An improvisation-based approach to instrumental music training for cochlear implant users (GAME), specifically designed to facillitate audiomotor learning

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In this study, we will investigate whether GAME musical training can provide additional benefits to CI users. The project is designed to provide scientific evidence for a music training program that will be aimed at to also be fun and engaging for...

Ethical review	Not approved
Status	Will not start
Health condition type	Hearing disorders
Study type	Interventional

Summary

ID

NL-OMON48563

Source ToetsingOnline

Brief title Play it by ear, Sam!

Condition

Hearing disorders

Synonym Cochlear implant, Hearingloss

Research involving

Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Groningen Source(s) of monetary or material Support: Ministerie van OC&W,MED-EL (CI maatschappij)

Intervention

Keyword: auditory perception, cochlear implants, music therapy

Outcome measures

Primary outcome

Main study parameters/endpoints:

The study endpoints are to evaluate the potential benefits of GAME what we have

split up in 5 domains.

1. Auditory perception, especially in challenging areas for CI users, as

measured in psychophysical test for

a. pitch perception,

b. voice perception (voice pitch, F0, VTL), voice gender

categorization,

- c. vocal emotion perception,
- d. speech in noise perception,
- e. music perception,

2. cognitive aspects, such as listening effort, attention, or working memory

capacity,

- 3. quality of life (QoL), measured in self-reported questionnaires,
- 4. psychosocial skills and social engagement, measured in
- a. confidence, general and music domains,
- b. ease in talking to strangers, communication over telephone,
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c. social integration/lonelinsess,

d. mood (depression),

5. feasibility, usability, and effectiveness of the GAME method as a training

method for CI users, as

a. enjoyment of GAME by CI users,

b. overall motivation, willingness to continue with lessons,

c. music enjoyment,

d. amount of music activities such as listening to music, going to

concerts,

e. feasibility of learning and implementing the training method by

piano teachers.

Secondary outcome

- Age
- Gender
- Age of implantation
- Period of deafness

- Information about the CI (type model, processor, speech processing strategies

used)

Study description

Background summary

Background

Research into the effects that playing a music instrument might have on aural perception has revealed enhanced hearing capacities in musicians, not only in the musical domain (Fujioka, Trainor et al. 2004, Lee, Skoe et al. 2009), but

also in other domains like speech perception (Kraus and Chandrasekaran 2010). Next to that, musicians have a greater ability to identify degraded music than non-musicians (Fuller, Galvin et al. 2014). This shows a general beneficial effect from conventional music training on sound perception skills. Such studies have been conducted typically on individuals who learned to play an instrument using sheet music, they have learned to reproduce music, not to improvise it. Furthermore, they have learned to reproduce music they *see* (notes), a practice which has been termed *score-dependence* (Harris, van Kranenburg et al. 2016). Basically there are two different kind of trainings, one is based on score-dependence and the second one on improvisation.

It has been shown that auditory training with CI users is effective. For example a study done by Lo, McMahon et al. (2015) with melodic contour training, showed an effect on speech perception. A small effect has been shown of both training methods in CI users on consonant identification and prosody identification but no effect on sentences in babble. Fuller, Galvin III et al. (2018) have showed a small cross-domain transfer on emotion identification with music training.

In this study however, we will make use of another approach for music training, namely improvisation. Research into the effects that improvisation and playing *by ear* has a greater effect on the auditory cortex (Woody 2010, Vuust, Brattico et al. 2012, Bianco, Novembre et al. 2018). Activation of the auditory cortex while listening to both familiar and unfamiliar music is significantly larger in improvising musicians than in score-dependent musicians (Harris and de Jong 2015). The existence of a dedicated dorsal pathway (Milner 2006), facilitating sensorimotor integration, implies that larger activation of the auditory cortex in improvising musicians might be due to top-down effects of enhanced audiomotor integration on conscious aural perception. While these benefits might derive from any type of music training, the observed difference between score-dependent and improvising musicians suggests that the type of training might be critical.

Study objective

In this study, we will investigate whether GAME musical training can provide additional benefits to CI users. The project is designed to provide scientific evidence for a music training program that will be aimed at to also be fun and engaging for the end user, as the pilot results indicated. If this aim is achieved, the ultimate long-term goal is to systematically create a musical training program for CI users, designed to improve auditory perception, improve working memory, and/or quality of life (QoL). Any benefit that can be provided to current and future CI users will lead to an improvement in overall satisfaction and happiness of this patient population..

Study design

The design will be a randomized controlled trial in three groups. The target CI-user group will receive GAME music training. Second group will receive a non-musical training (typing course). The third group, our control group, will get no training. The training effects in each group will be explored by comparing results over the duration of the study, and the potential benefits from music training will be explored by comparing results between groups. These evaluations will be for auditory perception, cognitive functioning, and will also include self-reported/questionnaires of other domains, such as QoL, social integration, mood. Overall feasibility will be analysed for applicability. For the GAME music training, we will recruit certified piano teachers who are motivated to teach playing the piano to CI users. The places of residence of CI users will in many cases be distant from Groningen, and the recruitment of piano teachers will be from around the country based on where the participants live. The number of teachers recruited will be based on such factors, but for practical purposes, we will aim to recruit piano teachers located near the centers with the largest number of MED-EL CI recipients. The instructors will be trained to use the GAME method, and coached for the duration of the intervention. Individual tutors will document their teaching and the progress of their pupils.

The CI users will be recruited from MED-EL CI users within Netherlands. Once they meet the inclusion criteria, they will be randomly assigned to one of the three training groups. To prevent any potential biases or priming, we will be careful with wording in advertisements. In each group, we will start with half of the participants first, and after a checkpoint after 2 months, refine the procedure if necessary, and continue with the other half of the participants.

The GAME music training group will receive a 45 min. piano lesson once a week for six months. In addition, these participants will be expected to practice playing the piano several times during the week. When participants do not have a piano themselves, they will either arrange a practice situation, for example at the local music school or at the house of someone they know, or rent a piano. If none of those options works out, we will facilitate the acquisition or loan of an instrument. This will be discussed and determined during enrollment. There will be two other training groups. Group 2 will be provided with a training intervention that is motivating and rewarding, involves some motor activity, in a manner similar to keyboard use, but will have no musical aspect. The comparison of benefits from GAME music training group to this group will show what benefits come specifically from involving music in training. Group 3 will receive no active training, but will receive training from repeated tests with feedback provided. Comparison of the GAME music training or non-music training groups to this group will show what benefits come from active training with instructions vs. passive repeated testing only, i.e., procedural learning.

To address ethical concerns about the non-musical training groups not benefiting from music training due to random assignments, the participants in both these groups will also be given the option for music training upon completion of the study, which will however be of shorter duration than the study training (2 months vs 6 months). This option will be provided only at the end of the study to prevent any form of priming or bias over the results during the study.

Testing will take place four times in the course of the study (see Figure 1). We have recently developed a test battery, PICKA (Perception of Indexical Cues in Kids and Adults) , that combines tests from similar studies from our lab (e.g., (Fuller, Galvin et al. 2014, Ba*kent and Gaudrain 2016). These tests include speech perception, vocal emotion identification, voice perception (F0/VTL/gender). We also have tests for melody contour identification and can implement simple tests of cognitive functioning/working memory. We will keep testing sessions under 3 hours, with occasional breaks as necessary. Additionally, questionnaires will be used to assess subjective benefits. Participants living nearby will come to UMCG, where testing will take place in an anechoic room or soundproof booth at the Department of Otorhinolaryngology. When participants live too far from the hospital, we will visit them with a portable test system (laptop and a portable speaker), either testing them at home or at a location in their neighborhood where we are able to find a room that is as silent as possible, a quiet office for example.

Intervention

GAME therapy.

Study burden and risks

In the experiment there are no known risks or benefits associated in the participation. In total the tests will lasts two to three hours. After every test the participant will get a break for about 15 min or longer if necessary.

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

- Native Dutch speaker

- Healthy MED-EL CI user that is willing and able to participate in all baseline and follow up testing

and the entire music training and practices

- Adult, defined as age 18 years or older, and 80 years or younger; special attention will be given to

have CI users from a wide range of age group to explore training effectiveness for older users

- Using CI on a daily basis for about 10 hours
- Experienced CI user: More than one year CI-experience, to ensure stable performance
- No prior experience in playing a piano or keyboard

Exclusion criteria

- Neurological and/or linguistic disorders

Study design

Design

Study type:
Intervention model:
Allocation:

Interventional Parallel Randomized controlled trial

Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL	
Recruitment status:	Will not start
Enrollment:	72
Туре:	Anticipated

Ethics review

Not approved	
Date:	19-03-2019
Application type:	First submission
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** NL67107.042.18