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Effects of Tinnitus Retraining Therapy with Different Colours of Sound

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Abstract

Background: In Tinnitus Retraining Therapy (TRT) sound stimulation is conventionally performed with low-level broadband sound generators; since the patient has to receive it for many hours in a day, it is important that the sound is tolerable and agreeable to the patient. A clinical trial was undertaken to evaluate the effect of different colour sound generators on tinnitus. The colour of a sound refers to the power spectrum of the signal. The sound generators used in this study provide the option to choose the preferred or most acceptable sound among white, red and pink noise. **Methods and Findings:** Changes in Tinnitus Handicap Inventory and Numeric Rating Scales were measured in 20 patients after 3 and 6 months following the fitting of ear-level multi-colour sound generators. The outcomes were compared to a similar group of 20 participants receiving the same management except through conventional white noise sound generators. Significant improvements were obtained in both groups following 3 and 6 months after fitting. No significant difference was found between the two groups using one or the other type of sound. Two thirds of the patient preferred white noise, making it the most appealing amongst the options. The rest of the patients indicated red noise as the preferred sound given that it reminded them of soothing noises like shower or rainfall. No one chose pink noise. **Conclusions:** TRT with different colour sound generators is effective in reducing the discomfort caused by tinnitus in normal hearing patients. Enabling the patients to choose their preferred sound after short trial periods achieved higher patient satisfaction. This practice could help tailor individualized treatment for each patient.

Keywords: tinnitus, tinnitus retraining therapy, sound therapy, treatment.

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INTRODUCTION

Tinnitus is generally defined as the perception of sound in the absence of a corresponding external stimulus. The etiology is not fully understood and hence no treatment method can definitively cure tinnitus. Various management strategies have been developed to reduce the effect of tinnitus on the patient's quality of life. Among the various treatments employed to attenuate discomfort related to tinnitus, the Tinnitus Retraining Therapy (TRT)[1] is one of the most commonly used.

TRT combines counselling, which is based on the neurophysiological model of tinnitus[2], and sound stimulation. Sound stimulation is aimed at facilitating the process of habituation of tinnitus by decreasing the difference between the tinnitus signal and the background neuronal activity, thus making the patient less likely to pay conscious attention to the tinnitus[1,3,4].

Broadband noise has been available as a masking sound since the late 1970s. Nowadays, the use of a low-level broadband sound, produced by open-canal bilateral ear-level sound generators, represents the most direct and convenient strategy for implementing sound therapy for tinnitus participants with little or no hearing loss[5]. This practice is based on theoretical assumptions that broadband noise may activate the greatest number of auditory nerve fibres facilitating habituation[6].

As the TRT protocol stipulates that the sound stimulation should be performed daily for at least 6 hours during 18 months, it is important that the sound is well tolerated by the patient. For this purpose, other types of sounds, equally effective in reducing the tinnitus annoyance, but more agreeable to the patient, have been proposed. Kim et al. compared the effect of different sounds on the treatment outcome of TRT and concluded that broadband sound is better than narrowband sound or mixed sound in relieving the patients from tinnitus[5]. Barozzi et al. evaluated the effects of sounds of nature on tinnitus, demonstrating significant improvements in tinnitus perception comparable to those obtained with conventional broadband noise stimulation[7].

No previous study assessed the effect of sounds of different colours on TRT. The colour of a sound refers to the power spectrum of the noise signal. Different colours of noise have significantly different properties and sound different to human ears. The colour names for sounds are derived from a loose analogy between the spectrum of sound wave frequencies and the equivalent spectrum of light wave frequencies. White noise contains all audible frequencies distributed uniformly throughout the spectrum. Pink noise has equal energy per octave (that is, the same energy from 100 to 200 Hz than it does from 200 to 400 Hz or 10,000 to 20,000 Hz). Its spectrum is linear in logarithmic space; it has equal power in bands that are proportionally wide. The spectral power density, compared with white noise, decreases by 3 dB per octave. Red noise, a synonym for Brownian noise, has a power density which decreases 6 dB per octave with increasing frequency (most amount of low frequency energy or power). The definition of red noise is not as precise as that of white and pink noise, and the term mostly refers to low-pitched noises.

Objective: To evaluate the effect of sound generators of different colours on the treatment outcome of TRT in subjects affected by subjective chronic debilitating tinnitus. We compared the effect of different colour sound generators, including those producing red and pink noise, to conventional white noise generators. We hypothesize that TRT with different colours of sound, selected as preferred or most acceptable by the patients, will be as effective on tinnitus annoyance as TRT with conventional sounds.

METHODS

Study design: Controlled trial with historical control group.

Power analysis/sample size: Based on the Dos Santos study[8], a standard deviation of 25 for THI change over time is expected. Having fixed type I error to 0.05, a study size of 20 patients per group has an 80% power in detecting a minimum clinically relevant effect of 12 (difference of THI change over time at the end of the study between the two groups).

Twenty-three tinnitus patients (Group 1) were recruited from the Tinnitus Clinic of Milan.

Inclusion criteria were: Normal hearing defined by Pure Tone Average (PTA) at 0.5, 1, 2 kHz ≤ 25 dB HL, tinnitus duration of at least 6 months, no prior experience with sound therapy. Patients with objective tinnitus or conductive hearing loss, Ménière's disease or tumors of the cerebellopontine angle were excluded.

As control group (Group 2), we used a sample of 20 patients, who had participated in previous studies on the effects of conventional sound generators and fell within the same inclusion criteria. All patients gave an informed consent.

At baseline, all patients underwent a complete audiological evaluation including a full history and physical examination, extended range pure-tone audiometry, immittance testing and tinnitus measurement.

Pure-tone audiometry was performed in a sound-attenuated booth. Hearing levels were measured in each ear separately at 0.25-16 kHz, at half octave steps for air conduction and at 0.5-4 kHz for bone conduction. The PTA at 0.5, 1, 2 kHz was calculated.

Tympanograms were recorded using a 226 Hz probe tone and classified as type A, type B, type C, type As and type Ad[9]. In patients with type a tympanograms, the contralateral Acoustic Reflexes were determined.

Tinnitus measurements consisted of the THI questionnaire in the Italian version[10], Numeric Rating

Scale (NRS) for annoyance (between 0 to 10, with 0 = "not annoying" and 10 = "extremely annoying") as well as tinnitus pitch. The same audiometric instruments were used by the same trained audiologists in both groups.

The patients were informed of the TRT option and motivated to try sound therapy with open-canal bilateral ear-level sound generators. A counselling session was provided before starting the sound therapy, including a clear explanation of the physiology of hearing and the present knowledge about tinnitus generation and perception.

Group 1 participants were fitted with combination hearing aids Oticon Alta 2 Pro Ti, with the tinnitus sound generator switched on and the hearing aid microphone deactivated. The devices provided options for the use of three sounds - white noise, pink noise and red noise – in order to let the patients choose the preferred or most acceptable sounds. None of the 'sounds of nature' in the sound generators were used and modulation options were not chosen.

Group 2 participants were fitted with conventional sound generators providing white noise. All participants were instructed to set the sound level to the lowest comfortable level at which mixing of the treatment sound and tinnitus occurred, as well as to use the device as much as possible, with a minimum of 8 hours per day.

Tinnitus treatment outcomes were assessed three (T3) and six months (T6) after commencing treatment. During the follow up visits, both the THI and the NRS were administered in order to quantify sound therapy benefit.

Statistical analysis

Fisher's exact test was used to compare the two groups considering categorical variables; for the numerical variables, Student t test, in the case of a normal distribution, and two-sample median test, in the case of an asymmetrical distribution were used.

We fitted two-level models to the THI and NRS profiles over time (regarding patients as random terms). We tested whether there was a decline of the response variable over time and whether there was any difference between the two groups of patients.

Statistical analysis was performed with SAS software version 9.4. Copyright, SAS Institute Inc. SAS and all other SAS Institute Inc. product or service names are registered trademarks or trademarks of SAS Institute Inc., Cary, NC, USA.

Primary and secondary outcome measurements

The primary outcome is the difference between the two groups in scores on the THI between baseline and follow-up, assessed longitudinally after 3 and 6 months of treatment. Secondary outcomes include change in NRS – annoyance.

RESULTS

In Group 1, three patients did not attend the final evaluation (2 moved far away, the other was no longer available for follow-up visits); hence the data refers to 20 participants (17 males and 3 females; median age 56 years). Group 2 consisted of 16 males and 4 females with median age of 53 years. The two groups were compared on these parameters and found statistically non-different (two-sample median test, $p = 0.5323$).

The tinnitus and demographic characteristics of both groups are reported in Table 1. No differences were observed between the two groups. In Group 1 tinnitus localization was in both ears in 9 subjects and in one ear in 11 subjects (left ear); in Group 2 tinnitus was bilateral in 13 patients and unilateral in 7 patients (6 left, 2 right; (Fisher's exact test, $p = 0.2003$)).

The mean air conduction thresholds and 95% confidence interval of right and left ear for both groups are illustrated in Figure 1. All patients had type A tympanograms with acoustic reflexes present.

Patients' choices of sounds were as follows: 2 patients chose red noise, 14 white noise, and 4 white and red noise. None chose the pink noise setting. 87.5% of the patients used the device 24 hours a day, every day.

The two outcomes, THI and NRS, at baseline, did not differ between the two groups: THI in group 1 has a mean value of 44.7 (SD: 25.9) and in group 2 48.5 (SD: 11.9), p for Student t test = 0.5553. NRS in group 1 has a mean value of 6.2 (SD: 2.2) and in group 2 6.0 (SD: 1.7), p for Student t test = 0.8155.

Mean THI and NRS scores over time of Group 1 and Group 2 are illustrated in Figures 2 and 3.

For the THI, we observed a significant ($p < 0.0001$) decline over time: we observed a significant difference between the THI mean at time 0 and at time 3 (-16.27, CI 95%: -22.00; -10.53, $p < 0.0001$), but we did not observe a significant difference between the THI mean at time 3 and at time 6 (-3.38, CI 95%: -7.16; 0.40, $p = 0.0781$).

For the NRS, we observed a significant ($p = 0.0001$) decline over time: in particular, we observed a significant difference between the NRS mean at time 0 and at time 3 (-1.93, CI95%: -2.56; -1.31, $p < 0.0001$), but we did not observe a significant difference between the NRS mean

Table 1. Baseline Audiological parameters and subjective Tinnitus Characteristics (median, min-max, Fisher's test for gender and two-sample median test for the other variables). PTA refers to pure tone averages of 0.5-1-2 kHz.

Characteristic	Group 1	Group 2	P
Number of patients	20	20	
Number of males	17	16	0.9999
Age (years)	56, 21-73	53, 30-75	0.5323
Right PTA (dB HL)	10.0, 10.0-25.0	12.5, 8.3-25.0	0.2117
Left PTA (dB HL)	11.7, 10.0-23.3	11.7, 10.0-21.7	0.9219
Tinnitus Pitch (kHz)	10.0, 2.0-14.0	9.0, 0.5-16.0	0.8469

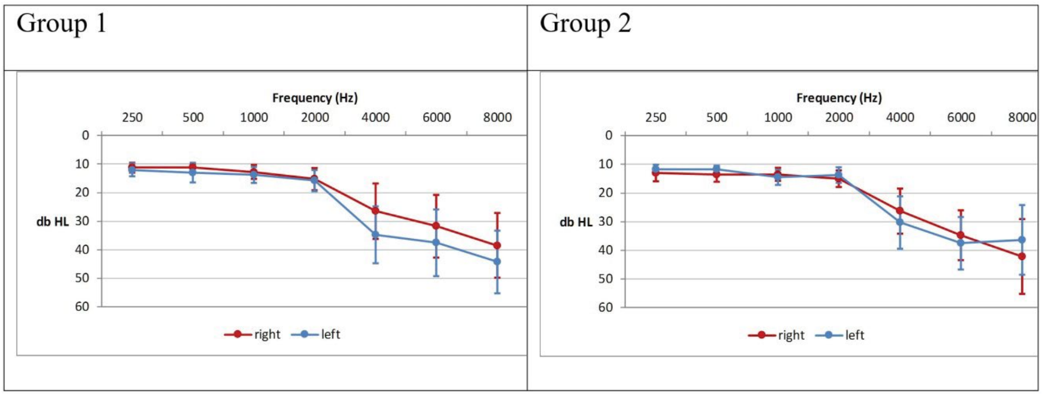

Figure 1. (A) Mean air conduction thresholds and 95% confidence interval of right and left ear in Group 1 patients. (B) Mean air conduction thresholds and 95% confidence interval of right and left ear in Group 2 patients.

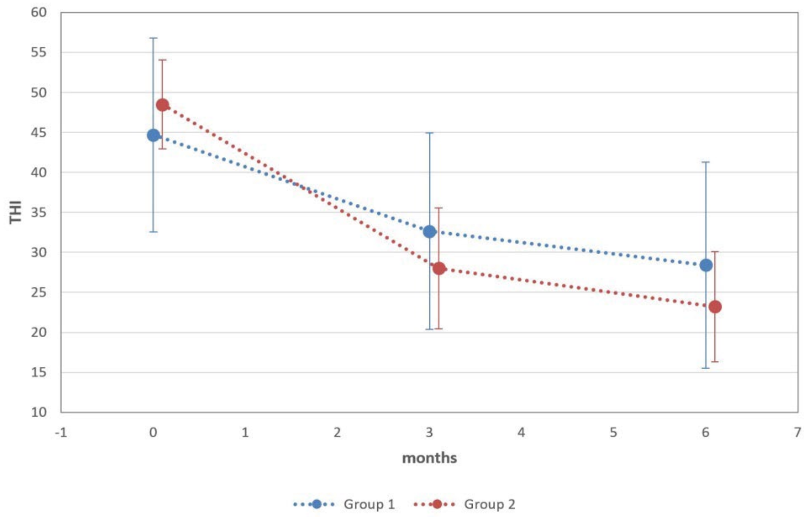

Figure 2. Mean THI scores over time of Group 1 and Group 2 patients. Whiskers show maximum and minimum levels.

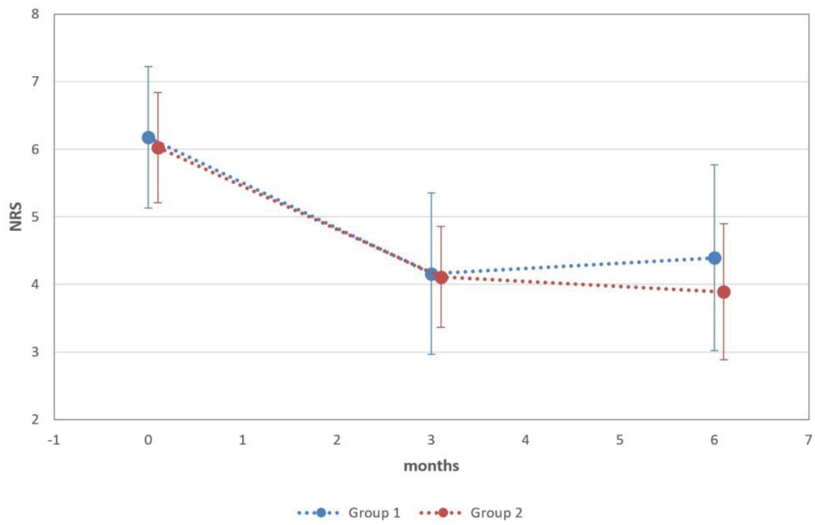

Figure 3. Mean NRS scores over time of Group 1 and Group 2 patients. Whiskers show maximum and minimum levels.

at time 3 and at time 6 (0.02, CI 95%: -0.46; 0.49, $p = 0.9429$).

For both THI and NRS no difference was observed between the two groups.

DISCUSSION

This study evaluated the effect of different colours of sound on the treatment outcome of TRT in subjects with annoying tinnitus. We observed a significant improvement of 12 points in THI scores and of 2 points on the numeric scale during three months of therapy; these positive results were still observed after 6 months of treatment, though no significant additional improvement between months 3 and 6 was found. Our results thus demonstrate the effectiveness of TRT with different colours of sound in reducing the discomfort caused by tinnitus.

Furthermore, both participants treated with different colour sound generators and conventional sounds presented similar responses in reduction of discomfort caused by tinnitus as measured using THI and NRS scores.

Despite the current lack of explanatory evidence, sound therapy is considered an essential component of any clinical program of tinnitus management[11]. In TRT, bilateral ear-level devices meeting certain performance criteria, including stability of the wideband noise, precision volume adjusting at low levels, and open-ear configurations are normally recommended[3]. According to Jastreboff[1], a constant sound in the background reduces the contrast between the tinnitus and the quiet environment thus making the tinnitus less likely to attract attention. The requirement is that the sound be relatively broad in its frequency spectrum[3]. Stimulation across a broad range of frequencies with neutral sounds, such as white noise, is considered effective in facilitating habituation.

This trial demonstrated that sound therapy using different colour sound generators has a positive effect on tinnitus patients. Different people with tinnitus have different sound preferences and one sound is not generally superior to another one. The sound generators used in this study provide the option to choose the preferred or most acceptable sound among white, red and pink noise. The most widely preferred complex sounds were white and red noise. White noise was preferred by about two thirds of the participants as it was perceived to overshadow the tinnitus pitch more effectively. Red noise has a dampened or soft quality compared to traditional white noise. The sound is a low roar, reminiscent of the sounds encountered in a shower, or those produced by a waterfall or heavy rainfall. It is not as overwhelming as white noise; some tinnitus patients considered it more pleasant for its soothing impact and easier to accept as a background. This finding is consistent with our previous study suggesting that sounds of nature, often evoking positive associations, can have beneficial effects on tinnitus[7]. Pink noise was not chosen by anyone in our sample.

No negative side effects of the sounds were reported. Most of our patients found the sound very comfortable over a daily 24 hour period and the amplification was generally appreciated. Because the sound has to be listened to for many hours every day in order to eventually achieve habituation, people found it is easier to tolerate a particular sound when given the possibility to choose among different broad band neutral sounds, as offered by different colours sound generators.

CONCLUSION

Based on the results of this study, it can be concluded that the combined use of counselling and different colour sound generators is effective in reducing the discomfort caused by tinnitus in normal hearing patients. Enabling the patients to choose their preferred sound after short trial periods achieved high patient satisfaction. This practice could help tailor individualized treatment for each patient. Some caution is required in interpreting these results, based on the relatively small number of subjects.

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