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Addressing clinical equipoise for hearing devices: the qualitative COACH (q-COACH) study protocol for Australian stakeholder involvement in the design of a randomised controlled trial

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ABSTRACT

Introduction Hearing loss is a common chronic problem which can be effectively managed with hearing devices. At present, only a limited number of people with hearing loss use hearing aids (HAs) and cochlear implants (CIs) to improve hearing and sound quality and enhance quality of life. Clinical equipoise, by which we mean healthcare professional uncertainty about which treatment options are the most efficacious due to the lack of evidence-based information, can lead to inconsistent and poorly informed referral processes for hearing devices.

A randomised controlled trial (RCT) that offers high-quality, generalisable information is needed to clarify which hearing device (HA or CI) is more suitable for different degrees of hearing loss and for which kinds of patients. Qualitative research can improve this RCT, by gathering the information on patient and provider perspectives, attitudes and values, which can inform design, conduct and information dissemination, either during preparatory stages of an intervention, or as a fully integrated methodology. The Comparison of Outcomes with hearing Aids and Cochlear implants in adults with moderately severe-to-profound bilateral sensorineural Hearing loss (COACH) study is being planned as an RCT with a qualitative arm (the qualitative COACH study, q-COACH), acting as a pretrial intervention examining views of HAs, CIs, equipoise and the impetus for an RCT of this nature.

Methods and analysis The q-COACH study involves semistructured interviews and a demographic questionnaire which will be collected from four participant cohorts: General Practitioners (GPs) and Ear, Nose and Throat Surgeons (ENTs); audiologists; adult HA users and their support networks. Data will be analysed thematically and through descriptive statistics.

Ethics and dissemination Macquarie University Human Research Ethics Committee, Australia, granted ethical approval (no. 5201833514848). Peer-reviewed journal articles, research conferences and a final report will present study findings.

Strengths and limitations of this study

- This pretrial study with key stakeholders (tThe qualitative COACH Study, q-COACH) will inform the design and conduct of a randomised controlled trial (RCT) (The COACH Study), which aims to address clinical equipoise regarding hearing loss devices.
- This study provides a greater understanding of the views of the key stakeholder groups; this is where qualitative information capturing stakeholder perspectives can inform more appropriate design and conduct of RCTs.
- Pretrial qualitative research is rarely conducted in audiology and is especially useful as the existing outcome measures in audiology do not capture this type of data, making it difficult to determine if the hearing treatment met the driving needs of the patient.
- The small sample size limits the scope of the findings. Even so, the study is designed to generate in-depth, nuanced data about stakeholder views, beliefs and attitudes.
- The data are not statistically generalisable but will adhere to quality measures for qualitative research such as credibility and confirmability.

INTRODUCTION

Background

In 2018, WHO submitted a call for action from the governments and their partners to stem an unprecedented rise in hearing loss after indicating that 466 million people (over 5% of the world's population) have disabling hearing loss (>40 dB for adults).[1] WHO has estimated that by 2050 over 900 million people (1 in 10) will have disabling hearing loss and that urgent action is needed to address this growing healthcare pandemic.[1] The evidence base on hearing loss and its impact on people's lives has identified that for an adult,

significant and untreated hearing loss is linked to social isolation and loneliness,[2 3] depression,[4 5] falls,[6] and cognitive impairment and dementia.[7 8] In order to manage this issue, WHO has stressed the importance of ensuring that people with hearing loss have access to appropriate and affordable assistive technologies.[1] Despite many decades of availability of hearing aids (HAs) and cochlear implants (CIs) as treatments for hearing loss, the uptake of both HAs and CIs remains low.[9 10]

HAs are electronic devices that use the remaining number of healthy hair cells in the cochlea to selectively amplify the acoustic signal. They are commonly recommended for adults with mild to profound hearing loss. When more damaged or non-functional hair cells in the cochlea lead to greater magnitudes of hearing loss, the amplification mechanism in HAs does little to support people's hearing needs.[11] Thus, people identified as having significant sensorineural hearing loss (moderately severe-to-profound) may find CIs beneficial. CIs are surgically implanted hearing devices, which include an electrode that is placed inside the cochlea, to provide electrical stimulation directly to the auditory nerve interface, therefore, bypassing the outer and middle ear passage of acoustic sound. Benefits of HAs and CIs include, but are not limited to: improved hearing ability, improved sound quality and enhanced quality of life.[12–15]

The low uptake of hearing technology for the treatment of hearing impaired individuals applies to both HAs and CIs, with multiple sources reporting that these devices remain underutilised despite their well-documented benefits.[16 17] CI utilisation remains low (10% or less of the people who clinically need them) in adult populations globally,[9] while the reported prevalence of HA use among those with hearing loss ranges from 14.2% to 33.1%.[18–20] One important barrier to uptake is the paucity of high-quality, accessible clinical evidence of their viability or effectiveness compared with other hearing loss treatments. Clinical equipoise is the term used to identify a state of genuine uncertainty with respect to treatment options within the expert medical community.[21] In this case, clinical equipoise describes the lack of certainty among both healthcare professionals (HCPs) and patients about appropriate decision-making processes to reveal relative merits of HAs and CIs. This state of affairs is exacerbated by the lack of systematic comparison of each device. Furthermore, there is a lack of knowledge and awareness of CIs and the benefits for patients with significant hearing loss among HCPs, which continues to affect referrals for implantation and limit informative discussions with patients about assessment and referral.[9 22–24] For instance, Australian general practitioners (GPs) acknowledge that they lack confidence and knowledge about CIs and about CI candidate eligibility criteria to provide adequate counsel and referral. This in turn has led to fewer GP referrals than might be expected with this patient cohort.[25] Moreover, some GPs report that they are unaware that CIs are available for treatment of hearing loss in adults.[25] It is believed that these factors are a direct result of the lack of high-quality, accessible clinical evidence evaluating the outcomes and cost-effectiveness of HAs and CIs.

The variability and/or absence of candidacy guidelines for each device also makes the referral processes for HCPs difficult to recognise. Candidacy guidelines vary between countries, states, insurance providers and clinics.[9 26] For instance, in Australia, there are no standardised national CI candidacy guidelines, making the formalisation of referral processes difficult, and care fragmented and variable. Some Australian audiologists have requested greater access to reliable information sources in order to increase their awareness and knowledge levels of CIs.[27] Unclear and variable guidelines do not provide adequate assistance regarding further clinical management when HAs alone are no longer an effective treatment option. Referral practice-based reliable and consistent information would enable clinicians and patients to make better informed decisions about the suitability of different devices in relation to the needs of each individual patient.

Education programmes for HCPs to inform them on the benefits of HAs and CIs, and to provide information pertaining to candidacy criteria, hold promise to increase referral rates,[28] are yet to be implemented at a national level. HCPs have also suggested that high-quality publications providing a strong level of evidence in peer-reviewed journals would help to increase professional awareness of HAs and CIs, and particularly in terms of GPs, and may lead to more informed practice among professional communities.[25] Though some avenues for knowledge dissemination have been suggested, this line of inquiry requires further exploration if knowledge of both HAs and CIs is to be increased and practice is to improve. Indeed, information regarding the impact of hearing loss and treatment options (ie, HAs and CIs) should ideally be designed in consultation with key stakeholders to ensure its acceptability and suitability[29] and dissemination in a manner preferred by stakeholders.[30]

Ethical referral pathways are difficult for both GPs and patients to navigate when commercial interests supersede independent clinical care in hearing clinics. In 2017, the Australian Competitive and Consumer Commission (ACCC) found that HA sales commissions and targets motivated audiologists to overprescribe HAs to patients, in particular at hearing clinics owned by HA manufacturers.[31] Moreover, these persistent sales techniques are often directed at vulnerable or disadvantaged populations (due to hearing loss, age, other medical conditions, income, etc) and the recommended HAs can be unnecessary or more expensive than a patient needs.[31] Consistent with the ACCC recommendations,[32] we argue that this calls for greater transparency about the qualities of various hearing devices so patients can make an informed, balanced decision about whether to use hearing devices and which hearing device (HAs or CIs) to use.

A randomised controlled trial (RCT) that offers high-quality, generalisable information is needed to clarify which hearing device (HA or CI) is more suitable for

different degrees of hearing loss and for which kinds of patients. Cochlear Ltd are designing an RCT which aims to address the gaps in clinical evidence through a systematic comparison of HAs and CIs randomly assigned to adults with moderately severe-to-profound hearing loss (≥56 dB HL mean pure tone threshold).[33] Evidence generated from the RCT would support the development of evidence-based guidelines for HCPs to facilitate a standard of care for the management of adults with significant hearing loss. This information would increase the awareness of people with a hearing loss of the qualities of different hearing devices. It would also clarify the different routes of care enabling them to make a more informed decision about the use of hearing devices and which device best meets their hearing needs. A rigorous RCT design and appropriate reporting mechanisms are necessary to ensure this outcome.

The present study, the qualitative Comparison of Outcomes with hearing Aids and Cochlear implants in adults with moderately severe to profound bilateral sensorineural Hearing loss study (q-COACH), will inform the design of a planned RCT, and aims to enable greater involvement of patients in the early stage of RCT development. This will ensure that more appropriate RCT questions are embedded in the RCT design and conduct, as well as the best method for information dissemination. The utility of such an approach is recognised through the trials literature,[34] to inform specific stages of a trial and to embed suitable information as input into the trials methodology, to guide data capture and analysis, and support full dataset analyses. This recognition has led to the development of a purpose-designed and tested standard operating procedure for qualitative methods in RCTs.[34]

This will help refine and enhance the RCT's feasibility and effectiveness, generating new ideas for inclusion in the design. For example, the pretrial qualitative study in this case aims to improve recruitment and retention rates, inform consent procedures, ensure that the intervention meets the needs of HCPs and patients. It will help to deliver vital information about the perceived value and benefits of data generated from the RCT and thus routes to intervention implementation.[35] Moreover, if the results of the COACH study are to be effective, it is important that q-COACH informs the RCT's consultation approach with patients and HCPs to ensure it meets with key stakeholders' standards of acceptability and suitability, and that the information produced is disseminated to stakeholder groups in their preferred manner.

METHOD AND ANALYSIS

Study objective

The objective of q-COACH is to gain the perspectives of hearing health professionals and other healthcare patient referring agents (such as GPs, ear, nose and throat (ENT) surgeons and audiologists), and HA users and their support network members (such as family members, friends and acquaintances) on how an RCT should be designed and conducted. The RCT in question aims to examine both viability and suitability of disseminating information about both HAs and CIs, and to ensure wide stakeholder perspectives are represented at the RCT design stage, and that all groups' information needs are met as the RCT design takes shape. Q-COACH will also examine stakeholder buy-in to an RCT of this nature, to consider whether RCT outcomes can be appropriately shared with broader stakeholder groups and where acceptability thresholds lie.

Aims

1. To explore stakeholders' experience of, and insights into, hearing loss and hearing loss devices.
2. To investigate how an RCT comparing hearing loss devices (CIs and HAs) should be designed, conducted and reported and for whose benefit.
3. To clarify how information about HA or CI candidacy and hearing loss devices is best disseminated, with which stakeholder groups, and how outcomes from dissemination might be assessed and sustained.

Study design

This is a qualitative, intramethod study. Individual or paired interviews and the completion of a demographic questionnaire are planned with 32 participants: 8 GPs and ENT surgeons, 8 HA and CI audiologists, 8 HA users and 8 members of HA users' support networks. The study will take place across Australian States, over a 1-year period between 2018 and 2019.

Study context

In Australia, HAs and unilateral CIs are available with public funding through the Australian Government Hearing Services Program, State Government funding and the Department of Veterans' Affairs for people who meet the eligibility criteria. The number of CIs that are publicly funded each year is limited and this often results in extensive waiting lists.[36] Private health insurance can be used to fund both HAs and the implantation of CIs.

Sample and recruitment

The proposed sample size (n=32) will allow for a comprehensive examination and assessment of the wide range of stakeholders' perceptions and experiences of hearing loss, hearing devices and available services, and the proposed COACH study. These data will underpin the rigorous design and conduct of the COACH study and its subsequent report and dissemination methods. Based on previous research,[25 37] it is expected that approximately 30 individual interviews across the four stakeholder groups will be required before data saturation can be achieved. Recruitment will cease when data saturation occurs. It is possible that we may not be able to achieve adequate sample sizes for all four cohorts. If this occurs, the cohort will be excluded from the final study results and this limitation will be acknowledged. It is important to note that the dedicated study researcher has no prior relationship with participants.

Participants will be recruited using time frame sampling.[37 38] During the recruitment period, the first 32 participants who meet the inclusion criteria (see below) will be included into the study in random order. Time frame sampling encourages researchers to outline a predefined recruitment period rather than a purposive or opportunistic cohort, thus ensuring any eligible individuals have an equal opportunity of being involved. Time frame sampling is a useful method for not only removing the possibility of recruitment becoming skewed towards certain groups of participants, it also removes researcher selection bias, while ensuring participants are willing and able to engage, by offering them the opportunity to express their views freely and openly. To ensure cohort numbers are achieved, time frame sampling will be supported by snowball sampling strategies,[39] if numbers are not reached in any given cohorts within the predefined time frame, to ensure targeted participant groups' views are fully expressed. Snowball sampling is a recruitment strategy that relies on enrolled study participants to offer study details to colleagues, peers, friends and other acquaintances. Snowball sampling, like time frame sampling, removes researcher bias and leaves the emphasis for recruitment on the needs and interests of the stakeholder group in question. Snowballing will only be used if the time frame sampling approach has not achieved the required participant numbers during the allotted time period.

Having conducted a previous research study with the same populations,[37] the research team will be able to add to the veracity of the proposed recruitment strategy by drawing on these tried and tested procedures. Promotional flyers will be sent to GP and ENT surgeries and clinics via professional network e-newsletters. Promotional flyers for audiologists will be distributed to audiology clinics, and if numbers are not achieved, promoted through hearing health conferences. Promotional flyers for potential candidates with significant hearing loss and their support networks will be distributed to hearing associations. The experienced study field researcher (EA) will also attend an Australian, University-based speech and hearing clinic where study flyers will be displayed, so that any potential participants (ie, audiologists, HA users and members of their support network) can freely apply for further information. Recruitment will take place Australia-wide.

Participant inclusion criteria

GPs, ENT surgeons and audiologists will be included if they: (1) consult with the target patient population and (2) are willing to take part in an interview and to complete a demographic questionnaire. HA users will be included if they are: (1) 18 years of age or older, (2) have moderately severe-to-profound hearing loss and (3) are proficient in English and are cognitively capable of engaging in an interview and completing a written demographic questionnaire. Support network members will be included if they are: (1) 18 years of age or older, (2) family members, acquaintances or friends of a participant with a moderately severe-to-profound hearing loss and (3) are proficient in English and cognitively capable of engaging in an interview and of completing a written demographic questionnaire.

Data collection

Demographic Questionnaires

Prior to the interview, all participants will be asked to complete a demographic questionnaire including both closed and open-ended questions, for data on participant characteristics (eg, age, location, health services attended, gender, etc). The demographic questionnaire will also provide contextual information such as distance needed to travel to meet an HCP, type of hearing loss and professional practice location. Three questionnaires will be produced; one for HCPs, one for adult HA users and one for the members of their support network.

Individual or paired interviews

Thirty-two semistructured interviews will be conducted and recorded in order to generate rich, nuanced datasets, ascertaining: (1) participants' knowledge of, and experiences with, HAs and perceptions of CIs, (2) how information is shared and how decisions are made around HA and CI choices for referral, fitting, testing and management, (3) opinions regarding the design and conduct of the proposed COACH study and (4) (in terms of the HCP cohort) views of different treatment and care options for patient cohorts, including views of patient pathways through hearing healthcare, patient referrals, hearing health management and ongoing healthcare needs. Semistructured interviews allow for the exploration of participant experience, opinion and perception while providing opportunities for participants to elaborate on their answers to questions. Semistructured interviews ensure meanings attributed to experience are participant driven rather than researcher driven.[39] The flexible nature of semistructured interviews may allow unanticipated but important issues to arise from the interview process and will also enable a more in-depth exploration of an idea or response.[39] Individual and paired interviews will be approximately 45 min long.

As q-COACH aims to interview people with hearing loss and their support persons (family members, friends, acquaintances, etc), paired interviews may be necessary—where two people are interviewed at the same time. This will only be recommended if it is the preferred option for both participants. Paired interviews, a technique which is gaining attention,[40–42] can reduce the discomfort felt by some participants in a one-on-one interview situation, providing more opportunity for thinking time while the paired partner is speaking, and thus a more comprehensive set of responses with paired partners augmenting each other's stories.[43] This technique also allows an interviewer to observe interactions between people with a hearing loss and their support person, and consider the dynamics of the pairing. Indeed, paired interviews

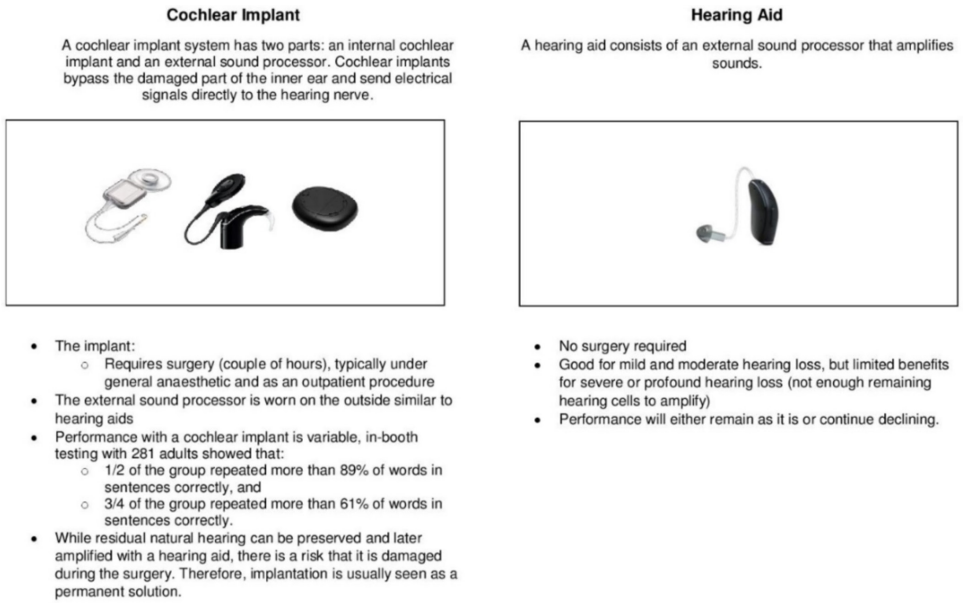

Figure 1 Comparing hearing aids and cochlear implants (authors' own work).

share some of the advantages of focus groups but, as we have found in past studies[25 37] none of the disadvantages of participant opinions being overlooked within the group context. Furthermore, focus groups can lead to communication difficulties in large rooms, particularly for those with hearing difficulties, and further challenges of arranging focus groups with medical professionals who are often time-poor.

In q-COACH, participants with a hearing loss will initially be asked to comment on their own experiences (including notions of quality of life and psychosocial well-being), experiences of associated hearing devices (HAs and CIs), while HCPs will also discuss the management or support needs of patients with a wide range of hearing healthcare problems. Following this, all participants will be shown a chart which compares HAs and CIs (figure 1) and asked to comment on any new or surprising information in the chart. Participants will then be shown a draft of a proposed COACH RCT design (figure 2) in order to facilitate a discussion on RCT design in general and specific to the preliminary proposed RCT design. Input on the proposed RCT's conduct, management and sustainability will also be obtained. Finally, participants will be asked to consider how the findings of such a study might be most usefully and appropriately shared with others, and what they perceive to be others' current and most typical information sources about HAs and CIs.

As q-COACH is a pretrial qualitative study, we will collect responses from various stakeholders in accordance with figures 1 and 2 and based on the data collected in

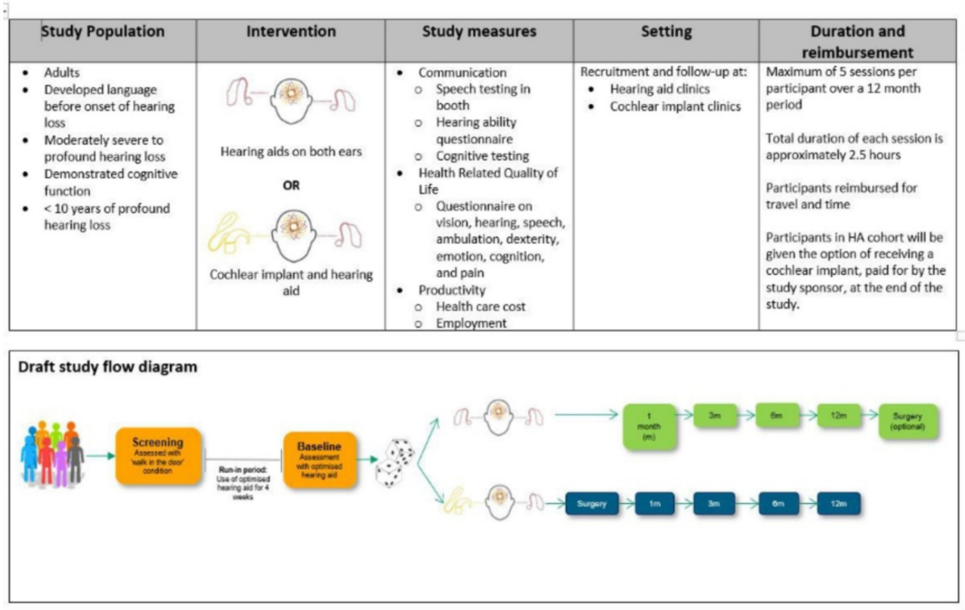

Figure 2 Draft study design and flow diagram: COACH RCT study (authors' own work). RCT, randomised controlled trial.

our study, we will make the appropriate changes to the COACH study design and associated documents. Indeed, one of the purposes of q-COACH is to elicit reactions to COACH in a methodologically robust way.

The study researcher (EA) will make notes about interview participant dynamics (particularly relevant for paired interviews), including body language, communication approaches and gestures. Participants will undertake interviews either face-to-face, via Skype or Skype Messenger, over the telephone or via email correspondence, depending on their preference. Clearly, where interviews are conducted by telephone, internet or email, there will be less opportunity to assess interview dynamics, but other than email interviews, vocal responses will also be noted. The video conferencing option in Skype will enable the study researcher to see interviewees and will support lip reading and speech understanding that is aided by facial gestures. We will encourage participants to undertake face-to-face interviews, however based on our previous qualitative research in audiology,[25] we decided to include multiple modes of interviewing to ensure participants are comfortable with the mode of communication, to allow those who are time-poor to participate (ie, GPs and ENT surgeons) and to allow for interviews to take place with participants who reside outside New South Wales, but within Australia. We acknowledge that email interviews may not generate high-quality data but have allowed for this form of interview because in our previous study[25] we found that some HA users are reluctant or unable to communicate via telephone or in a face-to-face interview.

For the interviews with hearing loss participants, the study researcher will adopt several strategies to ensure that communication is as smooth and as clear as possible. Disruptive background noise might pose an extra challenge for people with hearing loss in interviews, hence rooms will be quiet and devoid of auditory interference. Whenever possible, the study researcher will face the participant to ensure her face is unobstructed and will make certain she articulates questions and responses to answers as clearly as possible, watching for non-verbal signs that the participant has not understood the information. Additionally, a written interview guide will be provided to each participant to support the verbal delivery of questions. In paired interviews, communication support will be available on request in the form of a remote, live, real-time captioned stenographer.[44]

All interviews will be audio-recorded, and transcribed verbatim. Transcripts will be deidentified to maintain participant confidentiality and maintain their anonymity. All participants will be offered a stipend as a gesture of appreciation for any travel involved and for their time during data collection.

Data analysis

Interviews will be analysed using thematic analysis techniques[45] with two experienced qualitative analysts (primary and secondary) (EA and FR) working together to ensure the process is rigorous, and to enable them to discuss the major and minor themes arising and their concomitant categories. Working together of two qualitative analysts is a rigorous data analytical process as it ensures that a consensus agreement can be achieved. Issues of significance will be noted, as will any outlier themes, with recurring categories organised into the most common themes under overarching, thematic headings.[45] The secondary analyst will examine a subset of the complete dataset, to ensure methodological veracity during the analytic process. Demographic questionnaire data will be analysed using descriptive statistical techniques, while open-ended questions will be analysed using content analysis.[46 47] Having contextual data on all participants and recognising their personal characteristics will support the data interpretation and synthesis phases.

Patient and public involvement

Australian patient and public representatives will have a role to play in this study as the views and experiences of HA users, support persons, audiologists and medical professionals are integral to data collection. The results of this study will emphasise the value of patient and public involvement in the proposed COACH study. Study findings will be reported to trialists and others involved in an RCT development, as well as being made available to participants in q-COACH through an executive summary document. This will contain all the relevant information about study processes but formatted for general consumption.

ETHICS AND DISSEMINATION

All participants will provide written, informed consent prior to any data collection taking place. All participants will be assured of anonymity and the confidentiality of data, during all data management, handling and reporting processes. If undue stress occurs as a result of the study, the study researcher will respond in an appropriate manner (eg, stopping an interview if a participant becomes too upset), and all participants will be given the contact details for an HCP or another professional support person should that be necessary, as well as being given information for the study team supervisor should they wish to discuss any aspect of study progress, approach or management.

Data storage and retention

All electronic data will be stored on a password-protected computer belonging to the university and linked to certain members of the study team (core study team members will have access to the data). All hard copy data will be stored in locked cabinets within secure offices. All data will be destroyed 5 years following the completion of the study, in accordance with standard ethical guidelines.

Dissemination

Study findings will be reported widely through a variety of means including international, peer-reviewed journal articles, public and academic presentations, a participant executive summary and an end-of-study research report, which will be provided to the funders to help with the design and conduct of the COACH RCT. Study reports and other outputs may include deidentified verbatim quotations, following participant consent. Study data may also inform teaching and learning events and methodological seminars and workshops.

RESEARCH SIGNIFICANCE AND IMPACT

What is the significance of q-COACH in relation to the planned COACH RCT?

Q-COACH will improve the proposed COACH RCT design, conduct (including recruitment and sampling strategies) and methods of data reporting, management and the sustainability and usefulness of any implementable interventions.[35] For instance, successful recruitment is paramount for a high-quality RCT, and based on key stakeholders' insights, this study will generate a range of strategies to improve recruitment rates. Thus, the study will help to facilitate the feasibility, efficiency and acceptability of the proposed RCT.

What is the significance of q-COACH?

The various key stakeholders may also find the process of self-reflection valuable and will benefit from a clear executive summary for feedback and dissemination purposes, which will include study results and their implications for an RCT. This study will ensure that the results of the planned RCT are appropriately disseminated to HCPs, HA users and members of their support networks, with lessons learnt from the q-COACH dissemination approaches. The COACH RCT findings will thus provide HCPs, HA users and their support networks with mutually beneficial information on hearing loss and hearing devices (ie, HAs and CIs) that is clear, relevant, transparent and applicable. In turn, this may lead to improved clinical practices for HCPs that include assessment, identification and referral guidelines for the management of the hearing impaired adult.

Contributors FR led the overall conceptualisation of the study design and co-led the first and revised drafts of the manuscript. EA contributed to the study design, led the ethics approval procedure and co-led the first draft of the manuscript and revisions of the manuscript. CW contributed to the study design, and to the first and revised drafts of the manuscript. JB critically revised the manuscript for intellectual content. All authors provided final approval of the version submitted and accepted its accuracy and integrity.

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Disclaimer It should be emphasised that Cochlear Ltd did not influence the research agenda in any way, nor will they influence participant reporting during data collection, or analysis and data interpretation stages.

Competing interests CW is an employee of Cochlear Ltd and will, therefore, not be involved in the data collection, data analysis and reporting of the study findings. Would like to assure readers that no bias has taken place within this study and all employees of Cochlear Ltd were excluded from the data collection, analysis or reporting of results. In his capacity as Clinical Studies Research Manager at Cochlear Ltd, CW contributed to the research design to ensure that its general purpose would support the development of the COACH study and that research questions (which were not proposed by Cochlear) were consistent and appropriate for the COACH RCT. Given CW's valuable contributions to this aspect of oversight it would be unethical for the team to exclude CW as an author. As experienced qualitative researchers, FR and EA ensured that the design of this qualitative study was not driven by an industry agenda in any way. For example, both FR and EA drafted the interview questions and ensured that the final interview schedule was not leading or contained assumptions pertaining to industry. Also, during the interviews, EA made it clear to all participants that she was not an employee of Cochlear Ltd and was only concerned with understanding participants' genuine responses to hearing loss, hearing services and the proposed COACH study. Moreover, any attempts to influence participants towards a favourable perspective of Cochlear Implants or the proposed design would be counterproductive to the purpose of the research. That is, we are not seeking complete validation of the proposed COACH study, rather we are interested in the genuine response of a variety of stakeholders to the proposed COACH study in order to determine which aspects of the study are acceptable to stakeholders and why, as well whether the proposed study will need to be altered or improved on.

Patient consent for publication Not required.

Ethics approval Ethical approval for the study has been granted by Macquarie University Human Research Ethics Committee (approval number 5201833514848).

Provenance and peer review Not commissioned; externally peer reviewed.

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