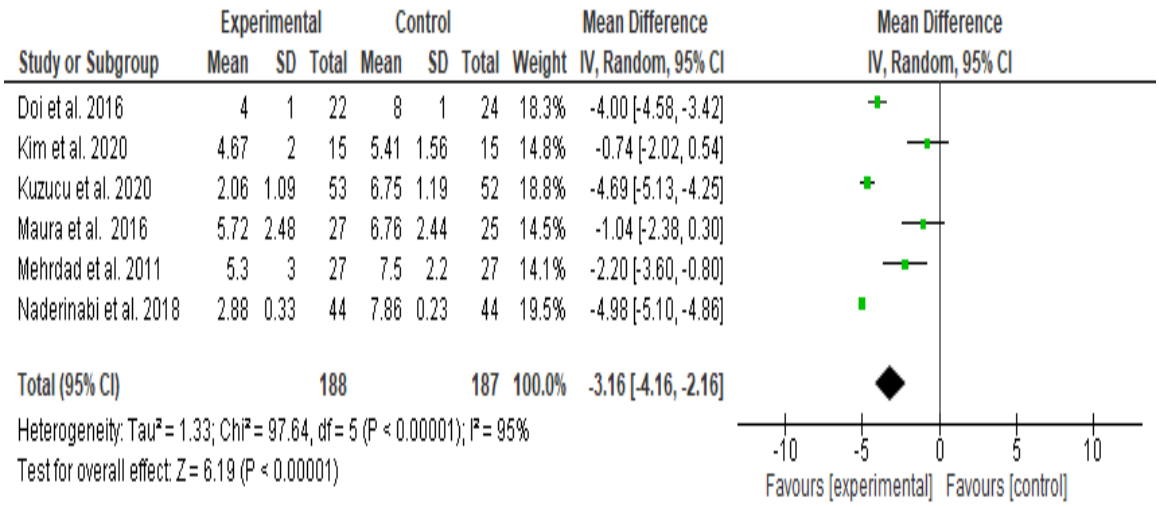

Figure 8. Forest plot with summary effect of meta-analysis of VAS

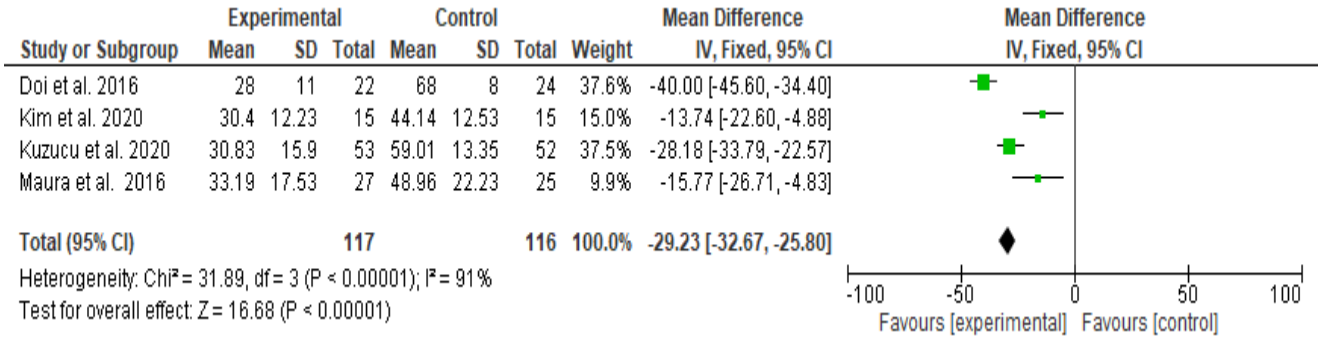

Figure 9. Forest plot with summary effect of meta-analysis of THI

3.6 VAS evaluation

The VAS score showed improved treatment in the acupuncture group compared to the control group, with a significant heterogeneity. [MD -4.85 (-4.96, -4.74), 95% CI, P < 0.00001] I^2 = 95% (Figure 8).

3.7 THI evaluation

The THI score showed improved treatment in the acupuncture group compared with

the control group with heterogeneity. [MD -29.23 (-32.67, -25.8), 95% CI, P < 0.00001] I^2 = 91% (Figure 9).

IV. DISCUSSION

Subjective tinnitus is a complex condition rooted in auditory system dysfunction. While incurable, affects 10–15% of adults globally, has been significantly impacted quality of life. So far, western medicine uses multidisciplinary strategies (such as audiologic, psychological, and medical) working on effectively mitigate its impact, and try to improve quality of life. So far, there is no specific therapy for tinnitus is acknowledged to be satisfactory in all patients, primarily because of its complicated etiopathogenesis and unclear mechanisms. Acupuncture and Oriental Medicine (AOM), an alternative therapy, use Herbal decoction and acupuncture and other method have positive effect to relieve the symptoms and signs of subjective tinnitus. In order to evaluate acupuncture's efficacy, mechanisms, and limitations, we conduct this systemic review and meta-analysis to review the qualified studies.

In Acupuncture and Oriental Medicine (AOM), subjective tinnitus can be caused by Kidney Deficiencies, Liver Imbalances, Heart Fire, Phlegm-Dampness Obstruction, Blood/Qi Deficiency, External Pathogens, and emotional factors. Treatment includes Nourish Kidney Yin and Yang, Harmonize Liver, Sedate Heart Fire, Remove the phlegm and dampness and open the obstruction, tonify the Blood and Qi, remove external pathogenic factors, resolve the emotion factors.

Based on the studies from Yu et al. 2024 [27], the mechanisms of the efficacy of acupuncture to treat subjective tinnitus came from regulation of the central nervous system, intervention in cortical hemodynamic activity, regulation of nervous system homeostasis, regulation of functional connectivity between brain regions, and modulating the inflammatory response.

In order to evaluating and analyze the findings of RCT study on Acupuncture and Oriental Medicine (AOM) treatment on subjective tinnitus, we conducted this systemic review and meta-analysis which comprise 6 randomized control trials, including 375 participants. All the studies showed the verum group who received acupuncture treatments has better result in reduction on both VAS and THI score compared with control groups with sham acupuncture treatments. The outcome we used to evaluate the studies are VAS and THI. All of 6 RCT studies concluded that the VAS score was significantly lower with Acupuncture treatments and 4 studies conclude the THI score was also significantly lower with Acupuncture treatments. (most studies had p values < 0.001, only study at Maura et al. showed p values < 0.01).

No serious adverse event of acupuncture treatment had been reported. Only two mild adverse effects reported from one study (Kim et al.), one participant had transient ear numbness near the acupoint, and another participant had vertigo. Overall, acupuncture therapy appeared to be a safe method of treatment with subjective tinnitus.

Most common points choose in the 6 RCT studies include: GB2, GB20, SI19, SJ17, SJ21, SJ22 on the affected side with other points according to the individual diagnosis. Only one study used the scalp acupuncture with location on vertigo-auditory area.

Overall, we found the significantly heterogeneity between verum groups and control groups (VAS: I^2= 95%, THI: I^2 = 91%,). This result shows a very high heterogeneity in this SR-MA, which suggests that the observed differences between study groups and control groups exist.

There are several limitations to this study. First, this SR-MA includes 6 RCT studies with 375 participants, the relatively small sample size in each trial and overall studies,

which limited the ability to understand the research fully. Second, the study only includes a short period of follow up (2 to 3 months), which limited the assessment of long-term efficacy. Third, most studies have issues with lack of binding, which limited the generalizability. Fourth, Funnel plot asymmetry raises our concern of publication bias. Even though the result prefers Acupuncture treatment over sham treatment on Subjective tinnitus for the future study, more standardized protocol and more high quality RCT studies are needed.

V. CONCLUSION

This systemic review and meta-analysis prove that Acupuncture treatment has a significant improvement in VAS score [MD -4.85 (-4.96, -4.74), 95% CI, $P < 0.00001$] $I^2 = 95\%$, and THI score [MD -29.23 (-32.67, -25.8), 95% CI, $P < 0.00001$] $I^2 = 91\%$, associated patients with subjective tinnitus. This study shows promise in improving quality of life for tinnitus patients. However, its effect on symptom severity remains uncertain. In order to establish definitive efficacy, future study should include more RCT studies, more standard protocols with improve blinding, large sample size, prioritize long-term follow-ups, and more detailed physiological outcome measures.

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APPENDIX

APPENDIX 1 Tinnitus-Visual Analog Scale (VAS)

						
T-VAS	0	2	4	6	8	10
Sound (loudness)	no	weak	moderately loud	loud to not very loud	very loud to very very loud	extremely loud
Distress	no	no to mild	mild to moderate	mild to moderately severe	Moderate to very severe	severe to worst
QOL	usual	not bad	a little bad to bad	moderately bad to bad	bad to severely bad	severely bad to worst

APPENDIX 2 Tinnitus Handicap Inventory (THI)

	SCORE	4	0	2
1.	Because of your tinnitus, do you have difficulties to concentrate?	Yes	No	Sometimes
2.	The volume (intensity) of your tinnitus makes it difficult for you to hear people?	Yes	No	Sometimes
3.	Does your tinnitus make you nervous?	Yes	No	Sometimes
4.	Does your tinnitus make you confuse?	Yes	No	Sometimes
5.	Because of your tinnitus, do you feel hopeless?	Yes	No	Sometimes
6.	Do you complain much of your tinnitus?	Yes	No	Sometimes
7.	Because of your tinnitus, do you have trouble to start sleeping at night?	Yes	No	Sometimes
8.	Do feel as if you could not get rid of your tinnitus?	Yes	No	Sometimes
9.	Does your tinnitus interfere in your capacity to enjoy social activities (such as dinners, going to the movies, etc.)?	Yes	No	Sometimes
10.	Because of your tinnitus, do you feel frustrated?	Yes	No	Sometimes
11.	Because of your tinnitus, do you think you may have some serious disease?	Yes	No	Sometimes
12.	Does your tinnitus make it difficult for you to enjoy life?	Yes	No	Sometimes
13.	Does your tinnitus interfere in your home or work activities?	Yes	No	Sometimes
14.	Because of your tinnitus, do you feel frequently irritated?	Yes	No	Sometimes
15.	Because of your tinnitus, do you have difficulties reading?	Yes	No	Sometimes
16.	Does your tinnitus make you upset?	Yes	No	Sometimes
17.	Do you feel your tinnitus impairs your relationship with family and friends?	Yes	No	Sometimes
18.	Do you find it hard to withdraw your attention from the tinnitus and concentrate in something else?	Yes	No	Sometimes
19.	Do you feel powerless to control you tinnitus?	Yes	No	Sometimes
20.	Because of your tinnitus, do you feel frequently tired?	Yes	No	Sometimes
21.	Because of your tinnitus, do you feel frequently depressed?	Yes	No	Sometimes
22.	Does your tinnitus make you feel anxious?	Yes	No	Sometimes
23.	Do you feel you can no longer withstand your tinnitus?	Yes	No	Sometimes
24.	Does your tinnitus get worse when you are stressed?	Yes	No	Sometimes
25.	Does your tinnitus make you feel insecure?	Yes	No	Sometimes