6th May 6, 2026

INFORMED CONSENT DOCUMENT

Institution: Hospital Clínico Universidad de Chile
Phone: +56 9 6855 0043
Department: Otolaryngology

Invitation to Participate: You are being invited to participate in the research project to evaluate the effects of mMIDST therapy on changes in tinnitus perception in adult subjects with chronic tinnitus

Before deciding whether to participate, please read this document carefully.

Introduction

This is an analytical study that evaluates the effect of a novel tinnitus therapy called "music-Integrated Modified Coordinated Reset Neuromodulation Therapy" in adult patients with persistent tinnitus, compared with a control group.

Objectives

The objective of this research is to evaluate the perceptual changes of this novel tinnitus therapy.

Procedures

If you agree to participate, you will undergo the following procedures over a 3-month period:

- Tinnitus Handicap Index (THI): Questionnaire to evaluate tinnitus
- Goldberg Test: Mood disorder assessment
- Otoscopy: Ear examination
- Audiometry and Tinnitometry: Hearing evaluation
- Impedance testing: Ear examination

These evaluations will be performed at study entry, and again at 1 month, and 3 months.

Additionally, this clinical trial requires that you perform home-based therapy for at least 45 minutes per day, 5 - 7 times per week, continuously throughout the study period.

This project does not involve harmful or painful stimulation, nor physical or mental risks.

Risks

This intervention does not entail risks for you.

Costs
All medications, supplies, or techniques under study will be provided by the investigators at no cost to you during the project.
Your participation will not generate additional expenses.

Benefits
In addition to contributing to scientific knowledge and improved treatment of future patients, your participation may provide:
- Evaluation of a new tinnitus therapy.
- Results will be published in a scientific journal when study ends.

Alternatives
If you decide not to participate, you will continue receiving the usual diagnostic evaluation and treatment.

Compensation
You will not receive financial compensation for participating.

Confidentiality
All information derived from your participation will be kept strictly confidential, including access by investigators or regulatory agencies.
Any scientific publication or communication of results will be completely anonymous.

Additional Information
You or your treating physician will be informed if new knowledge or complications arise during the study that could affect your willingness to continue.

Voluntariness and Withdrawal
Your participation is completely voluntary.
You may withdraw at any time by informing the investigator and your treating physician, without penalties or loss of benefits or changes in your usual treatment.

Similarly, your physician or the investigator may decide to withdraw you if this is considered in your best interest.

Complications
In the unlikely event of complications directly related to the auditory examinations, you will receive full medical treatment funded by the research team, at no cost to you or your insurance. This does not include complications related to the natural course of your disease.

Participant Rights
You will receive a signed copy of this document.
For further information, contact:
Pablo Henríquez – +56 9 6855 0043

Additional Participant Rights
For questions about your rights, contact the:
Scientific Ethics Committee – Hospital Clínico Universidad de Chile
Phone: 22 978 9008
Email: comiteetica@hcuch.cl
Address: Dr. Carlos Lorca Tobar Nº 999, 4th Floor Sector D, Independencia, Santiago.

Conclusion
After reading and understanding this document and having all questions answered, I understand that I may withdraw at any time.
I freely and voluntarily provide informed consent to participate in the project.

_____	_____	_____
Name of subject Run.	Sign	Date
_____	_____	_____
Name of investigator Run:	Sign	Date
_____	_____	_____
Name of director Run.	Sign	Date

If the participant is illiterate, visually impaired, or in another similar situation, record the name of the participant and their legal representative (witness).

_____	_____	_____
Name of witness	Sign	Date

Run.

REVOCATION OF INFORMED CONSENT

I, _____, voluntarily revoke the consent previously signed as of today's date _____, ending my participation.

I Accept / Do Not Accept that my data and samples held by the research team be stored and used confidentially for research purposes.

_____	_____	_____
Name of subject	Sign	Date

Run.

_____	_____	_____
Name of investigator	Sign	Date

Run:

If the participant is illiterate, visually impaired, or in another similar situation, record the name of the participant and their legal representative (witness).

_____	_____	_____
Name of witness	Sign	Date

Run.