Subjective assessment of a dereverberation algorithm for speech and music by cochlear implant users

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Ethical review	Approved WMO
Status	Pending
Health condition type	Hearing disorders
Study type	Observational non invasive

Summary

ID

NL-OMON56627

Source
ToetsingOnline

Brief title
Subjective assessment of (de)reverberated speech and music by CI users

Condition

- Hearing disorders

Synonym
Hearing loss

Research involving
Human

Sponsors and support

Primary sponsor: Leids Universitair Medisch Centrum
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: CI users, Dereverberation algoritm, MuSHRA, Speech and music appreciation

Outcome measures

Primary outcome

MuSHRA test outcomes, i.e., overall music quality/ enjoyment/ experience,

distortion/ naturalness, speech/ vocal quality, instrumental quality,

subjective ratings on a Likert scale, or a continuous scale when sliders are

used on a GUI.

Secondary outcome

na

Study description

Background summary

A cochlear implant (CI) is a device that provides people with severe hearing loss or deafness the ability to acquire functional hearing by electrically stimulating the auditory nerve. CIs are primarily designed to provide speech understanding. Their ability to convey music, however, is very limited due to the limitations of the implant and the way CIs decode sounds. One of the most pressing problems is that CIs convert sound into electrical signals by extracting the acoustic envelope and discarding the fine structure of the sound. CI users report a poor sound quality of music. The Multi Stimulus test with Hidden Reference and Anchor (MuSHRA) can be used to quantify these subjective claims. This is a standardized and commonly used method for subjective assessment to numerically quantify sound quality among CI users.

Study objective

The main objective is to assess the perceived sound quality of different speech and music excerpts that are modified using the dereverberation algorithm by CI users. To this end a suitable graphical user interface (GUI), the MuSHRA, will be optimized.

Study design

This study is a prospective semi-randomized single-centered cross-sectional study. The total duration of the study is estimated to be one year. CI users and normal-hearing (NH) subjects are included as study group.

Study burden and risks

Each subject will participate in a maximum of two non-consecutive test sessions. Each session lasts about three hours, with breaks between each sub-test if needed. The study is considered to involve negligible risk and minimal burden. Benefits to the CI population at large may be to provide CI users with a user-friendly and versatile research tool to quantitatively assess the sound quality, and aid in their overall sound experience. Given the small risk and high yield of this research it is an ethically justified study.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age

Adolescents (16-17 years)
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

Normal-hearing subjects:
- 16 year of age or older
- Normal-hearing listeners should have normal hearing, namely an average pure-tone threshold of 35 dB or less across a frequency range of 500-4000 Hz.

CI users:
- Implanted with a CI at least on one side;
- 16 years of age or older;
- Post-lingual deafness
- At least six months experience with their CI;
- A speech understanding score (CVC phoneme test) of at least 50%;
- Wearing a hearing aid in the nonimplanted ear is possible.
- Express interest and have affinity in participating in a study on music and CIs

Exclusion criteria

- Disorders other than a hearing impairment that could affect the study results, such as psychiatric disorders or physical disorders that would limit their ability to undergo testing (e.g., movement disorders or blindness)
- Prelingual deafness
- Not able to complete three hours of consecutive testing
- Not native Dutch speaker
- Pregnant women
- Women who are breastfeeding

Study design

Design

Study type:	Observational non invasive
Intervention model:	Crossover
Masking:	Single blinded (masking used)
Control:	Uncontrolled

Primary purpose:	Other

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-04-2024
Enrollment:	24
Type:	Anticipated

Medical products/devices used

Generic name:	Dereverberation (Weighted Prediction Error Post Filtering) algorithm
Registration:	No

Ethics review

Approved WMO Date:	08-03-2024
Application type:	First submission
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Approved WMO Date:	31-05-2024
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

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	NL85189.058.23