

Can assistive listening technology improve hearing after subarachnoid haemorrhage?

Submission date 15/07/2026	Recruitment status Recruiting	☒ Prospectively registered ☐ Protocol
Registration date 15/07/2026	Overall study status Ongoing	☐ Statistical analysis plan ☐ Results
Last Edited 15/07/2026	Condition category Circulatory System	☐ Individual participant data ☒ Record updated in last year

Plain English summary of protocol

Background and study aims

Some people who have had a subarachnoid haemorrhage have difficulty understanding speech when there is background noise, for example in restaurants, group conversations, meetings or other busy environments. This can happen even when standard hearing tests are normal.

This study aims to better understand this type of hearing difficulty after subarachnoid haemorrhage and to test whether an assistive hearing device can improve hearing in everyday noisy situations.

The device being tested is the Phonak Roger system. It includes a small receiver worn near the ear and a wireless microphone that can be placed near the person speaking. The system is designed to make speech clearer in background noise.

Who can participate?

Adults aged over 18 years may be able to take part if they have previously had an aneurysmal subarachnoid haemorrhage, and have normal standard hearing tests but evidence of difficulty with speech perception in noise.

What does the study involve?

Potential participants will first complete screening questionnaires about hearing and listening difficulties. Those whose answers suggest difficulty understanding speech in noise will be invited to a face-to-face appointment at the University of Southampton.

At this appointment, the research team will examine the ears, perform standard hearing tests, test hearing in background noise, collect clinical and demographic information, and ask participants to complete questionnaires about hearing, quality of life and mood.

If the assessment confirms that a participant is eligible, they will be randomly allocated by chance to one of two groups:

Device group: participants will receive the Phonak Roger system and will be shown how to use it in everyday situations where hearing speech in noise is difficult.

Control group: participants will not receive the device and will receive standard care, consisting of advice about managing speech perception-in-noise difficulty.

Participants cannot choose which group they are allocated to.

The main follow-up visit will take place after 3 months and will include repeat hearing tests and questionnaires. Further follow-up will take place at 6, 12 and 18 months. These later follow-ups will usually be completed remotely, for example online, by telephone or by post.

Participants allocated to the device group may be offered the option to keep the device after the trial has finished but will be responsible for device maintenance.

What are the possible benefits and risks of participating?

Participants may or may not benefit directly. Those allocated to the device group may find that the device helps them hear speech more clearly in noisy situations, but this is not guaranteed. The study may also help improve care for people with hearing difficulties after subarachnoid haemorrhage in the future.

The study is considered low risk. The hearing tests and questionnaires are non-invasive and are commonly used in research and clinical practice. The device is commercially available and is considered low risk.

Taking part may involve some inconvenience. The face-to-face visits may take up to 1–2 hours and may be tiring. Some questionnaire questions ask about hearing, mood, anxiety, depression, cognition and day-to-day functioning, which some people may find mildly upsetting. Participants can take breaks, stop an assessment, or choose not to answer any question they do not wish to answer.

Participants allocated to the device group may find the device unfamiliar or mildly uncomfortable, or may need time to get used to using it in daily life. Support will be available from the research team, and participants can stop using the device at any time.

Reasonable travel expenses for study visits may be reimbursed up to a maximum of £40 per visit, with receipts.

Where is the study run from?

The study is sponsored and run from by the University of Southampton. Face-to-face visits will take place at the University of Southampton. The University Hospital Southampton will be a patient identification centre.

When is the study starting and how long is it expected to run for?

July 2026 to January 2030. The study is expected to run for 3.5 years. Each participant will be followed up for 18 months after joining the trial.

Who is funding the study?

The study is funded by Sonova. Sonova is also providing the Phonak Roger devices used in the study.

Who is the main contact?

i-hear@soton.ac.uk

Contact information

Type(s)

Scientific

Contact name

Prof Ian Galea

Contact details

Clinical Neurosciences, Clinical & Experimental Sciences
Faculty of Medicine
University of Southampton
Mailpoint 806
Southampton General Hospital
Tremona Road
Southampton
United Kingdom
SO16 6YD
+44 23 8059 8502
i.galea@soton.ac.uk

Type(s)

Public

Contact name

Miss Isabel McGauley

Contact details

University of Southampton Auditory Implant Service (USAIS)
Building 19
Highfield
Southampton
United Kingdom
SO17 1BJ
+44 238059 4530
i-hear@soton.ac.uk

Type(s)

Principal investigator

Contact name

Dr Ben Gaastra

Contact details

Clinical Neurosciences, Clinical & Experimental Sciences
Faculty of Medicine
University of Southampton
Mailpoint 806
Southampton General Hospital
Tremona Road

Southampton
United Kingdom
SO16 6YD
+44 23 8059 8502
b.gaastra@soton.ac.uk

Additional identifiers

Integrated Research Application System (IRAS)
355839

Study information

Scientific Title

Improving hearing and speech perception-in-noise after subarachnoid haemorrhage

Acronym

I-HEAR

Study objectives

To evaluate the efficacy of assistive listening technology (Phonak Roger system) in improving speech perception-in-noise (SIN) hearing in the laboratory and real world, and hearing-related quality of life in adults with SIN difficulty after subarachnoid haemorrhage (SAH).

Ethics approval required

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Ethics approval(s)

Approved 07/07/2026, West Midlands - Coventry & Warwickshire Research Ethics Committee (2 Redman Place Stratford, London, E20 1JQ, United Kingdom; +44 02071048211; coventryandwarwick.rec@hra.nhs.uk), ref: 26/WM/0130

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

Speech perception-in-noise hearing difficulty following subarachnoid haemorrhage .

Interventions

Participants are pre-screened using the Hearing Handicap Inventory for Adults (HHIA), Speech, Spatial and Qualities of Hearing Scale-12 (SSQ-12), and the SAH and Hearing Screening Questionnaire. Participants with symptoms consistent with speech perception-in-noise hearing difficulty are invited for a baseline face-to-face hearing laboratory visit, where they undergo consent, demographic and clinical data collection, otoscopy, middle ear testing, pure tone audiometry, questionnaires, and laboratory speech-in-noise hearing tests. Eligible participants are randomly allocated in a 1:1 ratio using simple randomisation through a web-based randomisation system to either the intervention arm or the control arm. Participants in the intervention arm receive the Phonak Roger assistive listening system, consisting of Roger Focus II receivers and a Phonak Roger On 3 remote microphone, fitted by an audiologist with instructions for use. The device is used for 3 months in everyday situations where speech perception-in-noise difficulty arises. Participants in the control arm receive standard care, consisting of advice on how to manage speech perception-in-noise difficulty. Follow-up assessments are performed at 3, 6, 12 and 18 months.

Intervention Type

Device

Phase

Not Applicable

Drug/device/biological/vaccine name(s)

Phonak Roger assistive listening system

Primary outcome(s)

1. Speech-in-noise hearing tests performed in the laboratory environment measured using a Bench (BKB) speech-in-noise test at baseline and 3 months
2. Auditory performance in real-world tasks measured using a Speech, Spatial and Qualities of Hearing Scale (SSQ-12) questionnaire at baseline and 3 months
3. Hearing-related quality of life measured using a Hearing Handicap Inventory for Adults (HHIA) questionnaire at baseline and 3 months

Key secondary outcome(s)

1. Patient-reported measures of speech in noise hearing measured using the University of Cincinnati Auditory Processing Inventory (UCAPI) and Real World Custom questionnaires at baseline and 3 months
2. Quality of life measured using EQ-5D-5L questionnaire at baseline and 3 months
3. Mood measured using Hospital Anxiety and Depression Scale (HADS) at baseline and 3 months
4. Adherence to device usage measured using the Adherence and Acceptance Custom Questionnaire at baseline and 3 months

5. Acceptability of device measured using Adherence and Acceptance Custom Questionnaire at baseline and 3 months

Completion date

19/01/2030

Eligibility

Key inclusion criteria

1. Aneurysmal subarachnoid haemorrhage confirmed by CT or lumbar puncture and angiographic evidence of an aneurysm, three or more months post-ictus
2. Adult (age >18 years)
3. English-speaking
4. Able to provide consent
5. Difficulty with speech perception in noise despite normal peripheral hearing, i.e. a normal audiogram (based on HHIA, SSQ-12 and BKB adaptive SoNo score cut-offs as follows: HHIA: 18+, SSQ-12: ≤ 8.0 , BKB adaptive SoNo: $>-4\text{dB}$)

Healthy volunteers allowed

No

Age group

Mixed

Lower age limit

18 Years

Upper age limit

99 Years

Sex

All

Total final enrolment

0

Key exclusion criteria

1. Any neurological condition affecting the brain other than subarachnoid haemorrhage
2. Any language condition affecting communication and the ability to complete the questionnaires and do the audiological testing
3. Peripheral hearing loss and/or middle ear dysfunction

Date of first enrolment

20/07/2026

Date of final enrolment

19/07/2028

Locations

Countries of recruitment

United Kingdom

England

Study participating centre

University of Southampton

University Road

Southampton

England

SO17 1BJ

Sponsor information

Organisation

University of Southampton

ROR

<https://ror.org/01ryk1543>

Funder(s)

Funder type**Funder Name**

Sonova

Results and Publications

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study will be available upon request from Ian Galea (i.galea@soton.ac.uk).

IPD sharing plan summary

Available on request