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Impact of children's auditory technology: longitudinal study

Submission date 31/07/2026	**Recruitment status** Recruiting	[X] Prospectively registered [_] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [X] Record updated in last year
Registration date 05/08/2026	**Overall study status** Ongoing	
Last Edited 25/09/2026	**Condition category** Ear, Nose and Throat	

Plain English summary of protocol

Background and study aims
Children with mild-to-moderate hearing loss often face challenges with listening, learning and communication. Hearing aids and remote microphones are widely used to help, but researchers still need more evidence about which types of hearing technology work best for children in everyday life.
The iCAT (Impact of Children's Auditory Technology) study aims to find out how different hearing aid settings, with or without a remote microphone, affect children's hearing, listening, learning and communication skills over both the short term and long term. The study will also compare the results with those of children who do not have hearing loss. The findings may help improve advice and support for children, families, schools and healthcare professionals.

Who can participate?
Children aged 6 to 11 years can take part.
For children with hearing loss, participants must:
• Have mild-to-moderate hearing loss in both ears
• Have at least one year of hearing aid experience
• Normally use their hearing aids for at least 6 hours per day
• Attend a mainstream school
• Be able to understand instructions in English, with at least one caregiver who can also understand English
Children with typical hearing can also take part as a comparison group.

What does the study involve?
Children with hearing loss will be assigned to one of four groups. They will receive hearing aids programmed with one of two hearing aid settings and may or may not receive a remote microphone. Neither the families nor most of the research team will know which hearing aid setting has been assigned during the study.
Participants with hearing loss will:
1. Attend audiology clinic visits for hearing assessments, fitting of study devices, device checks and a final follow-up visit
2. Wear the study hearing aids for at least 8 hours per day throughout the study
3. Attend three research visits at Lancaster University over approximately 12 months

At the university visits, children will take part in activities and assessments that examine hearing, listening, attention, memory, learning and communication skills. These include listening tasks, thinking games, reading and maths activities, virtual reality tasks and electroencephalography (EEG), which measures brain activity using a comfortable cap worn on the head.
Parents or caregivers will complete questionnaires about their child's hearing, listening, development and wellbeing.
Children with typical hearing will attend the three university research visits but will not receive hearing technology.

What are the possible benefits and risks of participating?
Possible benefits include:
• Helping researchers improve hearing care and support for children with hearing loss
• Contributing to the development of future hearing technologies
• Receiving and trying new hearing technology during the study
• Having the opportunity to keep the study hearing aids and, where applicable, the remote microphone after the study
• Taking part in interesting research activities
Possible risks and disadvantages include:
• The time and travel needed to attend appointments and research visits
• Mild discomfort from wearing the EEG cap
• Mild nausea or discomfort when using virtual reality equipment in some children
• A period of adjustment while getting used to new hearing technology
The researchers consider these risks to be minor and will take steps to ensure children are comfortable and safe throughout the study.

Where is the study run from?
Lancaster University, United Kingdom.

When is the study starting and how long is it expected to run for?
August 2026 to May 2028.

Who is funding the study?
1. UK Research and Innovation (UKRI)
2. William Demant Foundation

Who is the main contact?
Dr Hannah Stewart, h.stewart5@lancaster.ac.uk

Contact information

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Additional identifiers

Integrated Research Application System (IRAS)
360926

Central Portfolio Management System (CPMS)
71387

Study information

Scientific Title
Impact of Children's Auditory Technology (iCAT): Short and long term effects of omnidirectional and adaptive/directional hearing aids and assistive listening devices in 6-to-11 year old children with mild-to-moderate hearing loss on key hearing and listening skills

Acronym
iCAT: Longitudinal study

Study objectives
This study aims to investigate the short (one month) and long-term (12 months) effects of two hearing aid algorithms (omnidirectional and adaptive/directional), with and without assistive listening devices (a remote microphone), on four key hearing and listening skills (spatial hearing, error listening, audio-visual integration, and listening and engagement skills), cognition and educational abilities

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 20/01/2026, HRA and Health and Care Research Wales (HCRW) (Floor Four, North Welsh Government Offices Cathays Park King Edward VII Avenue, Cardiff, CF10 3NQ, United Kingdom; +44 2920 230457; healthandcareresearch@wales.nhs.uk), ref: 25/EE/0259

Primary study design
Interventional

Allocation
Randomized controlled trial

Masking
Blinded (masking used)

Control
Active

Assignment
Parallel

Purpose
Treatment

Study type(s)

Health condition(s) or problem(s) studied
Mild-to-moderate hearing loss

Interventions
MMHL participants will receive: A) an omnidirectional OR an adaptive/directional hearing aid algorithm; and B) an assistive listening device (ALD) OR no ALD. When allocating the deaf children into these four groups, participants will be matched across groups based on age, sex, and hearing levels (pure tone averages). Furthermore, if the participant already has experience of using any assistive listening device (ALDs such as a remote microphone) for over a period of one year, they will be automatically allocated into one of the ALD groups during the randomisation process.

To simplify the recruitment and matching of participants, the first 12 participants recruited will be identified as diverse across the matching criteria and will be designated into a single (double blinded) group. Once these 12 participants have been recruited and engaged into the trial, further recruited participants will be matched to this first group on the matching criteria and randomly allocated into another available group. Clinic availability will then naturally mix up the participants so that the first 12 participants to reach the stage of research visits at LU will be in different groups, and not just the initial first group.

Participants are required to wear their study hearing aids full time (at least 8 hours per day average) during the duration of the study to remain compliant with the trial eligibility requirements.

• Group 1: MMHL – omnidirectional hearing aids with no ALD
• Group 2: MMHL – omnidirectional hearing aids with an ALD
• Group 3: MMHL – adaptive/directional hearing aids with no ALD
• Group 4: MMHL – adaptive/directional hearing aids with an ALD
• Group 5: Control group- hearing controls with no auditory technology

Double blinding will be applied to the hearing aid algorithm allocation. Double blinding includes the blinding of the participant and guardian, as well as the research team (Research Assistants, Trial Collaborators, Chief Investigator) at Lancaster University. The Lancaster University Trial Coordinator, NHS Research Teams, Principal Investigators at each clinic site and Audiologists will not be blinded to the allocation of hearing aid algorithms, as these are required to correctly allocate, fit, and check the quality of the hearing. All other members of the trial will be blinded to this allocation. Participants will be randomized on REDCap, a GDPR compliant online database application.

• Clinic visit 1: MMHL participants will have a standard of care hearing assessment at their usual audiology clinic.
• Clinic visit 2: At their usual audiology clinic, MMHL participants will be fitted with study devices - hearing aid with blinded algorithm and, if applicable, an assistive listening device (ALD).
• Research visit 1 (T0): Within one week after their device fitting the participants will come to Lancaster University to complete research activities.
• Research visit 2 (T1): Within one month after hearing aid fitting the participants will return to Lancaster University to repeat the research activities.
• Clinic visit 3: MMHL participants will have a device check-up at their usual audiology clinic for device fit, comfort and data logging.
• Research visit 3 (T2): Up to twelve months after device fitting the participants will return to Lancaster University to repeat the research activities.
• Clinic visit 4: MMHL participants will return to their usual audiology clinic for exiting from the study and for the participant and their family to be unblinded. Note that at this point the research team will continue to be blinded until all participants have completed the study. During the exit of the study, participants will be given the choice to either continue with their trial hearing aids, algorithm, and/or ALD if provided one or resume to their previous model and configurations. Participants who did not receive an ALD during the study will now be offered one.

Hearing participants will complete the above three research visits only, with a hearing assessment completed by the research team at Research Visit 1.

No investigational medicinal products (IMPs) will be used in this clinical trial. Devices used in this clinical trial are approved for use with children with mild-to-moderate hearing loss by the NHS and Department of Education in the UK respectively.

Intervention Type
Device

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Oticon Play SI and Oticon EduMic

Primary outcome(s)

1. Auditory attention measured using reaction times and error rate in an auditory attention behavioural task at T0 (within one week after their device fitting), T1 (within one month after hearing aid fitting), T2 (up to twelve months after device fitting)

2. Spatial hearing measured using virtual reality test of spatial hearing at T0 (within one week after their device fitting), T1 (within one month after hearing aid fitting), T2 (up to twelve months after device fitting)

3. Audio-visual integration ability measured using minimum time window for successful audiovisual integration of speech at T0 (within one week after their device fitting), T1 (within one month after hearing aid fitting), T2 (up to twelve months after device fitting)

4. Listening errors measured using electroencephalography (EEG) while listening to a story with mispronounced and nonsense words at T0 (within one week after their device fitting), T1 (within one month after hearing aid fitting), T2 (up to twelve months after device fitting)

Key secondary outcome(s)

1. Language development measured using the Peabody Picture Vocabulary Test-5 and Receptive Polysemy Vocabulary Test at T0 (within one week after device fitting), T1 (within one month after hearing aid fitting), and T2 (up to twelve months after device fitting)
2. Classroom listening skills measured using the Vanderbilt Classroom Listening Assessment Survey and Communication Supporting Classrooms Observation Tool at T0 (within one week after device fitting), T1 (within one month after hearing aid fitting), and T2 (up to twelve months after device fitting)
3. Educational achievement (mathematics and literacy) measured using the York Assessment of Reading for Comprehension and Wechsler Individual Achievement Scale III at T0 (within one week after device fitting), T1 (within one month after hearing aid fitting), and T2 (up to twelve months after device fitting)
4. Listening difficulties measured using the Evaluation of Children's Listening and Processing Skills questionnaire at T0 (within one week after device fitting), T1 (within one month after hearing aid fitting), and T2 (up to twelve months after device fitting)
5. Speech-in-noise discrimination ability measured using the BKB Sentences test and Who is Right? task at T0 (within one week after device fitting), T1 (within one month after hearing aid fitting), and T2 (up to twelve months after device fitting)
6. Hyperacusis and hypoacusis measured using the Hyperacusis in Children's Questionnaire at T0 (within one week after device fitting), T1 (within one month after hearing aid fitting), and T2 (up to twelve months after device fitting)
7. Listening effort measured using the Vanderbilt Fatigue Scale and paediatric NASA Task-Load Index at T0 (within one week after device fitting), T1 (within one month after hearing aid fitting), and T2 (up to twelve months after device fitting)
8. Hearing aid usage measured using hearing aid data logging and the Child and Parent Speech, Spatial, and Qualities of Hearing Scale at T0 (within one week after device fitting), T1 (within one month after hearing aid fitting), and T2 (up to twelve months after device fitting)
9. Self-reported hearing aid helpfulness measured using a semi-structured interview at T0 (within one week after device fitting), T1 (within one month after hearing aid fitting), and T2 (up to twelve months after device fitting)
10. Cognition measured using the NIH Toolbox (Flanker Test, Pattern Comparison, Dimensional Change Card Sort, List Sorting Working Memory Test, and Picture Sequence Memory Test), the Working Memory Test Battery for Children, and Raven's Progressive Matrices at T0 (within one week after device fitting), T1 (within one month after hearing aid fitting), and T2 (up to twelve

months after device fitting)
11. Wellbeing measured using the Strengths and Difficulties Questionnaire, Home Environment and Noise Questionnaire, and Confusion Hubbub and Order Scale at T0 (within one week after device fitting), T1 (within one month after hearing aid fitting), and T2 (up to twelve months after device fitting)

Completion date
31/05/2028

Eligibility

Key inclusion criteria
1. Aged 6-11 years old
2. With fluency in English
3. Who possess instructional comprehension, confirmed by their audiologist
4. At least one caregiver with English fluency for instructional comprehension for research visits at Lancaster University
5. Attending mainstream schools
6. Be able to wear their hair loose to enable us to access strands of natural hair and their scalp during fNIRS and EEG recordings

MMHL participants:
1. With bilateral/symmetrical sensorineural hearing loss (SNHL)
2. With a minimum of one year of hearing aid experience, confirmed by their audiologist and previous clinic notes
3. With a history of consistent hearing aid usage (minimum 6h/day)

The participants may be multilingual, as long as both the child and at least one caregiver understand English to ensure informed consent, assent, and instructional comprehension. However, an interpreter can be utilised at audiology clinics when necessary to support families

Healthy volunteers allowed
Yes

Age group
Child

Lower age limit
6 Years

Upper age limit
11 Years

Sex
All

Total final enrolment
0

Key exclusion criteria

1. Medical diagnosis of neurological, psychiatric, and/or attention deficits
2. History of ear surgeries

Further exclusion criteria for hearing children (control participants) only:
3. Medical diagnosis of learning, language, developmental delays, or hearing difficulties /disorders
4. Hearing loss of mild, moderate, severe, or profound degree (above 20 dB HL at standard frequencies)

Date of first enrolment
10/08/2026

Date of final enrolment
31/03/2027

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
East Lancashire Hospitals NHS Trust
Royal Blackburn Hospital
Haslingden Road
Blackburn
England
BB2 3HH

Sponsor information

Organisation
Lancaster University

ROR
https://ror.org/04f2nsd36

Funder(s)

Funder type

Funder Name
UK Research and Innovation

Alternative Name(s)
UKRI

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Funder Name
William Demant Fonden

Alternative Name(s)
William Demant Foundation

Funding Body Type
Private sector organisation

Funding Body Subtype
Trusts, charities, foundations (both public and private)

Location
Denmark

Results and Publications

Individual participant data (IPD) sharing plan
Anonymised datasets generated during and/or analysed during the current study will be stored in a publicly available repository (OSF: doi.org/10.17605/OSF.IO/F9SEZ)

IPD sharing plan summary
Stored in publicly available repository

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	Participant Information Sheet: Deaf 10-11 year olds version 1.2	19/03/2026	31/07/2026	No	Yes

Participant information sheet	Participant Information Sheet: Deaf 6-9 year olds version 1.2	19/03/2026	31/07/2026	No	Yes
Participant information sheet	Participant Information Sheet: Hearing 10-11 year olds version 1.2	10/03/2026	31/07/2026	No	Yes
Participant information sheet	Participant Information Sheet: Hearing 6-9 year olds version 1.2	10/03/2026	31/07/2026	No	Yes