Comparison of the comfort of De Tinnitus music plus a sound generator compared to De Tinnitus music in healthy people

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ABSTRACT

Introduction: Tinnitus is the perception of sounds a person hears without external stimulation. Tinnitus affects 10% to 15% of the adult population, with approximately 20% experiencing symptoms that negatively affect the quality of life. There are many ways to manage tinnitus, but no significant therapy can treat tinnitus patients.

Methods: This is the phase I of a clinical trial to determine whether de tinnitus music is comfortable in the healthy population. Comfort was assessed using the Visual Analog Scale (VAS) and audiometry.

Results: There was no difference in the comfort of De Tinnitus music plus a sound generator compared to De Tinnitus music in healthy people based on audiometry and VAS (p>0.05). There were no side effects such as ear ringing, blocked ears, dizziness, or other side effects. The use of a sound generator that is safe and comfortable for the ears is for 2 hours in 2 days with a maximum sound threshold of 91dB.

Discussion: A sound generator is a form of tinnitus therapy that produces sounds that mask tinnitus. De Tinnitus is a sound generator plus music developed by the authors. De Tinnitus is made from the frequency of tinnitus patients to masked tinnitus, combined with variations in the tone of music that calms tinnitus sufferers. The sound is made from acoustic music, violin, keyboard, and Balinese gamelan with a soothing tempo, plus a collection of songs from the Bongol band. De tinnitus can be entered into a mobile phone application to make it easier for patients to reach.

Conclusion: Tinnitus music plus a sound generator is comparable to comfort for healthy people compared to Tinnitus music alone. There were no side effects from using de tinnitus plus generator in healthy people.

Keywords: tinnitus, sound generator, de Tinnitus.

INTRODUCTION

Tinnitus is the perception of sounds a person hears without any external stimulation. Tinnitus affects 10% to 15% of the adult population, with approximately 20% experiencing symptoms that negatively affect the quality of life. It is estimated that there are almost a million general practice consultations annually with the chief complaint of tinnitus. Clinical management strategies for tinnitus are patient counseling and education, relaxation therapy, Tinnitus Retraining Therapy (TRT), cognitive behavioral therapy (CBT), in-ear sound generators or hearing aids, and pharmacological therapy to manage comorbid symptoms such as insomnia, anxiety or depression. Even though there are many tinnitus therapies, no therapies can significantly treat tinnitus patients. Hence, the management of tinnitus is still a big challenge for researchers.

A sound generator is a device that produces sounds to soothe and distract from tinnitus. The sound is obtained from data on frequency, amplitude, timbre, and basic tinnitus tone to mask the existing tinnitus sound. Sound generators can be combined with hearing aids or as separate devices. Previous research shows that sound generators can reduce the severity of tinnitus based on the Tinnitus Functional Index (TFI).

De Tinnitus is a sound generator, plus de Tinnitus music developed by the authors. De tinnitus is made from the frequency of tinnitus patients to mask tinnitus and combined with variations in the tone of music that calms tinnitus sufferers. The sound is made from acoustic music, violin, keyboard, and Balinese gamelan with a soothing tempo, plus a collection of songs from the Bongol band. These sounds and variations of sounds were mixed using the FL Studio computer program. The tempo and harmony of the sound are adjusted to form a harmonious sound mix. De Tinnitus can be included in an Android application to make it easier for tinnitus patients to reach and listen to 2 hours a day. De Tinnitus is a tool with great potential for innovation in tinnitus treatment and can be patented.

A phase I clinical trial is needed before launching De Tinnitus music to the public. The initial stage is determining whether de Tinnitus music is comfortable and safe for normal people. This is because De Tinnitus
music is listened to through earphones at close range and for a long period. The comfort in this study means providing both psychological and physical comfort to the user concerning sound. Ear comfort and safety were assessed using 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. This research is a Phase I Clinical Trial that compares the comfort of De Tinnitus music plus sound generator with De Tinnitus music alone to healthy people.

METHODS

This study is a phase I clinical trial to examine the safety and comfort of De Tinnitus music plus a sound generator, compared to De Tinnitus music alone. Comfort was assessed based on VAS and audiometry. Any side effects that occurred were recorded. The research took place at the Tinnitus laboratory in Bali, Indonesia.

The research population was healthy volunteers aged >18 years who took their families for treatment to the Ear, Nose Throat – Head Neck polyclinic at Prof. Dr. IGNG Ngoerah Hospital, Bali, Indonesia. The research sample is the population willing to participate in this clinical trial. Inclusion criteria were healthy people over 18 years old and willing to participate in the research. Exclusion criteria were suffering from tinnitus, middle ear, outer ear or inner ear disorders, vertigo or tumors.

The participants that have been recruited created an account on the Tinnitus application on their mobile phone. All participants were randomly divided into 2 groups: 1) the group that listened to De tinnitus + sound generator, referred to as group A; 2) the group that listened to De Tinnitus music only, referred to as group B. Randomization was carried out using simple randomization. The password to listen to De tinnitus music was made in even numbers, while the password to listen to the sound generator was in odd numbers. The password was printed on paper and placed in an opaque envelope. The participants who were called to the Tinnitus laboratory from 8.00 am to 8.00 pm. Envelopes were placed on the table, and each person could take the desired envelope. The first to take the envelope was the first person to arrive, and so on. Participants were measured audiometrically before intervention. The next day, the sample application was sent via cell phone. The participants were asked to enter the password inside the envelope that had been taken. The participants then listened to De tinnitus music or a sound generator for 2 hours a day for 3 months (Rahayu et al., 2022). The sample then filled out the VAS questionnaire to assess the comfort experienced when listening to the sound generator or De tinnitus. After 3 months of using tinnitus music or sound generators, the sample again filled out the VAS questionnaire to see the long-term effects. Samples were called back for audiometric examination at the Tinnitus Laboratory. Side effects that appear were recorded through anamnesis.

Data analysis was carried out using descriptive analysis and proportion comparison tests. Descriptive analysis was used to describe subject characteristics and research variables by group. Variables with categorical data scales were displayed using relative frequencies (number and percent). The results of the descriptive analysis were presented in a cross-distribution table. The proportion comparison test was used to compare the incidence of each comfort indicator based on treatment groups, carried out by creating a 2x2 cross table and using the Chi-square test. All data analysis in this research was done using SPSS IBM 21 for Windows.

RESULTS

This research was conducted on 69 volunteers who listened to music De Tinnitus only and 69 who listened to music De Tinnitus + sound generator. Volunteers in both groups were matched based on age and gender. Research characteristics can be seen in Table 1. Subjects in both groups were predominantly male (50.7%) and aged <40 years old (75.4%). The mean baseline audiometry for the right ear in the music De tinnitus group was 13.33 ± 5.83 dB, and for the left ear, 12.88 ± 5.47 dB. The mean of baseline audiometry for the right ear in the Music de tinnitus + sound generator group was 14.42 ± 5.55 dB, and for the left ear, 13.78 ± 5.61 dB.

The results of statistical analysis showed that there was no difference in the comfort of De Tinnitus music plus a sound generator compared to De Tinnitus music in healthy people based on audiometry and VAS (p>0.05) (Table 2). These results show that De Tinnitus music plus a sound

Table 1. Characteristics of Research Subject

<table>
<thead>
<tr>
<th>Characteristics</th>
<th>De Tinnitus Music (n=69)</th>
<th>De Tinnitus Music + Sound Generator (n=69)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Gender, n (%)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Male</td>
<td>35 (50,7)</td>
<td>35 (50,7)</td>
</tr>
<tr>
<td>Female</td>
<td>34 (49,3)</td>
<td>34 (49,3)</td>
</tr>
<tr>
<td>Age, n (%)</td>
<td></td>
<td></td>
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<tr>
<td>&lt;40 tahun</td>
<td>52 (75,4)</td>
<td>52 (75,4)</td>
</tr>
<tr>
<td>≥40 tahun</td>
<td>17 (24,6)</td>
<td>17 (24,6)</td>
</tr>
<tr>
<td>Audiometry Baseline</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Right Ear (dB)</td>
<td>13.33 ± 5.83</td>
<td>14.42 ± 5.55</td>
</tr>
<tr>
<td>Left Ear (dB)</td>
<td>12.88 ± 5.47</td>
<td>13.78 ± 5.61</td>
</tr>
<tr>
<td>VAS Baseline</td>
<td>5.36 ± 8.32</td>
<td>4.93 ± 7.59</td>
</tr>
</tbody>
</table>

Table 2. Comparison of Audiometry and VAS Between Groups

<table>
<thead>
<tr>
<th>Characteristics</th>
<th>De Tinnitus Music (n=69)</th>
<th>De Tinnitus Music + Sound Generator (n=69)</th>
<th>p - value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Right Ear Audiometry (dB)</td>
<td>11.97 ± 4.16</td>
<td>13.06 ± 4.75</td>
<td>0.264</td>
</tr>
<tr>
<td>Left Ear Audiometry (dB)</td>
<td>12.57 ± 4.61</td>
<td>13.59 ± 5.44</td>
<td>0.343</td>
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<tr>
<td>VAS</td>
<td>8.84 ± 8.32</td>
<td>11.74 ± 11.10</td>
<td>0.085</td>
</tr>
</tbody>
</table>
generator is comfortable for normal people. There were no side effects such as ear ringing, blocked ears, dizziness, or other side effects.

**DISCUSSION**

This study found no difference in the comfort of De Tinnitus music plus a sound generator compared to De Tinnitus music in normal people based on audiometry and VAS. There were no side effects such as ear ringing, blocked ears, dizziness, or other side effects. De Tinnitus music plus a safe and comfortable sound generator for the ears is for 2 hours in 2 days with a maximum sound threshold of 91dB. The results of this study show that De Tinnitus music plus a sound generator is comfortable for normal people, even if listened to through earphones at close range and for a long period. This research could 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 plus a sound generator versus De Tinnitus music. The results of this study are from previous clinical trials that have tested sound generators on tinnitus sufferers, and most patients felt comfortable without side effects. Previous research by Rahayu et al. also reported that the sound generator was comfortable for all participants. This study used the sound generator for 2 hours in 2 days with a maximum sound threshold of 91dB. Recent RCTs and a systematic review of RCT also showed that using sound generators was safe and had no side effects. Previous research by Rahayu et al. also reported that the sound generator was comfortable for all participants. This study used the sound generator for 2 hours in 2 days with a maximum sound threshold of 91dB. Recent RCTs and a systematic review of RCT also showed that using sound generators was safe and had no side effects.

De Tinnitus is a disorder that originates in the brain, but the trigger is in the peripheral area. Damage caused by hearing loss to the inner hair cells results in loss of normal function of the auditory nerve. Therapy that is believed to be able to overcome tinnitus is carried out by identifying the tinnitus sound, looking for the accuracy of the frequency and amplitude of the tinnitus, and then creating a sound generator in the form of sound masking and varying tones that calm the tinnitus sufferer, then matching it with the patient until the patient feels comfortable. This is given for a certain period so that the process of adaptation and improvement in the patient's tinnitus occurs.

De Tinnitus is a sound generator plus music developed by the author. De tinnitus is made from the frequency of tinnitus patients to disguise tinnitus, combined with variations in the tone of music that calms tinnitus sufferers. The sound is made from acoustic music, violin, keyboard and Balinese gamelan with a soothing tempo, plus a collection of songs from de Bongol. De tinnitus can be entered into a mobile phone application to make it easier for patients to reach.

The limitation of this research is that the sample size only consisted of 69 patients due to limited research time and being in the Denpasar area only. Future studies can be conducted in a wider geographic area with a larger sample size.

**CONCLUSION**

The comfort of De Tinnitus music plus a sound generator is comparable to Tinnitus music alone in healthy people. There are no side effects from using de Tinnitus plus sound generator in healthy people. The use of a sound generator that is safe and comfortable for the ears is for 2 hours in 2 days with a maximum sound threshold of 91dB. Because music de Tinnitus plus a sound generator was proven to be comfortable for normal people in Phase I clinical trials, it could proceed further research in the form of a Phase II clinical trial to assess the effectiveness of music de Tinnitus plus a sound generator as a tinnitus therapy.

**ETHICS CONSIDERATION**

This study has obtained an Ethics Approval issued by the Research Ethics Committee of the Faculty of Medicine, Udayana University, number 1879/UN14.2.2.VII.14/LT/2023 on 21st July 2023.

**CONFLICT OF INTEREST**

There is no conflict of interest in this study.

**FUNDING**

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