ISRCTN59618689 https://doi.org/10.1186/ISRCTN59618689

The impact of a daily sound therapy hour on tinnitus relief for people with chronic subjective tinnitus (ringing in the ears)

Submission date
24/11/2021

Recruitment status
No longer recruiting

Registration date
24/11/2021

Overall study status
Completed

Last Edited
06/10/2022

Condition category
Ear, Nose and Throat

[_] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Sound therapy has been considered a treatment option for people with subjective tinnitus. Several studies on sound therapy have reported that some participants, but not all, show significant relief from tinnitus with its use. Therefore, determining the factors influencing the effect of sound therapy is important to increase its effect. A major factor that affects the effectiveness of sound therapy is the duration of sound therapy, with several studies reporting that the longer the duration of sound therapy, the greater the tinnitus relief effect. Although the relationship between the duration of sound therapy and the tinnitus relief effect has been confirmed in previous studies to some extent, the relationship between the daily duration of sound therapy and the tinnitus relief effect remains unclear. In the present study, we aimed to measure the tinnitus relief effect according to the duration of daily sound therapy.

Who can participate?
People with chronic subjective tinnitus

What does the study involve?
Participants will be randomly allocated to receive sound therapy or treatment as usual for 3 months, they completed a number of tests and questionnaires at baseline and 3-month follow-up

What are the possible benefits and risks of participating?
Benefit: Participants can reduce their tinnitus loudness or adverse of tinnitus
Risk: None

Where is the study run from?
Hallym University (South Korea)

When is the study starting and how long is it expected to run for?
July 2018 to October 2021

Who is funding the study?
This work was supported by the Commercializations Promotion Agency for R&D Outcomes (Funding number: 2020 Customer Demand Correspondence Research-0002) and by the National Research Foundation of Korea grant funded by the Korean government (Ministry of Science and ICT; Grant NRF-2018R1C1B6003765).

Who is the main contract?
Prof. In-Ki Jin, inkijin@gmail.com

Contact information

Type(s)
Scientific

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
NRF 2018R1C1B6003765

Study information

Scientific Title
The impact of daily hours of sound therapy on tinnitus relief for people with chronic tinnitus: a randomized controlled study

Study objectives
The tinnitus relief effect increases with a longer duration of daily sound therapy.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 10/07/2020, The institutional review board of Hallym University (Hallym University 1 Hallymdaehak-gil, Chuncheon, Gangwon-do, Republic of Korea, 24252; no telephone number provided; irb@hallym.ac.kr), ref: HIRB-2020-069

Study design
Interventional randomized controlled trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Tinnitus relief for people with chronic subjective tinnitus

Interventions
Forty-three chronic subjective tinnitus participants were randomly assigned to three groups according to the duration of daily sound therapy (1hour, 3hour, and 5hour groups), and mixing point-based sound therapy was administered for 3 months. Sound therapy was administered using a self-developed sound therapy application and headphones. The duration of daily sound therapy was recorded via a data logging system of the application. In each group, the efficacy of sound therapy was determined based on changes in the tinnitus loudness level, Visual Analog Scale for loudness score, the Korean version of Tinnitus Primary Function Questionnaire score, and the effect size value between the baseline and 3-month time points.

Randomization by excel spreadsheet (Microsoft, Redmond, Washington, USA) was used for allocating participants. This randomization program assigned 58 participants from number 1 to number 58 and randomly changes the order. Those assigned to numbers 1 to 20 were assigned to a 1-hour group, people assigned to numbers 21 to 39 were assigned to a 3-hour group, and the rest were assigned to a 5-hour group.

Intervention Type
Behavioural

Primary outcome(s)
The efficacy of sound therapy was determined based on changes in the tinnitus loudness level, Visual Analog Scale for loudness score, the Korean version of Tinnitus Primary Function Questionnaire score, and the effect size value between the baseline and 3-month time points.

Key secondary outcome(s))
Hearing status according to the three groups (1H, 3H, 5H) was measured using puretone average at baseline and 3-month follow-up.

Completion date
06/10/2021

Eligibility

Key inclusion criteria
1. Persistent presence of tinnitus for over 1 year
2. Diagnosis of sensorineural tinnitus from medical doctor
3. Presence of discomfort or difficulty due to tinnitus
4. Pure-tone hearing thresholds of <40 dB hearing level at 0.5, 1, and 2 kHz
5. Average score of the Korean version of Tinnitus Primary Function Questionnaire (K-TPFQ) >30 points
6. Willingness to receive tinnitus sound therapy for 6 months
7. Willingness to wear headphones and use the sound therapy app for a set amount of time each day
8. Familiarity with smartphone

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Total final enrolment
43

Key exclusion criteria
1. Currently receiving tinnitus-related rehabilitation or treatment
2. Presence of current otologic problems (e.g., acoustic tumor, Meniere’s disease, and otitis media) or audiological problems (e.g., hyperacusis)
3. Psychiatric illness
4. Hearing aid user
5. Involvement in tinnitus-related litigation

Date of first enrolment
01/11/2020

Date of final enrolment
28/02/2021

Locations

Countries of recruitment
Korea, South

Study participating centre
Hallym University
1 Hallymdaehak-gil
Chuncheon
Korea, South
24252

Sponsor information

Organisation
National Research Foundation of Korea

ROR
https://ror.org/013aysd81

Organisation
Commercializations Promotion Agency for R&D outcomes

Funder(s)

Funder type
Government

Funder Name
National Research Foundation of Korea

Alternative Name(s)
, National Research Foundation (South Korea), NRF

Funding Body Type
Private sector organisation

Funding Body Subtype
Trusts, charities, foundations (both public and private)

Location
Korea, South

Funder Name
Commercializations Promotion Agency for R&D Outcomes

Results and Publications

Individual participant data (IPD) sharing plan

The data obtained in this study will be provided in the appendices of the submitted manuscript of the journal.

IPD sharing plan summary

Published as a supplement to the results publication

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		22/07/2022	25/07/2022	Yes	No
Participant information sheet	version 4.2	01/06/2020	24/11/2021	No	Yes
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Protocol file			06/10/2022	No	No