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

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Ethical review	Approved WMO
Status	Recruitment started
Health condition type	Hearing disorders
Study type	Interventional research applied for the first time in human subjects

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: Collectebussenfonds

Intervention

- Other intervention

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

Explanation

N.a.

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 and control participants will not receive an intervention. A separate group of CI controls will undergo the same test materials and the NH control group, but with some conditions including pre-processed sound that might improve listening quality.

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

Trial sites in the Netherlands

Universitair Medisch Centrum Groningen
Target size: 510

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)

Inclusion criteria

Healthy (normal hearing - control group)
- at least 18 years of age

- 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 - control group)
- at least 18 years of age
- 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
- use at least one cochlear implant, for at least one year before starting the study

Patient (CI user - training group)
- 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
- 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 control group)
- 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 -control group)

- younger than 18 years of age

-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 study

- received a CI less than one year before the start of the trial

Patient (CI user - training study)
- 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
- 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 phase:	N/A
Study type:	Interventional research applied for the first time in human subjects
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	No intervention
Primary purpose:	Other

Recruitment

NL

Recruitment status:	Recruitment started
Start date (anticipated):	18-05-2021
Enrollment:	510
Duration:	10 months (per patient)
Type:	Actual

Medical products/devices used

Product type:	N.a.

IPD sharing statement

Plan to share IPD: Undecided

Plan description
N.a.

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)
Approved WMO Date:	23-05-2025
Application type:	Amendment
Review commission:	METC UMCG

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	ID
CCMO	NL74624.042.20
Research portal	NL-008079