

# Effectiveness of group counseling and information provision via video clips in improving tinnitus: a comparative study

<b>Submission date</b> 02/07/2023	<b>Recruitment status</b> No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 03/07/2023	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 09/07/2024	<b>Condition category</b> Ear, Nose and Throat	<input type="checkbox"/> Individual participant data

## Plain English summary of protocol

### Background and study aims

Tinnitus is the name for hearing noises that do not come from an outside source. Counseling is considered a treatment option for people with subjective tinnitus. Several studies on counseling for tinnitus have reported that some participants, but not all, show significant relief from tinnitus. Furthermore, some participants show improvement in tinnitus distress even when tinnitus education counseling is conducted without the intervention of a hearing professional. Currently, YouTube is the most popular platform for obtaining information, with abundant tinnitus-related content. However, evidence is lacking on the effectiveness of providing tinnitus information to individuals with tinnitus via video.

### Who can participate?

People with chronic subjective tinnitus

### What does the study involve?

Participants will be randomly allocated into two groups according to treatment type (viewing tinnitus counseling content or counseling) for 2 weeks. The tinnitus counseling content contains 100 questions and answers, including suggestions from tinnitus experts, and identified difficulties, questions, and misunderstandings in daily life for 74 people diagnosed with tinnitus in a previous study. The group counseling group will receive a total of six sessions over 2 weeks, and the video content viewing group will watch seven or eight video clips on a new topic every day. Participants complete a number of tests and questionnaires 2 weeks before baseline, at baseline, and after treatment.

### What are the possible benefits and risks of participating?

Participants may experience reduced tinnitus annoyance or adverse tinnitus. There are no risks expected.

### Where is the study run from?

Hallym University (South Korea)

When is the study starting and how long is it expected to run for?  
June 2023 to June 2024

Who is funding the study?  
National Research Foundation of Korea (NRF) (South Korea)

Who is the main contract?  
Prof. In-Ki Jin, inkijin@hallym.ac.kr

## Contact information

**Type(s)**  
Scientific

**Contact name**  
Miss Sumin Lee

**ORCID ID**  
<https://orcid.org/0009-0002-7142-3978>

**Contact details**  
1, Hallymdaehak-gil  
Chuncheon-si  
Korea, South  
24252  
+82 (0)1047486913  
eaeno@naver.com

## Additional identifiers

**Clinical Trials Information System (CTIS)**  
Nil known

**ClinicalTrials.gov (NCT)**  
Nil known

**Protocol serial number**  
NRF 2022R1H1A2091291

## Study information

**Scientific Title**  
Comparison of tinnitus improvement between video-viewing of tinnitus counseling contents and group counseling

**Study objectives**

The counseling group may have greater tinnitus relief than the group viewing tinnitus counseling content, which is delivered in the form of video clips without interaction with an audiologist. However, the tinnitus counseling group may have shown some improvement in tinnitus.

### **Ethics approval required**

Ethics approval required

### **Ethics approval(s)**

approved 19/06/2023, The Institutional Review Board of Hallym University (Hallym University 1, Hallymdaehak-gil, Chuncheon, 24252, Korea, South; No telephone number provided; irb@hallym.ac.kr), ref: HIRB-2023-043

### **Study design**

Interventional randomized controlled trial

### **Primary study design**

Interventional

### **Study type(s)**

Treatment

### **Health condition(s) or problem(s) studied**

Chronic subjective tinnitus

### **Interventions**

Participants with chronic subjective tinnitus will be randomized into two groups according to treatment type (viewing tinnitus counseling content group and counseling group) for 2 weeks. The tinnitus counseling content utilized at this time contained 100 questions and answers, including suggestions from tinnitus experts, and identified difficulties, questions, and misunderstandings in daily life for 74 people diagnosed with tinnitus in a previous study. The group counseling group will receive a total of six sessions over 2 weeks, and the video content viewing group will watch seven or eight video clips on a new topic every day. The effectiveness of each group will be checked based on changes in the Visual Analog Scale for annoyance and loudness score, the Korean version of the Tinnitus Primary Function Questionnaire score.

Participants were randomly allocated to groups using an Excel spreadsheet (Microsoft, Redmond, Washington, USA). This randomization program assigned 36 participants (numbers 1 to 36) and randomly changed their order. Those assigned numbers 1 to 18 were assigned to the Group Counseling Group, while those assigned numbers 19 to 36 were assigned to the video content viewing group.

### **Intervention Type**

Behavioural

### **Primary outcome(s)**

1. Loudness and annoyance of tinnitus measured using the visual analog scale (100 points) at 2 weeks before baseline, baseline, and post-treatment

2. Quality of life impairment due to tinnitus measured using the Korean version of the Tinnitus Primary Function Questionnaire (K-TPFQ, 100 points) at 2 weeks before baseline, baseline, and post-treatment

**Key secondary outcome(s)**

1. Hearing threshold is measured using pure-tone audiometry (decibels) at baseline
2. Tinnitus frequency and loudness measured using tinnitogram (Herz and decibels) at baseline

**Completion date**

18/06/2024

## **Eligibility**

**Key inclusion criteria**

1. Presence of discomfort or difficulty due to tinnitus
2. Average score of the Korean version of Tinnitus Primary Function Questionnaire (K-TPFQ) >30 points
3. Not receiving other tinnitus treatments or counseling
4. Familiarity with smartphones or the Internet

**Participant type(s)**

Patient

**Healthy volunteers allowed**

No

**Age group**

Adult

**Lower age limit**

19 years

**Upper age limit**

75 years

**Sex**

All

**Total final enrolment**

36

**Key exclusion criteria**

1. Psychiatric illness
2. Involvement in tinnitus-related litigation

**Date of first enrolment**

01/08/2023

**Date of final enrolment**

31/10/2023

# Locations

## Countries of recruitment

Korea, South

## Study participating centre

### Hallym University

1 Hallimdaehak-gil

Chuncheon

Korea, South

24252

# Sponsor information

## Organisation

National Research Foundation of Korea

## ROR

<https://ror.org/013aysd81>

# 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

# Results and Publications

## Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study will be available upon request from In-Ki Jin (inkijin@hallym.ac.kr).

The type of data that will be shared: Excel spreadsheet

Dates of availability: 01/01/2024

Whether consent from participants was required and obtained: Yes

Comments on data anonymization: The data will be anonymized

## IPD sharing plan summary

Available on request

## Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Results article</a>	Participant information sheet	24/06/2024	09/07/2024	Yes	No
<a href="#">Participant information sheet</a>			03/07/2023	No	Yes
<a href="#">Participant information sheet</a>		11/11/2025	11/11/2025	No	Yes
<a href="#">Study website</a>	Study website	11/11/2025	11/11/2025	No	Yes