# Neural plasticity, hearing loss and tinnitus: changes in tonotopic maps of the auditory cortex

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| **Ethical review** | Approved WMO |
| **Status** | Recruitment stopped |
| **Health condition type** | Hearing disorders |
| **Study type** | Observational invasive |

## Summary

### ID

NL-OMON40455

**Source**
ToetsingOnline

**Brief title**
Plasticity HL

### Condition

- Hearing disorders

**Synonym**
hearing loss, tinnitus

**Research involving**
Human

### Sponsors and support

**Primary sponsor:** Universitair Medisch Centrum Groningen
**Source(s) of monetary or material Support:** Ministerie van OC&W,American Tinnitus Association (ATA)

## Intervention

**Keyword:** auditory cortex, hearing loss, tinnitus, tonotopy

## Outcome measures

### Primary outcome

The primary objective is to measure, characterize, and quantify the amount of neural plasticity, described as reorganisation of tonotopic maps in the auditory cortex using fMRI. Statistical assessments will be carried out to determine whether tonotopic maps differ in groups of subjects with hearing loss and subjects with hearing loss and tinnitus, both compared to normal hearing controls.

### Secondary outcome

In addition to the primary objective, the secondary objective is to measure the relation between the type of hearing loss (a steep-sloping and gradual-sloping hearing loss, respectively) and the degree of tonotopic reorganization. Statistical assessments will be carried out whether tonotopic maps differ between the groups of subjects with a steep-sloping hearing loss and subjects with a gradual-sloping hearing loss. Both groups will be compared to normal hearing controls.

# Study description

### Background summary

With an increased life expectancy and an ageing population, age-related dysfunctions are becoming more prevalent. The most widespread of all sensory impairments in an ageing population is hearing loss, which is characterized by a loss of sensitivity of the peripheral hearing organ, the inner ear. This

peripheral hearing loss is associated with less sensory input available to the brain. Animal research has shown that peripheral hearing loss may cause widespread plastic changes in the brain. Peripheral hearing loss is often associated with tinnitus: about 30% of the people with hearing loss also develop tinnitus. It has been suggested previously that tinnitus and tonotopic reorganization are causally related 1-3. Such cortical reorganization presumably contributes to the impaired communication skills experienced by humans with hearing loss. With an increasing demand for active participation of the elderly in society, it is crucially important to understand the neurobiological consequences of hearing loss and tinnitus.

### Study objective

The current study employs functional magnetic resonance imaging (fMRI) to investigate the relation between peripheral hearing loss, tinnitus and cortical reorganization. In particular, it aims to map the topographic representation of sound frequency, referred to as tonotopic maps, and how these change as a consequence of tinnitus and hearing loss. It also aims to investigate whether the type of hearing loss is related to the degree of reorganization.

### Study design

Three-group exploratory study.

### Study burden and risks

The clinical diagnostic tests involve several audiometric tests, and the administration of questionnaires (approx. 1.5-2 hours). A single fMRI scanning session will also take place (approx. 2 hours). None of the procedures expose the subject to known risks.

## Contacts

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# Trial sites

## Listed location countries

Netherlands

# Eligibility criteria

**Age**
Adults (18-64 years)
Elderly (65 years and older)

## Inclusion criteria

No hearing loss or reported tinnitus (controls, n=40)
Hearing loss (Hearing loss group, n=40)
Tinnitus (Hearing loss and tinnitus group, n=40)
< 30 dB difference between both ears for all the standard audiometric frequencies
Adults (18 - 75 yrs.)
No contraindications for MRI

## Exclusion criteria

Non-compliance with inclusion criteria

# Study design

## Design

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| Study type: | Observational invasive |
| Intervention model: | Other |
| Allocation: | Non-randomized controlled trial |
| Masking: | Open (masking not used) |
| Control: | Active |

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| Primary purpose: | Other |

### Recruitment

NL

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|---|---|
| Recruitment status: | Recruitment stopped |
| Start date (anticipated): | 04-02-2015 |
| Enrollment: | 120 |
| Type: | Actual |

## Ethics review

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| Approved WMO Date: | 03-12-2014 |
| Application type: | First submission |
| Review commission: | METC Universitair Medisch Centrum Groningen (Groningen) |
| Approved WMO Date: | 12-02-2016 |
| Application type: | Amendment |
| Review commission: | METC Universitair Medisch Centrum Groningen (Groningen) |

## Study registrations

### Followed up by the following (possibly more current) registration

No registrations found.

### Other (possibly less up-to-date) registrations in this register

ID: 27684
Source: Nationaal Trial Register
Title:

### In other registers

| Register | ID |
|---|---|
| CCMO | NL44470.042.13 |

| Register | ID |
| --- | --- |
| OMON | NL-OMON27684 |