



(RESEARCH ARTICLE)



## Comparison of the comfort of De Tinnitus music compared to sound generators in healthy individuals

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### Abstract

**Introduction:** Tinnitus is the perception of sounds that a person hears without external stimulation and can negatively affect the quality of life. There are many ways to manage tinnitus, including using a sound generator. However, there is no significant therapy that can treat tinnitus patients. De Tinnitus is a sound generator plus music developed by the author. This study aims to compare the comfort of music De Tinnitus with a sound generator in healthy individuals.

**Methods:** This study is a Phase I Clinical Trial conducted in healthy individuals in Denpasar, Bali, Indonesia. Samples were randomized to hear a sound generator or De Tinnitus music through a phone application and heard the intervention for 2 hours every day for three months. Before and after the intervention, a visual analog scale (VAS) and audiometry examination were performed. The data was then analyzed using the SPSS application.

**Results:** The results showed that volunteers in the De Tinnitus music group had better audiometric results than the sound generator group, both in the right ear ( $16.09 \pm 5.40$  vs.  $26.28 \pm 10.09$ ;  $p < 0.001$ ) to the left ear ( $15.99 \pm 4.93$  vs.  $26.22 \pm 9.79$ ;  $p < 0.001$ ). In addition, VAS was also significantly lower in the music De Tinnitus group compared to the sound generator ( $1.01 \pm 0.67$  vs  $2.11 \pm 0.57$ ;  $p = 0.023$ ).

**Conclusion:** This study showed that De Tinnitus music is more comfortable than sound generators in healthy individuals. There were no side effects such as ear ringing, blocked ears, dizziness, or other side effects. De Tinnitus music is safe and comfortable for the ears when used for 2 hours daily for three months with a maximum sound threshold of 91dB.

**Keywords:** De Tinnitus music; Sound generator; Tinnitus; Comfort

### 1. Introduction

Tinnitus, a condition characterized by the perception of sound without an external source, can significantly impact an individual's quality of life. Patients with tinnitus often experience ringing, buzzing, or hissing in the ears, leading to distress, sleep disturbances, and difficulty concentrating. Management of tinnitus is complex and typically involves a multidisciplinary approach, including sound therapy, counseling, and, in some cases, medication.[1]–[3]

Sound generators, which aim to provide relief by using external noise to mask or distract from tinnitus, are a common and noninvasive treatment option. They produce continuous noise, such as white noise or nature sounds, which can help mask tinnitus and provide temporary relief.[4], [5] However, some individuals find sound generators monotonous or uncomfortable for prolonged use. Music therapy, on the other hand, offers a more personalized and potentially enjoyable form of sound therapy. De Tinnitus music, a novel form of music therapy combined with a sound generator created by the author, is designed to blend therapeutic sound elements with musical compositions to create a more

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pleasant listening experience while providing the masking effect needed for relief. This approach aims not only to mask the tinnitus but also to improve the emotional state and overall comfort of the listener.[6], [7]

The perception of comfort is an essential factor in the effectiveness of sound therapy, as it directly influences patient adherence to treatment. If the therapy is uncomfortable or unpleasant, individuals are less likely to use it consistently, reducing its potential benefits.[8] A phase I clinical trial is needed before launching music De Tinnitus to the public. The initial stage is determining whether music De Tinnitus is comfortable and safe for normal people. This is because De Tinnitus music is listened to through earphones from a close distance and for a long time. The comfort in question provides the user with psychological and physical comfort with sound. Ear comfort and safety are assessed from the visual analog scale (VAS), the presence or absence of side effects (e.g., ear ringing, blocked ears, dizziness, etc.), and sound intensity. Previous clinical trials have tested sound generators on tinnitus sufferers, and most patients felt comfortable without side effects.[9] This study is a Phase I Clinical Trial that aims to compare the comfort of De Tinnitus music with sound generators in normal people.

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## 2. Material and methods

### 2.1. Research Design and Subjects

This study was a phase I clinical trial conducted at the Tinnitus laboratory in Denpasar, Bali, Indonesia. The study population consisted of healthy volunteers aged over 18 years who accompanied their families to the ENT polyclinic at Ngoerah Hospital. Subjects were taken from the population who were willing to participate. The inclusion criteria were individuals over 18 years old who could use an Android phone. Exclusion criteria included individuals suffering from tinnitus, ear disorders, vertigo, or tumors. The sample size was calculated using a hypothesis test of two paired group proportions. Based on the calculation, the minimum sample required was 69 people per group.

### 2.2. Study Procedure

All participants who met the inclusion criteria were divided into two groups: 1) The group that listened to de tinnitus music, from now on, referred to as group A, and 2) The group that listened to the sound generator, referred to as group B. Randomization was carried out by simple randomization. To ensure randomization and blinding, the password was printed on paper and then put into a non-transparent envelope that had been prepared.

The research subjects were called to come to the Tinnitus laboratory from 08.00 to 20.00 o'clock. Envelopes will be prepared according to the number of groups A and B. The envelopes were placed on the table, and everyone could take their desired envelope. The first to take the envelope is the first person to come. Envelopes were taken freely according to the wishes of participants. An audiometry test was performed on the participants in the laboratory before the intervention. The next day, the participants were emailed an Android application for De Tinnitus music. They were asked to install the De Tinnitus music application and create an account on the application. If they want to log in, they have to enter the password in the envelope that had been taken. The sample then listens to De Tinnitus music or a sound generator for 1x 2 hours a day for three months (Rahayu et al., 2022). The sample then filled out a VAS questionnaire to assess the comfort experienced when listening to De Tinnitus music or a sound generator. After three months of using De Tinnitus music or a sound generator, the participants filled out the VAS questionnaire again to see the long-term impact. The sample was then returned for an audiometry examination at the Tinnitus Laboratory. Side effects that appeared were recorded through history taking.

### 2.3. Data Analysis

Data were analyzed using descriptive analysis, proportion comparison test, and mean comparison test. Depending on the data distribution, the Chi-square test was used for proportion comparison, and the Independent T-test or Mann-Whitney test was used for mean comparison. The analysis was performed using SPSS IBM 21.

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## 3. Results

The study was conducted on a total of 138 individuals, consisting of 69 participants who listened to Music De Tinnitus and 69 who listened to the sound generator. The volume used was 50% for an average of 2 hours daily. The characteristics of the study can be seen in Table 1. Subjects in both groups were mostly female (60.9%) and aged <40 years (75.4%). The mean baseline audiometry of the right ear in the sound generator group was  $13.95 \pm 5.43$  dB, and the left ear was  $13.98 \pm 5.40$  dB. The mean baseline audiometry of the right ear in the De Tinnitus music group was

14.75 ± 6.06 dB and the left ear 14.06 ± 5.37 dB. There was no difference in baseline audiometry or VAS between the two groups ( $p > 0.05$ )

**Table 1** Study Subjects Characteristics

Variables	Sound Generator (n=69)	De Tinnitus Music (n=69)	p-value
Gender, n (%)			1,000
Male	27 (39.1)	27 (39.1)	
Female	42 (60.9)	42 (60.9)	
Age (years), n (%)			1.000
<40	52 (75.4)	52 (75.4)	
≥40	17 (24.6)	17 (24.6)	
Occupation			0.061
Students	13 (18.8)	17 (24.6)	
Housewife	12 (17.4)	7 (10.1)	
Laborer	3 (4.3)	3 (4.3)	
Private employee	18 (26.1)	16 (23.2)	
Teacher	2 (2.9)	0 (0.0)	
Farmer	3 (4.3)	3 (4.3)	
Merchant	3 (4.3)	10 (14.5)	
Unemployed	13 (18.8)	5 (7.2)	
Businessman	2 (2.9)	8 (11.6)	
Baseline Audiometry			
Right ear (dB)	13.95 ± 5.43	14.75 ± 6.06	0.414
Left ear (dB)	13.98 ± 5.40	14.06 ± 5.37	0.928
Baseline VAS	0.00 ± 0.00	0.00 ± 0.00	1.000
Duration (hours)	2	2	1.000

The Kolmogorov-Smirnov test showed that the data was not normally distributed, so the Mann-Whitney test was performed. The results of statistical analysis using the Mann-Whitney test showed that volunteers in the De Tinnitus music group had better audiometric results than the sound generator group, both in the right ear (16.09 ± 5.40 vs 26.28 ± 10.09;  $p < 0.001$ ), and the left ear (15.99 ± 4.93 vs 26.22 ± 9.79;  $p < 0.001$ ). In addition, VAS was also significantly lower in the De Tinnitus music group than the sound generator (1.01 ± 0.67 vs 2.11 ± 0.57;  $p = 0.023$ ). This shows that De Tinnitus music is more comfortable than the sound generator in healthy individuals. After listening to De Tinnitus, there were no side effects such as ear ringing, blocked ears, dizziness, or other side effects.

**Table 2** Differences in Audiometry and VAS Between Groups

Variables	Sound Generator (n=69)	De Tinnitus Music (n=69)	p-value
Right audiometry (dB)	26.28 ± 10.09	16.09 ± 5.40	<0.001
Left audiometry (dB)	26.22 ± 9.79	15.99 ± 4.93	<0.001
VAS	2.11 ± 0.57	1.01 ± 0.67	0.023

#### 4. Discussion

This study showed that the age and gender of the De Tinnitus music group and the sound generator group were comparable. All research subjects received treatment for the same time, which was 2 hours. This study found that the De Tinnitus music volunteers in the De Tinnitus music group had better audiometry results than the sound generator group, both in the right and left ear. In addition, VAS was also significantly lower in the De Tinnitus music group than the sound generator ( $1.01 \pm 0.67$  vs  $2.11 \pm 0.57$ ;  $p = 0.023$ ).

According to research by Sirh et al., the mean VAS in subacute tinnitus patients was 7.13, and in chronic tinnitus patients, it was 7.73.[10] According to research by van Uum, the mild VAS limit for ear pain is  $3.7 \pm 2.6$ . [11] The VAS of both interventions, De Tinnitus music and sound generators, were still below 3, so they did not cause significant pain, even lower than the pain generally felt by tinnitus patients.

There were no side effects such as ear ringing, blocked ears, dizziness, or other side effects. De Tinnitus music is safe and comfortable for the ears after being heard for 2 hours daily for three months with a maximum sound threshold of 91dB. The results of this study indicate that De Tinnitus music plus a sound generator is comfortable for normal people, even when listened to through earphones from a close distance and for a long period. This study can be the basis for a phase II clinical trial to test the effectiveness of De Tinnitus music plus a sound generator as a tinnitus therapy.

This study is the first to compare De Tinnitus music with a sound generator. The results are in accordance with previous clinical trials that have tested sound generators on tinnitus sufferers.[9], [12] Most patients felt comfortable without side effects. Previous research by Rahayu et al. also reported that combining music therapy with a sound generator was comfortable for all participants.[6] The study used sound generators for 2 hours in 2 days, with a maximum sound threshold of 91dB. A systematic review of RCT trials also showed that the use of sound generators is safe and has no side effects.[4], [5]

Exposure to sound with too high intensity or too long exposure duration can cause loss of hair cells (HCs), both damage to the outer hair cells (OHC) and stereocilia inner hair cells (IHC). In addition, rupture of the ear membrane, swelling of the synapses, and changes in the tectorial membrane can also occur. Listening to loud sounds for a long time can make the hair cells in the ear work too hard, which can cause the cells to die. Hair cell damage starts from dysfunction of the hair cell mechanotransduction complex to the loss of special ribbon synapses and can even cause hair cell death. Although hair cell damage is complex, it includes accumulating reactive oxygen species and activating intracellular stress pathways, which cause programmed and necrotic cell death. Permanent damage to cochlear neurons can also cause hearing loss. Hearing loss will continue as long as exposure continues.[13], [14]

Although most authors consider OHCs more susceptible to noise than IHCs, the stereocilia of IHCs and stereocilia of the first row of OHCs are also susceptible structures. The high susceptibility of OHCs may be related to the intensity effect. At low-intensity sounds, it is generally assumed that metabolic factors dominate. At the same time, direct mechanical action, possibly combined with the toxic effect of  $K^+$  ions due to membrane rupture, is responsible for the damage at high-intensity sounds.[15] According to the World Health Organization, the safe sound volume level for the ear is below 85 dB for a maximum duration of eight hours, while if it is 91 dB, then the maximum is listened to for 2 hours. In this study, audiometry remained within the normal range ( $<25$ dB) after listening to De Tinnitus music with an intensity of less than 91dB for 2 hours, which shows the safety of De Tinnitus music.[16], [17]

Tinnitus is a condition that originates in the brain, although it is triggered in the peripheral auditory system. Damage, such as hearing loss affecting the inner hair cells, disrupts the normal function of the auditory nerve. A therapeutic approach believed to be effective in managing tinnitus involves first identifying the characteristics of the tinnitus sound, including its frequency and amplitude. Afterward, a sound generator is created, which serves as a sound masker and includes soothing tonal variations for tinnitus sufferers. This sound is tailored to match the patient's tinnitus until they feel at ease. This therapy is administered over a set period, allowing for adaptation and potential improvement in the patient's tinnitus symptoms.[5]

De Tinnitus is a sound therapy tool that combines a sound generator with music, developed by the author specifically for tinnitus management. This tool uses the frequency specific to tinnitus patients to help mask the tinnitus sounds and is enhanced with soothing musical tones that are comforting for those with tinnitus. The auditory component consists of acoustic music, violin, keyboard, and Balinese gamelan played at a calming tempo, along with a selection of tracks from de Bongol. For user convenience, De Tinnitus can be integrated into a mobile phone application, allowing patients easier access.[6] Among all sound generators used for subjective tinnitus, approximately 3-5% operate at frequencies

below 20 Hz and above 20,000 Hz. Similarly, songs created through recordings in soundproof environments contain frequencies of 20 Hz and beyond 20,000 Hz, around 5-7%, which include frequencies that are not essential.

Music De Tinnitus has an amplitude of <85dB so that it can be adjusted with the volume control on the speaker. If the volume is 100%, it will produce a sound amplitude of around 85 dB. De Tinnitus music, as another control, can use headset specifications that support frequencies of 20 - 20,000 Hz with an amplitude of 85 dB.[6] The limitations of this study are that the sample size was limited to 69 patients due to limited research time and that it was only in the Denpasar area. Further research can be conducted in a wider geographic area and with a larger sample size.

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## 5. Conclusion

Music De Tinnitus is more comfortable for healthy individuals than sound generators based on audiometry and VAS results. There are no side effects from using music De Tinnitus or sound generators. The safe and comfortable use of De Tinnitus music for the ears is 2 hours daily for three months, with a maximum sound threshold of 91dB. As music De Tinnitus has been proven to be more comfortable than generators for healthy individuals in Phase I clinical trials, further research in Phase II clinical trials should be conducted to assess the effectiveness of music De Tinnitus as a tinnitus therapy.

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## Compliance with ethical standards

### *Disclosure of conflict of interest*

There is no conflict of interest.

### *Statement of informed consent*

Informed consent was obtained from all individual participants included in the study.

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