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The effectiveness of neuro-music therapy according to the Heidelberg model compared to a single session of educational counseling as treatment for tinnitus: A controlled trial

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ABSTRACT

Objectives: Tinnitus is a very common symptom, yet the quest for an effective treatment is challenging. Results from several clinical trials support the notion that neuro-music therapy is an effective means to reduce tinnitus distress with short duration and long lasting effect. However, until now, the effectiveness has not been tested in a controlled trial against an active comparator.
Methods: The trial was designed as two-center, parallel intervention group controlled study with two intervention groups: Counseling (50 minute individualized personal instruction) or neuro-music therapy (counseling plus eight 50-minute sessions of individualized music therapy). Data of $n = 290$ patients suffering from chronic tinnitus were analyzed. Outcome measure was the change in Tinnitus Questionnaire Total Scores (TQ) from baseline (admission) to end of treatment.
Results: Both treatment groups achieved a statistically relevant reduction in TQ scores, though 66% of patients in the music therapy group attained a clinically meaningful improvement compared to 33% in the counseling group. A binary logistic regression revealed two variables significantly influencing therapy outcome: initial tinnitus score and type of therapy with an OR for the music therapy compared to the counseling of 4.34 (CI 2.33–8.09).
Conclusions: Counseling is an appropriate treatment option with well above chance of improvement. The neuro-music therapy outperformed the counseling. This treatment targets the tinnitus sound itself, is short in duration, intrinsically motivating and easy to operate and thus presents a possible complement to the therapeutic spectrum in chronic tinnitus. The trial was registered at the ClinicalTrials.gov registry (ID: NCT01845155).

Introduction

Background

Tinnitus, i.e. a sensation of ringing or buzzing sounds without an external source has evolved into one of the most common symptoms in ENT medicine [1]. It has considerable economic impact [2].

Data from human neuroimaging studies support the hypothesis that tinnitus is caused by an interplay between sensory, cognitive and affective neuronal systems [3] and propose a compromised noise cancellation mechanism [4] to be liable for the enduring tinnitus percept. According to these assumptions, the tinnitus sounds originate from lesions in the auditory pathways [5]. Usually these sounds should be blocked off by feedback connections from limbic regions before reaching the auditory cortex. If however emotional reactions (possibly due to overly active amygdala and/or nucleus accumbens) suppress the inhibition, this „noise-cancelation system“ fails and the person affected is no longer able to fade out the sounds.

Currently there is no universal therapy available leading to resounding and profound relief from tinnitus. The majority of available treatment options focus on management strategies in order to alleviate the tinnitus distress [6,7]. Auditory stimulation procedures are very common in tinnitus therapy. Typically, sound therapies are backed up by psychological interventions including counseling procedures. In tinnitus retraining therapy (TRT) ear level sound generators are used in order to superpose the tinnitus percept [8,9]. Treatments that are more recent incorporate a variety of musical stimulants. The music is spectrally contoured to each individual's audiometric and tinnitus profile. Most prominent are Neuromonics and “tailor-made notched music training” (TMNMT). While Neuromonics® follows a surplus scheme by adding broadband

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frequency stimuli to relaxation music in order to stimulate the auditory pathways [10]; TMNMT modifies enjoyable music by suppressing ("notching") the frequency band centered at the individual tinnitus frequency [11]. Outcomes for both techniques are heterogeneous, both supporting the methods but also proposing possible hazards by an overcompensation of a potential hearing loss [12]. Methodological shortcomings in clinical trials limit the effectiveness compared to other treatments [13].

Rationale

In 2004, a novel treatment option, referred to as "Heidelberg Model of Neuro-Music Therapy", was first offered [14].

Results from several clinical trials [15,16] support the notion that the neuro-music therapy is an effective means to reduce tinnitus distress with short duration and long lasting effect [17].

However, until now, the effectiveness has not been tested in a controlled, large-scale clinical trial against an active comparator.

Due to ethical reasons, an active comparator with clinical impact rather than a placebo condition should be preferred. In the German good clinical practice (GCP) guidelines, "counselling" is scheduled as the primary intervention in chronic tinnitus [18]. Usually a single session intervention is said to be sufficient for patients with light to moderate tinnitus [19]. Therefore, an individualized personal instruction ("counselling") was chosen as control intervention and we decided to restrict the duration of the counseling to 50 minutes as recommended by the GCP guidelines.

The aim of the trial was to examine the efficacy of the Heidelberg Model of Neuro-Music Therapy compared to a standard educative counseling procedure.

Material and methods

Trials Design

The trial was designed as two-center, parallel intervention group controlled study. Standardized interventions were pre-defined within the structured tinnitus care GCP and amended by the application of music therapeutic interventions. Safety reporting followed the standard of good clinical practices.

Participants

Study population description

The population consisted of German speaking patients suffering from chronic tinnitus. The trial and the neuro-music therapy concept were announced by press releases leading to self-admittance to the Heidelberg Outpatient Center for Tinnitus. It was offered to patients by ENT-doctors in own practice nationwide and to patients attending the ENT-clinic of the university hospital Heidelberg.

Eligibility criteria (inclusion and exclusion)

Patients were eligible if they suffered from chronic tinnitus (duration of more than 6 months) which could be musically compiled (distinct frequency) and had no psychiatric co-morbidity requiring ongoing medicinal or psychotherapeutic care (severity grades I to III according to Ref. [19]). In case of hearing loss, adequate hearing devices had to be fitted, ensuring a hearing level better than 60 dB HL, i.e. at most moderate hearing loss [20] in the tinnitus frequency region. An audiologist rechecked appropriate hearing thresholds prior to the treatment.

Patients had to be excluded, if any tinnitus-related otological conditions were present, such as pronounced hyperacusis, dizziness or vertigo. Tinnitus etiology was screened for any history of somatic diseases currently causing tinnitus such as vestibular schwannoma or Ménière's disease (Table 1).

Examinations

All patients underwent a standardized initial audiological and otolaryngological examination as recommended by the Tinnitus Research Initiative [21]. If this work-up was without pathological findings, patients were admitted to a comprehensive intake interview, based on the Structured Tinnitus Interview (STI, [22]). The STI is a 58-item semi-structured interview designed to assess medical and psychological characteristics of tinnitus as well as factors associated with tinnitus (vertigo, hyperacusis).

Psychological complaints were assessed using the German version of the "Tinnitus Questionnaire" (TQ, [23]). This well validated inventory comprises 52 items and records tinnitus related complaints. The range of global TQ-score values is between the minimum score of 0 and the maximum score of 84, whereas high values indicate high tinnitus related distress.

Anxiety and depression as most common psychiatric co-morbidities were measured by questionnaire data from the Hospital Anxiety and Depression Scale (HADS, [24]).

Interventions

Counseling

Patients in the counseling condition received a comprehensive individualized personal instruction. This counseling lasted 50 minutes and consisted of a single session and was delivered by a trained psychologist. A cognitive model of tinnitus based on neuroscientific principles should be established. The counseling then targeted at a reclassification of tinnitus to a category of neutral, impartial signals. The aim was to

Table 1
Inclusion and exclusion criteria.

Inclusion	Exclusion
• Clinical diagnosis of chronic tinnitus persisting for a minimum of 6 months	• Tinnitus related to anatomic lesions of the ear, to retrocochlear lesions or to cochlear implantation
• Adults, aged 18 years or over	• Tinnitus is concomitant symptom of a known systemic disease (such as Ménière's disease, vestibular schwannoma, endolymphatic hydrops)
• Patients are able to understand, read and speak German fluently	• Status following craniocerebral trauma, cervicogenic or stomatognatogenic tinnitus
• Patients are able to give written informed consent	• Tinnitus is neither noisiform nor tonal (kricking, clacking, rumbling) or has different sound components or is pulsatile, intermittend or non-persistent
• Constant tinnitus (no interruptions > 1 hour	• Severe hearing impairment (greater than 60 dB HL in the region of the center tinnitus frequency)
• 6 months before admission)	• Severe hyperacusis
• Tinnitus with determinable center frequency ➔ tinnitus is musically educible either as "tonal" (sinus tone: e.g. beeping, whistling) or "noisiform" (broadband or narrow-band noise; e.g. hissing, whooshing)	• One or two-sided deafness
	• Clinical diagnosis of severe mental disorder or psychiatric or neurological disease (psychosis, epilepsy, Parkinson's disease, dementia, alcohol or drug abuse)
	• History of severe ischemic disorder (previous stoke, previous heart attack, peripheral arterial occlusion disease)
	• Inability to discontinue drugs known to be associated with tinnitus (high-dose aspirin, quinidine, aminoglycosides) or psychotropic medication before entry into the study
	• Patients are not able to understand, read and speak German fluently
	• Patients are not able to give written informed consent

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