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Defining a minimally clinically identifiable difference in the minimum level at which tinnitus is completely masked

Submission date
30/06/2023

Recruitment status
No longer recruiting

Registration date
03/07/2023

Overall study status
Completed

Last Edited
08/07/2025

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
Minimum masking level (MML) is a method of measuring the minimum intensity of a masking sound to mask tinnitus. If the MML decreases after tinnitus treatment, the patient's perception of tinnitus decreases. The MML has been suggested to be an important indicator of changes in neural activity that can detect tinnitus signals; however, no evidence exists showing that the MML is a reliable way to measure changes in tinnitus loudness. Therefore, once the minimally clinically identifiable difference (MCID) of a measurement method using the MML is determined, it can be a valid and effective measure of tinnitus loudness reduction in patients with chronic tinnitus. This study aimed to develop a reliable measure of loudness changes in tinnitus using the MCID of the MML.

Who can participate?
People aged 19 to 75 years with chronic subjective tinnitus

What does the study involve?
Participants will be allocated to receive treatment for 3 months and will complete a number of tests and questionnaires 3 months before, during, and after treatment. Participants will receive tinnitus counseling and sound therapy. The counseling will be educational, providing information about tinnitus and how to deal with it, and will consist of six to twelve sessions lasting about 2 weeks. Sound therapy will be provided for 2 hours a day for 3 months using a self-developed sound therapy application and headphones. The duration of the daily sound therapy will be recorded using the application's data-logging system.

What are the possible benefits and risks of participating?
Some participants may experience a reduction in the loudness of their tinnitus or an improvement in 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 contact?
Prof. In-Ki Jin, inkijin@hallym.ac.kr

Contact information

Type(s)
Public

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
NRF - 2023R1A2C1002929

Study information

Scientific Title
Quantifying tinnitus perception improvement: deriving the minimal clinically important difference of the minimum masking level

Study objectives
The minimum masking level (MML) can be a valid and effective way to measure tinnitus loudness reduction in patients with chronic tinnitus if the minimally clinically identifiable difference (MCID) is determined.

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 08/06/2023, 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-2023-033

Study design
Repeated measures within-subject study

Primary study design
Interventional

Study type(s)
Other, Treatment

Health condition(s) or problem(s) studied
Chronic subjective tinnitus

Interventions
Participants will receive tinnitus counseling and sound therapy. The counseling will be educational, providing information about tinnitus and how to deal with it, and will consist of six to twelve sessions lasting about 2 weeks. Sound therapy will be provided for 2 h a day for 3 months using a self-developed sound therapy application and headphones. The duration of the daily sound therapy will be recorded using the application's data-logging system.

Intervention Type
Behavioural

Primary outcome(s)
Current primary outcome measures as of 11/06/2024:
1. Tinnitus loudness is measured using the Clinical Global Impression (CGI, 5 points) at 3 months
2. Loudness of tinnitus is measured using the minimum masking level (MML, decibels) at baseline and 3 months

Previous primary outcome measures:
1. Tinnitus loudness is measured using the Clinical Global Impression (CGI, 5 points) at 1.5 and 3 months
2. Loudness of tinnitus is measured using the minimum masking level (MML, decibels) at 1.5 and 3 months

Key secondary outcome(s))
Current secondary outcome measures as of 11/06/2024:
1. Hearing threshold is measured using the puretone audiometry (decibels) at baseline and 3 months
2. Tinnitus frequency and loudness are measured using tinnitogram (Herz and decibels) at baseline and 3 months
3. Quality of life impairment due to tinnitus is measured by the Korean version of the Tinnitus Primary Function Questionnaire (K-TPFQ, 100 points) at baseline and 3 months

Previous secondary outcome measures:
1. Hearing threshold is measured using the puretone audiometry (decibels) at baseline, 1.5 months, and 3 months
2. Tinnitus frequency and loudness are measured using tinnitogram (Herz and decibels) at baseline, 1.5 months, and 3 months
3. Loudness and annoyance of tinnitus are measured using the visual analog scale (100 points) at baseline, 1.5 months, and 3 months
4. Quality of life impairment due to tinnitus is measured by the Korean version of the Tinnitus Primary Function Questionnaire (K-TPFQ, 100 points) at baseline, 1.5 months, and 3 months

Completion date
06/06/2024

Eligibility

Key inclusion criteria
Current inclusion criteria as of 11/06/2024:
1. Subjective chronic tinnitus
2. Participants complaining of discomfort and irritation due to tinnitus
3. Pure-tone hearing thresholds of <40-dB hearing level at 0.5, 1, and 2 kHz
4. Average score of the Korean version of the Tinnitus Primary Function Questionnaire (K-TPFQ) >30 points
5. Participants willing to undergo pure tone audiometry, tinnitogram, minimum masking Level (MML), the Korean version of the Tinnitus Primary Function Questionnaire (K-TPFQ), and Clinical Global Impression (CGI)

Previous inclusion criteria:
1. Subjective chronic tinnitus
2. Participants complaining of discomfort and irritation due to tinnitus
3. Pure-tone hearing thresholds of <40-dB hearing level at 0.5, 1, and 2 kHz
4. Average score of the Korean version of the Tinnitus Primary Function Questionnaire (K-TPFQ) >30 points
5. Participants willing to undergo pure tone audiometry, tinnitogram, minimum masking Level (MML), visual analog scale (VAS), the Korean version of the Tinnitus Primary Function Questionnaire (K-TPFQ), and Clinical Global Impression (CGI)

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
74

Key exclusion criteria
1. Participants experiencing a scientific disease (acoustic tumor, otitis media, hyperacusis, etc) or mental disorder
2. Participants currently undergoing litigation associated with tinnitus

Date of first enrolment
05/07/2023

Date of final enrolment
11/11/2023

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 and/or analyzed in the current study are available upon request from In-Ki Jin (inkijin@hallym.ac.kr)
The type of data that will be shared: Excel spreadsheet
Dates of availability: 01/03/2024
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		04/02/2025	08/07/2025	Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes