Listening Effort with Bimodal Hearing versus Cochlear Implant alone

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

Summary

ID

NL-OMON39238

Source
ToetsingOnline

Brief title
Listening Effort with a CI

Condition

- Hearing disorders

Synonym
Deafness, hard of hearing

Research involving
Human

Sponsors and support

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

Intervention

Keyword: Bimodal Hearing, Cochlear Implant, Listening Effort

Outcome measures

Primary outcome

The main study endpoint: Listening effort in terms of:

- Reaction times for secondary task

- Subjective task load (measured using the NASA TLX Questionaire)

As a function of parameters:

- Number of channels (simulated CI)

- Simulated Bimodal stimulation versus CI alone

- Number of channels (real CI)

- Real Bimodal CI + HA vs CI alone

Secondary outcome

Secondary parameters are:

- performance on the primary task in single- and dual-task situation

- performance on the secondary task in single- and dual-task situation

- response-times on the secondary tasks in single-task condition

and specifically for phase 3

- speech understanding on the simple response-time task (Accuracy)

- response times on the simple response-time task

Study description

Background summary

A Cochlear Implant (CI) allows profoundly deaf people to hear again by translating acoustical signals to electrical signals, which it passes on to the auditory nerve via electrodes in the cochlea. Listeners with state of the art cochlear implants achieve very good speech recognition results. However, in terms of listening effort there is still room for improvement. We hypothesize that a good way of reducing listening effort is combining both conventional hearing aids (HA) and cochlear implants (bimodal stimulation). The traditional listening tests are not sufficiently sensitive to reflect listening effort, and therefore a new method needs to be developed. The current study will first evaluate the dual task paradigm as a suitable method for measuring listening effort. Then we will look at differences in listening effort for CI alone vs Bilateral listening.

Study objective

Our first objective is two-fold; part of it is to evaluate the suitability of the dual task paradigm as a measure for listening effort in a series of simulation experiments. We will compare a linguistic and a non linguistic secondary task in this context. The other part is to identify the conditions for which the effect size is expected to be largest in real cochlear implant users through these simulation experiments.
Our second objective is to see if there is any benefit of bimodal stimulation, a.k.a combined acoustic and electric stimulation, for CI users in terms of listening effort.

Study design

Within subject comparison of performance on dual task experiments for:
- normal hearing participants simulated single CI * different nrs of channels vs unprocessed sound (regular hearing)
- normal hearing participants simulated bimodal hearing (HA + CI) vs single CI
- CI using participants - different nrs of channels
- CI using participants bimodal hearing (HA + CI) vs single CI

Subjects participate in a listening experiment combined with a secondary task. They are instructed to focus primarily on the listening task, and difference in performance on the secondary task - compared performance to the secondary task alone - is recorded as a measure of listening effort associated with the primary task. Additionally, the subjective mental taskload will be measured for each condition, using the Dutch version of the NASA Task Load Index (NASA TLX).

In phase 3 of the study, with CI users, an additional task will be performed. A simple response-time task that combines measures of speech understanding and

response-time in one task.

Study burden and risks

There are no known risks, nor benefits associated with participation.
The test session lasts for approximately 3 hours (including breaks) and requires the continuous attention of the subject. This may be fatiguing.

Phase 3 experiment 1 requires participants to come to the UMCG twice, once for 1 hour, and once for 2 hours, and train for 1 hour a day at home between visits. This may be considered an inconvenience.

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

All: Native Dutch speakers
For CI users: minimum 6 month experience in using CI

Exclusion criteria

Dyslexia
Knowledge of Japanese or Chinese script

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Other

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	14-03-2011
Enrollment:	190
Type:	Actual

Ethics review

Approved WMO

Date:	03-02-2011
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)

Approved WMO Date:	17-12-2012
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	12-02-2013
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	17-12-2013
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	ID
CCMO	NL34391.042.10