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Multimodal Therapeutic Effects of Sound Masking Combined with Electromagnetic Stimulation for the Treatment of Tinnitus

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Tinnitus is defined as the perception of a sound in the absence of an external source that generated it [1]. It is usually described by those who experience it as a hissing, buzzing, beeping, ringing sound, or a sound synchronous with the heartbeat [2].

Tinnitus can be objective or subjective. Objective tinnitus refers to the perception of a sound that can also be heard by the examiner and is usually due to turbulent blood flow or muscle contraction [3]. More commonly, however, tinnitus is subjective; the sound is heard only by the person experiencing it and no source of the sound is identified [4]. Tinnitus affects between 5% and 43% of the general population and the prevalence increases with age [5].

Tinnitus is a symptom, but due to its clinical characteristics it takes on the typical connotations of disabling pathologies [6]. For many people, tinnitus has disabling effects such as insomnia, difficulty concentrating, difficulty communicating and social interaction with negative emotional responses such as anxiety and depression [7]. In approximately 90% of cases, chronic tinnitus is comorbid with some degree of hearing loss, which can confound these disabling effects [8].

However, the association between hearing loss and tinnitus is not bidirectional, not all subjects with hearing loss suffer from tinnitus and, on the contrary, some subjects with clinically normal hearing have tinnitus [9].

To date, there is no standard procedure for the diagnosis or management of tinnitus, although the reference specialist remains the audiologist or ENT specialist, the complexity of the disorder requires a multidisciplinary evaluation. However, the different guidelines all lean towards the use of written questionnaires to comprehensively assess tinnitus and its impact on patients and their families, measuring the severity of symptoms (e.g. the impact of tinnitus on quality of life, daily activities or sleep) without neglecting the psychological distress that often accompanies this symptom [10].

Although several drugs with different effects are used, so far, no drug has been approved specifically for tinnitus by a regulatory body (e.g. the European Medicines Agency or the US Food and Drug Administration [11].

Clinical management strategies include various therapies including: laser therapy, tinnitus rehabilitation therapy (TRT), cognitive behavioral therapy (CBT), hyperbaric oxygen therapy (HBOT), neuromodulation, vagus nerve stimulation (VNS), transcranial electrical stimulation (TENS), auriculotherapy, sound therapies, and combined multimodal therapies[12- 21].

Sound therapies, although already used in the past, are attracting the interest of several researchers as technological innovation allows to modulate different types of sounds with different frequencies and different intensities with notable results in terms of improving the perception of tinnitus.

Sound therapy is a crucial element in the management of tinnitus, using acoustic stimuli to mask or modulate the perception of tinnitus. This approach is based on the neurophysiological model proposed by Jasterboff, according to which tinnitus is due to aberrant neuronal processing that can be modulated by exposure to external sounds [22].

Sound therapy has a long history, with the first observations of the effect of sounds on tinnitus dating back to 1821 when it was noted that natural sounds could alleviate the symptoms of tinnitus [23].

Sound therapy can be divided into personalized and non-personalized therapy, among the non-personalized therapies there is masking that uses sounds such as white noise to mask tinnitus or help patients to get used to it, providing in many cases immediate relief and reducing awareness of tinnitus [24]. The principle of masking was introduced by Vemon in 1977, suggesting that the introduction of an external noise can reduce the contrast between the tinnitus signal and the background activity of the auditory

system, decreasing the perception of tinnitus [25]. Hearing aids allow auditory rehabilitation in patients with hearing loss associated with tinnitus, providing a sound enrichment that can help mask tinnitus or make it less noticeable. Their effectiveness is documented in studies that demonstrate an improvement in the perception of tinnitus and quality of life [26]. Furthermore, sound enrichment prevents sensory deprivation, a mechanism believed to underlie the generation of tinnitus [27].

Personalized therapies are adapted to the specific characteristics of each patient's tinnitus and include various techniques. Heidelberg Neuro-Music Therapy (HNMT) uses music modified to adapt to the patient's tinnitus perception, aiming to reorganize the tonotopic map of the auditory cortex and reduce pathological neuronal synchronization [28].

Tailor-Made Notched Music Training (TMNMT) involves eliminating specific frequencies that match the patient's tinnitus frequency. Animal studies have shown that acoustic enrichment with these frequencies after acoustic trauma prevents reorganization of the tonotopic map in the auditory cortex and reduces abnormal spontaneous activity [29].

Pitch-Matched Sound Therapy uses sounds tailored to the specific frequency of the patient's tinnitus, aimed at desensitizing the auditory system and reducing the perception of tinnitus [30].

Initial approaches to sound therapy involved complete masking, in which the masking noise increased in intensity until the tinnitus became inaudible [31]. In the early 1980s, a large and complex study of sound therapy devices included white noise generators and combination hearing aids and noise generators [32]. Further work from this study showed that, rather than using a volume of noise that would mask the tinnitus, a low-level (minimally noticeable) white noise treatment could be used to achieve down-regulation (habituation of the disordered auditory perception) [33].

This was based on the principle that if the patient cannot hear their tinnitus (as in complete masking), they will not be able to habituate to it [34].

Another important benefit suggested by the use of sound therapy was the concept of sound enrichment, where white noise also acts as a source of stimulation for the central auditory system to compensate for the loss of auditory stimulation in patients with hearing loss [35]. This would prevent sensory deprivation, which is one of the theories of tinnitus generation [36].

Effective use of noise generators involves determining the optimal volume for the device and this will depend on the philosophy behind the management protocol. Protocols aimed at partial or complete masking aim to establish a level of masking that patients find more acceptable than their tinnitus [37]. If the philosophy is towards sound therapy and sound enrichment, then the noise generator is adjusted to a level where the patient can hear both their own tinnitus and the external noise [38].

Several sound-based technological innovations for tinnitus have been commercially produced, with experimental prototypes under study. Manufacturers claim that these devices not only mask the perception of tinnitus, but are also effective in other ways. For some of these sound treatments, the target site of action is the central auditory system, with the sound individually tailored to the hearing loss and characteristics of tinnitus to interrupt the maladaptive neuroplasticity that drives the sensation of tinnitus. Commercial devices are typically recommended as part of a holistic audiological management program that incorporates education and counseling. Other authors use sound primarily as a relaxant as in the case of Zen Therapy [39].

Bimodal and multimodal interventions that combine personalized sound therapy with neuromodulation strategies in a multimodal treatment approach have emerged in recent times as a prospective strategy to address the intricate nature of chronic tinnitus and its associated symptoms [40].

Sound therapy stands as a widely recognized intervention for its effectiveness; meanwhile, the integration of neuromodulation strategies, particularly involving electromagnetic waves, represents an area of increasing research progress, showing promising developments in the field [41].

Sound therapy combined with low and high frequency electromagnetic stimulation for chronic tinnitus examines a novel multimodal treatment for chronic tinnitus [42].

The use of low and high frequency electromagnetic waves as neuromodulation strategies represents an innovative approach in the management of tinnitus. These techniques aim to modulate the perceptual aspects and activity of the neural circuits of tinnitus, promoting neuroplasticity and modulating the abnormal activity of the auditory system involved in the perception and processing of tinnitus [43]. Stimulation

A very recent study conducted at the University Hospital of Tor Vergata in Rome, considered the synchronous use of personalized sound therapy together with electromagnetic waves through an innovative device recently developed and patented [44].

This treatment, defined as "synchronous trimodal treatment", for the simultaneous use of three therapeutic principles. A personalized pitch-matching Sound Therapy guided by tinnitus measurement and based on the selection of sound stimuli that simulate the specific frequencies of the patient's tinnitus. In this way, it aims to promote the desensitization of the auditory system, reduce the neuronal hyperactivity associated with tinnitus and re-adapt the brain to not focus on the pathological signal, promoting better management of the symptom.

An innovative aspect is the synchronous use of inductive Low Frequency (LF) electromagnetic waves and capacitive High Frequency (HF) electromagnetic waves with sound stimulation.

Low frequency stimulation may have inhibitory effects on hyperactive neurons in the auditory system, offering a potential mechanism to suppress tinnitus signals. On the other hand, high frequency stimulation is hypothesized to exert anti-inflammatory and antinociceptive effects, contributing to the potential relief of tinnitus symptoms [45].

The research involved 55 patients and used a portable medical device to administer the therapy. The LF electromagnetic waves are applied via an inductor inserted in the pavilion of the headphones that emits the sound therapy sound, so that it covers the cochlear area and the first section of the acoustic nerve, managing to obtain a saturation of the transmission capacity of tinnitus to the primary auditory cerebral cortex; AF electromagnetic waves are delivered via a capacitive dispenser (bipolar capacitor inserted above the area corresponding to the organ of Corti, with a local de-exciting and anti-inflammatory function.

The study protocol, approved from the Internal Ethics Committee of the Tor Vergata University Hospital of Rome, was based patients were enrolled using the following inclusion criteria: chronic tinnitus persisting for a minimum of 6 months, age over 18 years, Beck Depression Inventory II (BDI-II) score ≤ 29, Mini-Mental State Examination (MMSE) score ≥ 25, and normal to moderate hearing loss.

Exclusion criteria included duration of tinnitus less than 6 months, presence of pulsatile, fluctuating or poorly defined tinnitus, moderate or severe hearing loss, neurological and psychiatric disorders, BDI-II score > 29, MMSE score < 25, history of otological and vestibular disorders (e.g., middle or external ear tumors, Ménière's disease, sudden hearing loss, acoustic neuroma, otosclerosis), pregnancy and any concomitant disorder that could influence the final results of the study. The study adhered to the ethical principles of the Declaration of Helsinki for medical research, ensuring the protection of the well-being and rights of the participants. All eligible individuals provided written consent before being enrolled in the study. To strengthen the integrity and reliability of the results, it is essential to note that all data were subjected to thorough monitoring, extrapolation and certification by an external certification body.

This additional level of control ensures the robustness and quality of the data, underscoring the commitment to scientific rigor and ethical standards in medical research.

The effectiveness of the treatment was measured by the Tinnitus Functional Index (TFI), Tinnitus Handicap Inventory (THI), Visual Analogue Scale (VAS), Hyperacusis Questionnaire (HQ), and Short Form-36 Health Survey (SF-36).

Remarkably, 73% of participants experienced significant improvements in TFI scores, with 39% reporting a significant improvement of 13 points or more. This improvement was mirrored in secondary outcomes such as THI, VAS, and HQ scores, along with selected SF-36 domains, indicating improved quality of life and reduced tinnitus distress. The study highlighted high compliance and no adverse effects, suggesting the promising potential of combination therapy in the management of chronic tinnitus. Of great importance is the persistence of improvement in tinnitus even 1 year after the suspension of trimodal synchronous stimulation administration, suggesting that there is a causal and non-symptomatic therapeutic mechanism underlying its action. The results support further research to discern the distinct contributions of each treatment modality, postulating that this innovative approach could improve tinnitus symptoms and improve patient well-being, confirming its safety and efficacy.

In conclusion, tinnitus remains a complex and difficult symptom to manage and the search for effective treatments has been ongoing for some time [46].

In light of the growing scientific interest in multimodal therapeutic approaches for severe or complex diseases and symptoms, the results offer valuable insights into the potential of this multimodal approach in addressing tinnitus-related distress. In the multimodal approach, personalized sound therapy combined with other stimulations has assumed a crucial role in the management of tinnitus-related distress [47].

The integration of these neuromodulation strategies in multimodal treatments highlights the potential of targeting the underlying neurophysiological mechanisms to effectively mitigate tinnitus symptoms. Patients participating in multimodal treatments also report an increased ability to cope with the condition on a daily basis, improving not only the perception of sound, but also overall well-being. The most recent research offers a positive outlook, with effects that suggest that the multimodal approach could represent one of the most promising solutions in the treatment of tinnitus. These preliminary results provide a solid basis for future investigations, which could further validate and optimize the use of sound therapy and electromagnetic stimulation as a standardized treatment for this condition. Our research is ongoing with very promising results, to extend these synchronous therapeutic modalities with physical means also on the cervical spine and the central brain region to treat these subsites often associated with tinnitus.

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