

BMJ Open

BMJ Open is committed to open peer review. As part of this commitment we make the peer review history of every article we publish publicly available.

When an article is published we post the peer reviewers' comments and the authors' responses online. We also post the versions of the paper that were used during peer review. These are the versions that the peer review comments apply to.

The versions of the paper that follow are the versions that were submitted during the peer review process. They are not the versions of record or the final published versions. They should not be cited or distributed as the published version of this manuscript.

BMJ Open is an open access journal and the full, final, typeset and author-corrected version of record of the manuscript is available on our site with no access controls, subscription charges or pay-per-view fees (<http://bmjopen.bmj.com>).

If you have any questions on BMJ Open's open peer review process please email info.bmjopen@bmj.com

BMJ Open

Cochlear implant aesthetics and its impact on stigma, social interaction, and quality of life: a mixed methods study protocol

Journal:	<i>BMJ Open</i>
Manuscript ID	bmjopen-2021-058406
Article Type:	Protocol
Date Submitted by the Author:	15-Oct-2021
Complete List of Authors:	Rapport, Frances ; Macquarie University, Australian Institute of Health Innovation Lo, Chi Yhun; Macquarie University, Australian Institute of Health Innovation; Macquarie University, Department of Linguistics Elks, Beth; Cochlear Ltd Warren, Chris ; Cochlear Ltd Clay-Williams, Robyn; Macquarie University, Australian Institute of Health Innovation
Keywords:	Audiology < OTOLARYNGOLOGY, Adult otolaryngology < OTOLARYNGOLOGY, MENTAL HEALTH, Protocols & guidelines < HEALTH SERVICES ADMINISTRATION & MANAGEMENT

SCHOLARONE™
Manuscripts

1
2
3 1 **Cochlear implant aesthetics and its impact on stigma, social interaction, and quality of life: a mixed**
4
5 2 **methods study protocol**
6
7

8 3

10
11 4 Frances Rapport¹

13
14 5 Chi Yhun Lo^{1, 2, *}

16
17 6 Beth Elks³

19
20 7 Chris Warren³

22
23 8 Robyn Clay-Williams¹

25
26 9

28
29 10 ¹Faculty of Medicine, Health and Human Sciences, Australian Institute of Health Innovation,
30
31 Macquarie University, Sydney, Australia

32
33 12 ²Faculty of Medicine, Health and Human Sciences, Department of Linguistics, Macquarie University,
34
35 Sydney, Australia

36
37 13
38
39 14 ³Cochlear Limited, Macquarie University, Sydney, Australia

40
41 15

42
43
44
45 16 *Correspondence to Dr Chi Yhun Lo, chi.lo@mq.edu.au

46
47 17

48
49
50 18 **KEYWORDS:** cochlear implants, aesthetics, cosmetics, stigma, social interaction, quality of life

51
52
53 19 **WORD COUNT:** 3501/4000

54
55
56 20

1
2
3 21 **Abstract**
4
5

6 22 Introduction
7
8

9 23 Awareness of the benefits of cochlear implants is low, and barriers such as fear of surgery and ongoing
10
11 24 rehabilitation have been noted. Perceived stigma associated with hearing loss also plays a key role,
12
13 25 with many adults not wanting to appear old or be identified as a person with a disability. In effect, a
14
15 26 cochlear implant makes deafness visible. New technologies have led to a smaller external profile for
16
17 27 some types of cochlear implants, but qualitative assessments of benefit have not been explored. This
18
19 28 study will examine cochlear implant aesthetics and cosmetics, and its impact on perceived stigma,
20
21 29 social interactions, communication, and quality of life. A particular focus will be the examination of
22
23 30 totally implantable device concepts. A secondary aim is to understand what research techniques are
24
25 31 best suited and most appealing for cochlear implant recipients, to assist in future study design and
26
27 32 data collection methods.
28
29
30
31
32
33

34 34 Methods and analysis
35
36
37

38 35 This study utilises a mixed methods design. Three datasets will be collected from each participant with
39
40 36 an expected sample size of ten to 15 participants to allow for data saturation of themes elicited. Each
41
42 37 participant will complete a demographic questionnaire, a quickfire survey (a short concise
43
44 38 questionnaire on a topic of research familiarity and preference), and a semi-structured interview.
45
46 39 Questionnaire and quickfire survey data will be analysed using descriptive statistics. Interviews will be
47
48 40 transcribed and analysed thematically. All participants will be adults with more than one-year of
49
50 41 experience using cochlear implants.
51
52
53
54
55
56
57
58
59
60

1
2
3 44 Ethics and dissemination
4
5

6 45 This study has been granted ethical approval from Macquarie University (HREC: 520211056232432)
7
8 46 and meets the requirements set out in the National Statement on Ethical Conduct in Human Research.
9
10 47 Study findings will be disseminated widely through international peer-reviewed journal articles, public
11
12 48 and academic presentations, plain language summaries for participants, and an executive summary
13
14 49 for the project funder.
15
16
17
18
19

20
21 51 **Article Summary**
22
23

24 52 Strengths and Limitations of this study
25

- 26
27 53 • First study examining attitudes towards cochlear implant aesthetics including totally
28
29 54 implantable cochlear implants, and its impact on broad quality of life outcomes such as social
30
31 55 interactions and communication.
32
33 56 • This study provides a greater understanding of the role of cochlear implant aesthetics and
34
35 57 social impact, particularly in the context of barriers and facilitators, and motivation or
36
37 58 demotivation to device uptake.
38
39 59 • The exploration of familiarity and preferences around research participation should improve
40
41 60 recruitment strategies and improve engagement for future studies.
42
43 61 • The qualitative approach will provide rich, nuanced datasets in an area that has received
44
45 62 limited attention.
46
47 63 • The nature of a qualitative sample may limit generalisability of findings.
48
49
50
51
52
53
54
55
56
57
58
59
60

64 INTRODUCTION

65 The prevalence of hearing loss is common and increasing. In 2019, the incidence of some degree of
66 hearing loss was estimated at 1.57 billion people worldwide [1] and 3.6 million people in Australia
67 (representing 20% and 14% of their respective population) [2]. By 2050, an ageing population will
68 result in large demographic shifts with hearing loss projected to increase to 2.45 billion people
69 worldwide [1] and 8.7 million people in Australia (25% and 22% respectively) [2]. According to the
70 Global Burden of Diseases Study, hearing loss is the third leading cause of years lived with a disability
71 [1].

72 The impact of hearing loss for adults is highly variable, significant, and associated with a broad
73 range of outcomes. At the individual level, hearing loss is associated with communication challenges,
74 listening effort and fatigue, poorer physical health, social isolation, mental health problems, cognitive
75 decline, dementia, and overall diminished quality of life [3–6]. Communication partners also face
76 significant emotional and social burdens when adapting to a hearing loss in the family [7].
77 Economically, unaddressed or inadequately addressed hearing loss contributes to additional costs
78 related to healthcare, education, loss of productivity (unemployment, underemployment, and
79 premature retirement), and societal costs attributed to the impact of avoidance and stigma [8]. These
80 economic costs are estimated to be \$980 billion worldwide [8].

81 The severity of hearing loss is defined according to a wide spectrum of recently-revised
82 categories: mild, moderate, moderately-severe, severe, profound, and complete [8,9]; but regardless
83 of the *level* of hearing loss, outcomes and quality of life can be improved with appropriate
84 rehabilitation [10]. Optimal approaches for effective rehabilitation of adults are person-centred,
85 holistic, and sensitive to cultural and contextual settings, but typically include efficient access to
86 clinical and health services, and the use of a range of personalised hearing technologies [10–12]. While
87 this is the optimal approach, the literature indicates that effective rehabilitation, including access to
88 services and appropriate use of technologies is the exception rather than the rule [10,13–15].

1
2
3 89 Cochlear implants (CIs) are one technology that is being provided to support hearing loss
4
5 90 across a range of individual needs. CIs are an implantable hearing device that provides the sensation
6
7 91 of sound by directly stimulating the auditory nerve with electrical pulses [16]. CIs have been
8
9
10 92 commercially available for almost 40 years and are designed primarily for functional hearing and
11
12 93 speech perception [16,17]. A typical modern CI consists of external and internal components.
13
14 94 Externally, the microphone, processor and battery are housed together and sit behind-the-ear (which
15
16 95 collect, process, and digitise sound signals); and a headpiece is affixed by a magnet above and behind
17
18 96 the ear on the skull (which transmits the signals to the internal receiver). Internally, the receiver will
19
20 97 then convert the signals into pulses through the electrode array, which are interpreted as sound by
21
22 98 the brain [16]. Newer, commercially available systems such as the Nucleus Kanso™ 2 and RONDO™ 3
23
24 99 have a smaller external profile, incorporating the behind-the-ear and headpiece components together
25
26
27
28 100 [18,19]. Totally implantable CIs are another experimental device under development that incorporate
29
30 101 all components internally with no external hardware [20,21].
31
32

33 102 While outcomes are variable, CIs typically provide significant benefits for hearing-related
34
35 103 outcomes (such as communication) and quality of life [22,23], are cost-effective [24,25], and are
36
37 104 widely acknowledged as the most successful of all neural prosthetic devices available [16,26].
38
39 105 Although candidacy for implantation is constantly being revised and differs widely across jurisdiction
40
41 106 and CI manufacturers [27,28], the recent “60/60” guideline is being widely adopted in Australia (where
42
43 107 the present study will be situated). This guideline recommends adults be referred for a CI if they have
44
45 108 a sensorineural hearing loss of more than 60 dB (i.e. moderately-severe or worse under the current
46
47 109 hearing loss categories) and score less than 60% correct for an unaided monosyllabic word test [29].
48
49
50

51 110 Despite the noted effectiveness and benefits of CI use, adoption rates remain low and adult
52
53 111 utilisation is conservatively estimated at less than 10% globally [30], and 8.5% in Australia (noting this
54
55 112 data also includes children) [31]. Given both the incidence of hearing loss is increasing, and the criteria
56
57 113 for CI candidacy has also trended towards expansion over time [28], we can infer that the utilisation
58
59
60

1
2
3 114 rate is likely to increase. Our understanding of the potential barriers and facilitators that influence CI
4
5 115 uptake are limited, but some of the main barriers CI candidates face include fear of surgery,
6
7 116 complications, and side effects; not being prepared or ready for a CI; and concerns around post-
8
9 117 surgical care and ongoing rehabilitation [32].
10
11
12

13 118 Physical and cosmetic characteristics have been flagged as a significant barrier for the uptake
14
15 119 of hearing aids (HAs) and other assistive listening devices [15,33,34]. Although the literature is limited,
16
17 120 perceived stigma and its relation to physical and cosmetic concerns have been investigated in greater
18
19 121 detail for HAs than CIs. Given there are overlapping features between HAs and CIs, and as the majority
20
21 122 of adult CI recipients are former HA users [35], there is relevance in examining HA-related stigma.
22
23 123 Nonetheless, they should not be considered a homogenous experience given they address different
24
25 124 hearing needs and have distinct healthcare pathways.
26
27
28

29 125 While there is no well-defined theoretical framework around stigma and hearing loss; some
30
31 126 of the dimensions that have been reported include interrelated concepts such as self-perception
32
33 127 (being perceived or labelled as disabled, impaired, incomplete, and diminished), ageism (not wanting
34
35 128 to appear old and be associated with the elderly), and vanity (not wanting to appear unattractive)
36
37 129 [33]. Consequently, these concepts tend to manifest themselves as counterproductive strategies and
38
39 130 barriers to addressing hearing loss. These can lead to denial and concealment of hearing loss,
40
41 131 postponing seeking assistance, and social avoidance and isolation [33,34].
42
43
44

45 132 A recent cross-cultural study investigating the social representation of HA use in India, the
46
47 133 Republic of Korea, United Kingdom, and United States of America found that 'appearance and design'
48
49 134 was the second most reported concern of using a HA. Appearance and design also featured the highest
50
51 135 number of negative appraisals (51% in the negative) [36]. However, analysis of questionnaire data
52
53 136 from the study also indicated that appearance and design was a peripheral concern rather than a
54
55 137 centralised one, with users prioritising the importance of benefit, and the impact of cost and time [36].
56
57
58
59
60

1
2
3 138 Generally, CI candidates have indicated that while cosmetic issues are a concern, they are less
4
5 139 of a priority in comparison to surgical and rehabilitation considerations, and the desire to improve
6
7 140 communication [32]. Issues of CI visibility have often been perceived as something CI recipients must
8
9 141 accept, or utilise concealment strategies such as hiding external CI components behind hair [37].
10
11 142 Recently developed CIs such as the Nucleus Kanso™ 2 are worn entirely off the ear. As all the
12
13 143 components are integrated into a single unit, there is no coil cable and the form factor can be more
14
15 144 easily hidden compared to typical CIs. While they have received positive appraisals for comfort and
16
17 145 cosmetics from user surveys [38], the resulting attitudes around stigma, social experiences, or quality
18
19 146 of life have not been explored.

20
21
22
23
24 147 Alternatively, instead of utilising strategies of discretion, some users modify and customise
25
26 148 their HAs and CIs with stickers and jewellery to draw attention. This act of self-expression may
27
28 149 counteract perceived stigma by promoting feelings of agency, empowerment, confidence, and pride
29
30 150 [39]. One noted practical benefit of less discrete devices has been seen to be communication
31
32 151 signalling, in which bystanders may more easily identify the user's status as deaf or hard-of-hearing,
33
34 152 potentially improving communication [39]. There are likely significant age and gender effects to these
35
36 153 attitudes, as this study had little representation from younger children, older adults, and men, with
37
38 154 participants aged between 17 and 62 years ($M = 40$, $SD = 14.8$, 9 females and 1 male). Thus, the extent
39
40 155 to which this is indicative or can be applied to the broader CI community is relatively unknown.

41
42
43
44
45 156 Research into the aesthetic and cosmetic concerns around CIs and its association with
46
47 157 perceived stigma and quality of life is extremely limited. While the exterior design of CIs that sit on
48
49 158 the ear and scalp have remained consistent, the industry has moved toward the miniaturisation of
50
51 159 components. The Nucleus Kanso™ 2 and totally implantable CIs are tangible and conceptual examples,
52
53 160 respectively. Given the widespread underutilisation of CIs [30,31], an exploration of the relative
54
55 161 importance of cosmetic concerns with respect to these new technologies is warranted. As social
56
57 162 interactions have been identified as significant facilitators for CI uptake [32], and the International
58
59
60

1
2
3 163 Classification of Functioning, Disability, and Health (ICF) has identified activities and participation as
4
5 164 issues of concern [40]; the present study will also focus on social dimensions and dynamics.
6
7
8
9

10
11 165

12 166 **Study Objectives**

13
14 167 To examine the importance of cosmetic and physical characteristics of CIs, and how this may impact
15
16 168 CI recipients' quality of life and attitudes towards CIs. A particular topic of focus is around the
17
18 169 conceptualisation of TICIs. A secondary objective is to examine participant preferences for research
19
20 170 participation, to guide future study designs and improve participant recruitment and retention.
21
22
23

24 171

25 172 **Aims**

- 26
27
28
29 173 1. To establish the importance of CI aesthetics and its relationship with communication, social
30
31 174 experiences, psychosocial wellbeing, and quality of life.
32
33 175 2. To explore the impact that CI aesthetics may have as a barrier or facilitator to CI uptake and
34
35 176 use.
36
37 177 3. To understand what research techniques are best suited and most appealing for CI recipients.
38
39
40

41 178

42 179 **METHODS AND ANALYSIS**

43 180 **Study design**

44
45
46
47 181 This is a mixed methods study. Participants will complete (1) a demographic questionnaire, (2) a
48
49 182 quickfire survey (i.e. a short and concise questionnaire) on research participation preferences, and (3)
50
51 183 individual semi-structured interviews. This study will take place in Australia over a half-year period
52
53 184 between 2021 and 2022.
54
55
56
57
58
59
60

185 **Sample and recruitment**

186 Our participant sample size will depend on reaching data saturation, but is estimated to be between
187 10 and 15 participants. While smaller samples are common in qualitative health services research
188 studies [41], our choice of sample size was the result of the area of enquiry being entirely new, and
189 our understanding that to incorporate social dimensions of CI use alongside aesthetic considerations
190 was better suited to in-depth data capture from a purposive sample of adults [42]. We are interested
191 in taking a deep dive into understanding and experience. This study will help direct our approach for
192 a larger, longitudinal study with a mixed-demographic population. Taking an iterative approach to
193 data capture and knowledge-acquisition is common in qualitative health research. While data
194 saturation of concepts tends to occur after the first 10 interviews [41], the CI population is
195 heterogeneous, and consequently our purposive sampling method has been designed to capture the
196 views of a diverse cohort. We have built in flexibility to recruit additional participants beyond the initial
197 10 through secondary snowball sampling (initial cohort may recommend others to participate) to
198 ensure we can target what we have found through our previous research to be a hard to reach
199 community as well as representation across age, gender, people with different healthcare needs
200 (comorbidities), and from different economic and educational backgrounds, etc [32,43].

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

209

1
2
3 210 **Participant inclusion criteria**
4
5

6 211 Participants will be included if they are: (1) an adult aged 18 years and older, (2) a CI recipient with
7
8 212 more than one year of experience using their device, (3) proficient in English, with the cognitive
9
10 213 capacity to complete a demographic questionnaire and quickfire survey, and engage effectively in a
11
12 214 semi-structured interview.
13
14

15
16 215

17
18 216 **Data collection**
19

20
21 217 Both the demographic questionnaire and quickfire survey will be completed prior to the semi-
22
23 218 structured interview for a number of reasons. The surveys will familiarise participants with the study
24
25 219 topic, they will enable the study team to gather data to inform the direction of questioning at
26
27 220 interview stage and they will embellish understanding to allow for the most effective data to be
28
29 221 collected during interviews. The team have extensive experience of staged data collection from
30
31 222 previous studies in the health services field [44,45]. See box 1 for the demographic questionnaire and
32
33 223 quickfire survey topic guide.
34
35
36
37

38 224

39
40 225 **Demographic questionnaire**
41

42
43 226 Participants will complete a demographic questionnaire that consists of closed-ended questions on
44
45 227 personal characteristics such as: age, gender, socioeconomic status (relationship status, income,
46
47 228 education, and employment), language, comorbidities, hearing loss characteristics, and device use.
48
49

50
51 229

52
53
54 230 **Quickfire survey**
55

56
57 231 The quickfire survey is a short and concise questionnaire that will (1) capture participants' experience
58
59 232 and familiarity with research participation and (2) participants' preferences for how their participation
60

1
2
3 233 in research studies should be conducted. Participants may reflect on previous studies they have been
4
5 234 involved in or perceptions of the most effective, impactful and acceptable approaches to data
6
7 235 collection with no prior experience. Plain English descriptions and visual examples will be used to
8
9
10 236 ensure full understanding of research methods and to provide relevant context.

11
12
13 237 Research familiarity will be recorded using simple yes/no responses. For example, “have you
14
15 238 been involved in research or clinical studies using: interviews (one-to-one interviews, where a
16
17 239 researcher asks you questions?), focus groups (group-based workshops, where a researchers ask
18
19 240 questions and facilitates group discussion), or diaries and journals (keeping a regular log of
20
21 241 information such as your listening experience)”, etc.

22
23
24 242 Research preferences will be determined by ranked responses. Using the above exemplar,
25
26 243 participants would place ‘interviews’, ‘focus groups’, and ‘diaries or journals’ in rank order from most
27
28 244 preferred to least preferred. The quickfire survey is available in supplementary materials.

29
30
31
32 245

33
34
35 246 Box 1

36
37
38 247 Demographic questionnaire topics

- 39
40
41 248 • Age
42
43 249 • Gender
44
45 250 • Socioeconomic status (relationship status, income, education, and employment)
46
47 251 • Language use
48
49 252 • Comorbidities
50
51
52 253 • Hearing loss characteristics and device use.
53
54
55
56
57
58
59
60

1
2
3 255 Quickfire survey topics
4
5

- 6 256 • Familiarity and ranked preference of research methodologies: interviews, focus group, visual
7
8 257 method, questionnaire, diary or journal, and observation techniques.
9
10 258 • Ranked preference of research participation mode: face-to-face or online.
11
12
13 259 • Ranked preference of research medium: paper, digital (personal computer), or digital (smart
14
15 260 device).
16
17 261 • Familiarity and ranked preference of research scales: numerical rating, visual analogue, verbal
18
19 262 rating, Likert, binary choice.
20
21

22
23 263

24
25 264 Semi-structured interview
26

27
28 265 One week prior to the interview, participants will receive a Pre-Interview Information Sheet. This one-
29
30 266 page document will summarise and clarify key terms such as ‘discretion’ (defined in this study as how
31
32 267 unobtrusive or subtle a cochlear implant appears), provide close-up photographic examples of a
33
34 268 Nucleus Kanso™ being used by a man and a woman, and a conceptual schematic of a totally
35
36 269 implantable CI. This information will provide participants with a frame of reference in respect to
37
38 270 discreet CI aesthetics, use and value, prior to the interview.
39
40

41
42 271 The semi-structured interviews will be conducted online via the videoconference application
43
44 272 Zoom with on-screen captioning enabled by default, or by telephone, depending on the participant’s
45
46 273 preference. The interviews will provide rich and detailed information addressing the primary objective
47
48 274 of the study—to examine the importance of cosmetic and physical characteristics of CIs, and how this
49
50 275 may impact the quality of life for CI recipients. The interviewer (CYL) is a trained researcher that has
51
52 276 qualitative and quantitative experience working within the deaf and hard-of-hearing community but
53
54 277 will have no previous relationship with the participants. He will take fieldnotes during the interview
55
56 278 noting participant interactions, body language, and emotional states. Interviews will be audio
57
58
59
60

1
2
3 279 recorded, de-identified, and transcribed verbatim by an external transcription service. The interviews
4
5 280 are expected to take approximately one hour to complete, and participants will receive a gift card as
6
7 281 a token of appreciation for their time and effort. See Box 2 for the semi-structure interview topic guide
8
9
10 282 used in this study.
11

12
13 283 The flexibility of semi-structured interviews allows opportunities for participants to expand
14
15 284 and elaborate on topics of interest and for researchers to add prompts if desired to focus on certain
16
17 285 areas of enquiry (for example, researchers may wish to examine social and emotional as well as
18
19 286 physical impact of hearing loss and could prompt for responses to this). Many unanticipated responses
20
21 287 are welcomed and contribute to the rich dataset, but the research team has carefully considered that
22
23 288 some CI recipients may enquire about the availability of TICI devices and/or their suitability as a
24
25 289 candidate. At present, these devices are not commercially available, and we present them to
26
27 290 participants as conceptual ideas. Prepared responses have also been developed to respond to this
28
29 291 potential situation with care and consideration. The semi-structured interview schedule is available in
30
31 292 supplementary materials.
32
33
34
35
36 293
37
38

39 294 Box 2

- 40
41 295
- 42 • Benefits and challenges associated with their current CI use
 - 43 296 • Impact of discreet CI devices on communication, motivation, social interactions, and quality
44 297 of life
 - 45 298 • Hearing healthcare pathways
 - 46 299 • Trust, influence, and relationship with healthcare providers and stakeholders
 - 47 300 • Learning about CIs and information access
- 48
49
50
51
52
53
54
55
56 301
57
58
59 302
60

1
2
3 303 **Data analysis**
4
5

6 304 Descriptive statistics will be produced from participants' demographic characteristics, and research
7
8 305 familiarity and preferences (from the quickfire survey). This data will be analysed using IBM SPSS
9
10 306 Statistics for Windows, Version 27.0 [46], and presented as tabulated data and/or graphical figures.
11
12

13 307 Transcripts and fieldnotes from the semi-structured interviews will be analysed using a six-
14
15 308 phase approach to thematic analysis: (1) familiarisation with the data, (2) generation of initial codes,
16
17 309 (3) searching for themes, (4) reviewing themes, (5) defining and naming themes, and (6) producing
18
19 310 the report [47]. This will be conducted by three qualitative expert analysts (FR, RCW, CYL) working
20
21 311 together. This collaborative approach will ensure the process is robust and rigorous. Coding and
22
23 312 analysis of the demographic data, fieldnotes, and transcripts will be completed using NVivo (released
24
25 313 in March 2020) [48].
26
27
28
29

30 314 Quantitative and qualitative data will be analysed initially as discrete datasets, but
31
32 315 methodological and investigator triangulation approaches will also be utilised to confirm and enhance
33
34 316 our understanding of the findings [49].
35
36

37 317

38
39
40 318 **Patient and Public Involvement Statement**
41

42
43 319 Patients or the public will not be involved in the design, or conduct, or reporting, or dissemination
44
45 320 plans of our research.
46
47
48
49
50
51
52
53
54
55
56
57
58
59
60

321 **ETHICS AND DISSEMINATION**

322 **Ethics statement**

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

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

331

332 **Data storage and retention**

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

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

341

342

1
2
3 343 **Dissemination**
4
5

6 344 Study findings will be disseminated widely through international peer-reviewed journal articles, public
7
8 345 and academic presentations, plain language summaries for participants, and an executive summary
9
10 346 for the project funder. All quotes attributed to individual participants will be de-identified, and names
11
12 347 will be replaced with pseudonyms in any publicly accessible form of presentation.
13
14
15

16 348

17
18 349 **RESEARCH SIGNIFICANCE AND IMPACT**
19

20
21 350 The underutilisation of CIs is apparent in Australian and global contexts [30,31]. Given the incidence
22
23 351 of hearing loss is expected to increase with a globally ageing population [1], identifying ways to
24
25 352 improve access to services and hearing technologies is imperative. While our understanding of the
26
27 353 barriers and facilitators that affect uptake are limited, there is evidence that the physical and cosmetic
28
29 354 appearance of hearing solutions and its relationship to perceived stigma is one factor of concern
30
31 355 [15,32–34,37].
32
33
34

35 356 This study will examine the relationship of CI aesthetics with perceived stigma, social
36
37 357 interactions, communication, and quality of life using qualitative perspectives from adults with CIs.
38
39 358 This is significant, as we do not have a comprehensive understanding around the benefits of smaller
40
41 359 CI devices, or potential developments such as TICIs. Understanding their potential role as facilitators
42
43 360 to CI uptake will be significant in the context of individual and global hearing health that may improve
44
45 361 uptake, quality of life, and reduce the burden on health care and economic systems.
46
47
48

49 362 A secondary contribution is the exploration of CI recipients' familiarity and preferences
50
51 363 around research participation. These findings should improve recruitment strategies and improve
52
53 364 engagement with research participation. This is particularly relevant for a specialised cohort such as
54
55 365 CI recipients.
56
57
58
59
60

1
2
3 366 This study utilises and expands upon the research team's expertise exploring hearing health
4
5 367 systems [42,51–53]. Our findings will support a future clinical trial by providing a framework of themes
6
7 368 and topics of interest, and inform the feasibility of collecting data on a larger, longitudinal study across
8
9 369 a broad demographic population.
10
11
12

13 370

15 371 **AUTHOR CONTRIBUTIONS**

17
18 372 FR and RCW led the overall conceptualisation and design of the study, and provided feedback on the
19
20 373 manuscript drafts. CYL contributed to the design of the study and led the first manuscript draft. BE
21
22 374 and CW contributed to conceptualisation of the study and provided feedback on the manuscript
23
24 375 drafts. All authors provided final approval of the version submitted and accepted its accuracy and
25
26 376 integrity.
27
28
29

30 377

32 378 **DATA AVAILABILITY STATEMENT**

33
34
35
36 379 No data available.
37
38

39 380

41 381 **FUNDING STATEMENT**

42
43
44
45 382 This work was supported by Cochlear Limited (Cochlear Ltd.). The funder will have no role in
46
47 383 conducting or reporting on the study.
48
49

50 384

52 385 **COMPETING INTERESTS STATEMENT**

53
54
55
56 386 BE and CW are employees of Cochlear Ltd. and will not be involved in data collection, analysis and
57
58 387 reporting of the study findings. CYL has provided consulting expertise for Cochlear Ltd. on unrelated
59
60

1
2
3 388 projects in the past. As experienced qualitative researchers, FR and RCW ensured that the design of
4
5 389 this qualitative study was not driven by an industry agenda in any way. For example, the drafting of
6
7 390 the interview questions, demographic questionnaire and quickfire survey was completed by FR, RCW,
8
9 391 and CYL to ensure they were not leading or contained assumptions specific to Cochlear Ltd. or the
10
11 392 broader CI industry. Also, during the interviews, CYL will ensure all participants are aware he is not an
12
13 393 employee of Cochlear Ltd. and is only concerned with understanding participants' honest responses.
14
15 394 This study aims to learn from participants' lived-experience with hearing loss, hearing services, and
16
17 395 their thoughts and attitudes towards discreet CI concepts. This is also reiterated in the Information
18
19 396 and Consent Form. Any attempts to influence participants towards a favourable perspective towards
20
21 397 Cochlear Ltd. or CIs is antithetical to the purpose of this study.
22
23
24
25
26 398

399 REFERENCES

- 30
31
32 400 1 Haile LM, Kamenov K, Briant PS, *et al.* Hearing loss prevalence and years lived with disability,
33
34 401 1990-2019: Findings from the Global Burden of Disease Study 2019. *Lancet* 2021;**397**:996–
35
36 402 1009. doi:10.1016/S0140-6736(21)00516-X
37
38
39 403 2 Hearing Care Industry Association. The Social and Economic Cost of Hearing Loss in Australia.
40
41 404 2017.
42
43
44 405 3 Li-Korotky HS. Age-related hearing loss: Quality of care for quality of life. *Gerontologist*
45
46 406 2012;**52**:265–71. doi:10.1093/geront/gnr159
47
48
49 407 4 Arlinger S. Negative consequences of uncorrected hearing loss—a review. *Int J Audiol*
50
51 408 2003;**42**:17–20. doi:10.3109/14992020309074639
52
53
54 409 5 Dalton DS, Cruickshanks KJ, Klein BEK, *et al.* The Impact of Hearing Loss on Quality of Life in
55
56 410 Older Adults. *The Gerontologist* 2003;**43**:661–8. doi:10.2298/sarh1106286t
57
58
59 411 6 Livingston G, Huntley J, Sommerlad A, *et al.* Dementia prevention, intervention, and care:

- 1
2
3 412 2020 report of the Lancet Commission. *Lancet* 2020;**396**:413–46. doi:10.1016/S0140-
4
5 413 6736(20)30367-6
6
7
8 414 7 Vas V, Akeroyd MA, Hall DA. A Data-Driven Synthesis of Research Evidence for Domains of
9
10 415 Hearing Loss, as Reported by Adults With Hearing Loss and Their Communication Partners.
11
12 416 *Trends Hear* 2017;**21**:1–25. doi:10.1177/2331216517734088
13
14
15 417 8 World Health Organization. World report on hearing. Geneva: 2021.
16
17
18 418 9 Olusanya BO, Davis AC, Hoffman HJ. Hearing loss grades and the international classification of
19
20 419 functioning, disability and health. *Bull World Health Organ* 2019;**97**:725–8.
21
22 420 doi:10.2471/BLT.19.230367
23
24
25 421 10 Nieman CL, Lin FR. Increasing access to hearing rehabilitation for older adults. *Curr Opin*
26
27 422 *Otolaryngol Head Neck Surg* 2017;**25**:342–6. doi:10.1097/MOO.0000000000000386
28
29
30 423 11 Mulrow CD, Aguilar C, Endicott JE, *et al.* Quality-of-life changes and hearing impairment A
31
32 424 Randomized trial Quality-of-life changes and hearing impairment. A randomized trial. *Ann*
33
34 425 *Intern Med* 1990;**113**:188–94. doi:10.7326/0003-4819-113-3-188
35
36
37 426 12 Granberg S, Pronk M, De Swanepoel W, *et al.* The ICF core sets for hearing loss project:
38
39 427 Functioning and disability from the patient perspective. *Int J Audiol* 2014;**53**:777–86.
40
41 428 doi:10.3109/14992027.2014.938370
42
43
44 429 13 Yong M, Willink A, McMahon C, *et al.* Access to adults' hearing aids: Policies and technologies
45
46 430 used in eight countries. *Bull World Health Organ* 2019;**97**:699–710.
47
48 431 doi:10.2471/BLT.18.228676
49
50
51 432 14 Orji A, Kamenov K, Dirac M, *et al.* Global and regional needs, unmet needs and access to
52
53 433 hearing aids. *Int J Audiol* 2020;**59**:166–72. doi:10.1080/14992027.2020.1721577
54
55
56 434 15 Rolfe C, Gardner B. Experiences of hearing loss and views towards interventions to promote
57
58
59
60

- 1
2
3 435 uptake of rehabilitation support among UK adults. *Int J Audiol* 2016;**55**:666–73.
4
5 436 doi:10.1080/14992027.2016.1200146
6
7
8 437 16 Zeng F-G, Rebscher S, Harrison W, *et al*. Cochlear Implants: System Design, Integration, and
9
10 438 Evaluation. *IEEE Rev Biomed Eng* 2008;**1**:115–42. doi:10.1109/RBME.2008.2008250
11
12
13 439 17 Prochazka A, Mushahwar VK, McCreery DB. Neural prostheses. *J Physiol* 2001;**533**:99–109.
14
15 440 doi:10.1111/j.1469-7793.2001.0099b.x
16
17
18 441 18 Philips B, Plasmans A, Ingeborg P. Comfort and Listening Benefits of the Kanso Off-the-Ear
19
20 442 Sound Processor in Children. *Cochlear White Pap* 2016.
21
22
23 443 19 Manufacturers News. *Hear J* 2013;**66**:30. doi:10.1097/01.HJ.0000427119.41055.a4
24
25
26 444 20 Cohen N. The totally implantable cochlear implant. *Ear Hear* 2007;**28**:100–1.
27
28 445 doi:10.1097/AUD.0b013e31803150f4
29
30
31 446 21 Briggs RJS, Eder HC, Seligman PM, *et al*. Initial clinical experience with a totally implantable
32
33 447 cochlear implant research device. *Otol. Neurotol.* 2008;**29**:114–9.
34
35 448 doi:10.1097/MAO.0b013e31814b242f
36
37
38 449 22 Boisvert I, Reis M, Au A, *et al*. Cochlear implantation outcomes in adults: A scoping review.
39
40 450 *PLoS One* 2020;**15**:1–26. doi:10.1371/journal.pone.0232421
41
42
43 451 23 Gaylor JM, Raman G, Chung M, *et al*. Cochlear implantation in adults: A systematic review
44
45 452 and meta-analysis. *JAMA Otolaryngol - Head Neck Surg* 2013;**139**:265–72.
46
47 453 doi:10.1001/jamaoto.2013.1744
48
49
50 454 24 Crowson MG, Semenov YR, Tucci DL, *et al*. Quality of Life and Cost-Effectiveness of Cochlear
51
52 455 Implants: A Narrative Review. *Audiol Neurotol* 2018;**22**:236–58. doi:10.1159/000481767
53
54
55 456 25 Neve OM, Boerman JA, van den Hout WB, *et al*. Cost-benefit Analysis of Cochlear Implants.
56
57 457 *Ear Hear* 2021;**Publish Ah**. doi:10.1097/AUD.0000000000001021
58
59
60

- 1
2
3 458 26 Carlyon RP, Goehring T. Cochlear Implant Research and Development in the Twenty-first
4
5 459 Century: A Critical Update. *J Assoc Res Otolaryngol* Published Online First: 2021.
6
7 460 doi:10.1007/s10162-021-00811-5
8
9
10 461 27 Vickers D, De Raeve L, Graham J. International survey of cochlear implant candidacy. *Cochlear*
11
12 *Implants Int* 2016;**17**:36–41. doi:10.1080/14670100.2016.1155809
13 462
14
15 463 28 Moses LE, Friedmann DR. Cochlear implant indications: a review of third-party payers'
16
17 policies for standard and expanded indications. *Cochlear Implants Int* 2021;**22**:237–44.
18 464
19 doi:10.1080/14670100.2021.1877865
20 465
21
22
23 466 29 Zwolan TA, Schvartz-Leyzac KC, Pleasant T. Development of a 60/60 Guideline for Referring
24
25 467 Adults for a Traditional Cochlear Implant Candidacy Evaluation. *Otol Neurotol* 2020;**41**:895–
26
27 468 900. doi:10.1097/MAO.0000000000002664
28
29
30 469 30 Sorkin DL, Buchman CA. Cochlear implant access in six developed countries. *Otol Neurotol*
31
32 470 2016;**37**:e161–4. doi:10.1097/MAO.0000000000000946
33
34
35 471 31 Looi V, Bluett C, Boisvert I. Referral rates of postlingually deafened adult hearing aid users for
36
37 a cochlear implant candidacy assessment. *Int J Audiol* 2017;**56**:919–25.
38 472
39 doi:10.1080/14992027.2017.1344361
40 473
41
42
43 474 32 Bierbaum M, McMahon CM, Hughes S, *et al*. Barriers and Facilitators to Cochlear Implant
44
45 475 Uptake in Australia and the United Kingdom. *Ear Hear* 2019;**41**:374–85.
46
47 476 doi:10.1097/AUD.0000000000000762
48
49
50 477 33 Wallhagen MI. The stigma of hearing loss. *Gerontologist* 2010;**50**:66–75.
51
52 478 doi:10.1093/geront/gnp107
53
54
55 479 34 David D, Werner P. Stigma regarding hearing loss and hearing aids: A scoping review. *Stigma*
56
57 480 *Heal* 2016;**1**:59–71. doi:10.1037/sah0000022
58
59
60

- 1
2
3 481 35 Tolisano AM, Fang LB, Kutz JW, *et al.* Better defining best-aided condition: The role of hearing
4
5 482 aids on cochlear implantation qualification rates. *Am J Otolaryngol - Head Neck Med Surg*
6
7 483 2020;**41**. doi:10.1016/j.amjoto.2020.102431
8
9
10 484 36 Chundu S, Allen PM, Han W, *et al.* Social representation of hearing aids among people with
11
12 485 hearing loss: an exploratory study. *Int J Audiol* 2021;**0**:1–15.
13
14 486 doi:10.1080/14992027.2021.1886349
15
16
17 487 37 Dillon B, Pryce H. What makes someone choose cochlear implantation? An exploration of
18
19 488 factors that inform patient decision making. *Int J Audiol* 2020;**59**:24–32.
20
21 489 doi:10.1080/14992027.2019.1660917
22
23
24 490 38 Mauger SJ, Jones M, Nel E, *et al.* Clinical outcomes with the Kanso™ off-the-ear cochlear
25
26 491 implant sound processor. *Int J Audiol* 2017;**56**:267–76. doi:10.1080/14992027.2016.1265156
27
28
29 492 39 Profita HP, Stangl A, Matuszewska L, *et al.* ‘wear It Loud’: How and why hearing aid and
30
31 493 cochlear implant users customize their devices. *ACM Trans Access Comput* 2018;**11**.
32
33 494 doi:10.1145/3214382
34
35
36 495 40 World Health Organization. International classification of functioning, disability and health.
37
38 496 2001.
39
40
41 497 41 Malterud K, Siersma VD, Guassora AD. Sample Size in Qualitative Interview Studies: Guided
42
43 498 by Information Power. *Qual Health Res* 2016;**26**:1753–60. doi:10.1177/1049732315617444
44
45
46 499 42 Rapport F, Auton E, Warren C, *et al.* Addressing clinical equipoise for hearing devices: The
47
48 500 qualitative COACH (q-COACH) study protocol for Australian stakeholder involvement in the
49
50 501 design of a randomised controlled trial. *BMJ Open* 2019;**9**:1–8. doi:10.1136/bmjopen-2019-
51
52 502 030100
53
54
55 503 43 Valerio MA, Rodriguez N, Winkler P, *et al.* Comparing two sampling methods to engage hard-
56
57 504 to-reach communities in research priority setting. *BMC Med Res Methodol* 2016;**16**:1–11.
58
59
60

- 1
2
3 505 doi:10.1186/s12874-016-0242-z
4
5
6 506 44 Rapport F, Bierbaum M, McMahon C, *et al.* Qualitative, multimethod study of behavioural
7
8 507 and attitudinal responses to cochlear implantation from the patient and healthcare
9
10 508 professional perspective in Australia and the UK: study protocol. *BMJ Open* 2018;**8**:e019623.
11
12 509 doi:10.1136/bmjopen-2017-019623
13
14
15 510 45 Rapport F, Clement C, Doel MA, *et al.* Qualitative research and its methods in epilepsy:
16
17 511 Contributing to an understanding of patients' lived experiences of the disease. *Epilepsy Behav*
18
19 512 2015;**45**:94–100. doi:10.1016/j.yebeh.2015.01.040
20
21
22
23 513 46 IBM Corp. IBM SPSS Statistics for Windows, Version 27.0. 2020.
24
25
26 514 47 Braun V, Clarke V. Qualitative Research in Psychology Using thematic analysis in psychology
27
28 515 Using thematic analysis in psychology. *Qual Res Psychol* 2006;**3**:77–101.
29
30
31 516 48 QSR International Pty Ltd. NVivo (released in March 2020). 2020.
32
33
34 517 49 Rapport F, Hogden A, Faris M, *et al.* *Qualitative Research in Healthcare Modern Methods,*
35
36 518 *Clear Translation: a White Paper.* 2018.
37
38
39 519 50 National Health and Medical Research Council. *National statement on ethical conduct in*
40
41 520 *human research, 2007 (Updated 2018).* 2018. [https://www.nhmrc.gov.au/about-](https://www.nhmrc.gov.au/about-us/publications/national-statement-ethical-conduct-human-research-2007-updated-2018)
42
43 521 [us/publications/national-statement-ethical-conduct-human-research-2007-updated-2018](https://www.nhmrc.gov.au/about-us/publications/national-statement-ethical-conduct-human-research-2007-updated-2018)
44
45
46 522 51 Hughes SE, Watkins A, Rapport F, *et al.* Rasch Analysis of the Listening Effort Questionnaire—
47
48 523 Cochlear Implant. *Ear Hear* 2021;**Publish Ah**:1–13. doi:10.1097/aud.0000000000001059
49
50
51 524 52 Bierbaum M, Braithwaite J, Arnolda G, *et al.* Clinicians' attitudes to oncology clinical practice
52
53 525 guidelines and the barriers and facilitators to adherence: a mixed methods study protocol.
54
55 526 *BMJ Open* 2020;**10**:e035448. doi:10.1136/bmjopen-2019-035448
56
57
58 527 53 Rapport F, Hughes SE, Boisvert I, *et al.* Adults' cochlear implant journeys through care: A
59
60

1
2
3
4
5
6
7
8
9
10
11
12
13
14
15
16
17
18
19
20
21
22
23
24
25
26
27
28
29
30
31
32
33
34
35
36
37
38
39
40
41
42
43
44
45
46
47
48
49
50
51
52
53
54
55
56
57
58
59
60

528

qualitative study. *BMC Health Serv Res* 2020;**20**:1–9. doi:10.1186/s12913-020-05334-y

529

For peer review only

Quickfire Survey

Have you been involved in research or clinical studies using:	Yes	No
Interviews (one-to-one interviews, where a researcher asks you questions)		
Focus groups (group-based workshops, where a researcher asks questions and facilitates group-discussion)		
Visual methods (the use of visual documents such as drawings, painting, photographs to help express your thoughts and feelings)		
Questionnaires (a document with a series of questions)		
Diaries or journals (regular logging of information such as your listening experience)		
Observations (where a researcher observes your behaviours)		
Please rank these techniques (1=most preferred; 6=least preferred)	Rank (1-6)	
Interviews		
Focus groups		
Visual methods		
Questionnaires		
Diaries or journals		
Observations		
Please rank how you would like interviews, focus groups, and visual methods to be completed (1=most preferred, 2=least preferred)	Rank (1-2)	
Face-to-face, in-person		
Videotelephone (e.g. via Zoom, Skype, or Teams)		
Please rank how you would like questionnaires are completed (1=most preferred, 3=least preferred)	Rank (1-3)	
On paper		
Digitally, on a computer		
Digitally, on a smart phone or tablet		
Would you like the researcher present when you complete a questionnaire?	Yes	No
Please rank how you would like diaries or journals to be completed (1=most preferred, 3=least preferred)	Rank (1-3)	
On paper		
Digitally, on a computer		
Digitally, on a smart phone or tablet		
Have you completed questionnaires that use:	Yes	No
Numerical rating scale		
Visual analogue scale		
Verbal rating scale		
Likert scale		
Choice scale		
Please rank these types of questions (1=most preferred, 5=least preferred)	Rank (1-5)	
Numerical rating		
Visual analogue scale		
Verbal rating scale		
Likert scale		
Choice scale		

Semi-structured Interview Schedule

[Introduction] We are gathering insights from cochlear implants (CI) recipients to explore the impact that having an implant has on their lives. I am a researcher at the Australian Institute of Health Innovation, and welcome your views, feelings, and experiences. We are very interested in your honest opinions, and there are no right or wrong responses. This interview should take around 1-hour but as there are a range of topics that I would like to cover, I may need to move the interview along at different points along the way. Your comfort is of utmost importance. As a reminder, you are free to pause and stop this interview at any time, without consequence. Do you have any questions so far? Can I confirm you have read the Pre-interview Information Sheet? [if not, the interviewer will go through this sheet now].

- 1) How has your CI made a difference to your hearing?
(*PROMPT: Examples, if required. What is the most significant difference?*)
- 2) How does your CI impact your quality of life?
(*PROMPT: How does that compare to your quality of life before the implant?*)
- 3) What do you think are the greatest benefits with your CI?
(*PROMPT: How do these benefits make you feel?*)
- 4) Do you think a more discreet CI, but which works in a similar fashion to a CI, may make any of the benefits you described even more impactful?
(*PROMPT: Why/why not?*)
- 5) What do you think are the greatest challenges or disbenefits of your CI?
(*PROMPT: How do these challenges/disbenefits make you feel? Have you ever felt stigmatised because of your CI?*)
- 6) Do you think a more discreet CI, similar to the CI you currently use, may help overcome any of those challenges?
(*PROMPT: Why/why not?*)
- 7) Could you imagine any downsides to a more discreet device?
(*PROMPT: Why/why not?*)
- 8) How does your CI impact your social life, work life, and relationships?
(*PROMPT: Is the impact particularly noticeable in certain contexts? e.g., with family, friends, acquaintances, work colleagues? In groups or with individuals? In formal or informal settings? In groups or with individuals? In quiet or noisy settings? When you are nearer or further away from people? When you are listening to someone's voice or a broadcast/TV/etc.*)
- 9) Do you think that a discreet CI device would make a difference to your social life, work life, and/or relationships?
(*PROMPT: If so, how? Why do you think that? Under what circumstances might it make the most difference?*)
 - 9a) [If so] Would that influence your decision when choosing such a CI?

- 1
2
3 10) Before you received your CI, how did you learn about CI devices?
4 *(PROMPT: Was it difficult to find that information? The right information? Enough*
5 *information?)*
6
7
8 11) What has your hearing health care pathway been like?
9 *(PROMPT: Quick, fragmented, clear, supportive, shared between healthcare professionals?*
10 *Was information or support provided to other family members?).*
11 *(PROMPT: How were you diagnosed with a deafness, and what was the process of*
12 *implantation?)*
13
14 12) What is your relationship with hearing health professionals and organisations?
15 *(PROMPT: How did they influence you? What helped you the most, e.g., meeting facilitators, or*
16 *reading testimonials of CI recipients, speaking to a supportive healthcare professional,*
17 *speaking to a knowledgeable healthcare professional, being referred to the right person for*
18 *your individual needs?)*
19
20
21 13) How do you normally find or learn about new information regarding cochlear implants, implant
22 developments, or implant updates?
23
24 14) [Wrap-up] Do you have any final thoughts or comments, particularly regarding a discreet CI
25 device?
26
27
28
29
30
31
32
33
34
35
36
37
38
39
40
41
42
43
44
45
46
47
48
49
50
51
52
53
54
55
56
57
58
59
60

COREQ (CONsolidated criteria for REporting Qualitative research) Checklist

A checklist of items that should be included in reports of qualitative research. You must report the page number in your manuscript where you consider each of the items listed in this checklist. If you have not included this information, either revise your manuscript accordingly before submitting or note N/A.

Topic	Item No.	Guide Questions/Description	Reported on Page No.
Domain 1: Research team and reflexivity			
<i>Personal characteristics</i>			
Interviewer/facilitator	1	Which author/s conducted the interview or focus group?	
Credentials	2	What were the researcher's credentials? E.g. PhD, MD	
Occupation	3	What was their occupation at the time of the study?	
Gender	4	Was the researcher male or female?	
Experience and training	5	What experience or training did the researcher have?	
<i>Relationship with participants</i>			
Relationship established	6	Was a relationship established prior to study commencement?	
Participant knowledge of the interviewer	7	What did the participants know about the researcher? e.g. personal goals, reasons for doing the research	
Interviewer characteristics	8	What characteristics were reported about the interviewer/facilitator? e.g. Bias, assumptions, reasons and interests in the research topic	
Domain 2: Study design			
<i>Theoretical framework</i>			
Methodological orientation and Theory	9	What methodological orientation was stated to underpin the study? e.g. grounded theory, discourse analysis, ethnography, phenomenology, content analysis	
<i>Participant selection</i>			
Sampling	10	How were participants selected? e.g. purposive, convenience, consecutive, snowball	
Method of approach	11	How were participants approached? e.g. face-to-face, telephone, mail, email	
Sample size	12	How many participants were in the study?	
Non-participation	13	How many people refused to participate or dropped out? Reasons?	
<i>Setting</i>			
Setting of data collection	14	Where was the data collected? e.g. home, clinic, workplace	
Presence of non-participants	15	Was anyone else present besides the participants and researchers?	
Description of sample	16	What are the important characteristics of the sample? e.g. demographic data, date	
<i>Data collection</i>			
Interview guide	17	Were questions, prompts, guides provided by the authors? Was it pilot tested?	
Repeat interviews	18	Were repeat interviews carried out? If yes, how many?	
Audio/visual recording	19	Did the research use audio or visual recording to collect the data?	
Field notes	20	Were field notes made during and/or after the interview or focus group?	
Duration	21	What was the duration of the interviews or focus group?	
Data saturation	22	Was data saturation discussed?	
Transcripts returned	23	Were transcripts returned to participants for comment and/or	

Topic	Item No.	Guide Questions/Description	Reported on Page No.
		correction?	
Domain 3: analysis and findings			
<i>Data analysis</i>			
Number of data coders	24	How many data coders coded the data?	
Description of the coding tree	25	Did authors provide a description of the coding tree?	
Derivation of themes	26	Were themes identified in advance or derived from the data?	
Software	27	What software, if applicable, was used to manage the data?	
Participant checking	28	Did participants provide feedback on the findings?	
<i>Reporting</i>			
Quotations presented	29	Were participant quotations presented to illustrate the themes/findings? Was each quotation identified? e.g. participant number	
Data and findings consistent	30	Was there consistency between the data presented and the findings?	
Clarity of major themes	31	Were major themes clearly presented in the findings?	
Clarity of minor themes	32	Is there a description of diverse cases or discussion of minor themes?	

Developed from: Tong A, Sainsbury P, Craig J. Consolidated criteria for reporting qualitative research (COREQ): a 32-item checklist for interviews and focus groups. *International Journal for Quality in Health Care*. 2007. Volume 19, Number 6: pp. 349 – 357

Once you have completed this checklist, please save a copy and upload it as part of your submission. DO NOT include this checklist as part of the main manuscript document. It must be uploaded as a separate file.

BMJ Open

Cochlear implant aesthetics and its impact on stigma, social interaction, and quality of life: a mixed methods study protocol

Journal:	<i>BMJ Open</i>
Manuscript ID	bmjopen-2021-058406.R1
Article Type:	Protocol
Date Submitted by the Author:	09-Feb-2022
Complete List of Authors:	Rapport, Frances ; Macquarie University, Australian Institute of Health Innovation Lo, Chi Yhun; Macquarie University, Australian Institute of Health Innovation; Macquarie University, Department of Linguistics Elks, Beth; Cochlear Ltd Warren, Chris ; Cochlear Ltd Clay-Williams, Robyn; Macquarie University, Australian Institute of Health Innovation
Primary Subject Heading:	Ear, nose and throat/otolaryngology
Secondary Subject Heading:	Ear, nose and throat/otolaryngology, Mental health, Qualitative research, Research methods
Keywords:	Audiology < OTOLARYNGOLOGY, Adult otolaryngology < OTOLARYNGOLOGY, MENTAL HEALTH, Protocols & guidelines < HEALTH SERVICES ADMINISTRATION & MANAGEMENT

SCHOLARONE™
Manuscripts

1
2
3 1 **Cochlear implant aesthetics and its impact on stigma, social interaction, and quality of life: a mixed**
4
5 2 **methods study protocol**
6
7

8 3

10
11 4 Frances Rapport¹

13
14 5 Chi Yhun Lo^{1, 2, *}

16
17 6 Beth Elks³

19
20 7 Chris Warren³

22
23 8 Robyn Clay-Williams¹

25
26 9

28
29 10 ¹Faculty of Medicine, Health and Human Sciences, Australian Institute of Health Innovation,
30
31 Macquarie University, Sydney, Australia

32
33 12 ²Faculty of Medicine, Health and Human Sciences, Department of Linguistics, Macquarie University,
34
35 Sydney, Australia

36
37 13
38
39 14 ³Cochlear Limited, Macquarie University, Sydney, Australia

40
41 15

42
43
44
45 16 *Correspondence to Dr Chi Yhun Lo, chi.lo@mq.edu.au

46
47 17

48
49
50 18 **KEYWORDS:** cochlear implants, aesthetics, cosmetics, stigma, social interaction, quality of life

51
52
53 19 **WORD COUNT:** 3501/4000

54
55
56 20

1
2
3 21 **Abstract**
4
5

6 22 Introduction
7
8

9 23 Awareness of the benefits of cochlear implants is low, and barriers such as fear of surgery and ongoing
10
11 24 rehabilitation have been noted. Perceived stigma associated with hearing loss also plays a key role,
12
13 25 with many adults not wanting to appear old or be identified as a person with a disability. In effect, a
14
15 26 cochlear implant makes deafness visible. New technologies have led to a smaller external profile for
16
17 27 some types of cochlear implants, but qualitative assessments of benefit have not been explored. This
18
19 28 study will examine cochlear implant aesthetics and cosmetics, and its impact on perceived stigma,
20
21 29 social interactions, communication, and quality of life. A particular focus will be the examination of
22
23 30 totally implantable device concepts. A secondary aim is to understand what research techniques are
24
25 31 best suited and most appealing for cochlear implant recipients, to assist in future study design and
26
27 32 data collection methods.
28
29
30
31
32
33

34 34 Methods and analysis
35
36
37

38 35 This study utilises a mixed methods design. Three datasets will be collected from each participant with
39
40 36 an expected sample size of ten to 15 participants to allow for data saturation of themes elicited. Each
41
42 37 participant will complete a demographic questionnaire, a quickfire survey (a short concise
43
44 38 questionnaire on a topic of research familiarity and preference), and a semi-structured interview.
45
46 39 Questionnaire and quickfire survey data will be analysed using descriptive statistics. Interviews will be
47
48 40 transcribed and analysed thematically. All participants will be adults with more than one-year of
49
50 41 experience using cochlear implants.
51
52
53
54
55
56
57
58
59
60

1
2
3 44 Ethics and dissemination
4
5

6 45 This study has been granted ethical approval from Macquarie University (HREC: 520211056232432)
7
8 46 and meets the requirements set out in the National Statement on Ethical Conduct in Human Research.
9
10 47 Study findings will be disseminated widely through international peer-reviewed journal articles, public
11
12 48 and academic presentations, plain language summaries for participants, and an executive summary
13
14 49 for the project funder. This work was supported by Cochlear Limited (Cochlear Ltd.). The funder will
15
16 50 have no role in conducting or reporting on the study.
17
18
19
20
21
22

23 52 **Article Summary**
24
25

26 53 Strengths and Limitations of this study
27
28

- 29 54 • Mixed-methods study assessing attitudes towards cochlear implant aesthetics, and its impact
30
31 55 on broad quality of life outcomes.
32
33 56 • Thematic analyses of interview transcripts provides rich, nuanced datasets in an area that has
34
35 57 received limited attention.
36
37 58 • Familiarity, preferences, and motivations for participation examined using a quickfire survey.
38
39 59 • Participant recruitment and sampling designed to capture a broad cross-section of cochlear
40
41 60 implant recipients.
42
43 61 • The nature of a qualitative sample may limit generalisability of findings.
44
45
46
47
48
49

50 63 **INTRODUCTION**
51
52

53 64 The prevalence of hearing loss is common and increasing. In 2019, the incidence of some degree of
54
55 65 hearing loss was estimated at 1.57 billion people worldwide [1] and 3.6 million people in Australia
56
57 66 (representing 20% and 14% of their respective population) [2]. By 2050, an ageing population will
58
59
60

1
2
3 67 result in large demographic shifts with hearing loss projected to increase to 2.45 billion people
4
5 68 worldwide [1] and 8.7 million people in Australia (25% and 22% respectively) [2]. According to the
6
7 69 Global Burden of Diseases Study, hearing loss is the third leading cause of years lived with a disability
8
9
10 70 [1].
11

12
13 71 The impact of hearing loss for adults is highly variable, significant, and associated with a broad
14
15 72 range of outcomes. At the individual level, hearing loss is associated with communication challenges,
16
17 73 listening effort and fatigue, poorer physical health, social isolation, mental health problems, cognitive
18
19 74 decline, dementia, and overall diminished quality of life [3–6]. Communication partners also face
20
21 75 significant emotional and social burdens when adapting to a hearing loss in the family [7].
22
23 76 Economically, unaddressed or inadequately addressed hearing loss contributes to additional costs
24
25 77 related to healthcare, education, loss of productivity (unemployment, underemployment, and
26
27 78 premature retirement), and societal costs attributed to the impact of avoidance and stigma [8]. These
28
29 79 economic costs are estimated to be \$980 billion worldwide [8].
30
31
32

33
34 80 The severity of hearing loss is defined according to a wide spectrum of recently-revised
35
36 81 categories: mild, moderate, moderately-severe, severe, profound, and complete [8,9]; but regardless
37
38 82 of the *level* of hearing loss, outcomes and quality of life can be improved with appropriate
39
40 83 rehabilitation [10]. Optimal approaches for effective rehabilitation of adults are person-centred,
41
42 84 holistic, and sensitive to cultural and contextual settings, but typically include efficient access to
43
44 85 clinical and health services, and the use of a range of personalised hearing technologies [10–12]. While
45
46 86 this is the optimal approach, the literature indicates that effective rehabilitation, including access to
47
48 87 services and appropriate use of technologies is the exception rather than the rule [10,13–15].
49
50
51

52
53 88 Cochlear implants (CIs) are one technology that is being provided to support hearing loss
54
55 89 across a range of individual needs. CIs are an implantable hearing device that provides the sensation
56
57 90 of sound by directly stimulating the auditory nerve with electrical pulses [16]. CIs have been
58
59 91 commercially available for almost 40 years and are designed primarily for functional hearing and
60

1
2
3 92 speech perception [16,17]. A typical modern CI consists of external and internal components.
4
5 93 Externally, the microphone, processor and battery are housed together and sit behind-the-ear (which
6
7 94 collect, process, and digitise sound signals); and a headpiece is affixed by a magnet above and behind
8
9 95 the ear on the skull (which transmits the signals to the internal receiver). Internally, the receiver will
10
11 96 then convert the signals into pulses through the electrode array, which are interpreted as sound by
12
13 97 the brain [16]. There are newer, commercially available systems that are often marketed as “all-in-
14
15 98 one” which have a smaller external profile, incorporating the behind-the-ear and headpiece
16
17 99 components together [18,19]. Totally implantable CIs are another experimental device under
18
19 100 development that incorporate all components internally with no external hardware [20,21].
20
21
22
23

24 101 While outcomes are variable, CIs typically provide significant benefits for hearing-related
25
26 102 outcomes (such as communication) and quality of life [22,23], are cost-effective [24,25], and are
27
28 103 widely acknowledged as the most successful of all neural prosthetic devices available [16,26].
29
30 104 Although candidacy for implantation is constantly being revised and differs widely across jurisdiction
31
32 105 and CI manufacturers [27,28], the recent “60/60” guideline is being widely adopted in Australia (where
33
34 106 the present study will be situated). This guideline recommends adults be referred for a CI if they have
35
36 107 a sensorineural hearing loss of more than 60 dB (i.e. moderately-severe or worse under the current
37
38 108 hearing loss categories) and score less than 60% correct for an unaided monosyllabic word test [29].
39
40
41

42 109 Despite the noted effectiveness and benefits of CI use, adoption rates remain low and adult
43
44 110 utilisation is conservatively estimated at less than 10% globally [30], and 8.5% in Australia (noting this
45
46 111 data also includes children) [31]. Given both the incidence of hearing loss is increasing, and the criteria
47
48 112 for CI candidacy has also trended towards expansion over time [28], we can infer that the utilisation
49
50 113 rate is likely to increase. Our understanding of the potential barriers and facilitators that influence CI
51
52 114 uptake are limited, but some of the main barriers CI candidates face include fear of surgery,
53
54 115 complications, and side effects; not being prepared or ready for a CI; and concerns around post-
55
56 116 surgical care and ongoing rehabilitation [32].
57
58
59
60

1
2
3 117 Physical and cosmetic characteristics have been flagged as a significant barrier for the uptake
4
5 118 of hearing aids (HAs) and other assistive listening devices [15,33,34]. Although the literature is limited,
6
7 119 perceived stigma and its relation to physical and cosmetic concerns have been investigated in greater
8
9 120 detail for HAs than CIs. Given there are overlapping features between HAs and CIs, and as the majority
10
11 121 of adult CI recipients are former HA users [35], there is relevance in examining HA-related stigma.
12
13 122 Nonetheless, they should not be considered a homogenous experience given they address different
14
15 123 hearing needs and have distinct healthcare pathways.
16
17
18

19 124 While there is no well-defined theoretical framework around stigma and hearing loss; some
20
21 125 of the dimensions that have been reported include interrelated concepts such as self-perception
22
23 126 (being perceived or labelled as disabled, impaired, incomplete, and diminished), ageism (not wanting
24
25 127 to appear old and be associated with the elderly), and vanity (not wanting to appear unattractive)
26
27 128 [33]. Consequently, these concepts tend to manifest themselves as counterproductive strategies and
28
29 129 barriers to addressing hearing loss. These can lead to denial and concealment of hearing loss,
30
31 130 postponing seeking assistance, and social avoidance and isolation [33,34].
32
33
34
35

36 131 A recent cross-cultural study investigating the social representation of HA use in India, the
37
38 132 Republic of Korea, United Kingdom, and United States of America found that 'appearance and design'
39
40 133 was the second most reported concern of using a HA. Appearance and design also featured the highest
41
42 134 number of negative appraisals (51% in the negative) [36]. However, analysis of questionnaire data
43
44 135 from the study also indicated that appearance and design was a peripheral concern rather than a
45
46 136 centralised one, with users prioritising the importance of benefit, and the impact of cost and time [36].
47
48
49

50 137 Generally, CI candidates have indicated that while cosmetic issues are a concern, they are less
51
52 138 of a priority in comparison to surgical and rehabilitation considerations, and the desire to improve
53
54 139 communication [32]. Issues of CI visibility have often been perceived as something CI recipients must
55
56 140 accept, or utilise concealment strategies such as hiding external CI components behind hair [37].
57
58 141 Recently developed all-in-one sound processors are worn entirely off the ear. As all the components
59
60

1
2
3 142 are integrated into a single unit, there is no coil cable and the form factor can be more easily hidden
4
5 143 compared to typical CIs. While they have received positive appraisals for comfort and cosmetics from
6
7 144 user surveys [38], the resulting attitudes around stigma, social experiences, or quality of life have not
8
9
10 145 been explored.

11
12
13 146 Alternatively, instead of utilising strategies of discretion, some users modify and customise
14
15 147 their HAs and CIs with stickers and jewellery to draw attention. This act of self-expression may
16
17 148 counteract perceived stigma by promoting feelings of agency, empowerment, confidence, and pride
18
19 149 [39]. One noted practical benefit of less discrete devices has been seen to be communication
20
21 150 signalling, in which bystanders may more easily identify the user's status as deaf or hard-of-hearing,
22
23 151 potentially improving communication [39]. There are likely significant age and gender effects to these
24
25 152 attitudes, as this study had little representation from younger children, older adults, and men, with
26
27 153 participants aged between 17 and 62 years ($M = 40$, $SD = 14.8$, 9 females and 1 male). Thus, the extent
28
29 154 to which this is indicative or can be applied to the broader CI community is relatively unknown.

30
31
32
33 155 Research into the aesthetic and cosmetic concerns around CIs and its association with
34
35 156 perceived stigma and quality of life is extremely limited. While the exterior design of CIs that sit on
36
37 157 the ear and scalp have remained consistent, the industry has moved toward the miniaturisation of
38
39 158 components. All-in-one sound processors and totally implantable CIs are tangible and conceptual
40
41 159 examples, respectively. Given the widespread underutilisation of CIs [30,31], an exploration of the
42
43 160 relative importance of cosmetic concerns with respect to these new technologies is warranted. As
44
45 161 social interactions have been identified as significant facilitators for CI uptake [32], and the
46
47 162 International Classification of Functioning, Disability, and Health (ICF) has identified activities and
48
49 163 participation as issues of concern [40]; the present study will also focus on social dimensions and
50
51 164 dynamics.

52
53
54
55
56
57 165
58
59 166
60

167 **Study Objectives**

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

172

173 **Aims**

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

179

180 **METHODS AND ANALYSIS**

181 **Study design**

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

186

187 **Sample and recruitment**

188 Our participant sample size will depend on reaching data saturation, but is estimated to be between
189 10 and 15 participants. While smaller samples are common in qualitative health services research

1
2
3 190 studies [41], our choice of sample size was the result of the area of enquiry being entirely new, and
4
5 191 our understanding that to incorporate social dimensions of CI use alongside aesthetic considerations
6
7 192 was better suited to in-depth data capture from a purposive sample of adults [42]. We are interested
8
9
10 193 in taking a deep dive into understanding and experience. This study will help direct our approach for
11
12 194 a larger, longitudinal study with a mixed-demographic population. Taking an iterative approach to
13
14 195 data capture and knowledge-acquisition is common in qualitative health research. While data
15
16 196 saturation of concepts tends to occur after the first ten interviews [41], the CI population is
17
18 197 heterogeneous, and consequently our purposive sampling method has been designed to capture the
19
20 198 views of a diverse cohort. We have built in flexibility to recruit additional participants beyond the initial
21
22 199 ten if necessary, through secondary snowball sampling (initial cohort may recommend others to
23
24 200 participate), to ensure we can target what we have found through our previous research to be a hard-
25
26 201 to-reach community. In addition, this will ensure wide representation across age, gender, people with
27
28 202 different healthcare needs (comorbidities), and from different economic and educational
29
30 203 backgrounds, etc [32,43].

31
32
33
34
35 204 Participants will be recruited Australia-wide through flyers distributed to Cochlear Limited (a
36
37 205 global leader and manufacturer of implantable hearing solutions) and Australian community
38
39 206 organisations such as Deafness Forum of Australia (Australia's peak body representing Australians with
40
41 207 deafness, and the peak representative for Australian consumers in the World Hearing Forum), Hear
42
43 208 For You (a charity organisation that supports and mentors young deaf and hard-of-hearing adults),
44
45 209 Hearing Matters Australia (an advocacy organisation dedicated to helping Australians with hearing
46
47 210 loss), and CICADA Australia (a volunteer support group for cochlear implant recipients and potential
48
49 211 candidates). The flyers will be disseminated via their social media platforms and/or online newsletters.
50
51
52
53
54 212
55
56 213
57
58
59
60

1
2
3 214 **Participant inclusion criteria**
4
5

6 215 Participants will be included if they are: (1) an adult aged 18 years and older, (2) a CI recipient with
7
8 216 more than one year of experience using their device, (3) proficient in English, with the cognitive
9
10 217 capacity to complete a demographic questionnaire and quickfire survey, and engage effectively in a
11
12
13 218 semi-structured interview.
14

15
16 219

17
18 220 **Data collection**
19

20
21 221 Both the demographic questionnaire and quickfire survey will be completed prior to the semi-
22
23 222 structured interview for a number of reasons. The surveys will familiarise participants with the study
24
25 223 topic, they will enable the study team to gather data to inform the direction of questioning at
26
27 224 interview stage and they will embellish understanding to allow for the most effective data to be
28
29 225 collected during interviews. The team have extensive experience of staged data collection from
30
31 226 previous studies in the health services field [44,45]. See box 1 for the demographic questionnaire and
32
33 227 quickfire survey topic guide.
34
35
36
37

38 228

39
40
41 229 **Demographic questionnaire**
42

43 230 Participants will complete a demographic questionnaire that consists of closed-ended questions on
44
45 231 personal characteristics such as: age, gender, socioeconomic status (relationship status, income,
46
47 232 education, and employment), language, comorbidities, hearing loss characteristics, and device use.
48
49

50
51 233

52
53
54 234 **Quickfire survey**
55

56
57 235 The quickfire survey is a short and concise questionnaire that will (1) capture participants' experience
58
59 236 and familiarity with research participation and (2) participants' preferences for how their participation
60

237 in research studies should be conducted. Participants may reflect on previous studies they have been
238 involved in or perceptions of the most effective, impactful and acceptable approaches to data
239 collection with no prior experience. Plain English descriptions and visual examples will be used to
240 ensure full understanding of research methods and to provide relevant context.

241 Research familiarity will be recorded using simple yes/no responses. For example, “have you
242 been involved in research or clinical studies using: interviews (one-to-one interviews, where a
243 researcher asks you questions?), focus groups (group-based workshops, where a researchers ask
244 questions and facilitates group discussion), or diaries and journals (keeping a regular log of
245 information such as your listening experience)”, etc.

246 Research preferences will be determined by ranked responses. Using the above exemplar,
247 participants would place ‘interviews’, ‘focus groups’, and ‘diaries or journals’ in rank order from most
248 preferred to least preferred. The quickfire survey is available in supplementary material file 1.

249
250 Box 1

251 Demographic questionnaire topics

- 252 • Age
- 253 • Gender
- 254 • Socioeconomic status (relationship status, income, education, and employment)
- 255 • Language use
- 256 • Comorbidities
- 257 • Hearing loss characteristics and device use.

258

259

1
2
3 260 Quickfire survey topics
4
5

- 6 261 • Familiarity and ranked preference of research methodologies: interviews, focus group, visual
7
8 262 method, questionnaire, diary or journal, and observation techniques.
9
10 263 • Ranked preference of research participation mode: face-to-face or online.
11
12 264 • Ranked preference of research medium: paper, digital (personal computer), or digital (smart
13
14 265 device).
15
16 266 • Familiarity and ranked preference of research scales: numerical rating, visual analogue, verbal
17
18 267 rating, Likert, binary choice.
19
20
21
22
23
24

25 269 Semi-structured interview
26

27
28 270 One week prior to the interview, participants will receive a Pre-Interview Information Sheet. This one-
29
30 271 page document will summarise and clarify key terms such as ‘discretion’ (defined in this study as how
31
32 272 unobtrusive or subtle a cochlear implant appears), provide close-up photographic examples of an all-
33
34 273 in-one sound processor being used by a man and a woman, and a conceptual schematic of a totally
35
36 274 implantable CI. This information will provide participants with a frame of reference in respect to
37
38 275 discreet CI aesthetics, use and value, prior to the interview.
39
40
41

42 276 The semi-structured interviews will be conducted online via the videoconference application
43
44 277 Zoom with on-screen captioning enabled by default, or by telephone, depending on the participant’s
45
46 278 preference. The interviews will provide rich and detailed information addressing the primary objective
47
48 279 of the study—to examine the importance of cosmetic and physical characteristics of CIs, and how this
49
50 280 may impact the quality of life for CI recipients. The interviewer (CYL) is a trained researcher that has
51
52 281 qualitative and quantitative experience working within the deaf and hard-of-hearing community but
53
54 282 will have no previous relationship with the participants. He will take fieldnotes during the interview
55
56 283 noting participant interactions, body language, and emotional states. Interviews will be audio
57
58
59
60

1
2
3 284 recorded, de-identified, and transcribed verbatim by an external transcription service. The interviews
4
5 285 are expected to take approximately one hour to complete, and participants will receive a gift card as
6
7 286 a token of appreciation for their time and effort. See Box 2 for the semi-structure interview topic guide
8
9
10 287 used in this study.
11

12
13 288 The flexibility of semi-structured interviews allows opportunities for participants to expand
14
15 289 and elaborate on topics of interest and for researchers to add prompts if desired to focus on certain
16
17 290 areas of enquiry (for example, researchers may wish to examine social and emotional as well as
18
19 291 physical impact of hearing loss and could prompt for responses to this). Many unanticipated responses
20
21 292 are welcomed and contribute to the rich dataset, but the research team has carefully considered that
22
23 293 some CI recipients may enquire about the availability of TICI devices and/or their suitability as a
24
25 294 candidate. At present, these devices are not commercially available, and we present them to
26
27 295 participants as conceptual ideas. Prepared responses have also been developed to respond to this
28
29 296 potential situation with care and consideration. The semi-structured interview schedule is available in
30
31 297 supplementary material file 2.
32
33
34
35

36 298

37
38
39 299 Box 2

- 40
41 300
- 42 • Benefits and challenges associated with their current CI use
 - 43 301 • Impact of discreet CI devices on communication, motivation, social interactions, and quality
 - 44 of life
 - 45 302
 - 46 303 • Hearing healthcare pathways
 - 47
 - 48 304 • Trust, influence, and relationship with healthcare providers and stakeholders
 - 49
 - 50 305 • Learning about CIs and information access
 - 51
 - 52
 - 53
 - 54
 - 55

56 306

57 307

58
59
60

1
2
3 308 **Data analysis**
4
5

6 309 Descriptive statistics will be produced from participants' demographic characteristics, and research
7
8 310 familiarity and preferences (from the quickfire survey). This data will be analysed using IBM SPSS
9
10 311 Statistics for Windows, Version 27.0 [46], and presented as tabulated data and/or graphical figures.
11
12

13 312 Transcripts and fieldnotes from the semi-structured interviews will be analysed using a six-
14
15 313 phase approach to thematic analysis: (1) familiarisation with the data, (2) generation of initial codes,
16
17 314 (3) searching for themes, (4) reviewing themes, (5) defining and naming themes, and (6) producing
18
19 315 the report [47]. This will be conducted by three qualitative expert analysts (FR, RCW, CYL) working
20
21 316 together. This collaborative approach will ensure the process is robust and rigorous. Coding and
22
23 317 analysis of the demographic data, fieldnotes, and transcripts will be completed using NVivo (released
24
25 318 in March 2020) [48].
26
27
28
29

30 319 Quantitative and qualitative data will be analysed initially as discrete datasets, but
31
32 320 methodological and investigator triangulation approaches will also be used to confirm and enhance
33
34 321 our understanding of the findings [49].
35
36

37 322

38
39 323 **Patient and Public Involvement Statement**
40
41

42 324 Patients or the public will not be involved in the design, or conduct, or reporting, or dissemination
43
44 325 plans of our research.
45
46

47 326

48
49
50 327
51
52
53
54
55
56
57
58
59
60

328 **ETHICS AND DISSEMINATION**

329 **Ethics statement**

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

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

338

339 **Data storage and retention**

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

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

348

349

1
2
3 350 **Dissemination**
4
5

6 351 Study findings will be disseminated widely through international peer-reviewed journal articles, public
7
8 352 and academic presentations, plain language summaries for participants, and an executive summary
9
10 353 for the project funder. All quotes attributed to individual participants will be de-identified, and names
11
12 354 will be replaced with pseudonyms in any publicly accessible form of presentation.
13
14
15

16 355

17
18 356 **RESEARCH SIGNIFICANCE AND IMPACT**
19

20
21 357 The underutilisation of CIs is apparent in Australian and global contexts [30,31]. Given the incidence
22
23 358 of hearing loss is expected to increase with a globally ageing population [1], identifying ways to
24
25 359 improve access to services and hearing technologies is imperative. While our understanding of the
26
27 360 barriers and facilitators that affect uptake are limited, there is evidence that the physical and cosmetic
28
29 361 appearance of hearing solutions and its relationship to perceived stigma is one factor of concern
30
31 362 [15,32–34,37].
32
33
34

35 363 This study will examine the relationship of CI aesthetics with perceived stigma, social
36
37 364 interactions, communication, and quality of life using qualitative perspectives from adults with CIs.
38
39 365 This is significant, as we do not have a comprehensive understanding around the benefits of smaller
40
41 366 CI devices, or potential developments such as TICIs. Understanding their potential role as facilitators
42
43 367 to CI uptake will be significant in the context of individual and global hearing health that may improve
44
45 368 uptake, quality of life, and reduce the burden on health care and economic systems.
46
47
48

49 369 A secondary contribution is the exploration of CI recipients' familiarity and preferences
50
51 370 around research participation. These findings should improve recruitment strategies and improve
52
53 371 engagement with research participation. This is particularly relevant for a specialised cohort such as
54
55 372 CI recipients.
56
57
58
59
60

1
2
3 373 This study utilises and expands upon the research team's expertise exploring hearing health
4
5 374 systems [42,51–53]. Our findings will support a future clinical trial by providing a framework of themes
6
7
8 375 and topics of interest, and inform the feasibility of collecting data on a larger, longitudinal study across
9
10 376 a broad demographic population.
11
12

13 377

14 15 378 **AUTHOR CONTRIBUTIONS**

16
17
18 379 FR and RCW led the overall conceptualisation and design of the study, and provided feedback on the
19
20 380 manuscript drafts. CYL contributed to the design of the study and led the first manuscript draft. BE
21
22 381 and CW contributed to conceptualisation of the study and provided feedback on the manuscript
23
24 382 drafts. All authors provided final approval of the version submitted and accepted its accuracy and
25
26 383 integrity.
27
28
29

30 384

31 32 33 385 **DATA AVAILABILITY STATEMENT**

34
35
36 386 No data available.
37
38

39 387

40 41 42 388 **FUNDING STATEMENT**

43
44
45 389 This work was supported by Cochlear Ltd (ID167333389). The funder will have no role in conducting
46
47 390 or reporting on the study.
48
49

50 391

51 52 53 392 **COMPETING INTERESTS STATEMENT**

54
55
56 393 BE and CW are employees of Cochlear Ltd. and will not be involved in data collection, analysis and
57
58 394 reporting of the study findings. CYL has provided consulting expertise for Cochlear Ltd. on unrelated
59
60

1
2
3 395 projects in the past. As experienced qualitative researchers, FR and RCW ensured that the design of
4
5 396 this qualitative study was not driven by an industry agenda in any way. For example, the drafting of
6
7 397 the interview questions, demographic questionnaire and quickfire survey was completed by FR, RCW,
8
9 398 and CYL to ensure they were not leading or contained assumptions specific to Cochlear Ltd. or the
10
11 399 broader CI industry. Also, during the interviews, CYL will ensure all participants are aware he is not an
12
13 400 employee of Cochlear Ltd. and is only concerned with understanding participants' honest responses.
14
15 401 This study aims to learn from participants' lived-experience with hearing loss, hearing services, and
16
17 402 their thoughts and attitudes towards discreet CI concepts. This is also reiterated in the Information
18
19 403 and Consent Form. Any attempts to influence participants towards a favourable perspective towards
20
21 404 Cochlear Ltd. or CIs is antithetical to the purpose of this study.
22
23
24
25
26
27
28
29
30
31
32
33
34
35
36
37
38
39
40
41
42
43
44
45
46
47
48
49
50
51
52
53
54
55
56
57
58
59
60

407 REFERENCES

- 408 1 Haile LM, Kamenov K, Briant PS, *et al.* Hearing loss prevalence and years lived with disability,
409 1990-2019: Findings from the Global Burden of Disease Study 2019. *Lancet* 2021;**397**:996–
410 1009. doi:10.1016/S0140-6736(21)00516-X
- 411 2 Hearing Care Industry Association. The Social and Economic Cost of Hearing Loss in Australia.
412 2017.
- 413 3 Li-Korotky HS. Age-related hearing loss: Quality of care for quality of life. *Gerontologist*
414 2012;**52**:265–71. doi:10.1093/geront/gnr159
- 415 4 Arlinger S. Negative consequences of uncorrected hearing loss—a review. *Int J Audiol*
416 2003;**42**:17–20. doi:10.3109/14992020309074639
- 417 5 Dalton DS, Cruickshanks KJ, Klein BEK, *et al.* The Impact of Hearing Loss on Quality of Life in
418 Older Adults. *The Gerontologist* 2003;**43**:661–8. doi:10.2298/sarh1106286t
- 419 6 Livingston G, Huntley J, Sommerlad A, *et al.* Dementia prevention, intervention, and care:
420 2020 report of the Lancet Commission. *Lancet* 2020;**396**:413–46. doi:10.1016/S0140-
421 6736(20)30367-6
- 422 7 Vas V, Akeroyd MA, Hall DA. A Data-Driven Synthesis of Research Evidence for Domains of
423 Hearing Loss, as Reported by Adults With Hearing Loss and Their Communication Partners.
424 *Trends Hear* 2017;**21**:1–25. doi:10.1177/2331216517734088
- 425 8 World Health Organization. World report on hearing. Geneva: 2021.
- 426 9 Olusanya BO, Davis AC, Hoffman HJ. Hearing loss grades and the international classification of
427 functioning, disability and health. *Bull World Health Organ* 2019;**97**:725–8.
428 doi:10.2471/BLT.19.230367
- 429 10 Nieman CL, Lin FR. Increasing access to hearing rehabilitation for older adults. *Curr Opin*

- 1
2
3 430 *Otolaryngol Head Neck Surg* 2017;**25**:342–6. doi:10.1097/MOO.0000000000000386
4
5
6 431 11 Mulrow CD, Aguilar C, Endicott JE, *et al.* Quality-of-life changes and hearing impairment A
7
8 432 Randomized trial Quality-of-life changes and hearing impairment. A randomized trial. *Ann*
9
10 433 *Intern Med* 1990;**113**:188–94. doi:10.7326/0003-4819-113-3-188
11
12
13 434 12 Granberg S, Pronk M, De Swanepoel W, *et al.* The ICF core sets for hearing loss project:
14
15 435 Functioning and disability from the patient perspective. *Int J Audiol* 2014;**53**:777–86.
16
17 436 doi:10.3109/14992027.2014.938370
18
19
20
21 437 13 Yong M, Willink A, McMahon C, *et al.* Access to adults' hearing aids: Policies and technologies
22
23 438 used in eight countries. *Bull World Health Organ* 2019;**97**:699–710.
24
25 439 doi:10.2471/BLT.18.228676
26
27
28 440 14 Orji A, Kamenov K, Dirac M, *et al.* Global and regional needs, unmet needs and access to
29
30 441 hearing aids. *Int J Audiol* 2020;**59**:166–72. doi:10.1080/14992027.2020.1721577
31
32
33 442 15 Rolfe C, Gardner B. Experiences of hearing loss and views towards interventions to promote
34
35 443 uptake of rehabilitation support among UK adults. *Int J Audiol* 2016;**55**:666–73.
36
37 444 doi:10.1080/14992027.2016.1200146
38
39
40
41 445 16 Zeng F-G, Rebscher S, Harrison W, *et al.* Cochlear Implants: System Design, Integration, and
42
43 446 Evaluation. *IEEE Rev Biomed Eng* 2008;**1**:115–42. doi:10.1109/RBME.2008.2008250
44
45
46 447 17 Prochazka A, Mushahwar VK, McCreery DB. Neural prostheses. *J Physiol* 2001;**533**:99–109.
47
48 448 doi:10.1111/j.1469-7793.2001.0099b.x
49
50
51 449 18 Philips B, Plasmans A, Ingeborg P. Comfort and Listening Benefits of the Kanso Off-the-Ear
52
53 450 Sound Processor in Children. *Cochlear White Pap* 2016.
54
55
56 451 19 Manufacturers News. *Hear J* 2013;**66**:30. doi:10.1097/01.HJ.0000427119.41055.a4
57
58
59 452 20 Cohen N. The totally implantable cochlear implant. *Ear Hear* 2007;**28**:100–1.
60

- 1
2
3 453 doi:10.1097/AUD.0b013e31803150f4
4
5
6 454 21 Briggs RJS, Eder HC, Seligman PM, *et al.* Initial clinical experience with a totally implantable
7
8 455 cochlear implant research device. *Otol. Neurotol.* 2008;**29**:114–9.
9
10 456 doi:10.1097/MAO.0b013e31814b242f
11
12
13 457 22 Boisvert I, Reis M, Au A, *et al.* Cochlear implantation outcomes in adults: A scoping review.
14
15 458 *PLoS One* 2020;**15**:1–26. doi:10.1371/journal.pone.0232421
16
17
18 459 23 Gaylor JM, Raman G, Chung M, *et al.* Cochlear implantation in adults: A systematic review
19
20 460 and meta-analysis. *JAMA Otolaryngol - Head Neck Surg* 2013;**139**:265–72.
21
22 461 doi:10.1001/jamaoto.2013.1744
23
24
25
26 462 24 Crowson MG, Semenov YR, Tucci DL, *et al.* Quality of Life and Cost-Effectiveness of Cochlear
27
28 463 Implants: A Narrative Review. *Audiol Neurotol* 2018;**22**:236–58. doi:10.1159/000481767
29
30
31 464 25 Neve OM, Boerman JA, van den Hout WB, *et al.* Cost-benefit Analysis of Cochlear Implants.
32
33 465 *Ear Hear* 2021;**Publish Ah**. doi:10.1097/AUD.0000000000001021
34
35
36 466 26 Carlyon RP, Goehring T. Cochlear Implant Research and Development in the Twenty-first
37
38 467 Century: A Critical Update. *J Assoc Res Otolaryngol* Published Online First: 2021.
39
40 468 doi:10.1007/s10162-021-00811-5
41
42
43
44 469 27 Vickers D, De Raeve L, Graham J. International survey of cochlear implant candidacy. *Cochlear*
45
46 470 *Implants Int* 2016;**17**:36–41. doi:10.1080/14670100.2016.1155809
47
48
49 471 28 Moses LE, Friedmann DR. Cochlear implant indications: a review of third-party payers'
50
51 472 policies for standard and expanded indications. *Cochlear Implants Int* 2021;**22**:237–44.
52
53 473 doi:10.1080/14670100.2021.1877865
54
55
56 474 29 Zwolan TA, Schwartz-Leyzac KC, Pleasant T. Development of a 60/60 Guideline for Referring
57
58 475 Adults for a Traditional Cochlear Implant Candidacy Evaluation. *Otol Neurotol* 2020;**41**:895–
59
60

- 1
2
3 476 900. doi:10.1097/MAO.0000000000002664
4
5
6 477 30 Sorkin DL, Buchman CA. Cochlear implant access in six developed countries. *Otol Neurotol*
7
8 478 2016;**37**:e161–4. doi:10.1097/MAO.0000000000000946
9
10
11 479 31 Looi V, Bluett C, Boisvert I. Referral rates of postlingually deafened adult hearing aid users for
12
13 480 a cochlear implant candidacy assessment. *Int J Audiol* 2017;**56**:919–25.
14
15 481 doi:10.1080/14992027.2017.1344361
16
17
18 482 32 Bierbaum M, McMahon CM, Hughes S, *et al*. Barriers and Facilitators to Cochlear Implant
19
20 483 Uptake in Australia and the United Kingdom. *Ear Hear* 2019;**41**:374–85.
21
22 484 doi:10.1097/AUD.0000000000000762
23
24
25
26 485 33 Wallhagen MI. The stigma of hearing loss. *Gerontologist* 2010;**50**:66–75.
27
28 486 doi:10.1093/geront/gnp107
29
30
31 487 34 David D, Werner P. Stigma regarding hearing loss and hearing aids: A scoping review. *Stigma*
32
33 488 *Heal* 2016;**1**:59–71. doi:10.1037/sah0000022
34
35
36 489 35 Tolisano AM, Fang LB, Kutz JW, *et al*. Better defining best-aided condition: The role of hearing
37
38 490 aids on cochlear implantation qualification rates. *Am J Otolaryngol - Head Neck Med Surg*
39
40 491 2020;**41**. doi:10.1016/j.amjoto.2020.102431
42
43
44 492 36 Chundu S, Allen PM, Han W, *et al*. Social representation of hearing aids among people with
45
46 493 hearing loss: an exploratory study. *Int J Audiol* 2021;**0**:1–15.
47
48 494 doi:10.1080/14992027.2021.1886349
49
50
51 495 37 Dillon B, Pryce H. What makes someone choose cochlear implantation? An exploration of
52
53 496 factors that inform patient decision making. *Int J Audiol* 2020;**59**:24–32.
54
55 497 doi:10.1080/14992027.2019.1660917
56
57
58 498 38 Mauger SJ, Jones M, Nel E, *et al*. Clinical outcomes with the Kanso™ off-the-ear cochlear
59
60

- 1
2
3 499 implant sound processor. *Int J Audiol* 2017;**56**:267–76. doi:10.1080/14992027.2016.1265156
4
5
6 500 39 Profita HP, Stangl A, Matuszewska L, *et al.* ‘wear It Loud’: How and why hearing aid and
7
8 501 cochlear implant users customize their devices. *ACM Trans Access Comput* 2018;**11**.
9
10 502 doi:10.1145/3214382
11
12
13 503 40 World Health Organization. International classification of functioning, disability and health.
14
15 504 2001.
16
17
18 505 41 Malterud K, Siersma VD, Guassora AD. Sample Size in Qualitative Interview Studies: Guided
19
20 506 by Information Power. *Qual Health Res* 2016;**26**:1753–60. doi:10.1177/1049732315617444
21
22
23 507 42 Rapport F, Auton E, Warren C, *et al.* Addressing clinical equipoise for hearing devices: The
24
25 508 qualitative COACH (q-COACH) study protocol for Australian stakeholder involvement in the
26
27 509 design of a randomised controlled trial. *BMJ Open* 2019;**9**:1–8. doi:10.1136/bmjopen-2019-
28
29 510 030100
30
31
32
33 511 43 Valerio MA, Rodriguez N, Winkler P, *et al.* Comparing two sampling methods to engage hard-
34
35 512 to-reach communities in research priority setting. *BMC Med Res Methodol* 2016;**16**:1–11.
36
37 513 doi:10.1186/s12874-016-0242-z
38
39
40
41 514 44 Rapport F, Bierbaum M, McMahon C, *et al.* Qualitative, multimethod study of behavioural
42
43 515 and attitudinal responses to cochlear implantation from the patient and healthcare
44
45 516 professional perspective in Australia and the UK: study protocol. *BMJ Open* 2018;**8**:e019623.
46
47 517 doi:10.1136/bmjopen-2017-019623
48
49
50 518 45 Rapport F, Clement C, Doel MA, *et al.* Qualitative research and its methods in epilepsy:
51
52 519 Contributing to an understanding of patients’ lived experiences of the disease. *Epilepsy Behav*
53
54 520 2015;**45**:94–100. doi:10.1016/j.yebeh.2015.01.040
55
56
57
58 521 46 IBM Corp. IBM SPSS Statistics for Windows, Version 27.0. 2020.
59
60

- 1
2
3 522 47 Braun V, Clarke V. Qualitative Research in Psychology Using thematic analysis in psychology
4
5 523 Using thematic analysis in psychology. *Qual Res Psychol* 2006;**3**:77–101.
6
7
8 524 48 QSR International Pty Ltd. NVivo (released in March 2020). 2020.
9
10
11 525 49 Rapport F, Hogden A, Faris M, *et al.* *Qualitative Research in Healthcare Modern Methods,*
12
13 526 *Clear Translation: a White Paper.* 2018.
14
15
16 527 50 National Health and Medical Research Council. *National statement on ethical conduct in*
17
18 528 *human research, 2007 (Updated 2018).* 2018. [https://www.nhmrc.gov.au/about-](https://www.nhmrc.gov.au/about-us/publications/national-statement-ethical-conduct-human-research-2007-updated-2018)
19
20 529 [us/publications/national-statement-ethical-conduct-human-research-2007-updated-2018](https://www.nhmrc.gov.au/about-us/publications/national-statement-ethical-conduct-human-research-2007-updated-2018)
21
22
23
24 530 51 Hughes SE, Watkins A, Rapport F, *et al.* Rasch Analysis of the Listening Effort Questionnaire—
25
26 531 Cochlear Implant. *Ear Hear* 2021;**Publish Ah**:1–13. doi:10.1097/aud.0000000000001059
27
28
29 532 52 Bierbaum M, Braithwaite J, Arnolda G, *et al.* Clinicians' attitudes to oncology clinical practice
30
31 533 guidelines and the barriers and facilitators to adherence: a mixed methods study protocol.
32
33 534 *BMJ Open* 2020;**10**:e035448. doi:10.1136/bmjopen-2019-035448
34
35
36 535 53 Rapport F, Hughes SE, Boisvert I, *et al.* Adults' cochlear implant journeys through care: A
37
38 536 qualitative study. *BMC Health Serv Res* 2020;**20**:1–9. doi:10.1186/s12913-020-05334-y
39
40
41 537
42
43
44
45
46
47
48
49
50
51
52
53
54
55
56
57
58
59
60

Quickfire Survey

Have you been involved in research or clinical studies using:	Yes	No
Interviews (one-to-one interviews, where a researcher asks you questions)		
Focus groups (group-based workshops, where a researcher asks questions and facilitates group-discussion)		
Visual methods (the use of visual documents such as drawings, painting, photographs to help express your thoughts and feelings)		
Questionnaires (a document with a series of questions)		
Diaries or journals (regular logging of information such as your listening experience)		
Observations (where a researcher observes your behaviours)		
Please rank these techniques (1=most preferred; 6=least preferred)	Rank (1-6)	
Interviews		
Focus groups		
Visual methods		
Questionnaires		
Diaries or journals		
Observations		
Please rank how you would like interviews, focus groups, and visual methods to be completed (1=most preferred, 2=least preferred)	Rank (1-2)	
Face-to-face, in-person		
Videotelephone (e.g. via Zoom, Skype, or Teams)		
Please rank how you would like questionnaires are completed (1=most preferred, 3=least preferred)	Rank (1-3)	
On paper		
Digitally, on a computer		
Digitally, on a smart phone or tablet		
Would you like the researcher present when you complete a questionnaire?	Yes	No
Please rank how you would like diaries or journals to be completed (1=most preferred, 3=least preferred)	Rank (1-3)	
On paper		
Digitally, on a computer		
Digitally, on a smart phone or tablet		
Have you completed questionnaires that use:	Yes	No
Numerical rating scale		
Visual analogue scale		
Verbal rating scale		
Likert scale		
Choice scale		
Please rank these types of questions (1=most preferred, 5=least preferred)	Rank (1-5)	
Numerical rating		
Visual analogue scale		
Verbal rating scale		
Likert scale		
Choice scale		

Semi-structured Interview Schedule

[Introduction] We are gathering insights from cochlear implants (CI) recipients to explore the impact that having an implant has on their lives. I am a researcher at the Australian Institute of Health Innovation, and welcome your views, feelings, and experiences. We are very interested in your honest opinions, and there are no right or wrong responses. This interview should take around 1-hour but as there are a range of topics that I would like to cover, I may need to move the interview along at different points along the way. Your comfort is of utmost importance. As a reminder, you are free to pause and stop this interview at any time, without consequence. Do you have any questions so far? Can I confirm you have read the Pre-interview Information Sheet? [if not, the interviewer will go through this sheet now].

- 1) How has your CI made a difference to your hearing?
(*PROMPT: Examples, if required. What is the most significant difference?*)
- 2) How does your CI impact your quality of life?
(*PROMPT: How does that compare to your quality of life before the implant?*)
- 3) What do you think are the greatest benefits with your CI?
(*PROMPT: How do these benefits make you feel?*)
- 4) Do you think a more discreet CI, but which works in a similar fashion to a CI, may make any of the benefits you described even more impactful?
(*PROMPT: Why/why not?*)
- 5) What do you think are the greatest challenges or disbenefits of your CI?
(*PROMPT: How do these challenges/disbenefits make you feel? Have you ever felt stigmatised because of your CI?*)
- 6) Do you think a more discreet CI, similar to the CI you currently use, may help overcome any of those challenges?
(*PROMPT: Why/why not?*)
- 7) Could you imagine any downsides to a more discreet device?
(*PROMPT: Why/why not?*)
- 8) How does your CI impact your social life, work life, and relationships?
(*PROMPT: Is the impact particularly noticeable in certain contexts? e.g., with family, friends, acquaintances, work colleagues? In groups or with individuals? In formal or informal settings? In groups or with individuals? In quiet or noisy settings? When you are nearer or further away from people? When you are listening to someone's voice or a broadcast/TV/etc.*)
- 9) Do you think that a discreet CI device would make a difference to your social life, work life, and/or relationships?
(*PROMPT: If so, how? Why do you think that? Under what circumstances might it make the most difference?*)
 - 9a) [If so] Would that influence your decision when choosing such a CI?

- 1
2
3 10) Before you received your CI, how did you learn about CI devices?
4 *(PROMPT: Was it difficult to find that information? The right information? Enough*
5 *information?)*
6
7
8 11) What has your hearing health care pathway been like?
9 *(PROMPT: Quick, fragmented, clear, supportive, shared between healthcare professionals?*
10 *Was information or support provided to other family members?).*
11 *(PROMPT: How were you diagnosed with a deafness, and what was the process of*
12 *implantation?)*
13
14 12) What is your relationship with hearing health professionals and organisations?
15 *(PROMPT: How did they influence you? What helped you the most, e.g., meeting facilitators, or*
16 *reading testimonials of CI recipients, speaking to a supportive healthcare professional,*
17 *speaking to a knowledgeable healthcare professional, being referred to the right person for*
18 *your individual needs?)*
19
20
21 13) How do you normally find or learn about new information regarding cochlear implants, implant
22 developments, or implant updates?
23
24 14) [Wrap-up] Do you have any final thoughts or comments, particularly regarding a discreet CI
25 device?
26
27
28
29
30
31
32
33
34
35
36
37
38
39
40
41
42
43
44
45
46
47
48
49
50
51
52
53
54
55
56
57
58
59
60

COREQ (CONsolidated criteria for REporting Qualitative research) Checklist

A checklist of items that should be included in reports of qualitative research. You must report the page number in your manuscript where you consider each of the items listed in this checklist. If you have not included this information, either revise your manuscript accordingly before submitting or note N/A.

Topic	Item No.	Guide Questions/Description	Reported on Page No.
Domain 1: Research team and reflexivity			
<i>Personal characteristics</i>			
Interviewer/facilitator	1	Which author/s conducted the interview or focus group?	
Credentials	2	What were the researcher's credentials? E.g. PhD, MD	
Occupation	3	What was their occupation at the time of the study?	
Gender	4	Was the researcher male or female?	
Experience and training	5	What experience or training did the researcher have?	
<i>Relationship with participants</i>			
Relationship established	6	Was a relationship established prior to study commencement?	
Participant knowledge of the interviewer	7	What did the participants know about the researcher? e.g. personal goals, reasons for doing the research	
Interviewer characteristics	8	What characteristics were reported about the interviewer/facilitator? e.g. Bias, assumptions, reasons and interests in the research topic	
Domain 2: Study design			
<i>Theoretical framework</i>			
Methodological orientation and Theory	9	What methodological orientation was stated to underpin the study? e.g. grounded theory, discourse analysis, ethnography, phenomenology, content analysis	
<i>Participant selection</i>			
Sampling	10	How were participants selected? e.g. purposive, convenience, consecutive, snowball	
Method of approach	11	How were participants approached? e.g. face-to-face, telephone, mail, email	
Sample size	12	How many participants were in the study?	
Non-participation	13	How many people refused to participate or dropped out? Reasons?	
<i>Setting</i>			
Setting of data collection	14	Where was the data collected? e.g. home, clinic, workplace	
Presence of non-participants	15	Was anyone else present besides the participants and researchers?	
Description of sample	16	What are the important characteristics of the sample? e.g. demographic data, date	
<i>Data collection</i>			
Interview guide	17	Were questions, prompts, guides provided by the authors? Was it pilot tested?	
Repeat interviews	18	Were repeat interviews carried out? If yes, how many?	
Audio/visual recording	19	Did the research use audio or visual recording to collect the data?	
Field notes	20	Were field notes made during and/or after the interview or focus group?	
Duration	21	What was the duration of the interviews or focus group?	
Data saturation	22	Was data saturation discussed?	
Transcripts returned	23	Were transcripts returned to participants for comment and/or	

Topic	Item No.	Guide Questions/Description	Reported on Page No.
		correction?	
Domain 3: analysis and findings			
<i>Data analysis</i>			
Number of data coders	24	How many data coders coded the data?	
Description of the coding tree	25	Did authors provide a description of the coding tree?	
Derivation of themes	26	Were themes identified in advance or derived from the data?	
Software	27	What software, if applicable, was used to manage the data?	
Participant checking	28	Did participants provide feedback on the findings?	
<i>Reporting</i>			
Quotations presented	29	Were participant quotations presented to illustrate the themes/findings? Was each quotation identified? e.g. participant number	
Data and findings consistent	30	Was there consistency between the data presented and the findings?	
Clarity of major themes	31	Were major themes clearly presented in the findings?	
Clarity of minor themes	32	Is there a description of diverse cases or discussion of minor themes?	

Developed from: Tong A, Sainsbury P, Craig J. Consolidated criteria for reporting qualitative research (COREQ): a 32-item checklist for interviews and focus groups. *International Journal for Quality in Health Care*. 2007. Volume 19, Number 6: pp. 349 – 357

Once you have completed this checklist, please save a copy and upload it as part of your submission. DO NOT include this checklist as part of the main manuscript document. It must be uploaded as a separate file.