

Natural Therapeutics in Tinnitus: A Prospective Clinical Comparison Between Caffeine and Ginkgo Biloba in Alleviating Tinnitus in Adults

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Abstract: *Introduction:* This prospective study evaluates and compares the therapeutic efficacy of caffeine capsules and Ginkgo biloba in managing tinnitus symptoms among adult patients. *Background:* Tinnitus, characterized by the perception of sound without an external stimulus, significantly disrupts daily activities, concentration, and quality of life. Caffeine, a commonly consumed stimulant, has shown inconsistent effects on tinnitus, while Ginkgo biloba is widely used in alternative medicine due to its potential neurovascular benefits. Despite their popularity, robust comparative evidence on their effectiveness remains limited. *Objective:* To compare the impact of caffeine and Ginkgo biloba supplementation on tinnitus severity in adults. *Methods:* The study was conducted over six months at the Department of ENT, Saveetha Medical College and Hospital, Chennai. A total of 84 adult patients with tinnitus were randomized into two groups: Group A (n = 42) received 200 mg caffeine capsules daily, and Group B (n = 42) received Ginkgo biloba extract. Symptom severity was assessed using the Tinnitus Handicap Inventory (THI). *Results:* Both treatments led to symptom relief; however, Group B (Ginkgo biloba) reported more substantial improvement in THI scores than Group A. *Conclusion:* Ginkgo biloba showed greater effectiveness than caffeine in reducing tinnitus severity. Larger, multicenter studies are recommended to validate these results.

Keywords: Tinnitus, Tinnitus Handicap Inventory, Caffeine, Ginkgo biloba.

INTRODUCTION

Tinnitus is a persistent auditory condition where individuals perceive sound—such as ringing or buzzing—without an external auditory source. It affects a considerable proportion of adults and is often associated with sleep disturbances, concentration difficulties, and emotional distress [1]. Despite its prevalence, the treatment of tinnitus remains challenging due to the variability in its etiology and the absence of a universally effective therapy [1].

Caffeine, known for its central nervous system stimulation, has yielded mixed results in tinnitus management. Some evidence suggests it may exacerbate symptoms due to increased neural excitability, while other studies highlight its potential to improve mood and alertness, which may indirectly alleviate symptom perception [2]. Conversely, Ginkgo biloba, a herbal supplement with vasodilatory and neuroprotective effects, has been promoted for tinnitus treatment, though clinical outcomes remain inconsistent [3,4]. Some trials have found limited benefits [5], while others report modest reductions in tinnitus severity [6,7].

This prospective study aims to directly compare the efficacy of caffeine and Ginkgo biloba in alleviating tinnitus symptoms using a standardized clinical tool, the Tinnitus Handicap Inventory (THI). The results may guide clinicians in choosing more effective treatment options for tinnitus patients.

Aims and Objectives:

To assess and compare the effectiveness of caffeine capsules and Ginkgo biloba supplementation in reducing tinnitus severity in adult patients.

METHODOLOGY:

Study Design and Setting:

This prospective clinical study was carried out in the Department of ENT at Saveetha Medical College and Hospital, Chennai, over a six-month duration beginning in October 2024.

Participants:

A total of 84 adults diagnosed with non-pulsatile, subjective tinnitus participated in the study. They were randomly assigned into two equal groups for evaluation:

- **Group A:** Received a daily dose of 200 mg caffeine capsules.
- **Group B:** Received standardized Ginkgo biloba extract.

Inclusion Criteria:

1. Adults aged 18 to 60 years with non-pulsatile, subjective tinnitus.
2. Tinnitus duration of at least three months.
3. Written informed consent obtained.
4. No prior use of caffeine or Ginkgo biloba for tinnitus.
5. Stable or normal hearing confirmed via audiometry.
6. Cognitive ability to complete tinnitus assessments.

Exclusion Criteria:

1. Pulsatile or objective tinnitus.
2. Existing psychiatric or cognitive impairments affecting participation.
3. Allergic reactions to caffeine or Ginkgo biloba.
4. Concurrent use of auditory-affecting drugs or supplements.
5. Pregnancy or breastfeeding.
6. Serious systemic illnesses like cardiovascular, hepatic, or renal diseases.
7. Recent ear infections, trauma, or surgical interventions.

Assessment Tool:

Tinnitus severity and its impact on daily life were measured using the Tinnitus Handicap Inventory (THI). This validated questionnaire assesses functional, emotional, and catastrophic dimensions of tinnitus. THI scores were recorded both before treatment and after completion of the intervention.

Tinnitus Handicap Inventory (THI)

This form is for informational purposes only and should not take the place of consultation and evaluation by a healthcare professional.

Your Name: _____ Date: _____

Instructions: The purpose of this questionnaire is to identify, quantify, and evaluate the difficulties that you may be experiencing because of tinnitus. Please do not skip any questions. When you have answer all the questions, add up your total score, based on the values for each response.

1. Because of your tinnitus, is it difficult for you to concentrate?	☐ Yes (4)	☐ Sometimes (2)	☐ No (0)
2. Does the loudness of your tinnitus make it difficult for you to hear people?	☐ Yes (4)	☐ Sometimes (2)	☐ No (0)
3. Does your tinnitus make you angry?	☐ Yes (4)	☐ Sometimes (2)	☐ No (0)
4. Does your tinnitus make you feel confused?	☐ Yes (4)	☐ Sometimes (2)	☐ No (0)
5. Because of your tinnitus, do you feel desperate?	☐ Yes (4)	☐ Sometimes (2)	☐ No (0)
6. Do you complain a great deal about your tinnitus?	☐ Yes (4)	☐ Sometimes (2)	☐ No (0)
7. Because of your tinnitus, do you have trouble falling to sleep at night?	☐ Yes (4)	☐ Sometimes (2)	☐ No (0)
8. Do you feel as though you cannot escape your tinnitus?	☐ Yes (4)	☐ Sometimes (2)	☐ No (0)
9. Does your tinnitus interfere with your ability to enjoy your social activities (such as going out to dinner, to the movies)?	☐ Yes (4)	☐ Sometimes (2)	☐ No (0)
10. Because of your tinnitus, do you feel frustrated?	☐ Yes (4)	☐ Sometimes (2)	☐ No (0)
11. Because of your tinnitus, do you feel that you have a terrible disease?	☐ Yes (4)	☐ Sometimes (2)	☐ No (0)
12. Does your tinnitus make it difficult for you to enjoy life?	☐ Yes (4)	☐ Sometimes (2)	☐ No (0)
13. Does your tinnitus interfere with your job or household responsibilities?	☐ Yes (4)	☐ Sometimes (2)	☐ No (0)
14. Because of your tinnitus, do you find that you are often irritable?	☐ Yes (4)	☐ Sometimes (2)	☐ No (0)
15. Because of your tinnitus, is it difficult for you to read?	☐ Yes (4)	☐ Sometimes (2)	☐ No (0)
16. Does your tinnitus make you upset?	☐ Yes (4)	☐ Sometimes (2)	☐ No (0)
17. Do you feel that your tinnitus problem has placed stress on your relationships with members of your family and friends?	☐ Yes (4)	☐ Sometimes (2)	☐ No (0)
18. Do you find it difficult to focus your attention away from your tinnitus and on other things?	☐ Yes (4)	☐ Sometimes (2)	☐ No (0)
19. Do you feel that you have no control over your tinnitus?	☐ Yes (4)	☐ Sometimes (2)	☐ No (0)
20. Because of your tinnitus, do you often feel tired?	☐ Yes (4)	☐ Sometimes (2)	☐ No (0)
21. Because of your tinnitus, do you feel depressed?	☐ Yes (4)	☐ Sometimes (2)	☐ No (0)
22. Does your tinnitus make you feel anxious?	☐ Yes (4)	☐ Sometimes (2)	☐ No (0)
23. Do you feel that you can no longer cope with your tinnitus?	☐ Yes (4)	☐ Sometimes (2)	☐ No (0)
24. Does your tinnitus get worse when you are under stress?	☐ Yes (4)	☐ Sometimes (2)	☐ No (0)
25. Does your tinnitus make you feel insecure?	☐ Yes (4)	☐ Sometimes (2)	☐ No (0)

The sum of all responses is your THI Score >>>

0

Newman C.W., Jacobson G.P., Spitzer JB. (1996) "Development of the Tinnitus Handicap Inventory." *Archives of Otolaryngology - Head and Neck Surgery*. 122(2):143-8.

McCombe, A., Baguelly, D., Coles, R., McKenna, L., McKinney, C. & Windle-Taylor, P. (2001). "Guidelines for the Grading of Tinnitus Severity: the Results of a Working Group Commissioned by the British Association of Otolaryngologists, Head and Neck Surgeons." *Clinical Otolaryngology*. 26, 388-393.

0-16: Slight or no handicap (Grade 1)

18-36: Mild handicap (Grade 2)

38-56: Moderate handicap (Grade 3)

58-76: Severe handicap (Grade 4)

78-100: Catastrophic handicap (Grade 5)

Data Analysis:

An independent t-test was conducted to assess the variation in Tinnitus Handicap Inventory (THI) scores between the two treatment groups. A p-value of less than 0.05 was established as the threshold for determining statistical significance in evaluating the effectiveness of the interventions.

RESULTS:

Study Design	Prospective Randomized Controlled Trial (RCT)
Study Population	Tinnitus patients aged 18–45 years

Sample Size	84 participants (42 in each group)
Duration	8 weeks
Outcome Measure	Tinnitus Handicap Inventory (THI) scale
Statistical Analysis	Independent t-test, Chi-square test
Statistical Power	0.951
Effect Size (Cohen's d)	0.8 (Large)

This research utilized a prospective randomized controlled trial (RCT) approach to evaluate the effectiveness of treatments for tinnitus in individuals aged 18 to 45 years. A total of 84 participants were randomly divided into two groups of 42 each. The intervention lasted for 8 weeks, and the outcomes were measured using the Tinnitus Handicap Inventory (THI) scale. Statistical analysis included independent t-tests and Chi-square tests to compare the results between the two groups.

Group	Mean THI Score (Pre-Treatment)	Mean THI Score (Post-Treatment)	Mean Difference	p-value	Effect Size (Cohen's d)
Group A (Caffeine)	55 ± 8	35 ± 6	20	<0.01	0.8
Group B (Ginkgo Biloba)	54 ± 7	48 ± 7	6	0.15	0.3

- **Statistical Power (0.951):** This indicates a 95.1% probability of detecting a true effect, suggesting a high confidence that the observed differences are not random.
- **Effect Size (Cohen's d = 0.8):** A large effect size suggests a significant difference between the two groups, with the caffeine group showing a more pronounced improvement in THI scores compared to the Ginkgo biloba group.
- **p-value (<0.01):** The p-value indicates strong evidence against the null hypothesis, supporting the effectiveness of caffeine in reducing tinnitus severity.

DISCUSSION:

This prospective, randomized controlled trial aimed to evaluate and compare the therapeutic efficacy of caffeine and Ginkgo Biloba in alleviating tinnitus symptoms among young to middle-aged adults. A total of 84 participants, aged between 18 and 45 years, were randomly assigned in equal numbers to one of two intervention groups. The study spanned a period of eight weeks, during which participants received either caffeine supplementation (Group A) or Ginkgo Biloba extract (Group B). To assess treatment outcomes, the Tinnitus Handicap Inventory (THI), a validated and widely used tool for measuring the severity and impact of tinnitus, was administered at baseline and at the end of the intervention.

The study was designed with high methodological rigor, and the statistical power was calculated at 0.951. This indicates a strong capacity to detect meaningful differences between groups, thereby enhancing the credibility and reliability of the observed results. [8]

In terms of treatment efficacy, the caffeine group (Group A) experienced a notable improvement in tinnitus-related symptoms. Specifically, the mean reduction in THI scores was 20 points, which was statistically significant ($p < 0.01$). Furthermore, the effect size was calculated at 0.8, representing a large and clinically meaningful impact of caffeine on tinnitus severity.

On the other hand, the group receiving Ginkgo Biloba (Group B) showed only a minor improvement. The average reduction in THI score was 6 points, a change that was not statistically significant ($p = 0.15$). The effect size for this group was relatively small (Cohen's $d = 0.3$), suggesting limited clinical benefit.

Overall, the findings from this trial suggest that caffeine may be more effective than Ginkgo Biloba in reducing tinnitus symptoms in younger adults. These results challenge traditional assumptions and may have implications for future treatment recommendations. [5-7]

CONCLUSION:

The study demonstrated, indicated a strong ability to detect true differences between groups and ensuring the reliability of the findings [8]. These results align with emerging research suggesting that caffeine, despite its previously assumed aggravating role, may not worsen tinnitus and could have neurostimulatory effects that improve auditory processing or patient perception of tinnitus [9–11]. Some studies have even noted caffeine's positive influence on mood and cognitive function, which could indirectly reduce tinnitus distress [12,13].

Although Ginkgo Biloba has been widely studied for its vasoregulatory and neuroprotective properties [14],

multiple high-quality trials and meta-analyses have failed to show consistent efficacy in tinnitus management [15–17]. These findings reinforce that caffeine may have therapeutic potential in alleviating tinnitus severity and challenge longstanding beliefs about its detrimental auditory effects. However, further long-term studies with larger samples are advised to validate these findings in attempting to investigate underlying mechanisms.

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