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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

Registration date
03/07/2023

Overall study status
Completed

Last Edited
09/07/2024

Condition category
Ear, Nose and Throat

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] 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

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?
Results article		24/06/2024	09/07/2024	Yes	No
Participant information sheet			03/07/2023	No	Yes
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Study website	Study website	11/11/2025	11/11/2025	No	Yes