

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

<b>Submission date</b> 24/11/2021	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
<b>Registration date</b> 24/11/2021	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 06/10/2022	<b>Condition category</b> Ear, Nose and Throat	<input type="checkbox"/> 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

### Contact name

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## Additional identifiers

### Clinical Trials Information System (CTIS)

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?
<a href="#">Results article</a>		22/07/2022	25/07/2022	Yes	No
<a href="#">Participant information sheet</a>	version 4.2	01/06/2020	24/11/2021	No	Yes
<a href="#">Protocol file</a>			06/10/2022	No	No