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Relief for chronic tinnitus – without pharmaceuticals

Results of a clinical observation study with the “tailor-made notched music” method

What do Phil Collins, Keanu Reeves and Barbara Streisand have in common with Ludwig van Beethoven and Friedrich Smetana? Correct: they all suffer or suffered from distressing noises in the ear, tinnitus [1]**.**

Epidemiology and definition of tinnitus

But it’s not just celebrities who suffer from tinnitus by any means. A phone survey of 3,000 people showed that 1 in 4 people has suffered at least once from ear noise or is still suffering from it. A third of those affected (around 8% of those surveyed) said tinnitus had a serious impact on them. In absolute terms, this means there are around 20 million people suffering from tinnitus in the Federal Republic, and of those, around 7 million are heavily affected [2].

“Tinnitus” (lat.: tinnire, ringing, jingling) refers to perceived acoustic phenomena of any origin that only the patient can hear and which have no objective source.

What does conventional medicine say?

The recommendations of conventional medicine are based on the Clinical Practice Guidelines of the Association of the Scientific Medical Societies in Germany (AWMF). The guidelines have medicolegal ramifications and must be followed to avoid adverse consequences in the event of a legal dispute [3].

For tinnitus, the guidelines insist on a thorough otoneurological and general medical examination of the patient. This is valid as occasionally physical and therefore also treatable causes of tinnitus can be found.

If a thorough examination including imaging procedures (neurocranial MRI) can produce no explanation for the ear noise, this is called idiopathic tinnitus – a euphemistic term to mean there is nothing more conventional medicine can discover.

If the onset of the complaint is not more than three months prior (acute tinnitus), cortisone pulse therapy (prednisolone administered in 250 mg doses via IV on three consecutive days) should take place. If no improvement is shown, the recommendation is to administer cortisone directly into the tympanic cavity or to begin positive pressure oxygen treatment.

If the complaints last longer than three months despite following the guidelines for treatment, this is called chronic tinnitus. Conventional medicine considers this incurable. If suffering is absent to negligible (compensated tinnitus), according to the guidelines, no further treatment is required. If suffering is high and secondary symptoms are present (e.g. disrupted sleep, loss of concentration, irritability, depression, or even suicidal ideation), the guidelines recommend symptomatic treatment of the secondary symptoms.

In practice, this means that a patient with chronic decompensated tinnitus is placed on medication such as sleeping pills, sedatives and antidepressants long-term, with considerable side effects.

Are there alternatives to pharmaceuticals?

The long-term use of such medication can never achieve the goal of a holistic and human-focused therapy oriented around natural medicine. To that end, there have been repeated attempts to provide tinnitus patients with relief via a gentle means. In 2014, the author was able to demonstrate in an observational study that non-pharmaceutical therapeutic interventions are also very suitable in achieving statistically significant improvements of chronic decompensated tinnitus [4]. Evaluated using a survey inventory [5], a reduction in tinnitus intensity of around 17% could be achieved with spin matrix therapy. However, for a considerable 38% of patients, the tinnitus remained unchanged or was even experienced as worse.

A new, non-pharmaceutical treatment method for chronic decompensated tinnitus was developed by audiologists in the ENT department at Münster University Hospital (UMK) under Christo Pantev. With “tailor-made notched music” (TMNM), tinnitus patients listen to music modulated to the frequency and volume of their own tinnitus. After a short period of time, inhibitory effects on the tinnitus could be observed [6].

On the basis of this study, the Swiss company Resaphene developed the tinnitus therapy device Tinniwell [7]. The remainder of this article reports on the results of an observational study of patients with chronic decompensated tinnitus using the device.

The tinnitus treatment device Tinniwell

Tinniwell is essentially an MP3 player but one which is equipped with special functions. Using headphones with active noise cancellation, the tinnitus sufferer can configure the device to their ear noise very precisely with respect to character (tone or sound), frequency (pitch) and volume.

The music data contains peaceful and relaxing music (“Seaside”, “Visions”, “Indian Summer”). The tinnitus programmed in by the user modulates the music in three ways: “fade-out”, “differential mode”, and “overlay”. The user selects the type of modulation that feels comfortable to them and can alter this at any time. The treatment takes place through special therapeutic headphones with built-in, individually adjustable heating. The light warming helps to stimulate the vagus nerve, producing a pleasant relaxing effect. Tinnitus sufferers should

use the therapy for at least 30 minutes a day. A clock is shown on the device's display.

The study's participants

From October 2016 to July 2017, all patients with chronic decompensated tinnitus in the author's ENT practice were informed about the Tinniwell therapy device and invited to take part in an observational study. All patients underwent an otoneurological examination with ear microscopy, tone threshold audiometry, video nystagmography, orientational clinical neurological examination, and neurocranial magnetic resonance imaging.

Exclusion criteria were the discovery of an organic cause of tinnitus (symptomatic tinnitus) and unwillingness to participate in the study.

Thirty patients were recruited in total. One participant left the study after two weeks without explanation. This left 29 participants who could be assessed.

The oldest participant was 72, the youngest was 17. 14 participants were male, 15 were female.

The course of the study

At the start of the Tinniwell therapy, each participant was questioned using Göbel and Hiller's Tinnitus Mini Questionnaire [5] and a tinnitus severity level (score) was established. For seven patients, the psycho-vegetative tension level could also be established using the heart rate variability (HRV) method. The choice of these seven patients was coincidental and relied on the availability of the examination equipment. More detail on the HRV can be found in [8]. Finally, the patients were instructed in the handling of the Tinniwell device.

The participants were instructed to use the Tinniwell therapy device for at least 30 minutes each day over the next following four weeks. Any treatment duration above and beyond that was expressly desired. Light activities such as reading, walking, light house or garden work during the use of the therapy were permitted.

After four to six weeks, the tinnitus score was re-established and a new HRV measurement carried out where applicable. The participants were also surveyed regarding user-friendliness, recommendation level, music preference and preferred therapy mode.

Results

In contrast to one of the author's earlier investigations [4], significant improvements in the amount of tinnitus perceived (measured using the questionnaire score) were observed for all patients. Some patients experienced greater improvement than others. Not a single participant experienced a worsening of the condition. One patient lost their tinnitus completely.

The average tinnitus score (highest possible score: 24 points) dropped from an initial 15.5 points to 7.3 points.

This corresponds to a reduction in tinnitus from average moderately severe tinnitus to mild tinnitus.

Expressed in percentages, on average the tinnitus decreased by 52.9%. The results ranged from a 100% reduction (complete disappearance) and a 20% improvement (fig. 1).

User-friendliness: Rated using “simple”, “difficult” and “too complicated”, two participants (6.9%) evaluated operation of the device as “difficult”. All other participants found operation “simple”; no one found it “too complicated” (fig. 2).

Recommendation level: This used a scale of “would definitely recommend/would recommend”, “would recommend conditionally”, “would recommend less”, “would not recommend”. 58% of participants said they would definitely recommend or would recommend Tinniwell. 30% opted for “would recommend conditionally” and 12% for “would recommend less”. No participant selected “would not recommend” (fig. 3).

Operating mode: The choices here were “fade-out”, “differential mode”, and “overlay”. 81% of the participants predominantly used fade-out mode. 11% chose differential mode and 8% chose overlay (fig. 4).

Music preference: The device comes with three melodies installed: “Seaside”, “Indian Summer” and “Visions”. It is also possible to load music onto the Tinniwell. These tracks are also modulated through the TMNM principle. Only one patient used this feature during the study (fig. 5).

42% preferred “Seaside”, 35% preferred “Indian Summer” and 23% preferred “Visions”.

Heart rate variability (HRV) measurement results:

For seven participants, we were able to take an HRV measurement at the start of the treatment and after four weeks. At the same time, the parameters stress index, energy reserve, psycho-emotional state, and biological age were analysed.

After a four-week Tinniwell treatment, the stress index had decreased by an average of 45.6%. The energy reserve had increased by an average of 15.5%, the psycho-emotional state had improved by 22.5%, and the biological age had decreased by 6.3 years (13.1%).

Conclusion

The ascertainment reached in the guidelines that chronic decompensated tinnitus is at best manageable through long-term pharmaceutical treatment of the secondary psychological symptoms needs to be revisited if not completely revised. The results of this observational study suggest the conclusion that non-pharmaceutical therapeutic interventions can achieve good results – without unwanted side effects.

The results of the HRV measurements show that the efficacy of the TMNM method is in no way restricted to a local effect on the primary symptom of tinnitus; rather, Tinniwell treatment is attendant to a holistic, harmonising regulatory effect on the organism as a whole.

This observational study represents a first step, providing reasonable grounds for hope for many people suffering from tinnitus. To increase the evidence level

of the TMNM method, a comprehensive double-blind placebo-controlled study at a large university hospital is planned. We eagerly look forward to the results. But tinnitus can already be relieved effectively – without pharmaceuticals.

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