Reduction of listening effort with speech enhancement strategies in cochlear implant users

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

Summary

ID

NL-OMON52777

Source
ToetsingOnline

Brief title
Reduction of listening effort in CI users

Condition

- Hearing disorders

Synonym
Deafness, sensorineural 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,Advanced Bionics supports this research

Intervention

Keyword: Cochlear implant, Front-end processing, Listening effort, Speech understanding

Outcome measures

Primary outcome

Pupil diameter (LE), speech reception thresholds (SRTs) or words/sentence correct rates (SU)

Secondary outcome

The before-and-after results of the two User Experience questionnaires will be analyzed by calculating effect size to assess whether subjects deem the SES to be better, the same, or worse than their regular program. The user satisfaction rating will be subject to descriptive statistics only to describe SES comfort levels.

Study description

Background summary

A cochlear implant (CI) is a prosthetic device for the inner ear, able to directly stimulate the auditory nerve. With a CI it is possible to bypass damaged inner hair cells and provide audible sensations to profoundly deaf implant recipients. Hearing in quiet with a CI is generally sufficient with word recognition scores approaching 100% for the best performing CI users. However, listening in noise degrades this speech understanding substantially, and more so when compared to normal-hearing listeners. Much of the present research focuses on improving speech understanding (SU) in noise by means of noise reduction algorithms in the speech processing chain of the device. Meanwhile, listening effort (LE) has been largely neglected, but is receiving increasing attention in recent years. Due to the advances in technology, CI users are increasingly able to understand the desired sounds in adverse listening conditions. However, listening in such challenging conditions leads to listening fatigue in CI users. Because fatigue decreases speech recognition performance, it is critical to minimize LE in CI users. This proposal will focus on measuring LE and the effectiveness of different SESs in reducing LE.

Measuring LE alongside SU is a powerful combination. Generally, speech-enhancement strategies (SESs), such as noise reduction algorithms, are tested for effectiveness only by assessing SU scores. An often overlooked fact is that if the test subject consciously or unconsciously puts less effort in the task when the SES is switched on, then SU may not improve at all, hence underestimating the true benefits of the noise reduction strategy.

One method to measure LE is pupillometry, which is rapidly gaining popularity in recent years. Pupillometry assesses the pupil diameter, which is a proxy for cognitive load, and hence a useful outcome measure to assess LE.

Study objective

There are 2 main limbs to this study:

1. Create a benchmark, in which we will assess the three most commonly used Dutch speech-in-noise tests, namely the LIST, Matrix, DIN and Plomp for their associated LE in noise. This is necessary as pupillometry provides a measure of cognitive load; the LIST and Plomp sentences are meaningful sentences where it has been hypothesized that more mental load is necessary than in meaningless sentences as applied in the Matrix and DIN tests. In our lab we use the Matrix and LIST tests, and we wish to compare the performance of these tests against the DIN and Plomp sentences. For the Plomp sentences, LE has been firmly established [2, 3].

2. We will test a number of promising SESs using pupillometry, including
2a. SoftVoice: diminishes system noise in the CI and allows for better SU especially at low sound levels.
2b. Dereverberation algorithm: diminishes reverberations which enter the CI. And creates therefore a better speech understanding in an environment with lots of reverberations, e.g. a swimming pool or a restaurant.
2c. Bimodal hearing: The addition of a hearing aid to the CI has been tested previously in a successful study. However, at the time of that study we were not able to perform pupillometry. While our subjects were overwhelmingly positive about the bimodal hearing solution (added a hearing aid), the overall improvement in speech understanding was marginal (yet significant). We hypothesize that the main benefit of bimodal hearing is to be sought in LE, and not in SU per se.

Study design

This will be an observational cross-over trial. The total duration of the study is estimated to be 4 years. Each subject will typically participate in one limb, that is, for 4 sessions, but they are free to participate in more limbs. Each session lasts approximately 2.5 hours. Optionally, an SES may be fitted on their home-use CI. In that case subjects will be asked to use the SES for

anywhere between a few days to a few months at home. Hence, subjects may be enrolled in this ongoing study for a few months, during which they will have to come in to undergo speech testing, typically for 4 sessions. They will participate in more sessions when they participate in multiple sub-studies, but nor more than 12 sessions in total to limit the burden, except when they insist to complete all substudies. The setting is in the LUMC. It is a cross-over trial as every subject will be their own control when an SES is tested: SES ON (test) versus OFF (control) (limb 2), or when speech tests are compared (limb 1).

Study burden and risks

Minimal burden and negligible risk

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

- Fluent in Dutch, preferably being their native language;
- Implanted with a CI from Advanced Bionics at least on one side;
- 18 years of age or older;
- At least 6 months experience with their CI;
- Speech scores in quiet of at least 50%;
- Bimodal listeners need to wear a hearing aid or be willing to start wearing one;
- Normal-hearing listeners should have normal haring, namely an average pure-tone threshold loss of 50 dB or less across a frequency range of 500 - 4000 Hz.

Exclusion criteria

Conditions other than hearing loss that may affect the experiments (e.g., speech impairments)

Study design

Design

Study type: Observational non invasive

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	12-04-2019
Enrollment:	108
Type:	Actual

Ethics review

Approved WMO

Date:	28-01-2019
Application type:	First submission
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Approved WMO Date:	25-08-2020
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Approved WMO Date:	30-09-2022
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	NL67179.058.18