

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

<b>Submission date</b> 30/06/2023	<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> 08/07/2025	<b>Condition category</b> Ear, Nose and Throat	<input type="checkbox"/> 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

**Contact name**  
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## Additional identifiers

**Clinical Trials Information System (CTIS)**  
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?
<a href="#">Results article</a>		04/02/2025	08/07/2025	Yes	No
<a href="#">Participant information sheet</a>	Participant information sheet	11/11/2025	11/11/2025	No	Yes