

# Guided Audiomotor Exploration (GAME) music intervention for cochlear implant (CI) users

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<b>Ethical review</b>	Approved WMO
<b>Status</b>	Recruiting
<b>Health condition type</b>	Hearing disorders
<b>Study type</b>	Interventional

## Summary

### ID

NL-OMON55016

### Source

ToetsingOnline

### Brief title

CIMUGAME

### Condition

- Hearing disorders

### Synonym

impaired hearing / cochlear implant

### Research involving

Human

### Sponsors and support

**Primary sponsor:** Universitair Medisch Centrum Groningen

**Source(s) of monetary or material Support:** NWO Vici, Heinsius Houbolt Fonds; Friends of the Prins Claus foundation; Dorhout-Mees foundation

## Intervention

**Keyword:** cochlear implant, music appreciation, musical training, speech perception

## Outcome measures

### Primary outcome

The primary parameters are the difference between music intervention and control groups in the baseline-to-endpoint change for speech-on-speech accuracy and music appreciation ratings.

### Secondary outcome

The secondary parameters are the difference between music intervention and control groups in the baseline-to-endpoint change for other nuanced aspects of speech- and music perception and HR-QoL questionnaires.

## Study description

### Background summary

A cochlear implant (CI) provides hearing via electric stimulation of the auditory nerve for people with severe hearing loss to deafness. Yet even with CIs, this population experiences difficulties in both speech and music perception. Previous research implies that musical training can benefit perception of not only music, but also of speech\*although this is not consistently shown, or shown often with small effect sizes. A recent improvisation-based musical training method, Guided AudioMotor Exploration (GAME), has shown great potential for more robust improvement in functional MRI studies in normal-hearing populations. We investigate whether our GAME training may improve speech and music perception, with a primary focus on two particular challenges for CI users: speech perception in cocktail party (speech-on-speech) settings and music appreciation. Another reported benefit of musical training\*or music making\*is an accompanying sense of social belonging and improved quality of life. Considering that CI users often experience a sense of social isolation, we also wish to explore the impact on health-related quality of life (HR-QoL) from our music intervention. To assess the impact of our music intervention, two control groups will be established: One will follow Minecraft serious gaming lessons (with the same lesson-taking format as the music

intervention) to control for potential influences solely due to increased social activity and communication, and one will do nothing during the same time period to control for repeated testing effects.

## **Study objective**

The objective of the study is to explore potential beneficial effects of improvisation-based musical training: 1) on speech-on-speech perception and music appreciation in CI users, 2) on HR-QoL-related aspects as well as to explore other nuances in speech and music perception. The ultimate goal is to explore and fine-tune training approaches to meet the clinical need for improved speech and music perception in CI users.

## **Study design**

The intervention study will be a randomized controlled trial with three arms.

## **Intervention**

CI users will be randomized across three 6-month treatments: (1) improvisation-based piano lessons (music intervention), (2) Minecraft serious gaming lessons (control intervention), and (3) do nothing (do-nothing control). NH control participants will not receive an intervention.

## **Study burden and risks**

There are no known risks associated with participation in the study. The participation for NH controls includes one data collection point consisting of behavioral perception tests, questionnaires, and physiological metrics. The participation for CI users includes 18 weekly 45-minute lessons (intervention groups only), and four data collection points (before, during, after, follow-up) consisting of the same behavioral perception tests, questionnaires, and physiological metrics as NH controls (with the addition of an HR-QoL questionnaire). To reduce potential burden due to fatigue, data will be collected across multiple sessions adjusted to the stamina of each participant. Benefit may befall CI-user participants in both intervention groups. The study's purpose is to investigate if there is a benefit in auditory perceptual abilities and/or HR-QoL due to musical training. Improved HR-QoL in the social domain may be experienced by both intervention groups, as they will join a new social community (Minecraft serious gamers). Further, both intervention groups will have the chance to gain a new learning experience, and will potentially acquire new skills (playing piano, playing Minecraft) which may provide them further benefits beyond the study scope.

## 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

Healthy (normal hearing)

- at least 18 years of age
- native Dutch speaker
- has no language impairment or disorder such as dyslexia
- normal visual acuity (after correction)
- is of general sound health
- normal hearing score on a hearing screening

Patient (CI user)

- at least 18 years of age
- native Dutch speaker
- has no language impairment or disorder such as dyslexia

- has normal visual acuity (after correction)
- has general health as it relates to the ability to participate in the trial
- postlingually deafened
- use at least one cochlear implant, for at least one year before starting the trial
- never learned piano or similar keyboard instrument
- has had no more than three years of musical training
- has had no regular music making or training within three years prior to the study
- does not have more than basic knowledge of the serious game \*Minecraft\*

## Exclusion criteria

Healthy (normal hearing)

- younger than 18 years of age
- non-native Dutch speaker
- has a language impairment or disorder such as dyslexia
- has poorer-than-normal visual acuity (after correction)
- is not of general sound health
- has poorer-than-normal hearing as determined by a hearing screening

Patient (CI user)

- younger than 18 years of age
- non-native Dutch speaker
- has a language impairment or disorder such as dyslexia
- has poorer-than-normal visual acuity (after correction)
- has poor general health that impedes the ability to participate in the trial
- prelingually deafened
- received a CI less than one year before the start of the trial
- has already learned a keyboard instrument such as piano
- has had more than three years of musical training
- has had no regular music making or training within three years prior to the study
- has more than basic knowledge of the serious game \*Minecraft\*

## Study design

### Design

Study type:	Interventional
Intervention model:	Parallel

Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Other

## Recruitment

NL	
Recruitment status:	Recruiting
Start date (anticipated):	18-05-2021
Enrollment:	459
Type:	Actual

## Ethics review

Approved WMO	
Date:	19-03-2021
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO	
Date:	12-08-2021
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

No registrations found.

## In other registers

### Register

CCMO

### ID

NL74624.042.20