NIHR | Nottingham Biomedical Research Centre

COACH

NOTTINGHAM CLINICAL TRIALS UNIT

Help us reach your adult hearing aid patients:
An update on the COACH trial (comparing cochlear implants with hearing aids in adults with severe hearing loss)

Catherine Killan[1], Trish Hepburn[1], Mara Ozolins[1], Caroline Rick[1], Rachel Haines[1], Terry Nunn[2], Tracey Twomey[3], Liz Hartshorne[1], Ellen Temple[1], Garry Meakin[1], Imogen Gould[1], Yuhuang Xi[1], Megan Peacock[1], Alan Montgomery[1], Pádraig Kitterick[1,4], Douglas Hartley[1,3].

[1]University of Nottingham, Nottingham, UK. [2]Guy's and St Thomas' Foundation NHS Trust, London, UK [3]Nottingham University Hospitals NHS Foundation Trust, Nottingham, UK, [4]National Acoustic Laboratories, Sydney, Australia.

NIHR Nottingham Biomedical Research Centre

What is the COACH trial and why is it important?

- Despite revised NICE guidance for cochlear implant (CI) candidacy TA566 (2019), there remains concern that some adults who do not meet NICE guidance struggle to hear well enough with acoustic hearing aids (HAs).
- There is a lack of high-quality evidence to base candidacy guidance on. Gold standard evidence is normally from randomised, controlled, clinical trials (RCTs).
- COACH is an RCT comparing the effectiveness of CI to HAs for adults just outside NICE guidance TA566 (2019).
- The inclusion criteria are based on data collected by the British Cochlear Implant Group working party on candidacy, to target adults where there is acceptable uncertainty as to whether CI or HAs would be best. The study is powered to detect clinically meaningful changes in speech perception.
- COACH was designed and is run jointly by hearing researchers, a clinical trials unit, NHS partners and a patient advisory group.
- We have recruited 35 of our target 130 participants at a rate slower than expected. The faster we recruit, the faster we can inform guidance.

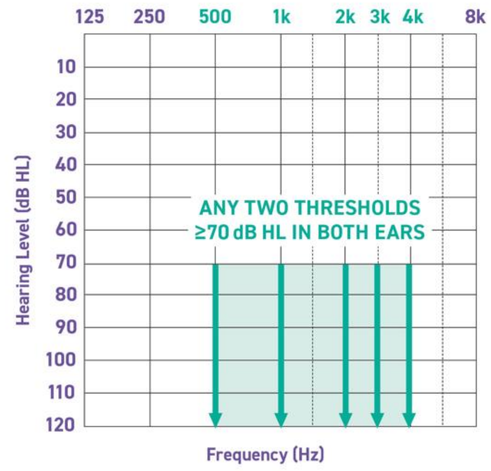
Who are we looking for?

Hearing aid patients who

- Are 18 years or older
- Have post-lingual acquired or progressive bilateral sensorineural hearing loss (symmetric or asymmetric)
- Have one or two well-fitted HAs
- Have good spoken and written English language skills
- Are able to give informed consent

It doesn't matter whether or not they have previously been assessed for CI eligibility

AND have **any two** unaided thresholds including **0.5, 1, 2, 3, or 4 kHz ≥70 dB** HL in both ears



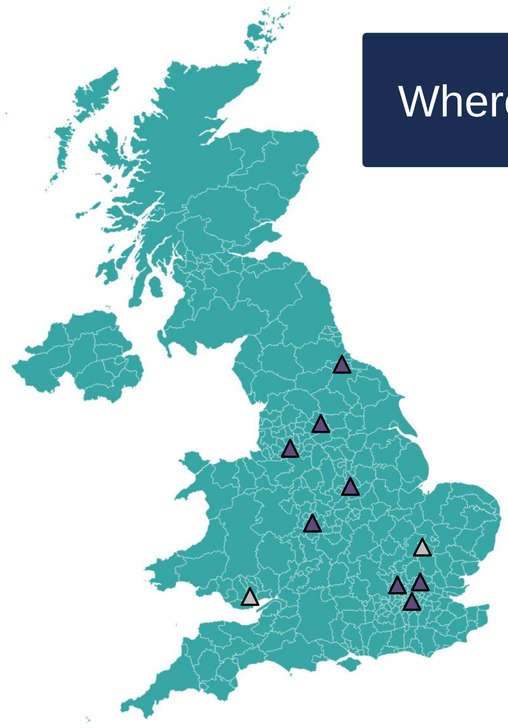
What can you do to help?

- All you need to do is direct patients to our expression of interest form via our website or on paper so they can find out more and identify themselves to us. This does not commit them to take part.
- Everything else on the patient pathway is carried out by our research sites.

We would be very grateful for your support!

Website

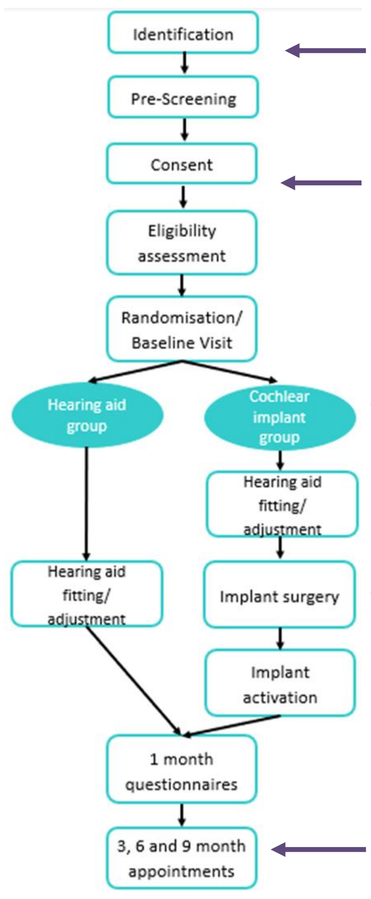
Where are the research sites?



Open and recruiting now:
- South Tees
- Bradford
- Manchester
- Nottingham
- Birmingham
- Guy's and St Thomas' London
- University College London
- St George's London

On hold: Cardiff
In site set-up: Cambridge

COACH participant pathway



Adults are identified when they complete an expression of interest form, online or on paper.

Every adult assessed for eligibility to take part in COACH is also assessed for eligibility for a CI under TA566. Adults within TA566 are offered implantation on the NHS if deemed appropriate by the CI team at the research site.

Eligible participants who consent to take part in the trial are randomised by a computer algorithm 1:1 to the CI or HA arms.

HA arm participants are offered new GN danalogic aids (if wanted). CI arm participants are implanted with a standard length electrode array and fitted with a speech processor and offered a new GN hearing aid for the other ear if appropriate.

The primary outcome measure is the change in word test phoneme perception from baseline to 9 months post-intervention. Tests are videoed and scored by an independent assessor who is blinded to intervention and test interval, to minimise bias.

Ways you can help your patients find out more

- Visit the COACH stand at this conference to pick up resources and say hello!
- Pick up printed shaded audiogram prompts from our stand and put up in your clinics to remind staff
- Inform your ENT colleagues about COACH
- Direct eligible patients to our website to complete an EOI form
- Order a free banner poster and display in your waiting room
- Become a Patient Identification Centre - contact us to find out more
- Add COACH participant identification to your team meeting agendas
- Read the information for professionals on our website: www.coachtrial.ac.uk
- Give out COACH leaflets to patients with severe or profound hearing loss
- Work with your CI Champion to identify potential participants
- Contact us at coach@nottingham.ac.uk
- Invite us to talk to your team! We can present at your department or regional meetings

The COACH team at Nottingham Clinical Trials Unit: COACH@Nottingham.ac.uk. Corresponding author: Catherine.Killan1@Nottingham.ac.uk

This research is funded by Cochlear Corp.
COACH is designed, run, analysed, and disseminated independently of the funder. ISRCTN: 15352106

Cochlear®
Hear now. And always

The NIHR Nottingham Biomedical Research Centre is a partnership between Nottingham University Hospitals NHS Trust and the University of Nottingham, supported by Nottinghamshire Healthcare NHS Foundation Trust and Sherwood Forest Hospitals NHS Foundation Trust. We are hosted by Nottingham University Hospitals.