Introduction

Subjective tinnitus is a condition in which a ringing, roaring, whistling, buzzing or clicking sound inside the head is experienced in the absence of any external sound.

Tinnitus affects about 10-15% of the adult population and, in five to ten people out of a hundred, it is a disabling disorder. The noises may be located in one or both ears or in the middle of the head. Tinnitus sounds may be low-, medium- or high-pitched. There may be a single noise or two or more components. The noise may be continuous or it may come and go.

Subjective tinnitus is frequently associated with hearing loss. About 90% of patients have sensorineural hearing loss, 5% suffer from conductive hearing loss, 5% have normal hearing.

Various models for tinnitus pathogenesis were reviewed recently, emphasizing the importance of neurological processes in the development of tinnitus.

Therapies for tinnitus vary from drug treatment, vitamin therapy, biofeedback, lidocaine injections and acupuncture to hypnosis. These types of treatments have been helpful for some people.

Others have experienced a temporary improvement after broadband white noise masking. Tinnitus masking has been a widely used method for treating clinically significant tinnitus. The method, referred to here as “sound-based relief”, typically uses ear-level devices (“maskers”) for palliative tinnitus relief.

Patients who underwent Tinnitus Retraining Therapy (TRT) and Cognitive Behavioural Therapy have also reported positive effects. TRT treatment is based on Jastreboff’s neurophysiological model. TRT consists of two components: counselling and sound therapy with dedicated hearing aids and sound generators. It has proven useful in reducing tinnitus-related symptoms.

Cognitive behavioural therapy (CBT) uses relaxation, cognitive restructuring of attitudes, and exposure to exacerbating situations to promote habituation. It may benefit tinnitus patients, as may the treatment of associated psychological conditions. Research has shown that CBT can have an effect on the qualitative aspects of tinnitus and contributes positively to the management of tinnitus.

Phase-shift tinnitus treatment: an open prospective clinical trial

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Key-words. Tinnitus; treatment; clinical trial; pure tones


Thirty-five patients with pure tone tinnitus unresponsive to all previous treatment were enrolled in the study. All patients were treated three times in one week. If the patient noticed an improvement, the therapy was continued for six weeks with a home device customised to their specific treatment frequency.

Twenty-one of the 35 patients (60%) responded positively to the initial therapy sessions. Tinnitus was assessed before treatment, after three in-office Tinnitus Phase-Out™ System therapy sessions, and after six weeks of home use of the Patient Treatment Device. The assessment instruments were a VAS loudness scale and the quality of life Tinnitus Questionnaire. Significant tinnitus reduction was obtained on VAS after three office Tinnitus Phase-Out™ System therapy sessions (before treatment: mean VAS = 6.4; after three therapy sessions: mean VAS = 4.9; p = 0.042) and after six weeks of home use of the Patient Treatment Device (mean VAS = 4.9; p = 0.005). When analysing the mean TQ score over treatment, there was a significant improvement in total score from pretreatment (mean TQ score = 41.9) to six weeks after home use of the Patient Treatment Device use (mean TQ score = 36.4) (p = 0.003). In view of the results obtained, the Phase-Out Treatment™ for tinnitus may provide the majority of patients with a significant improvement in their symptoms. Further evaluation, comparing this specific Phase-Out Treatment™ with more general noise stimulation treatment, will further specify the indications for this treatment option.
Tinnitus Phase-Out™ Treatment is a new non-invasive technique and works through the sequential phase-shifting of the patient’s individual psycho-acoustically-assessed tinnitus pitch. This is similar to the technology used in commercial sound-cancellation headphones. It was hypothesised that the introduction of a sound wave phase-shifted 180 degrees from a patient’s tinnitus wave could result in sound cancellation by interfering with the complex of neural signals perceived in the auditory cortex as tinnitus. This method assumes pure tone tinnitus.

The purpose of this study was to determine the efficacy of the new Tinnitus Phase-Out™ Treatment in conjunction with the counselling component of TRT.

Materials and methods

Participants
A total of 35 participants with pure tone tinnitus were recruited. The pretreatment of tinnitus-related disturbance had to be clinically significant. No improvement had been experienced for the preceding three months with cognitive tinnitus retraining or medical treatment. Every patient underwent otoneurological examination, audiological assessment (audiometry, speech audiometry, ABR) and MRI imaging of the posterior fossa to exclude organic pathology. In every participant, the tinnitus was carefully sound-typed, with assessments of frequency and loudness. The possibilities of masking and residual inhibition of the tinnitus were examined for each participant.

The mean age of the patients was 50.9 years (standard deviation [SD] = 12) with a range of 25 to 75 years. The mean duration of tinnitus was 6.1 years (SD = 5.6). Twenty-two participants had bilateral tinnitus; thirteen participants had unilateral tinnitus.

Figure 1 illustrates the mean level of hearing loss among the subjects. The mean pure tone threshold (PTA; average of 500, 1000 and 2000 Hz) was 16.8 dB HL (SD = 11.8).

Measurement device

The Tinnitus Phase-Out™ System works through the phase-shifting of sound waves, using a technology that is similar in principle to that used in noise-cancelling headphones and industrial noise-reduction applications. The Tinnitus Phase-Out™ System is designed to address pure tone single-pitch tinnitus. The Tinnitus Phase-Out™ System uses a set of headphones to deliver a pure sine wave at 6 degrees out of phase, sequentially for 30 seconds during 30 minutes.

Study design

The clinician used the Tinnitus Phase-Out™ System to ‘sound-type’ patients and determine individual tinnitus characteristics. Patients made their own assessment of the frequency (Hz) and amplitude (dB) of their tinnitus five times to ensure accuracy. Once the tinnitus had been sound-typed, patients were exposed to a prescribed, electronically manipulated phase-shifting tone through headphones for 30 minutes. The treatment programme consisted of a series of three in-office Tinnitus Phase-Out™ System therapy sessions, each lasting for 30 minutes. Post-treatment measurements were made and registered after each session.

If the Tinnitus Phase-Out™ System therapy was found to achieve the desired therapeutic effect, participants were provided with a Patient Treatment Device for home use, with earphones and an acoustic stimulus modified to their individual tinnitus profile. They were instructed to listen to the therapeutic sound pattern through headphones for just 30 minutes three times a week in a convenient, quiet location of their choosing.

Visual Analogue Scale

All subjects scored the loudness of their tinnitus on a Visual Analogue Scale.
Phase-shift tinnitus treatment

Scale (VAS). The left-hand side of the scale was assigned a score of 0 (= no tinnitus) and the right-hand side of the scale was a score of 10 (= extremely loud tinnitus). The subjects were asked to mark with an X where they perceived the loudness of their tinnitus to be. The VAS was administered before the phase-out treatment, before and after each treatment session, and after 6 weeks of home treatment.

The tinnitus questionnaire
To evaluate the distress caused by the tinnitus, all subjects completed the tinnitus questionnaire. It consists of 52 questions, giving a description of common complaints seen in tinnitus patients. The level of tinnitus is defined on the basis of the total score (max score: 84). A score of 0 to 30 is considered to represent mild tinnitus (degree 1), 31 to 46 corresponds to moderate tinnitus (degree 2); severe tinnitus is a score between 47 and 59 (degree 3); finally, a score of 60 or more corresponds to very severe tinnitus (degree 4). The tinnitus questionnaire was administered before the phase-out treatment, before and after each treatment session and after 6 weeks of home treatment.

Results
Of the 35 patients included in the trial, fourteen (40%) had no reduction in perceived tinnitus after three in-office Tinnitus Phase-Out™ System therapy sessions. In accordance with the protocol, these patients were not given the treatment device for use at home. When the results were analysed, it was found that this group of patients also had no significant improvement after the three in-office Tinnitus Phase-Out™ System therapy sessions (paired t-test; p = 0.194).

The results for the 21 patients that did take the Patient Treatment Device home for six weeks are shown in Figure 2. The mean VAS before the treatment was 6.4 (SD = 2.2). After three in-office therapy sessions, the VAS fell significantly to a mean of 4.9 (SD = 2.9) (paired t-test; p = 0.042). After six weeks of home use of the Patient Treatment Device, the mean VAS was 4.9 (SD = 2.1) (p = 0.005). This VAS is not significantly different from the VAS after the third in-office therapy session (p = 0.848).

Analysis of the mean TQ score over the course of treatment showed that the total score at pre-treatment (mean 41.9; SD = 18.2) improved after six weeks of home use of the Patient Treatment Device use (mean 36.4; SD = 15.9). This improvement was significant (p = 0.003).

Figure 3 shows individual treatment outcomes. Statistical analysis revealed a significant correlation between the improvement after 1 week and the improvement after 6 weeks (p = 0.02).

A 2-way repeated-measures ANOVA showed no significant influence of unilateral or bilateral tinnitus, or of age on the VAS score (p = 0.578; p = 0.620) or on the total score of the TQ (p = 0.302; p = 798).

There was no statistical correlation between the pretreatment masking results of the tinnitus and the effect of the Tinnitus Phase-Out™ Treatment (p = 0.471).

Discussion
Of the 35 patients included in the trial, 21 (60%) had a significant improvement in their tinnitus loudness (VAS) after three in-office Tinnitus Phase-Out™ System therapy sessions (p = 0.042). The result even improved after six weeks of home use of the Patient Treatment Device (p = 0.005). The mean TQ score improved significantly after six weeks using the Patient Treatment Device (p = 0.003).

This study is based on the hypothesis that shifting the phase of a sound wave based on a predominant tone frequency and

![Figure 2](image-url) Average tinnitus loudness (VAS) at different time intervals
amplitude may have a positive effect on tinnitus.

The patients included in this study had predominantly pure tone tinnitus that had been stable during the preceding three months and that had proved unresponsive to previous treatment (TRT, drug treatment). The significant positive effect of the Tinnitus Phase-Out™ Treatment is therefore unlikely to be due to spontaneous recovery. However, a placebo effect cannot be excluded.

The results of this study also show that residual inhibition, as determined by audiological tinnitus assessment, is not a predictive factor for the effectiveness of the treatment.

The treatment effects presented here correspond to those reported by Lipman and Lipman. Phase-shift treatment significantly benefitted 57% of the patients, with 37% reporting a decrease by one grade on the Tinnitus Handicap Inventory.

The outcomes of this study concur with results from Tinnitus Retraining Therapy. In traditional sound enrichment therapy, the effectiveness of the treatment is evaluated over a period of twelve months. The lack of a significant difference between VAS after three in-office Tinnitus Phase-Out™ System therapy sessions and after six weeks in our study may be due to the short evaluation time. Extending the evaluation period could identify a significant improvement over time.

These outcomes also compare favourably with published results from alternative approaches that have been developed in recent years. The Neuromonics Tinnitus Treatment is a new approach that incorporates the principles of systematic desensitisation. The Neuromonics Tinnitus Treatment combines the use of acoustic stimulation with a structured programme of counselling and support from a clinician trained in tinnitus rehabilitation. A recent study found that the Neuromonics Tinnitus Treatment achieves rapid and significant improvements in the severity of tinnitus symptoms and their effect on the subject’s quality of life. The Neuromonics Tinnitus Treatment is customised to each patient’s audiogram and the stimulus is embedded and delivered at specific intervals coordinated with precisely designed music. The Tinnitus Phase-Out™ Treatment, on the other hand, is based on the patient’s individual psycho-acoustically-assessed tinnitus pitch and the stimulus is a prescribed, electronically manipulated tone.

The results obtained suggest that the Phase-Out Treatment™ for tinnitus may result in a significant improvement in the symptoms of the majority of patients. Further evaluation comparing this specific Phase-Out Treatment™ with more general noise stimulation treatment will further specify the indications for this treatment option.

References


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