Re-exploring adult cochlear implant assessment referrals in the United Kingdom (CIRCA-2): study protocol for a national multicentre retrospective observational study

Clinical Audit Department Registration Letter

To Whom it may concern,

We are requesting permission to collect data from this trust for the Cochlear Implant Referral Criteria Re Audit (CIRCA-2): a national multicentre retrospective observational study.

Overview of the Audit

Cochlear implantation (CI) is a highly effective intervention for adults with severe-to-profound hearing loss, yet uptake across the United Kingdom remains low despite clear National Institute for Health and Care Excellence (NICE) guidance and well-established clinical benefits.

The original 2022 Cochlear Implant Referral Criteria Audit (CIRCA) identified significant inequities in access, with lower referral rates among older adults, males, individuals from socioeconomically deprived areas, and those from minority ethnic backgrounds. Since then, national awareness initiatives and the expansion of the existing local “CI champions” scheme have aimed to address these disparities.

CIRCA2 is a national multicentre retrospective observational study to re-evaluate adult CI referral pathways and measure progress since the first audit cycle.

In addition to individuals who meet current NICE criteria, there remains interest in the role of cochlear implantation for those who fall outside current thresholds. The ongoing COmpAring Cochlear implants with Hearing aids in adults (COACH) trial will inform this area, and the present audit will again report the proportion of patients meeting COACH entry criteria. This will provide real-world context on the potential increased demand and capacity implications of potentially lowering the threshold of audiometric criteria for CI candidacy.

The study will identify and extract anonymised demographic, audiometric, and service-level data for adults assessed in secondary-care ENT and Audiology departments between July and December 2025 whose audiometric thresholds meet NICE TA566 criteria and, separately, COACH trial criteria.

Audit Aim & Objectives:

Aim:

To re-assess referral patterns for patients suitable for cochlear implantation in the UK, building on findings from the original CIRCA study.

Objectives:

1. Measure the proportion of adults meeting current NICE TA566 criteria for cochlear implant assessment on audiometric testing who are referred for assessment, and compare these proportions with those from the CIRCA-1 study.
2. Measure the proportion of adults meeting current NICE TA566 criteria for cochlear implant assessment on audiometric testing who are told that they are eligible for assessment, and compare these proportions with those from the CIRCA-1 study.
3. Identify predictors of discussion of implantation and referral for assessment, and assess whether the strength or pattern of these predictors differs from those identified in the CIRCA-1 study.
4. Report adherence to British Cochlear Implant Group (BCIG) and British Association of Audiology (BAA) recommendations that each site should have a CI champion, and evaluate whether uptake has improved compared to the original study.
5. To measure the proportion of adults who meet COACH trial criteria

Study Design

A national, multicentre, retrospective observational audit of practice.

Time period for data required

The study launches on 1st January 2026 to allow the collection of retrospective data for patients tested between 1st July 2025 - 31st December 2025. Final submission of data is anticipated to be 2 months from the launch date, with a provisional deadline of 1st March 2026. There is scope to extend to promote data completeness.

Consent

This audit will report on the outcomes of investigative management that have already taken place. All data will be anonymised, and no patients will be identifiable in any subsequent reports, presentations or publications. As such, consent from individual patients will not be required.

Receiving Organisation

Organisation Name: INTEGRATE

INTEGRATE is a UK Trainee Research Network aiming to support trainee engagement in ENT research and audit through the participation of multicentre collaborative audits.

The group's otology committee has a long history of successfully delivering national audits and studies, including the original CIRCA study (2022), the ACCePT audit (2025), and the ongoing STARFISH RCT.

Data Collection

At each participating unit, the local ENT or audiology leads will run a search in Auditbase/Practice Navigator (delete as appropriate) to identify a list of patients for inclusion into the study. The searches will highlight eligible adults with an audiogram meeting current NICE criteria for cochlear implantation and those within COACH trial criteria.

Anonymised data will be locally entered into pre-defined data extraction forms. Data extracted will include: Outcome of CI discussion (if any), date of audiogram, aided AB phoneme score performed (Yes/No), aided AB word speech testing score range, patient's spoken languages and main language, age, sex, ethnicity, medical co-morbidities, learning disability, cognitive impairment, visual impairment, history of meningitis, physical disability, audiometric data, details of current hearing aids (if any).

Data Anonymisation:

No identifiable patient information will be submitted to the project management team (PMT) at ENT INTEGRATE. Local sites will only be able to access their own data for the purposes of data entry and review, with only members of the PMT having access to the entire data set for the purpose of review and analysis.

NHS numbers will be anonymised before data submission using a provided Excel spreadsheet, used *offline* on a Trust computer. The spreadsheet will: 1) subject the NHS number to an MD5 cryptogenic hash function to generate a unique 32 character hexadecimal code; 2) trim the

resulting code to 20 characters by removing the initial 12 characters. The same NHS number will always produce the same code, allowing tracking of NHS numbers between sites, but without the need to share identifiable data. This is a one-way anonymisation process that will ensure the resulting code is impossible to decrypt, with a negligible chance of duplication (16^20). Local site leads will keep a note of the patients' study identifier as well as their local identifier (NHS number). The local identifier will not be shared with the Project Management Team.

Data Management:

At the end of the archiving period, data will be deleted from shared server space and all backups will be overwritten or destroyed in line with NHS approved information destruction/deletion standards. Files will be securely deleted from computer systems (including any copies held on backup or archive media).

All members of the PMT are employed by the NHS, and have completed Information Governance training in accordance with their own Trusts requirements. This project has received no funding and the PMT does not receive any financial incentive for running this study.

Members of the PMT are aware of their obligations and legal requirements regarding personal confidential data. It is a condition of employment that all employees abide by their organisation's Data Protection Policy and confidentiality clause within their contract of employment.

Ethical Approval:

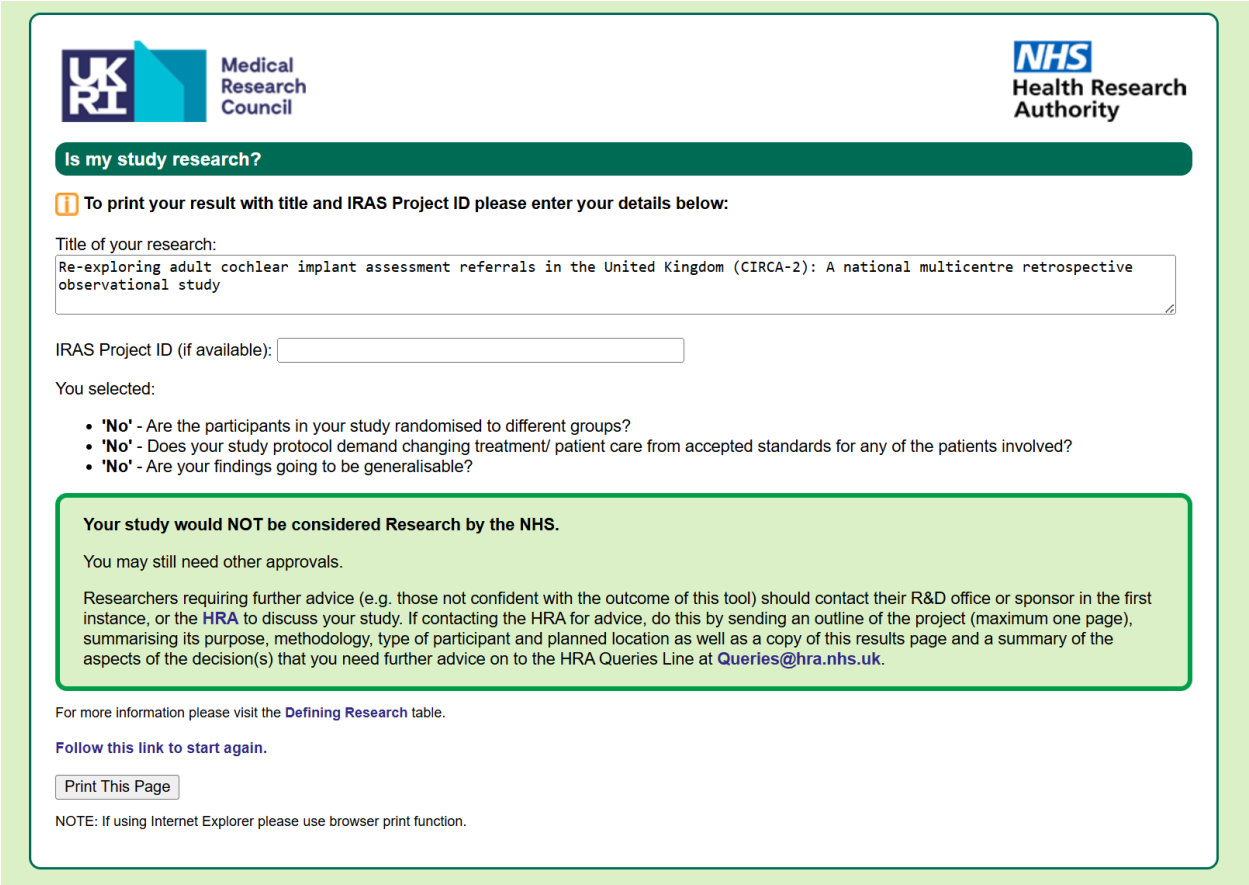
This project has been determined to be an audit using the HRA decision tool available, and therefore does not require further ethical approval (Supplementary Image 1). There will be no impact on the management of patients included in this audit.

You can read more about the CIRCA2 here. If you require any further clarification, please contact the study team at: circa2@entintegrate.co.uk

Yours Sincerely,

ENT INTEGRATE Otology Committee and INDICIA

Supplementary Image 1:



Supplementary Figure 1: Outcome of the Health Research Authority decision tool showing that this study would not qualify as research, therefore not requiring formal ethical approval.