ISRCTN32577283 https://doi.org/10.1186/ISRCTN32577283

# Study evaluating the effectiveness of sound therapy in individuals with chronic tinnitus

**Submission date**
06/08/2026

**Recruitment status**
No longer recruiting

**Registration date**
06/08/2026

**Overall study status**
Completed

**Last Edited**
06/08/2026

**Condition category**
Ear, Nose and Throat

[_] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[X] Record updated in last year

**Plain English summary of protocol**
Background and study aims
Tinnitus is the perception of sound, such as ringing, buzzing, or hissing, when no external sound is present. Tinnitus affects about 10-15% of adults and can negatively affect quality of life, concentration, sleep, emotional well-being, and daily activities. Sound therapy delivered through hearing aids or sound generators is commonly used to manage tinnitus, but there is limited high-quality evidence regarding its effectiveness, particularly in people with mild hearing loss.
The aim of this study is to determine whether acoustic stimulation therapy delivered through sound generators alone or in combination with hearing aid amplification reduces tinnitus-related distress and improves quality of life more effectively than a placebo intervention in adults with chronic tinnitus and mild hearing loss.

Who can participate?
Adults aged 18 years and older who have had continuous tinnitus for at least 3 months and mild hearing loss in both ears

What does the study involve?
Participants first attend an assessment with an ear, nose and throat (ENT) specialist, where hearing, tinnitus characteristics, and eligibility for the study are evaluated. Eligible participants provide informed consent and complete a series of questionnaires and hearing tests.
Participants are then randomly assigned to one of three treatment groups:
1. Placebo amplification (control group)
2. Sound generator therapy
3. Combined sound generator and hearing aid amplification therapy
Neither the participants nor the investigators assessing outcomes know which treatment has been assigned. During the first 6 weeks, participants use only the treatment assigned to them. Follow-up visits are conducted to verify device use, comfort, and technical functioning. After 6 weeks, participants in the active treatment groups are provided access to three listening programs (amplification alone, sound generator alone, and combined therapy) and may choose which program to use according to their preferences and daily listening needs for the remaining 6 weeks. Participants complete questionnaires throughout the study to assess tinnitus severity, quality of life, sleep quality, hearing abilities, anxiety, depression, and treatment benefit. The total duration of participation is about 12 weeks.

What are the possible benefits and risks of participating?
Participants may experience improvements in tinnitus-related distress, hearing-related functioning, sleep quality, and overall quality of life. However, improvement cannot be guaranteed.
The risks associated with participation are minimal and similar to those associated with routine use of hearing aids and sound therapy devices. Some participants may experience temporary discomfort, annoyance, or dissatisfaction with the sounds produced by the devices.

Where is the study run from?
The study is conducted at six specialized tinnitus clinics in France involving multidisciplinary teams of ENT specialists and audiologists/hearing care professionals.

When is the study starting and how long is it expected to run for?
April 2021 to April 2024

Who is funding the study?
The study is funded through AFREPA self-funding and research support obtained by the study investigators. Hearing devices used in the study are provided by participating manufacturers (Signia, Phonak, and Starkey).

Who is the main contact?
Dr Philippe Fournier, philippe.fournier@fmed.ulaval.ca

# Contact information

### Type(s)
Public, Scientific, Principal investigator


### Contact name
Dr Philippe Fournier

### ORCID ID
https://orcid.org/0000-0003-2423-3434

### Contact details
Centre interdisciplinaire de recherche en réadaptation et intégration sociale (Cirris)
Site Hamel
525, boul. Wilfrid-Hamel, aile H local 1300
Québec
Canada
G1M 2S8
+1 (0)418 529 9141 ext 46123
philippe.fournier@fmed.ulaval.ca


# Additional identifiers

# Study information

### Scientific Title

Efficacy of sound therapy in chronic tinnitus patients with mild hearing loss: a multicentre, double-blind, placebo-controlled randomized clinical trial

## Study objectives
Primary objective:
To determine whether acoustic stimulation therapy delivered through sound generators alone or in combination with hearing aid amplification is more effective than placebo sound therapy in reducing tinnitus-related handicap and distress and improving quality of life in adults with chronic tinnitus and mild bilateral hearing loss.

Secondary objectives:
1. To compare the effects of placebo therapy, sound generators alone, and combined sound generator and amplification therapy on tinnitus outcomes over a 12-week treatment period
2. To evaluate the impact of treatment on sleep quality, auditory functioning, anxiety, and depression
3. To assess changes in tinnitus annoyance and tinnitus intensity
4. To examine the effectiveness of a flexible polytherapy approach in which participants can select among amplification, sound generation, or combined therapy according to their preferences and daily needs

## Ethics approval required
Ethics approval required

## Ethics approval(s)
Approved 07/01/2021, Comité de Protection des Personnes Ile de France IV (Hôpital Saint-Louis Porte 5 du carré Historique 1 avenue Claude Vellefaux, Paris, 75475, France; +33 (0)1 42 38 92 88; cpp.iledefrance4@orange.fr), ref: 2020-A02812-37

## Primary study design
Interventional

## Allocation
Randomized controlled trial

## Masking
Blinded (masking used)

## Control
Placebo

## Assignment
Parallel

## Purpose
Treatment

## Study type(s)

## Health condition(s) or problem(s) studied
Chronic tinnitus associated with mild hearing loss

## Interventions
Participants are randomly allocated in a double-blind manner to one of three treatment groups for a 12-week intervention period.

Arm 1 (placebo control):
Participants receive placebo amplification through hearing aids programmed to provide no therapeutic amplification or sound therapy effect. Devices are worn according to standard clinical recommendations during daily activities for 12 weeks.

Arm 2 (sound generator):
Participants receive acoustic stimulation therapy delivered through bilateral sound generators. Participants use the devices daily during waking hours for 12 weeks.

Arm 3 (combination therapy):
Participants receive acoustic stimulation therapy delivered through devices providing both hearing aid amplification and sound generator functions. Participants use the devices daily during waking hours for 12 weeks.

During the first 6 weeks (monotherapy phase), participants use only the intervention assigned by randomization. During the subsequent 6 weeks (polytherapy phase), participants in the active treatment groups are allowed to select among amplification alone, sound generator alone, or combined amplification and sound generator therapy according to personal preference, listening needs, and daily circumstances. Participants in the placebo group continue to receive placebo treatment throughout the study.

Allocation is performed using randomized assignment, and participants and study personnel involved in outcome assessment remain blinded to treatment allocation throughout the trial.

## Intervention Type
Device

## Phase
Not Applicable

## Drug/device/biological/vaccine name(s)
Hearing aids - sound therapy

## Primary outcome(s)
1. Tinnitus distress measured using the Tinnitus Functional Index (TFI) at 6 and 12 weeks

2. Global overall improvement measured using the Global Rating Change Scale, a clinical meaningful change was defined as at least a slight improvement in the overall condition following therapy, at 6 and 12 weeks

## Key secondary outcome(s)
1. Auditory functioning measured using the Speech, Spatial and Qualities of Hearing Scale – Short Form at 6 and 12 weeks

2. Anxiety and depression measured using the Hospital Anxiety and Depression Scale at 6 and 12 weeks

3. Tinnitus annoyance and intensity measured using Visual Analog Scales at 6 and 12 weeks

4. Quality of life measured using SF12-v2 at 6 and 12 weeks

### Completion date
02/04/2024

## Eligibility

### Key inclusion criteria
1. Adults seeking clinical care for tinnitus as the primary complaint
2. Continuous bilateral or centrally perceived tinnitus present for at least 3 months
3. Mild bilateral hearing loss meeting one of the predefined eligible audiometric profiles
4. Disabling tinnitus, defined as a score ≥38 on the French version of the Tinnitus Handicap Inventory (THI)
5. Ability and willingness to provide informed consent and comply with study procedures

### Healthy volunteers allowed
No

### Age group
Mixed

### Lower age limit
18 Years

### Upper age limit
100 Years

### Sex
All

### Total final enrolment
145

### Key exclusion criteria
1. Identifiable otolaryngological disorder explaining the tinnitus
2. Hearing loss not meeting the predefined eligible audiometric profiles
3. Use of hearing aids, sound generators, or combination devices within the previous 12 months
4. Any condition likely to interfere with study participation or outcome assessment

### Date of first enrolment
26/04/2021

### Date of final enrolment
22/12/2023

## Locations

### Countries of recruitment

France

# Sponsor information

### Organisation
AFREPA (Association Française Equipe Pluridisciplinaire Acouphène)

# Funder(s)

### Funder type

### Funder Name
AFREPA (Association Française Equipe Pluridisciplinaire Acouphène)

# Results and Publications

### Individual participant data (IPD) sharing plan

### IPD sharing plan summary
Not expected to be made available

### Study outputs

| Output type | Details | Date created | Date added | Peer reviewed? | Patient-facing? |
|---|---|---|---|---|---|
| Protocol file | English version 2.0 | 10/04/2021 | 06/08/2026 | No | No |
| Protocol file | French version 2.0 | 10/04/2021 | 06/08/2026 | No | No |