

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

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

Study website
<https://nrf.re.kr/index>

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
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

Secondary study design

Randomised controlled trial

Study setting(s)

Internet/virtual, Laboratory, Telephone

Study type(s)

Treatment

Participant information sheet

<https://drive.google.com/file/d/1kqxAbxQH2hYQnvDS2w4xISS0BVnb0FFx/view?usp=sharing>

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 measure

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

Secondary outcome measures

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

Overall study start date

19/06/2023

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

Age group

Adult

Lower age limit

19 Years

Upper age limit

75 Years

Sex

Both

Target number of participants

36

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

Sponsor details

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Sponsor type

Government

Website

<https://www.nrf.re.kr/eng/index>

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

Publication and dissemination plan
Research using this data will be published in a peer-reviewed hearing journal.

Intention to publish date
18/07/2024

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?
Participant information sheet			03/07/2023	No	Yes
Results article		24/06/2024	09/07/2024	Yes	No