

The impact of communication possibilities on psychosocial difficulties in children with hearing loss

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The primary objective of this study is to determine the effect of specific communicative abilities (speech recognition in noise; vocal emotion recognition and emotion expression) in children with hearing loss on their psychological (emotional and...

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

Summary

ID

NL-OMON54134

Source

ToetsingOnline

Brief title

ICOPE

Condition

- Hearing disorders
- Communication disorders and disturbances
- Age related factors

Synonym

Mental health, social functioning

Research involving

Human

Sponsors and support

Primary sponsor: Erasmus MC, Universitair Medisch Centrum Rotterdam

Source(s) of monetary or material Support: Ministerie van OC&W, Dorhout Mees Stichting

Intervention

Keyword: children, communication, hearing, psychosocial

Outcome measures

Primary outcome

Main study parameter/endpoint

Psychosocial difficulties as estimated with the HEAR-QL, and the CBCL, TRF, and YSR.

Auditory functioning as estimated with pure tone audiometry, speech perception in quiet measured with the NVA for soft speech, speech intelligibility in noise, measured with the Digits in Noise test (DIN).

Vocal emotion score as estimated with the EmoHI emotion recognition test, and with the vocal emotion expression test.

Psychosocial difficulties

HEAR-QL

The Hearing Environments and Reflection on Quality of Life questionnaire is a valid, reliable and sensitive quality of life assessment tool for children with hearing loss (35). It is available in two versions, one for children (7-12 yrs) and one for adolescents (12-18 yrs). The child version consists of 34 questions divided into the four subscales: hearing loss, environment, activities, emotions. The total scores can range from 26 to 130, where 26 indicates no difficulties on any scale and 130 indicates most difficulties on all scales.

The adolescents version contains 36 questions, divided into the four subscales: listening, social, school, emotions. The total scores can range from 29 to 145, where 29 indicates no difficulties on any scale and 145 indicates most difficulties on all scales. The child- and adolescent*s version can be found in appendix 2a and 2b respectively.

The HEAR-QL is part of the clinical routine, it may be that children have already filled out the questionnaire. Children that have not filled out the questionnaire, or their submission is more than six months ago, are required to fill it in as part of this study. The duration of administration is 10 minutes.

The HEAR-QL will be filled out by the participants. This will be done online, at home.

The HEAR-QL will serve as the outcome measure for the participants* hearing related quality of life and coping with social situations.

Child Behavior Checklist (CBCL), Teacher Report Form (TRF), Youth Self Report (YSR)

The CBCL (36) is a parent report form to screen for emotional, behavioral, and social problems in children between 6 and 18 years of age. It will serve as the assessment of the participants* psychosocial difficulties. The CBCL contains a total of 113 questions in eight different categories: anxious/depressed, withdrawn/depressed, somatic complaints, social problems, thought problems, attention problems, rule-breaking behavior, and aggressive behavior. The CBCL also has a scale set to show scores associated with disorders from the Diagnostic and Statistical Manual of Mental Disorders (DSM) (37): anxiety,

oppositional defiant disorder, conduct problems, somatic problems, affective problems, and attention deficit disorder. Many studies have demonstrated a high rate of reliability between the scales of the CBCL and psychological diagnoses (38). Teacher and Child versions of the CBCL are also available. Those are the Teacher Report Form (TRF) and the Youth Self Report (YSR). The Dutch CBCL, YSR and TRF can be found in appendix 3a, 3b, 3c respectively.

The problem items can be completed by most parents and teachers in about 10 minutes and the competence items in another 5 to 10 minutes. This will be done online, at home.

The CBCL, YSR, and TRF will serve as outcome measures for the participants* mental health and psychosocial difficulties. Additionally, the school performance section in the CBCL and TRF will serve as an indicator of intelligence.

Audiometry: pure tone/speech/Digits in Noise

Pure tone audiometry

Hearing levels are obtained in a sound-proofed booth. Hearing is measured with a clinical audiometer. Pure-tone air-conduction thresholds are obtained at frequencies 0.5, 1, 2, 3, 4, 6, and 8 kHz by an experienced audiometrist.

Thresholds are defined by the intensity level at which the tone was heard in 1 out of 2 ascents, resulting in a true clinical audiogram.

Bone conduction testing is done by placing an oscillator on the mastoid process and measuring threshold at the same frequencies.

This test is applicable from the age of six. The duration is 15 minutes.

The test is part of the clinical routine, it may be that children have already been tested. Children that have not been tested as part of the clinical routine in the prior six months are required to undergo pure tone audiometry for the purpose of this study.

This test will serve as one of the measures for the participants* auditory functioning.

Speech audiometry in quiet

To test speech perception in quiet, the clinically used Dutch speech test of the Dutch Society of Audiology was used (39), which consists of phonetically balanced monosyllabics (consonant-vowel-consonant). Stimuli are presented at a comfortable sound level, corresponding to the range of speech levels that participants perceive in daily life. Speech perception is measured in the best aided condition, therefore children wear the hearing devices (cochlear implants or hearing aids) as they would wear in daily life.

This test is applicable from the age of four. The duration is 15 minutes.

This may be part of the clinical routine, though this must be within 6 months of the questionnaire answering. If not, then the test or the questionnaires will be administered within that time limit.

This test will serve as one of the measures for the participants* auditory functioning.

Speech audiometry applied as Digits in Noise (DIN) test

The DIN is a speech-in-noise test where the listener is requested to return the spoken numbers (digits) that are offered to them along with audible noise (40). The prerecorded male-spoken speech-signal consists of three consecutive digits (from zero to nine). The listener's echoed triplet is rated correct or incorrect by an experienced audiometrist. In total, 24 digit triplets are presented for each DIN test. The speech recognition threshold is defined as the average of the SNRs and is calculated automatically by the computer. This test is applicable from the age of three years and six months.

The duration is 6 minutes.

This may be part of the clinical routine, though this must be within 6 months of the questionnaire answering. If not, then the test or the questionnaires will be administered within that time limit.

This test will serve as one of the measures for the participants' auditory functioning.

Emotion expression and recognition in speech

Emotion recognition in speech applied as EmoHI test

The EmoHI test is a recently developed tool to estimate the recognition of emotion in speech by hearing impaired children (32). During the test, participants are asked to link images of a depicted emotion to audio clips containing non-existent words or sentences expressed with a certain emotion. The test is administered to the children in the otorhinolaryngology department.

On a computer screen, three clowns are depicted, each expressing one of the

three emotions: anger, sadness, happiness. Audio clips with the vocal cues are accompanied with a visual stimulus of a parrot moving its beak, to indicate that a cue has been given. Participants are asked to touch or click on the clown of choice, after which either a video of confetti falling, or the parrot shaking its head is shown, to indicate a correct or wrong answer. The test has been validated and normdata is available (32).

The EmoHI test is applicable from the age of four.

The average duration of the test is 7 minutes.

The score on the test will serve as an age-adjusted indicator of the child's ability to recognize emotion in speech.

Emotion expression in speech

To estimate the participants' ability to express emotion in speech, participants will be asked to repeat six sentences and simultaneously express a requested emotion. The test will be administered in the otorhinolaryngology section of the hospital. A set of standard sentences will be used. The child is requested to repeat the sentence while expressing either happiness, sadness, or anger. The expressed sentence is recorded with a microphone. The recordings are analysed and scored to the degree of adequately expressed emotion.

The test is applicable from the age of four.

The average duration of the test is 5 minutes.

The score on this test will serve as an indicator of the child's ability to express emotion in speech.

Speech/language abilities

Children*s Communication Checklist

The Dutch version of the Children*s Communication Checklist (CCC) will be used to identify social and pragmatic language abilities indicated by parents or caregivers (33). This questionnaire (with 70 items divided over eight scales) has been validated with children aged 4 to 16. A general composite of communication is conventionally obtained by using the scales Speech production, Syntax, Semantics, Coherence, Inappropriate initiation, Stereotyped conversation, Use of context, and Nonverbal communication. A copy of the second version of the Dutch CCC can be found in appendix 4.

On average, it takes 15 minutes to complete the questionnaire.

The score on this questionnaire will serve as an indicator of the child*s language abilities.

Secondary outcome

Secondary study parameters/endpoints

Gender; age; comorbidity; socio-economic status; degree of hearing loss; age of onset; experience with a hearing device; type of hearing device; modality of aided hearing; communication mode (sign language/spoken/combination); type of schooling. Intelligence estimates based upon existing test results from patient files and school functioning. Speech/language score as estimated with the CCC-2.

Study description

Background summary

Psychosocial difficulties (e.g. peer problems, depression, anxiety, aggression, hyperactivity) occur more often in children with hearing loss than in the general population (1-15). These difficulties in turn can lead to future behavioral problems, lesser peer acceptance, and lower academic achievement (16). Previous findings suggest that psychosocial difficulties may be related to poorer communicative abilities (17). Compared to normal hearing peers, children with hearing loss exhibit less adequate communication skills, both hearing related (e.g.; speech perception, especially in challenging listening environments) and language related (e.g.; pronunciation, vocabulary, and syntax) (12, 18-20). Also, it is suggested that children with hearing loss (both with and without cochlear implants or hearing aids) are likely to make less use of the psycho-emotional elements of communication, such as interpreting intonation (21-25). Hearing-impaired children therefore may be more likely to become isolated from their social environment, which is supported by studies observing lesser bonding and attachment (14). Several communicative domains have not been investigated before. Therefore, we intend to investigate what specific communicative domains are related to psychosocial difficulties and how these domains relate to one another. We intend to compose a multivariate model to determine the individual effect of communicative factors (e.g.; hearing status, speech recognition, vocal emotion perception and emotion expression) on psychosocial difficulties, while identifying confounding variables.

Study objective

The primary objective of this study is to determine the effect of specific communicative abilities (speech recognition in noise; vocal emotion recognition and emotion expression) in children with hearing loss on their psychological (emotional and behavioral problems, quality of life) and social (peer relationships, social behavior) outcomes.

The secondary objective is to determine the relationship between psychological and social outcomes in hearing-impaired children and their gender; age; intelligence; comorbidity; socio-economic status; degree of hearing loss; speech/language abilities; age of onset of hearing loss; experience (in years) with a hearing device; type of hearing device; side of aided hearing; communication mode (sign language/spoken/combination); type of schooling.

Hypothesis: The psychosocial difficulties known to exist among hearing impaired children is related to the following specific aspects of communication: speech recognition in complex listening situations, emotion recognition and emotion

production in speech.

Study design

Over the period of March to September 2021 we aim to include at least 113 participants in this study. During this period, a total of ten measures will be administered. Several of these measures are used in the standard clinical care, therefore, in a share of the participants, these measures do not have to be administered in addition.

The following questionnaires will be administered:

HEAR-QL (10 minutes), filled out at home by the child

CBCL (20 minutes), filled out at home by the child, parents, and teacher

CCC-2 (15 minutes), filled out at home by the parents

The following tests will be administered:

pure tone audiometry (15 minutes), performed at the hospital by the child

speech audiometry (15 minutes), performed at the hospital by the child

Digits in Noise test (6 minutes), performed at the hospital by the child

EmoHI test (7 minutes), performed at the hospital by the child

Emotion expression in speech test (5 minutes), performed at the hospital by the child

The total time burden for the child is 1 hr 18 minutes, for the parents 35 minutes, for the teachers 20 minutes

Study Sites

- Erasmus Medisch Centrum Rotterdam, The Netherlands (Erasmus MC), department of Otorhinolaryngology, Head and Neck Surgery.

- Universitair Medisch Centrum Groningen, The Netherlands (UMC Groningen), department of Otorhinolaryngology, Head and Neck Surgery.

Psychosocial difficulties

Psychosocial difficulties will be measured with the Child Behavior Checklist (CBCL) and the Hearing Environments and Reflections on Quality of Life questionnaire (HEAR-QL). The parents of the participants will be requested to fill out the CBCL. Also the CBCL teacher version and child version will be used. These are the Teacher Report Form (TRF), and the Youth Self Report (YSR), respectively. The YSR is applicable in children from the age of 11 and onwards. The HEAR-QL will be filled out by the participants that are 7 years or older. All questionnaires will be administered through Zorgmonitor in the Erasmus MC and LimeSurvey in the UMC Groningen. Zorgmonitor is an online platform used to administer and assess clinical questionnaires, it is used daily by healthcare professionals in the Erasmus MC. Limesurvey is an application for capturing clinical research data. This survey software provides a flexible platform and wide host of tools for developing surveys and survey questions (31).

Hearing status, communicative abilities, and intelligence

Hearing status will be assessed through pure tone audiometry (for children with hearing aids), speech perception in quiet in best aided condition, and the Digits in Noise (DIN) test. Emotion perception will be estimated with the EmoHI test, where the children are asked to select the emotion that the provided audio sample is expressing (32).

Emotion production will be estimated with an emotion production test, where children are asked to vocally express a requested emotion while repeating a set of standard sentences.

Language abilities will be estimated with the Children's Communication Checklist (33), to be filled out by the parents or caregivers.

Intelligence will be estimated with the *school functioning* section in the TRF and CBCL, and additionally using the results of intelligence measures recorded in the participants' clinical files.

Several tests are implemented in the standard clinical care of the patients. This study requires recent test scores, therefore, it may be possible that participants are required to be tested again outside the standard clinical care. The measurements regarding this are the HEAR-QL, pure tone audiometry, speech audiometry, and the DIN.

Study burden and risks

Benefits

Examining the psychosocial difficulties and -development may assist children and parents in forming realistic expectations of their child's development, and it will help them to understand the behavior of the child. Additionally, relevant discoveries will allow the parents to decide earlier on intervening. Participants eligible for inclusion are all children with hearing loss that have been using a hearing aid or Cochlear Implant for at least one year. Because the project aims to investigate the psychosocial difficulties of children with hearing loss, there is no other population that could be eligible for inclusion. Therefore the research may be regarded as group-related.

Risks

The right not to know is a medical-ethical right that should be taken into account when applying new measures for investigation.

Children may be flagged as being psychosocially divergent. This may result in stigma, psychiatric diagnoses, and the ensued burden of therapy, that otherwise may never have occurred. Therefore we offer the possibility to not reveal the test results to the participants and/or their parents.

There are no risks involved in participating in the study.

Contacts

Public

Erasmus MC, Universitair Medisch Centrum Rotterdam

Dr.Molewaterplein 40
ROTTERDAM 3015GD
NL

Scientific

Erasmus MC, Universitair Medisch Centrum Rotterdam

Dr.Molewaterplein 40
ROTTERDAM 3015GD
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age

Adolescents (12-15 years)
Adolescents (16-17 years)
Adults (18-64 years)
Children (2-11 years)

Inclusion criteria

1. Children between 6 and 18 years of age with hearing loss;
 2. Children that have been using a hearing aid or cochlear implant for at least one year;
- 1A. Children with normal hearing between 13 and 18 years of age

Exclusion criteria

1. Refusal to participate;

2. Severe cognitive or physical impairment in the children that leads to the inability of participating in all tests and inability of filling out the questionnaires administered in this study;
3. Inadequacy in the Dutch language that leads to the inability of participating in the tests and questionnaires;
4. Illiteracy of the parents that leads to the inability to answer the questionnaires.

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:	Diagnostic

Recruitment

NL	
Recruitment status:	Pending
Start date (anticipated):	14-04-2021
Enrollment:	161
Type:	Anticipated

Ethics review

Approved WMO	
Date:	04-05-2021
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO	
Date:	31-01-2023
Application type:	Amendment

Review commission:

METC Erasmus MC, Universitair Medisch Centrum Rotterdam
(Rotterdam)

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	NL76699.078.21