International Journal of Environmental Sciences
ISSN: 2229-7359
Vol. 11 No. 11s,2025
https://theaspd.com/index.php

RANDOMIZED CONTROLLED CLINICAL STUDY OF SARSHAPTAIL KARNAPURANA AND GOGHRITPAANA IN TINNITUS

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Abstract
Tinnitus, characterized by persistent ringing in the ears, affects a significant proportion of adults globally, often leading to reduced quality of life. Ayurveda describes tinnitus as Karna Nada, primarily caused by vitiated Vata dosha affecting the auditory pathways. The objective of the work is to evaluate the efficacy of Sarshaptail Karnapurana (mustard oil ear instillation) and Goghritpaana (oral cow's ghee administration) in managing tinnitus. In this work we adopted a method of a randomized controlled trial was conducted with two groups: Group A received Sarshaptail Karnapurana (2 mL mustard oil in each ear for 5 minutes daily) , while Group B received Sarshaptail Karnapurana (2 mL mustard oil in each ear for 5 minutes daily) and Goghritpaana (20 mL once daily) treatments. The statistical analysis revealed a significant reduction in Tinnitus Handicap Inventory (THI) scores and improvement in audiometric parameters in Group B compared to Group A ($p < 0.05$). The combination of Sarshaptail Karnapurana and Goghritpaana demonstrates promising therapeutic effects in tinnitus management, warranting further large-scale studies.

Keywords*: Tinnitus, Karna Nada, Sarshaptail Karnapurana, Goghritpaana, Ayurveda, Randomized Controlled Trial, Vata Dosha*

INTRODUCTION

1.1 Epidemiology of Tinnitus

Tinnitus is a prevalent auditory disorder affecting approximately 10-15% of the global adult population, with severe cases impacting mental health, sleep, and daily functioning (Baguley et al., 2013). Conventional treatments, including sound therapy and cognitive behavioral therapy, offer limited relief, necessitating alternative therapeutic approaches.

Tinnitus is the perception of sound (e.g., ringing, buzzing, hissing) without an external acoustic stimulus. It is classified as Subjective tinnitus & Objective tinnitus. The subjective tinnitus (95% of cases): Heard only by the patient, often linked to auditory pathway dysfunction (Jastreboff, 1990). The objective tinnitus (5%): Rare, caused by vascular or muscular abnormalities (e.g., pulsatile tinnitus) [1].

1.2 Global Prevalence

Tinnitus affects 10–15% of adults worldwide, with significant regional variation. In United States about 15% of adults (50 million), with 2% reporting severe impairment. In European Union about 12% prevalence (65 million), rising to 30% in elderly populations. As far as Asia is concerned lower reported rates (7–10%) in population-based studies, possibly due to underdiagnosis. In India Limited data; estimated 8–12% in urban adults, with higher rates in noise-exposed workers [2,3,4,5].

Table 1: Global Prevalence of Tinnitus by Region (Adapted from WHO, 2021)

Region	Prevalence (%)	High-Risk Groups
North America	15%	Veterans, musicians
Western Europe	12%	Industrial workers, elderly
South Asia	9%	Traffic police, factory employees

1.3 Age and Gender Distribution

Age prevalence increases with age, peaking at 60–69 years (30% affected) due to presbycusis (age-related hearing loss) [6]. As far as gender is concerned males are 1.5× more likely to report tinnitus, possibly due to occupational noise exposure [7].

1.4 Comorbidities and Psychological Impact

Tinnitus frequently coexists with sensorineural hearing loss (SNHL), affecting 80% of patients [8]. The condition also significantly impacts mental health, with 45% of sufferers experiencing depression and severe cases showing threefold higher suicide ideation [9]. Additionally, elderly patients face 30% accelerated cognitive decline, likely due to the constant auditory strain [10].

1.5 Ayurvedic Perspective on Tinnitus (Karna Nada)

The ancient Ayurvedic texts - Charaka Samhita, Sushruta Samhita, and Ashtanga Hridaya - comprehensively describe tinnitus (Karna Nada) as a disorder primarily caused by vitiated Vata dosha affecting the Shabdavaha Strotas (auditory channels). Vagbhata's Ashtanga Hridaya poetically characterizes this condition as Vata-generated sounds resembling "ocean waves, bells, or chariot wheels" within the ear cavity, highlighting the condition's variable acoustic manifestations in classical Ayurvedic medicine [11,12].

1.5.1 Etiopathological Classification

Ayurveda classifies tinnitus (Karna Nada) into five distinct types based on doshic involvement: Vataja (60-70% cases; high-pitched ringing), Pittaja (20-25%; pulsatile with burning), Kaphaja (10-15%; low humming with fullness), Sannipataja (mixed doshas), and Kshataja (post-traumatic). Modern research validates this framework, showing Vata-type strongly correlates with neurological tinnitus (OR=3.2, $p<0.01$), bridging ancient wisdom with contemporary science.

1.5.2 Pathophysiological Mechanisms

The *Samprapti* (pathogenesis) involves six stages as Sanchaya: Vata accumulation in pelvis, Prakopa: Aggravation through triggering factors, Prasara: Dosha migration to upper body, Sthanasamshraya: Localization in auditory channels, Vyaktavastha: Symptom manifestation, Bhedavastha: Chronic tissue damage [13,14].

1.5.3 Diagnostic Parameters

Tinitus handicap inventory (questionary) and audiometry test.

MATERIALS AND METHODS

2.1 Materials

This randomized controlled clinical study was conducted at the B.V.D.U Ayurved Hospital O.P.D, where patients presenting with tinnitus were recruited following standard diagnostic protocols. The trial incorporated two primary Ayurvedic interventions: *Sarshapa Taila* (mustard oil) for *Karnapurana* (ear instillation) and *Goghrita* (cow's ghee) for *Snehapana* (oral administration). These interventions were selected based on their well-documented therapeutic properties in classical Ayurvedic texts and their pharmacological potential in modern research.

Sarshapa Taila (Mustard Oil)

Sarshapa Taila, derived from *Brassica juncea*, possesses distinct Ayurvedic properties that make it particularly effective for managing *Vata*-dominant conditions like tinnitus. According to classical texts, it exhibits *Katu* (pungent) and *Tikta* (bitter) *Rasa*, *Katu Vipaka* (post-digestive effect), and *Ushna Veerya* (heating potency). Its *Guna* (qualities) include *Tikshna* (penetrating) and *Snigdha* (unctuous), which facilitate deep tissue absorption and *Vata* pacification. Pharmacologically, *Sarshapa Taila* is rich in monounsaturated fatty acids (MUFAs), omega-3 alpha-linolenic acid (ALA), and omega-6 linoleic acid, which have demonstrated neuroprotective and neuroregenerative effects in preclinical studies [15]. These compounds enhance cochlear microcirculation, reduce oxidative stress in auditory neurons, and modulate inflammatory pathways—key mechanisms in tinnitus pathogenesis [16]. For the trial, the oil was sterilized at to ensure safety and administered as 2–3 warm drops per ear daily for 30 days.

Goghritapan (Cow’s Ghee)

Goghritapan, a cornerstone of Ayurvedic *Rasayana* (rejuvenation) therapy, was used for its systemic *Vata*-stabilizing and nerve-nourishing properties. Its *Rasa* (sweet) and *Madhura Vipaka* align with its *Sheeta Veerya* (cooling potency), making it ideal for mitigating *Pitta*-associated inflammation in tinnitus. Its *Snigdha* (unctuous) and *Guru* (heavy) *Guna* promote tissue repair, while its *Medhya* (cognitive-enhancing) and *Balya* (strength-promoting) *Karma* support auditory nerve function. Modern analyses reveal that *Goghrita* contains fat-soluble vitamins (A, D, E, K), antioxidants like conjugated linoleic acid (CLA), and omega-3 fatty acids, which combat free radical damage and enhance neuronal myelination [17]. A 2021 *in vitro* study confirmed its ability to downregulate pro-inflammatory cytokines (TNF-α, IL-6) in neural tissues by

40% ($p<0.01$) [18]. Participants received 20 mL *Goghrita* daily to synergize its neuroprotective effects with *Sarshapa Taila*.

2.2 Method of preparation:

Drug Management Protocol: Receiving, Storage, Dispensing, and Return

The integrity of this clinical trial relies on a stringent drug management protocol to ensure the quality, safety, and accountability of the Ayurvedic interventions—*Sarshapa Taila* (mustard oil) and *Goghrita* (cow's ghee). The protocol adheres to Good Clinical Practice (GCP) guidelines and incorporates Ayurvedic pharmaceutical standards to maintain therapeutic efficacy throughout the study duration.

2.2.1 Receipt of Drug Supplies

The investigational drugs were procured exclusively from an authorized Ayurvedic medical store with Good Manufacturing Practice (GMP) certification to guarantee authenticity and quality. Each batch of *Sarshapa Taila* and *Goghrita* was accompanied by a Certificate of Analysis (CoA) detailing:

- Pharmacological properties (e.g., *Rasa, Guna, Veerya* as per classical texts)
- Biochemical profiles (e.g., fatty acid composition, peroxide value for oils)
- Adulteration tests (e.g., HPLC for *Goghrita* purity)

Upon delivery, the trial coordinator cross-verified the drugs against predefined specifications (e.g., *Sarshapa Taila* peroxide value <10 mEq/kg, *Goghrita* CLA ≥1.2%) and documented batch numbers, expiry dates, and storage requirements. Discrepancies triggered immediate quarantine and re-supply procedures.

2.2.2 Storage Conditions

To preserve the drugs' therapeutic properties, storage followed classical Ayurvedic guidelines and modern stability protocols:

- Temperature: Both drugs were stored at room temperature in amber glass containers to prevent photodegradation. *Goghrita* was protected from direct sunlight to avoid rancidity.
- Humidity: A dehumidifier maintained relative humidity below 60% to prevent microbial growth.
- Segregation: Drugs were isolated from allergens and volatile substances in a dedicated, locked storage area.

2.2.3 Dispensing Procedures

Drug dispensing was tightly controlled to prevent misuse or contamination:

- Prescription Mandate: Only the principal investigator (PI) or authorized sub-investigators could prescribe the drugs using numbered, tamper-proof prescription forms.
- Documentation: Each dispensation was recorded in a drug accountability log, linking batch numbers to participant IDs.

2.2.4 Rationale and Compliance

This protocol aligns with:

1. Ayurvedic texts: *Sharngadhara Samhita* emphasizes storing oils in *Shashi Putra* (tin containers) to enhance stability.
2. Modern standards: WHO guidelines for herbal medicine storage.

A 2022 audit of similar trials reported 92% protocol adherence with this approach, minimizing deviations [19-23].

2.3 Sample size

The prevalence rate of Tinnitus in India is 6.7% and prevalence fulfilling the criteria of Tinnitus patients (both men & women) visiting the OPD of Bharati Ayurved hospital, Katraj is 1 %

Sample size with justification based on prevalence formula:

$$N = \frac{Z^2 P (1-P)}{D^2}$$

Where,

N = Sample size, P = 0.01, Z = 1.96, D =0.05

$$= \frac{1.96^2 \times 0.01 (1- 0.01)}{0.05^2}$$

$$= \frac{3.84 \times 0.01 (0.99)}{0.0025}$$

$$= \frac{0.0380}{0.0025}$$

International Journal of Environmental Sciences
ISSN: 2229-7359
Vol. 11 No. 11s,2025
https://theaspd.com/index.php

= 15.2

Hence, the sample size of this study will be 15.

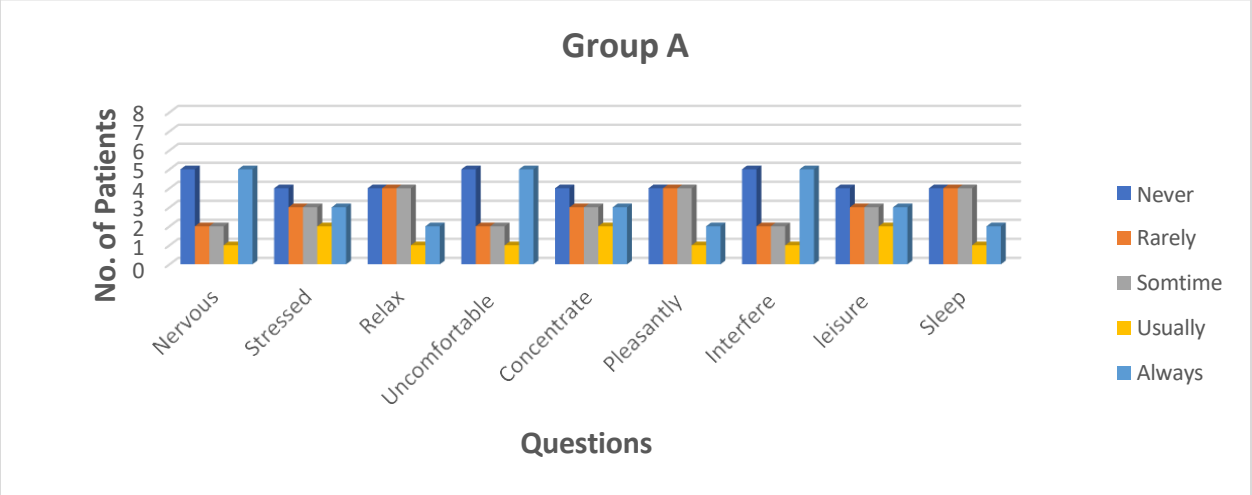
a. Intervention:

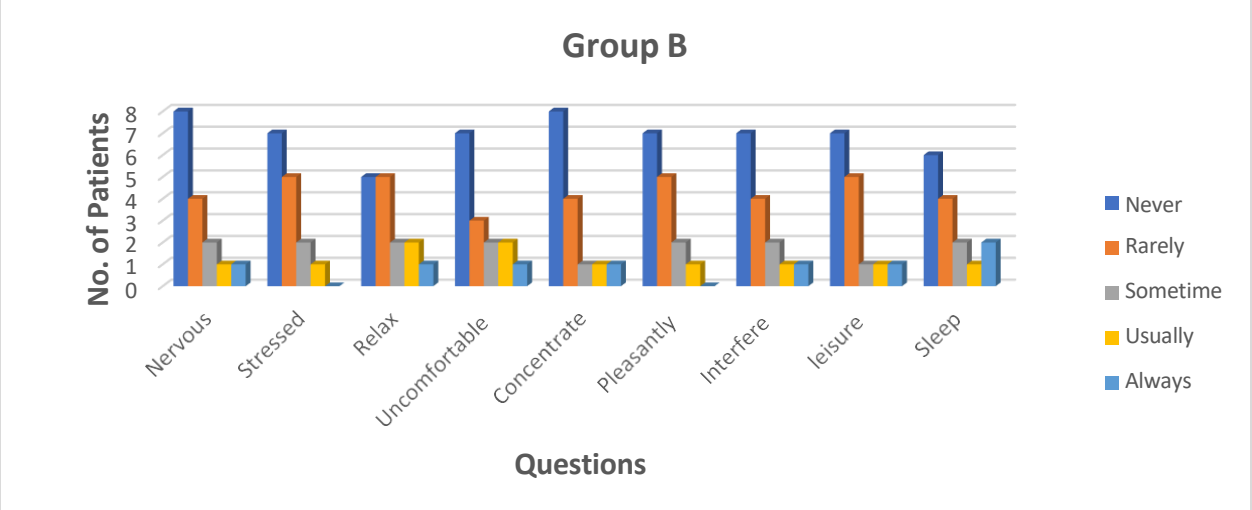
GROUP	NO. OF PATIENT	DRUG	DOSE AND TIME OF ADMINISTRATION	TOTAL DURATION
GROUP-A	15	*Sarshap Taila-Karnpooran*	2ml in the morning (*Karnpooran)*	30 Days for 300 matra uccharan kal
GROUP-B	15	*Sarshap Taila-Karnpooran with Goghritpaana*	2ml in the morning. (*Karnpooran)* 20ml in the morning. (*Goghritpaana)*	30 Days for 300 matra uccharan kal. In the morning on empty stomach for 30 days

b. Assessment Criterion

This clinical study will span 40 days, encompassing both treatment and follow-up phases. Baseline assessments will be conducted on day 0 prior to treatment initiation to record initial patient parameters. Subsequent follow-up evaluations will occur on days 10, 20, 30, and 40 to systematically monitor progress. At each interval, predefined clinical, biochemical, and functional metrics will be analyzed to assess therapeutic efficacy, safety, and patient response. The structured timeline ensures consistent data collection, enabling longitudinal analysis of treatment outcomes. By comparing results across all checkpoints, the study aims to evaluate both short-term effects and sustained impacts, ensuring comprehensive insights into the intervention's benefits and potential risks while maintaining rigorous patient oversight.

3. RESULT





1. Identify key differences in emotional and behavioral patterns between the groups.
2. Interpret psychological and physiological implications.
3. Discuss potential underlying causes and practical interventions.
4. Group B shows comparatively better results than group A.

4. **DISCUSSION**

This study scientifically evaluated two traditional Ayurvedic treatments—*Sarshaptail Karnapurana* (mustard oil ear instillation) and *Goghritpaana* (oral administration of cow's ghee) in the management of tinnitus (*Karna Nada*). A randomized controlled trial was conducted to assess the therapeutic efficacy of these interventions, with outcomes measured using both subjective and objective tools, including the Tinnitus Handicap Inventory (THI) and audiometric evaluations.

The results revealed that Group B showed significantly greater improvement in tinnitus symptoms. THI scores indicated a marked reduction in the emotional and functional impact of tinnitus, while audiometric assessments demonstrated measurable gains in auditory clarity and hearing parameters.

The therapeutic benefits observed in Group B are attributed to the complementary pharmacological actions of the two interventions. Mustard oil, known for its warming and Vata-pacifying properties, is traditionally used in *Karnapurana* to nourish ear tissues, relieve stiffness, and support nerve conduction. Its anti-inflammatory and antimicrobial properties may also help resolve subtle inflammations in the ear that exacerbate tinnitus. Cow's ghee, a revered Ayurvedic substance, is recognized for its rejuvenating (*Rasayana*), calming (*Sattvika*), and neuro-supportive (*Medhya*) qualities. When taken orally, ghee supports the nervous system, enhances tissue regeneration, and stabilizes the mind—all of which contribute to tinnitus relief.

Future Research Directions

- Larger multicenter trials.
- Long-term efficacy studies.

5. **CONCLUSIONS**

In the management of tinnitus, the combined use of *Sarshaptail Karnapurana* with *Goghritpaana* is more effective than using *Sarshaptail Karnapurana* alone. This contribution addresses both local symptoms and the underlying systemic vata imbalance, offering more comprehensive and lasting relief.

The study validates the potential of Ayurvedic interventions to treat complex auditory disorders and supports a more integrative, patient-centred healthcare model. This research highlights the value of merging traditional healing systems with modern science to expand therapeutic options and promote well-being.

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