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Impact of children's auditory technology: classroom 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 05/08/2026	**Condition category** Ear, Nose and Throat	

Plain English summary of protocol

Background and study aims

Children with mild-to-moderate hearing loss can find it harder to listen, learn and communicate, especially in busy classrooms. Hearing aids and remote microphones are often used to help, but researchers still do not fully understand how children use these technologies during everyday classroom activities.

The iCAT Classroom Study aims to explore how children with mild-to-moderate hearing loss listen and interact with teachers and other children in classroom settings. The study will compare situations with and without background classroom noise and will examine whether a remote microphone helps children hear and take part more effectively. The findings may help improve support, advice and hearing technology for children, families, schools and healthcare professionals.

Who can participate?

Children aged 6 to 11 years can take part.

Children with hearing loss must:

• Have mild-to-moderate hearing loss in both ears
• Have used hearing aids for at least one year
• Regularly wear 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 attend audiology appointments and research visits at Lancaster University.

Participants with hearing loss will:

1. Attend hearing assessments and have study hearing aids fitted
2. Be assigned either to receive a remote microphone or not receive one during the study
3. Take part in two research visits at Lancaster University
4. Return to their audiology clinic for a final study visit

At the university visits, children will take part in classroom-style activities with a teacher. Some

activities will involve only one child and a teacher, while others will involve a teacher and several children. The activities will take place in both quiet and noisy classroom conditions.
Researchers will use equipment such as eye-tracking glasses, motion-tracking technology and a soft brain-monitoring cap called functional near-infrared spectroscopy (fNIRS) to understand how children listen, communicate and interact during classroom tasks.
Children will also complete activities that measure attention, memory, thinking skills, reading and maths. Parents or caregivers will be asked to complete questionnaires about their child's hearing, listening and wellbeing.
Children with typical hearing will attend the university visits and complete similar activities but will not receive hearing technology.

What are the possible benefits and risks of participating?
There may be no direct benefit to taking part. However, participants may:
• Help researchers improve support and hearing care for children with hearing loss
• Contribute to the development of better hearing technology for children
• Experience university-based research activities
• Try new hearing technology and, if eligible, keep the study devices after the study has finished
The risks are expected to be minor. These may include:
• The time and travel required to attend appointments
• Mild discomfort from wearing eye-tracking glasses
• Mild discomfort from wearing the fNIRS cap
• Mild discomfort from wearing a small microphone attached to clothing
• A period of adjustment while becoming familiar with new hearing technology
Researchers will monitor participants throughout the study and can stop or adjust activities if a child becomes uncomfortable.

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 June 2028.

Who is funding the study?
The study is funded by:
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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Study information

Scientific Title
Impact of Children’s Auditory Technology (iCAT): Impact of adaptive/directional hearing aids and assistive listening devices on classroom hearing and listening strategies in 6-to-11 year old children with mild-to-moderate hearing loss

Acronym
iCAT: Classroom study

Study objectives
This study aims to assess hearing and listening strategies used by MMHL children in a naturalistic classroom environment, including social listening behaviours and interbrain synchronicity, both with and without classroom level noise. These strategies will be relevant for both: child to teacher situations; and multi-talker situations with a teacher and their peers. This study is split into two parts (A and B). Part A will investigate hearing and listening strategies in a naturalistic classroom when there is one child and one teacher in the classroom. Part B will investigate the same, but with three children (one with MMHL, two normal-hearing controls) and one teacher. Outside of this difference in the number of children present at the research visit, all other aspects will remain the same between the two parts.

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
Open (masking not 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 be allocated to receive a study assisted listening device (ALD) OR no ALD. Any existing experienced users of ALDs will be placed in the ALD group. The remaining participants recruited will be matched across groups based on age, sex and hearing level (pure tone average). Participants will be randomized on REDCap, a GDPR compliant online database application.

• Group 1: MMHL – omnidirectional hearing aid without ALD
• Group 2: MMHL – omnidirectional hearing aid with ALD
• Group 3: Control group - hearing controls with no auditory technology

We will use two classroom scenarious during classroom activities in a naturalistic classroom lab:
• Quiet: no noise played during classroom activities
• Noisy: naturalistic classroom noise played during activities

We will use different tasks where the talker is attended to or not. For example, the participant will be asked to attend to the teacher talking (attended talker), but not their talker peers (unattended talkers).

• 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: Within four to six weeks after their device fitting the participants will come to Lancaster University to complete research activities.
• Research visit 2: Within one month from Research Visit 1 the participants will return to Lancaster University to do different research activities.
• Clinic visit 2: MMHL participants will return to their usual audiology clinic for exiting from 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 two 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. Social behavioural signs of listening measured using eye-tracking to assess speech-reading; motion-tracking to assess synchronised head tilts and distance between talkers at Research Visit 1: Within four to six weeks after their device fitting

2. Synchronisation of neural activity relative to listening measured using functional near-infrared spectroscopy to assess interbrain synchronicity at Research Visit 1: Within four to six weeks after their device fitting

Key secondary outcome(s)
1. Language development measured using the Peabody Picture Vocabulary Test-5 and Test of Child Speechreading at research visit 1 (within four to six weeks after device fitting)
2. Classroom listening skills measured using the Vanderbilt Classroom Listening Assessment Survey and Communication Supporting Classrooms Observation Tool at research visit 1 (within four to six weeks 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 research visit 1 (within four to six weeks after device fitting)
4. Listening difficulties measured using the Evaluation of Children's Listening and Processing Skills questionnaire at research visit 1 (within four to six weeks after device fitting)
5. Speech-in-noise discrimination ability measured using the BKB Sentences test and Who is Right? test at research visit 1 (within four to six weeks after device fitting)
6. Hyperacusis/hypoacusis measured using the Hyperacusis in Children's Questionnaire at research visit 1 (within four to six weeks after device fitting)
7. Listening effort measured using the Paediatric NASA Task-Load Index at research visit 1

(within four to six weeks 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 research visit 1 (within four to six weeks after device fitting)
9. Self-reported hearing aid helpfulness measured using a semi-structured interview at research visit 1 (within four to six weeks after device fitting)
10. Cognition measured using the NIH Toolbox (Flanker Test, Pattern Comparison, Dimensional Change Card Sort, List Sorting Working Memory Test, Picture Sequence Memory Test), Working Memory Test Battery for Children, and Raven's Progressive Matrices at research visit 1 (within four to six weeks after device fitting)
11. Wellbeing measured using the Strengths and Difficulties Questionnaire, Home Environment and Noise Questionnaire, and Confusion, Hubbub and Order Scale at research visit 1 (within four to six weeks after device fitting)

Completion date
30/06/2028

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 criterion 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
18/08/2026

Date of final enrolment
31/03/2028

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