

PARTICIPANT INFORMATION SHEET

Study title: Effects of individualized frequency discrimination training compared with fixed frequency discrimination training and a wait-list control on frequency discrimination and tinnitus severity in adults with chronic tinnitus: a three-arm randomized controlled trial

This study investigates the effects of frequency discrimination training on tinnitus relief in people with tinnitus. Before deciding whether to participate, please read this information sheet and the consent form carefully. It is important that you understand why this study is being conducted and what participation involves. The principal investigator, In-Ki Jin, or the researcher, Hye-Kyung Gong, will explain the study to you. Only individuals who voluntarily agree to participate will be enrolled. Please review the information below before making your decision. You may discuss it with family or friends if you wish. If you have any questions, the study researcher will provide a detailed explanation.

By signing the consent form, you acknowledge that the study and its risks have been explained to you and that you (or your legally authorized representative) agree to your participation in this study.

1. Background and Purpose of the Study

This study aims to investigate the effects of a tinnitus rehabilitation program on tinnitus relief in adults aged 19 years or older who experience tinnitus.

Tinnitus is more than the discomfort of hearing a sound in the ears. It can also cause sleep disturbances and psychological difficulties, such as anxiety and depressive symptoms, thereby reducing quality of life. However, the causes and underlying mechanisms of tinnitus have not yet been fully established.

Tinnitus is often associated with hearing loss. In regions where hearing is impaired, the ability to distinguish between frequencies may decrease, and excessive auditory nerve activity or changes in the brain areas responsible for auditory processing may occur. Frequency discrimination training (FDT) has been proposed as one rehabilitation approach to address these problems. This training involves repeatedly distinguishing between sounds of different frequencies and may improve auditory function and help relieve tinnitus.

Previous studies have generally used fixed-frequency sound stimuli near each participant's tinnitus pitch. However, because frequency discrimination ability varies between individuals, individually tailored training that takes into account each participant's just-noticeable difference (JND) may be more effective.

In this study, adults with tinnitus will complete either personalized frequency discrimination training based on their individual JND or fixed-frequency discrimination training using predetermined frequency differences. A waitlist control group will complete assessments without training during the initial study period. We will measure JND changes and examine their relationship to tinnitus-related outcomes; we do not know in advance whether either training approach will relieve an individual participant's tinnitus.

2. Eligibility for Participation

The study is expected to enroll 102 adults aged 19 years or older who experience tinnitus. Participants will be included in one of the training groups or the waitlist control group.

Inclusion criteria: (1) age 19 years or older; (2) tinnitus lasting for at least 6 months; (3) an air-conduction pure-tone threshold of 65 dB HL or better within the individually assigned training frequency band, with audibility of the training stimuli through headphones or earphones confirmed before enrollment; and (4) the ability to independently use a personal computer or mobile application and complete the frequency discrimination training while wearing headphones or earphones.

Exclusion criteria: (1) participants with middle- or inner-ear disorders, such as otitis media or Ménière's disease, or those who have received treatment for sudden sensorineural hearing loss within the past 3 months; (2) participants with moderate-to-severe depression or anxiety disorders, cognitive impairment, or neurological conditions that interfere with their ability to complete the training tasks; and (3) participants with severe hyperacusis that prevents the safe presentation of auditory stimuli, defined as an uncomfortable loudness level (ULL) below 60 dB SPL.

3. Study Procedures

1) Personalized FDT and Fixed FDT Training Groups

If you agree to participate, the following procedures will take place.

After signing the consent form, you will be asked to participate in the tinnitus rehabilitation program administered by the researchers and to undergo the evaluations relevant to your participation. First, you will receive and review the detailed written study information. Before starting the rehabilitation program, you will complete subjective tinnitus questionnaires, hearing tests, tinnitus psychoacoustic testing, and an assessment of your individual JND. You will then complete frequency discrimination training in which you listen to three tones and identify which of the three tones sounds different.

Each training session consists of 100 trials across three tone-pair conditions with different frequency intervals. Your total participation period will be approximately 8 weeks, from the start of training to the follow-up assessment 1 month after training ends.

You will attend two in-person assessment visits: one before training (pre-intervention) and one at the end of training (post-intervention). Frequency discrimination training will take place online for 4 weeks. Each training session takes approximately 20–25 minutes, although the duration may vary by around 10 minutes depending on your performance.

At the follow-up assessment (1 month after the end of training), tinnitus-related questionnaires and a JND assessment will be conducted remotely, without an in-person visit. EEG recording, hearing tests, and tinnitus psychoacoustic testing will not be conducted at this follow-up time point.

2) Control (Waitlist) Group

If you are assigned to the waitlist control group, the following procedures will apply. After signing the consent form, you will receive the information relevant to your participation.

After reviewing the detailed written study information, you will complete assessments at the same time points as the training groups. You will take part in these assessments without receiving training during the study period. The assessment items, schedule, and procedures will follow those of the training groups.

Each in-person assessment visit will take approximately 2 hours, although the actual time may vary according to your performance. After the study ends, you will be provided with the same tinnitus rehabilitation program as the participants in the training groups.

4. Duration of Participation

If you are assigned to a training group, your total participation period will be approximately 8 weeks. You will undergo 4 weeks of frequency discrimination training, with assessments conducted before and at the end of the training period. A follow-up assessment will be conducted approximately one month after the completion of training.

If you are assigned to the waitlist control group, you will undergo assessments at the same time points as the training groups without receiving training during the initial study period. After the study ends, you will be provided with the same tinnitus rehabilitation program as the participants in the training groups.

5. Potential Benefits of Participation

You are expected to receive compensation of KRW 200,000 for participating in this study. The amount may vary depending on the study schedule and conditions of participation. In addition, the frequency discrimination training provided in this study may help relieve your tinnitus.

6. Side Effects, Risks, and Discomfort

No known adverse effects have been reported in previous studies of tinnitus rehabilitation training programs. If you have any questions about potential side effects or risks during your participation, please contact the study researcher immediately.

7. Compensation or Treatment for Study-Related Injury or Loss

No injury or loss is expected as a result of participation in this study. However, if you experience any unpleasant symptoms or discomfort during your participation, appropriate measures will be taken to stop the procedure immediately.

8. Financial Compensation for Participation

In consideration of the time required and the inconvenience caused by your visits during your participation in this study, a modest monetary compensation will be provided to cover participation and transportation expenses. This compensation is not intended to induce or coerce participation in the study or to guarantee treatment efficacy, and it will be paid upon completion of the study schedule.

9. Voluntary Participation and Withdrawal

You are free to decline participation in this study, and doing so will not result in any disadvantage to you. You may also withdraw from the study at any time after agreeing to participate.

If you wish to withdraw, please inform the study researcher or principal investigator immediately. If you withdraw, your data will not be used in the study and will be destroyed by shredding.

10. Personal Information and Confidentiality

The personal information collected from you for this study will include your name, sex, age, and occupational category. This information will be used for research purposes for 3 years and will be managed appropriately in accordance with the Personal Information Protection Act.

The information will be stored in the principal investigator's locked laboratory (Room 7526-1), and only the principal investigator will have access to it. Every effort will be made to protect the confidentiality of all personal information obtained through this study. If study findings are published in an academic journal or presented at a conference, neither your name nor other personal identifiers will be disclosed.

However, your personal information may be disclosed if required by law. In addition, study monitors, auditors, and the Institutional Review Board may directly inspect study findings, within the limits established by applicable regulations and without compromising participants' confidentiality, to verify study procedures and data reliability. By signing the consent form, you acknowledge that you have been informed of and agree to these provisions.

Research-related materials will be retained for three years after the study ends. After this period, the principal investigator will personally destroy all study-related materials by shredding.

11. Study Contacts

If you have any questions about the study or encounter any problems during participation, you may contact the following study personnel at any time.

Researcher	Hye-Kyung Gong
Telephone	010-9073-3132
Email	onemicha12@gmail.com
Principal Investigator	In-Ki Jin
Telephone	010-8363-2588
Email	inkijin@hallym.ac.kr

If you have questions about your rights as a research participant at any time, please contact the Hallym University Institutional Review Board:

Telephone: 033-248-3021–3022 **Email:** irb@hallym.ac.kr