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Tinnitus therapy using tailor-made notched music delivered via a smartphone application and Ginko combined treatment: A pilot study

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ABSTRACT

Objective: Notched music therapy has been suggested to be effective for relieving tinnitus. We have developed a smartphone application using tailor-made notched music for tinnitus patients. This study aimed to evaluate the effect of this smartphone application on reducing tinnitus. In addition, we investigated the predictive factors for tinnitus treatment outcome using this smartphone application.

Methods: A total of 26 patients who were chronically distressed by tinnitus with a ≥ 18 Tinnitus Handicap Inventory (THI) score were recruited from March 2013 to March 2015 (National Clinical Trial (NCT) Identifier Number 01663467). Patients were instructed to listen to tailor-made notched music through our smartphone application for 30–60 min per day and were prescribed Ginkgo biloba for 3 months. Treatment outcome was evaluated using the THI, a visual analogue scale that measures the effects of tinnitus in terms of loudness, noticeable time, annoyance, and disruption of daily life. Demographic data, including age, sex, duration of tinnitus, and pre-treatment scores on questionnaires such as the Beck Depression Inventory (BDI), State Trait Anxiety Inventory (TAI), and Pittsburgh Sleep Quality Index (PSQI) scores were compared between the effective and non-effective groups according to the differences between their pre- and post-treatment THI scores.

Results: Smartphone application-delivered notched music therapy and Ginko combined treatment improved the THI score from 33.9 ± 18.9 to 23.1 ± 15.2 ; the effect was particularly marked for the emotional score of the THI. Improvement in the THI score was positively correlated with the initial THI score ($P = 0.001$, adjusted estimated value = 0.49, 95% confidence interval = 0.25–0.73).

Conclusion: Chronic tinnitus patients who underwent smartphone application-delivered notched music therapy and Ginko combined treatment showed improved THI scores, particularly the emotional score of the THI. A smartphone application-delivered therapy and Ginko combined treatment may be more effective in tinnitus patients who have had a higher initial THI.

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1. Introduction

Subjective tinnitus is defined as auditory perception without external sound stimulation. Tinnitus is known to affect between 5% and 15% of the population, and 1% of the population has debilitating tinnitus [1,2]. Tinnitus can affect almost all aspects of life, including sleep and rest, cognitive function, work, leisure, relaxation, sense of control, auditory perception, and quality of life [3]. In particular, tinnitus has been suggested to be associated with emotional discomfort; for instance, depression and trait anxiety [4–6].

Several approaches have been used to develop cost-effective and clinically effective therapeutic tools for tinnitus. Computer software for tinnitus therapy delivered via the Internet is a particularly good means of achieving these goals. In addition, it enables tinnitus patients to participate in therapy with a low threshold, and it is a viable alternative tool for patients who cannot visit a clinic for various reasons, such as a living far from the clinic, not wanting to be stigmatized by going to a clinic, and hearing impairment. Several studies have reported that Internet-delivered tinnitus therapies demonstrated cost- and time-effectiveness [7,8]. Smartphone applications are more widely accessible than computer-based Internet applications due to the devices' portability. Therefore, smartphone-delivered tinnitus therapy is a more promising method in terms of both cost and clinical outcomes.

Recently, tailor-made notched music has received attention due to its ability to effectively reduce tinnitus loudness and tinnitus-related auditory cortex activity [9]. A randomized controlled study demonstrated the tailor-made notched music significantly relived the tinnitus loudness perception compared to the control group [10]. Based on the mechanism of tinnitus, which is caused by maladaptive auditory cortex reorganization, listening to notched music has been suggested to be a promising causal treatment approach that reduces cortical activity of the center frequency by lateral inhibition. Through a lateral inhibition mechanism, listening to notched music is known to reduce cortical activity of the center frequency area of the notch [11]. Previous studies demonstrated this lateral inhibition by demonstrating a reduction of evoked activity in the auditory cortex area identical to the tinnitus frequency [9,11], and high-resolution MRI scans showed cortical reorganization in the precuneus, medial superior frontal area, and auditory cortex [12].

To overcome the high cost of equipment for notched music therapy and enhance the availability of the treatment, we developed a smartphone-delivered notched music system for tinnitus patients. The aims of this pilot study were to investigate the effect of a smartphone-based notched music system for tinnitus patients and identify the factors associated with a good response to the notched music therapy. This is, to our knowledge, the first study of notched music treatment delivered via a smartphone application.

2. Materials and methods

2.1. Ethical considerations

This study was approved by the Institutional Review Board (IRB) at the Seoul National University Hospital (IRB number:

H-1207-112-419). Written informed consent was obtained from all participating subjects.

2.2. Study design

This study was prospectively conducted from March 2013 to March 2015 at the Department of Otorhinolaryngology – Head and Neck Surgery of Seoul National University Hospital. The inclusion criteria were subjective tinnitus of more than 3-months duration; $a < 40$ dB average hearing threshold on pure-tone averages of 0.5, 1, 2 and 4 kHz; and a score of ≥ 18 on the Tinnitus Handicap Inventory (THI) [13]. The patients with hearing loss were excluded to minimize the effects of hearing impairment on the sound therapy. The tinnitus patients with hearing loss applied hearing aid prior to other tinnitus therapy including sound therapy. Subjects were excluded if they were < 20 years or > 65 years; and had objective tinnitus, vertigo, Ménière's disease, or tumors. Clinical evaluations included age, sex, duration of tinnitus, medical history, physical examination, pure-tone audiometry, and tinnitogram. On the tinnitogram, tinnitus pitch, loudness, minimal masking level, and residual inhibition matching were measured. A pure tone with a frequency well below the subjective tinnitus pitch was given, followed by different frequencies in octave intervals to identify the octave frequency that was closest to the subjective tinnitus pitch. Inter-octave frequencies were given to allow for increased identification of the tinnitus frequency. The identified matched-pitch was compared with frequencies one octave higher and lower. The loudness of the matched-pitch was measured to the closest 1 dB HL. The tone was raised in 1 dB HL intervals to identify the matched-loudness at the matched-frequency.

Before tinnitus therapy was initiated, emotional distress was quantified via the Beck Depression Inventory (BDI) [14] for depressive mood, State Trait Anxiety Inventory (STAI) [15] for transitory apprehensive mood and general anxious tendency, and Pittsburgh Sleep Quality Index (PSQI) [16] for sleep quality and disturbance in all participants.

Pure-tone audiograms were obtained using a GSI 10 audiometer (VIASYS Healthcare, Inc., Conshohocken, PA, USA) in a quiet room. The four-dimensional method was used at 0.5, 1, 2, and 4 kHz to obtain the pure-tone average (PTA) hearing threshold. The Korean version of the THI [13,17] was checked at the beginning and after use of notched music for 3 months. Loudness, annoyance and effects of tinnitus on daily life were recorded using a visual analogue scale (VAS): 0 represented no tinnitus, and 10 represented the worst symptom ever experienced and the loudest tinnitus. Awareness of tinnitus for 24 h per day except sleeping time was checked as a score of 10.

This was part of a study entitled “Efficacy of Internet and Smartphone Application-delivered Tinnitus Retraining Therapy” (NCT01663467; Clinicaltrials.gov).

2.3. Use of notched music

After pre-assessment of the subjects as described above, all participants received explanations with regard to the mechanisms of chronic tinnitus and how to use the application at the beginning of the notched music therapy. No other instruction

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