Development and verification of a binaural loudness-based first-fit procedure

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The purpose of this study is to investigate the individual characteristics of loudness perception in typical candidates for bilateral hearing aids. Data on spectral loudness summation and binaural loudness summation and their mutual interactions as...

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

Summary

ID

NL-OMON46206

Source
ToetsingOnline

Brief title
Fit2Ears

Condition

- Hearing disorders

Synonym
hearing-impairment, reduced dynamic range

Research involving
Human

Sponsors and support

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

Intervention

Keyword: Binaural loudness summation, Broadband signals, Loudness, Loudness scaling

Outcome measures

Primary outcome

Test results on spectral loudness summation and binaural loudness summation

will be analysed for descriptive statistics.

Secondary outcome

Secondary study parameters that will be studied are the differences between

types of hearing loss and the kind of BB noise (high frequency noises and low

frequency noises). Furthermore we want to evaluate the loudness based fitting

method Fit2Ears to the NAL-NL2 fitting method by using the SRT results.

Study description

Background summary

Complaints concerning loudness settings are the most often mentioned reasons for revisiting the hearing aid dispenser. In practice restoring the narrowband (NB) loudness perception in hearing-impaired (HI) listeners can lead to overly loud perception of broadband (BB) signals. The level of detail of knowledge about loudness perception required for an effective first-fit setting is still in debate. Two aspects of loudness perception are not taken into account: spectral loudness summation and binaural loudness summation. This includes also the binaural loudness perception of broadband signals. This combined effect has to be considered because the hearing aid later will typically process binaural broadband signals.
This research will reveal more knowledge about individual loudness perception. The data about the different aspects of loudness perception can result in a new first-fit prescriptive rule for hearing aids.

Study objective

The purpose of this study is to investigate the individual characteristics of loudness perception in typical candidates for bilateral hearing aids. Data on

spectral loudness summation and binaural loudness summation and their mutual interactions as well as the interactions with NB en BB loudness perception will be collected in this project.

Study design

Data collection will be spread over two appointments. Participants will be invited to the lab to take a pure tone audiometry and speech audiometry test. After that the individual loudness perception will be measured for different signals, presented unilaterally and bilaterally. An experimental hearing aid will be fitted based on the loudness measurements and a the speech in nosie will be measured. The measurement will take in total three hours, including several breaks.

Study burden and risks

The burden for the participants is minimal. For loudness scaling we will be using the ACALOS procedure4,5, a standardized measurement of loudness perception. The participants will be exposed to loud stimuli. At forehand we instruct the participants that they can stop the test at any time. When the response of the participant during the measurement is *extremely loud* the signal will automatically be switched off immediately. Loudness scaling can be exhausting that is why data collection will be spread over two appointments.

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

- Age above 18 years.
- Mild to moderate hearing loss.
- Symmetric hearing loss;
- Focus primarily on audiometric configurations N2, N3, N4, S2, and S3 according to Bisgaard
- Native speaker of the Dutch language

Exclusion criteria

- Language problems
- Hyperacusis
- Discrimination loss larger than 30%

Study design

Design

Study type: Observational non invasive

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	29-08-2016

Enrollment:	20
Type:	Actual

Ethics review

Approved WMO Date:	02-02-2016
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	16-02-2016
Application type:	Amendment
Review commission:	METC Amsterdam UMC

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	NL55890.018.15