ABSTRACT
Introduction Awareness of the benefits of cochlear implants is low, and barriers such as fear of surgery and ongoing rehabilitation have been noted. Perceived stigma associated with hearing loss also plays a key role, with many adults not wanting to appear old or be identified as a person with a disability. In effect, a cochlear implant makes deafness visible. New technologies have led to a smaller external profile for some types of cochlear implants, but qualitative assessments of benefit have not been explored. This study will examine cochlear implant aesthetics and cosmetics, and its impact on perceived stigma, social interactions, communication and quality of life. A particular focus will be the examination of totally implantable device concepts. A secondary aim is to understand what research techniques are best suited and most appealing for cochlear implant recipients, to assist in future study design and data collection methods.
Methods and analysis This study utilises a mixed-methods design. Three datasets will be collected from each participant with an expected sample size of 10–15 participants to allow for data saturation of themes elicited. Each participant will complete a demographic questionnaire, a quickfire survey (a short concise questionnaire on a topic of research familiarity and preference) and a semi-structured interview. Questionnaire and quickfire survey data will be analysed using descriptive statistics. Interviews will be transcribed and analysed thematically. All participants will be adults with more than 1 year of experience using cochlear implants.
Ethics and dissemination This study has been granted ethical approval from Macquarie University (HREC: 520211056232432) and meets the requirements set out in the National Statement on Ethical Conduct in Human Research. Study findings will be disseminated widely through international peer-reviewed journal articles, public and academic presentations, plain language summaries for participants and an executive summary for the project funder. This work was supported by Cochlear Limited (Cochlear Ltd). The funder will have no role in conducting or reporting on the study.

INTRODUCTION
The prevalence of hearing loss is common and increasing. In 2019, the estimated incidence of some degree of hearing loss was 1.57 billion people worldwide and 3.6 million people in Australia (representing 20% and 14% of their respective population). By 2050, an ageing population will result in large demographic shifts with hearing loss projected to increase to 2.45 billion people worldwide and 8.7 million people in Australia (25% and 22%, respectively). According to the Global Burden of Diseases Study, hearing loss is the third leading cause of years lived with a disability.

The impact of hearing loss for adults is highly variable, significant and associated with a broad range of outcomes. At the individual level, hearing loss is associated with communication challenges, listening effort and fatigue, poorer physical health, social isolation, mental health problems, cognitive decline, dementia and overall diminished quality of life. Communication partners also face significant emotional and social burdens when adapting to a hearing loss in the family. Economically, unaddressed or inadequately addressed hearing loss contributes to additional costs related to healthcare,
education, loss of productivity (unemployment, under-employment and premature retirement) and societal costs attributed to the impact of avoidance and stigma. These economic costs are estimated to be $A980 billion worldwide.

The severity of hearing loss is defined according to a wide spectrum of recently revised categories: mild, moderate, moderately severe, severe, profound and complete, but regardless of the level of hearing loss, outcomes and quality of life can be improved with appropriate rehabilitation. Optimal approaches for effective rehabilitation of adults are person-centred, holistic and sensitive to cultural and contextual settings, but typically include efficient access to clinical and health services, and the use of a range of personalised hearing technologies. While this is the optimal approach, the literature indicates that effective rehabilitation, including access to services and appropriate use of technologies, is the exception rather than the rule.

Cochlear implants (CIs) are one technology that is being provided to support hearing loss across a range of individual needs. CIs are an implantable hearing device that provides the sensation of sound by directly stimulating the auditory nerve with electrical pulses. CIs have been commercially available for almost 40 years and are designed primarily for functional hearing and speech perception. A typical modern CI consists of external and internal components. Externally, the microphone, processor and battery are housed together and sit behind-the-ear (which collect, process and digitise sound signals); and a headpiece is affixed by a magnet above and behind the ear on the skull (which transmits the signals to the internal receiver). Internally, the receiver will then convert the signals into pulses through the electrode array, which are interpreted as sound by the brain. There are newer, commercially available systems that are often marketed as ‘all-in-one’ which have a smaller external profile, incorporating the behind-the-ear and headpiece components together. Totally implantable CIs (TICIs) are another experimental device under development that incorporate all components internally with no external hardware.

While outcomes are variable, CIs typically provide significant benefits for hearing-related outcomes (such as communication) and quality of life, are cost-effective, and are widely acknowledged as the most successful of all neural prosthetic devices available. Although candidacy for implantation is constantly being revised and differs widely across jurisdiction and CI manufacturers, the recent ‘60/60’ guideline is being widely adopted in Australia (where the present study will be situated). This guideline recommends adults be referred for an unaided monosyllabic word test. Despite the noted effectiveness and benefits of CI use, adoption rates remain low and adult utilisation is conservatively estimated at less than 10% globally and 8.5% in Australia (noting this data also includes children). Given both the incidence of hearing loss is increasing and the criteria for CI candidacy has also trended towards expansion over time, we can infer that the utilisation rate is likely to increase. Our understanding of the potential barriers and facilitators that influence CI uptake are limited, but some of the main barriers CI candidates face include fear of surgery, complications and side effects; not being prepared or ready for a CI; and concerns around post-surgical care and ongoing rehabilitation.

Physical and cosmetic characteristics have been flagged as a significant barrier for the uptake of hearing aids (HAs) and other assistive listening devices. Although the literature is limited, perceived stigma and its relation to physical and cosmetic concerns have been investigated in greater detail for HAs than CIs. Given there are overlapping features between HAs and CIs, and as the majority of adult CI recipients are former HA users, there is relevance in examining HA-related stigma. Nonetheless, they should not be considered a homogeneous experience given they address different hearing needs and have distinct healthcare pathways.

While there is no well-defined theoretical framework around stigma and hearing loss; some of the dimensions that have been reported include interrelated concepts such as self-perception (being perceived or labelled as disabled, impaired, incomplete and diminished), ageism (not wanting to appear old and be associated with the elderly) and vanity (not wanting to appear unattractive). Consequently, these concepts tend to manifest themselves as counterproductive strategies and barriers to addressing hearing loss. These can lead to denial and concealment of hearing loss, postponing seeking assistance, and social avoidance and isolation.

A recent cross-cultural study investigating the social representation of HA use in India, the Republic of Korea, UK and USA found that ‘appearance and design’ was the second most reported concern of using a HA. Appearance and design also featured the highest number of negative appraisals (51% in the negative). However, analysis of questionnaire data from the study also indicated that appearance and design was a peripheral concern rather than a centralised one, with users prioritising the importance of benefit, and the impact of cost and time. Generally, CI candidates have indicated that while cosmetic issues are a concern, they are less of a priority in comparison with surgical and rehabilitation considerations and the desire to improve communication. Issues of CI visibility have often been perceived as something CI recipients must accept or use concealment strategies such as hiding external CI components behind hair. Recently developed all-in-one sound processors are worn entirely off the ear. As all the components are integrated into a single unit, there is no coil cable and the form factor can be more easily hidden compared with typical CIs. While they have received positive appraisals for comfort...
and cosmetics from user surveys, the resulting attitudes around stigma, social experiences or quality of life have not been explored.

Alternatively, instead of utilising strategies of discretion, some users modify and customise their HAs and CIs with stickers and jewellery to draw attention. This act of self-expression may counteract perceived stigma by promoting feelings of agency, empowerment, confidence and pride. One noted practical benefit of less discrete devices has been seen to be communication signalling, in which bystanders may more easily identify the user’s status as deaf or hard-of-hearing, potentially improving communication. There are likely significant age and gender effects to these attitudes, as this study had little representation from younger children, older adults and men, with participants aged between 17 and 62 years (M=40, SD=14.8, nine females and one male). Thus, the extent to which this is indicative or can be applied to the broader CI community is relatively unknown.

Research into the aesthetic and cosmetic concerns around CIs and its association with perceived stigma and quality of life is extremely limited. While the exterior design of CIs that sit on the ear and scalp has remained consistent, the industry has moved towards the miniaturisation of components. All-in-one sound processors and TICIs are tangible and conceptual examples, respectively. Given the widespread underutilisation of CIs, an exploration of the relative importance of cosmetic concerns with respect to these new technologies is warranted. As social interactions have been identified as significant facilitators for CI uptake, and the International Classification of Functioning, Disability, and Health (ICF) has identified activities and participation as significant facilitators for CI uptake, the present study will also focus on social dimensions and dynamics.

### Study objectives

To examine the importance of cosmetic and physical characteristics of CIs, and how this may impact CI recipients’ quality of life and attitudes towards CIs. A particular topic of focus is around the conceptualisation of TICIs. A secondary objective is to examine participant preferences for research participation, to guide future study designs and to improve participant recruitment and retention.

### Aims

1. To establish the importance of CI aesthetics and its relationship with communication, social experiences, psychosocial well-being and quality of life.
2. To explore the impact that CI aesthetics may have as a barrier or facilitator to CI uptake and use.
3. To understand what research techniques are best suited and most appealing for CI recipients.

### METHODS AND ANALYSIS

#### Study design

This is a mixed-methods study. Participants will complete (1) a demographic questionnaire, (2) a quickfire survey (ie, a short and concise questionnaire) on research participation preferences and (3) individual semi-structured interviews. This study will take place in Australia over a half-year period between 2021 and 2022.

### Sample and recruitment

Our participant sample size will depend on reaching data saturation, but is estimated to be between 10 and 15 participants. While smaller samples are common in qualitative health services research studies, our choice of sample size was the result of the area of enquiry being entirely new, and our understanding that to incorporate social dimensions of CI use alongside aesthetic considerations was better suited to in-depth data capture from a purposive sample of adults. We are interested in taking a deep dive into understanding and experience. This study will help direct our approach for a larger, longitudinal study with a mixed demographic population. Taking an iterative approach to data capture and knowledge acquisition is common in qualitative health research. While data saturation of concepts tends to occur after the first 10 interviews, the CI population is heterogeneous, and consequently our purposive sampling method has been designed to capture the views of a diverse cohort. We have built in flexibility to recruit additional participants beyond the initial 10 if necessary, through secondary snowball sampling (initial cohort may recommend others to participate), to ensure we can target what we have found through our previous research to be a hard-to-reach community. In addition, this will ensure wide representation across age, gender, people with different healthcare needs (comorbidities) and from different economic and educational backgrounds, etc.

Participants will be recruited Australia-wide through flyers distributed to Cochlear Ltd (a global leader and manufacturer of implantable hearing solutions) and Australian community organisations such as Deafness Forum of Australia (Australia’s peak body representing Australians with deafness, and the peak representative for Australian consumers in the World Hearing Forum), Hear For You (a charity organisation that supports and mentors young deaf and hard-of-hearing adults), Hearing Matters Australia (an advocacy organisation dedicated to helping Australians with hearing loss) and CICADA Australia (a volunteer support group for CI recipients and potential candidates). The flyers will be disseminated via their social media platforms and/or online newsletters.

#### Participant inclusion criteria

Participants will be included if they are: (1) an adult aged 18 years and older, (2) a CI recipient with more than 1 year of experience using their device, (3) proficient in English, with the cognitive capacity to complete a demographic questionnaire and quickfire survey, and engage effectively in a semi-structured interview.
**Box 1 Demographic questionnaire and quickfire survey topic guide**

| Demographic questionnaire topics |
|----------------------------------|
| Age                              |
| Gender                           |
| Socioeconomic status (relationship status, income, education and employment) |
| Language use                     |
| Comorbidities                    |
| Hearing loss characteristics and device use. |

| Quickfire survey topics |
|-------------------------|
| Familiarity and ranked preference of research methodologies: interviews, focus group, visual method, questionnaire, diary or journal, and observation techniques. |
| Ranked preference of research participation mode: face-to-face or online. |
| Ranked preference of research medium: paper, digital (personal computer) or digital (smart device). |
| Familiarity and ranked preference of research scales: numerical rating, visual analogue, verbal rating, Likert, binary choice. |

**Data collection**

Both the demographic questionnaire and the quickfire survey will be completed prior to the semi-structured interview for a number of reasons. The surveys will familiarise participants with the study topic, they will enable the study team to gather data to inform the direction of questioning at interview stage and they will establish understanding to allow for the most effective data to be collected during interviews. The team have extensive experience of staged data collection from previous studies in the health services field.\(^4\) See box 1 for the demographic questionnaire and quickfire survey topic guide.

**Demographic questionnaire**

Participants will complete a demographic questionnaire that consists of closed-ended questions on personal characteristics such as: age, gender, socioeconomic status (relationship status, income, education and employment), language, comorbidities, hearing loss characteristics and device use.

**Quickfire survey**

The quickfire survey is a short and concise questionnaire that will (1) capture participants’ experience and familiarity with research participation and (2) participants’ preferences for how their participation in research studies should be conducted. Participants may reflect on previous studies they have been involved in or perceptions of the most effective, impactful and acceptable approaches to data collection with no prior experience. Plain English descriptions and visual examples will be used to ensure full understanding of research methods and to provide relevant context.

Research familiarity will be recorded using simple yes/no responses. For example, ‘have you been involved in research or clinical studies using: interviews (one-to-one interviews, where a researcher asks you questions?), focus groups (group-based workshops, where a researchers ask questions and facilitates group discussion), or diaries and journals (keeping a regular log of information such as your listening experience)’. Research preferences will be determined by ranked responses. Using the above exemplar, participants would place ‘interviews’, ‘focus groups’ and ‘diaries or journals’ in rank order from most preferred to least preferred. The quickfire survey is available in online supplemental material file 1.

**Semi-structured interview**

One week prior to the interview, participants will receive a Pre-Interview Information Sheet. This one-page document will summarise and clarify key terms such as ‘discretion’ (defined in this study as how unobtrusive or subtle a CI appears), provide close-up photographic examples of an all-in-one sound processor being used by a man and a woman, and a conceptual schematic design of a TICI. This information will provide participants with a frame of reference with respect to discreet CI aesthetics, use and value, prior to the interview.

The semi-structured interviews will be conducted online via the videoconference application Zoom with on-screen captioning enabled by default, or by telephone, depending on the participant’s preference. The interviews will provide rich and detailed information addressing the primary objective of the study—to examine the importance of cosmetic and physical characteristics of CIIs, and how this may impact the quality of life in CI recipients. The interviewer (CYL) is a trained researcher that has qualitative and quantitative experience working within the deaf and hard-of-hearing community but will have no previous relationship with the participants. He will take fieldnotes during the interview noting participant interactions, body language and emotional states. Interviews will be audio recorded, de-identified and transcribed verbatim by an external transcription service. The interviews are expected to take approximately 1 hour to complete, and participants will receive a gift card as a token of appreciation for their time and effort. See box 2 for the semi-structured interview topic guide used in this study.

The flexibility of semi-structured interviews allows opportunities for participants to expand and elaborate on topics of interest and for researchers to add prompts if desired to focus on certain areas of enquiry (eg, researchers may wish to examine social and emotional as well as physical impact of hearing loss and could prompt for responses to this). Many unanticipated responses are welcomed and contribute to the rich dataset, but the research team has carefully considered that some CI recipients may enquire about the availability of TICI devices and/or their suitability as a candidate. At present, these devices are not commercially available, and we present them to participants as conceptual ideas. Prepared responses have also been developed to respond...
and presented as tabulated data and/or graphical figures.

This will be conducted (4) reviewing themes, (5) defining and naming themes generation (6) producing the report.47

Data analysis

Descriptive statistics will be produced from participants’ demographic characteristics, and research familiarity and preferences (from the quickfire survey). This data will be analysed using IBM SPSS Statistics for Windows, V.27.0,46 and presented as tabulated data and/or graphical figures.

Transcripts and fieldnotes from the semi-structured interviews will be analysed using a six-phase approach to thematic analysis: (1) familiarisation with the data, (2) generation of initial codes, (3) searching for themes, (4) reviewing themes, (5) defining and naming themes and (6) producing the report.17 This will be conducted by three qualitative expert analysts (FR, R-CW, CYL) working together. This collaborative approach will ensure the process is robust and rigorous. Coding and analysis of the demographic data, fieldnotes and transcripts will be completed using NVivo (released in March 2020).48

Quantitative and qualitative data will be analysed initially as discrete datasets, but methodological and investigator triangulation approaches will also be used to confirm and enhance our understanding of the findings.49

Patient and public involvement statement

Patients or the public will not be involved in the design, or conduct, or reporting, or dissemination plans of our research.

ETHICS AND DISSEMINATION

Ethics statement

This study has been granted ethical approval from the Macquarie University Human Research Ethics Committee, Humanities and Social Sciences Committee, reference number: 520211056232432 and meets the requirements set out in the National Statement on Ethical Conduct in Human Research.50

Participant comfort and well-being is paramount. While it is not envisaged that participants will experience distress, if any aspects of the interview, demographic survey or quickfire questionnaire cause concern or distress, data collection will be paused immediately, and the necessary support provided. Participants will be reminded that their participation is completely voluntary and that they have the right to withdraw from the study at any time, without giving a reason for doing so.

Data storage and retention

All data will be stored on an encrypted disk on a password-protected computer belonging to Macquarie University for the purposes of data retention and analysis. Only FR, R-CW, CYL and a research assistant (LvB) will have access to this. All data will be retained and archived for a 5-year period, which will be stored on an on-premise bespoke network drive that has been configured for the research team.

The audio recordings from the interviews will be uploaded to an external transcription service. This audio and their subsequent transcription will be permanently deleted from their server after 30 days.

Dissemination

Study findings will be disseminated widely through international peer-reviewed journal articles, public and academic presentations, plain language summaries for participants and an executive summary for the project funder. All quotes attributed to individual participants will be de-identified, and names will be replaced with pseudonyms in any publicly accessible form of presentation.

RESEARCH SIGNIFICANCE AND IMPACT

The underutilisation of CIs is apparent in Australian and global contexts.30 31 Given the incidence of hearing loss is expected to increase with a globally ageing population,1 identifying ways to improve access to services and hearing technologies is imperative. While our understanding of the barriers and facilitators that affect uptake are limited, there is evidence that the physical and cosmetic appearance of hearing solutions and its relationship to perceived stigma is one factor of concern.15 32–34 37

This study will examine the relationship of CI aesthetics with perceived stigma, social interactions, communication and quality of life using qualitative perspectives from adults with CIs. This is significant, as we do not have a comprehensive understanding around the benefits of smaller CI devices or potential developments such as TICIs. Understanding their potential role as facilitators to CI uptake will be significant in the context of individual and global hearing health that may improve uptake, quality of life, and reduce the burden on healthcare and economic systems.

A secondary contribution is the exploration of CI recipients’ familiarity and preferences around research participation. These findings should improve recruitment strategies and improve engagement with research participation. This is particularly relevant for a specialised cohort such as CI recipients.

This study utilises and expands on the research team’s expertise exploring hearing health systems.52 54–59 Our findings will support a future clinical trial by providing a framework of themes and topics of interest and inform
the feasibility of collecting data on a larger, longitudinal study across a broad demographic population.

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Contributors FR and R-CW led the overall conceptualisation and design of the study and provided feedback on the manuscript drafts. CYL contributed to the design of the study and led the first manuscript draft. BE and CW contributed to conceptualisation of the study and provided feedback on the manuscript drafts. All authors provided final approval of the version submitted and accepted its accuracy and integrity.

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Competing interests BE and CW are employees of Cochlear Ltd and were not involved in data collection, analysis and reporting of the study findings. CYL has provided consulting expertise for Cochlear Ltd on unrelated projects in the past. As experienced qualitative researchers, FR and R-CW ensured that the design of this qualitative study was not driven by an industry agenda in any way. For example, the drafting of the interview questions, demographic questionnaire and quickfire survey was completed by FR, R-CW and CYL to ensure they were not leading or contained assumptions specific to Cochlear Ltd or the broader CI industry. Also, during the interviews, CYL will ensure all participants are aware he is not an employee of Cochlear Ltd and is only concerned with understanding participants’ honest responses. This study aims to learn from participants’ lived experience with hearing loss, hearing services and their thoughts and attitudes towards discreet CI concepts. This is also reflected in the Information and Consent Form. Any attempts to influence participants towards a favourable perspective towards Cochlear Ltd or CIs is antithetical to the purpose of this study.

Patient and public involvement Patients and/or the public were not involved in the design, or conduct, or reporting, or dissemination plans of this research.

Patient consent for publication Not applicable.

Provenance and peer review Not commissioned; externally peer reviewed.

Supplemental material This content has been supplied by the author(s). It has not been vetted by BMJ Publishing Group Limited (BMJ) and may not have been applicable. This is also reflected in the Information and Consent Form. Any attempts to influence participants towards a favourable perspective towards Cochlear Ltd or CIs is antithetical to the purpose of this study.

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