Insomnia, Anxiety and Depression in Adult Cochlear Implant Users With Tinnitus

Robert H. Pierzycki1,2 and Pádraig T. Kitterick1,2,3

**Objective:** Determine the prevalence of clinical insomnia and its associations with anxiety, depression, and tinnitus in adult cochlear implant (CI) users.

**Design:** Self-reported information on tinnitus, sleep, and demographic variables was collected from adult CI users (n = 127). Tinnitus presence, its persistence, related emotional distress, and difficulties with sleep were assessed using questions from the UK Biobank study (www.ukbiobank.ac.uk). Tinnitus-related handicap was assessed using the Tinnitus Handicap Inventory. Clinical insomnia symptoms were characterized using the Insomnia Severity Index (ISI), and clinical anxiety and depression symptoms using the Hospital Anxiety and Depression Scale (HADS). Regression models were used to compare the data from CI users with and without tinnitus, and to test the associations between clinical insomnia, anxiety, depression and tinnitus handicap.

**Results:** About a half (53%) of CI users reported tinnitus, of whom 54% described it as persistent, 41% as emotionally distressing and 73% reported having difficulties with sleep based on the UK Biobank questions. The ISI suggested that clinically abnormal insomnia symptoms were more likely to occur with tinnitus (odds ratio [OR] = 2.60, 95% confidence interval 1.04 to 6.45; \( p = 0.040 \)) and were found in 41% of CI users with tinnitus. Post-hoc exploratory analyses on the ISI suggested that CI users with tinnitus experienced greater levels of difficulty falling asleep, lower satisfaction with sleep patterns, greater interference of sleep problems with daily activities, and a greater impact on their quality of life. The HADS scores suggested that those with tinnitus were also more likely to have clinically abnormal anxiety (42%; OR = 3.50, 95% confidence interval 1.49 to 8.22; \( p = 0.004 \)) and depression symptoms (14%; OR = 6.18, 95% confidence interval 1.17 to 32.82; \( p = 0.032 \)). The clinical insomnia observed in CI users with tinnitus was associated with tinnitus handicap (\( p = 0.028 \)), and the levels of clinical anxiety (\( p = 0.012 \)) and depression (\( p < 0.001 \)).

**Conclusions:** Clinically abnormal insomnia symptoms are prevalent, potentially affecting over 40% of CI users with tinnitus. The associations between clinical insomnia, anxiety, and depression symptoms, and tinnitus-related handicap suggest that all of these symptoms should be considered when assessing the tinnitus-related burden and its impact on the quality of life after cochlear implantation. The present findings also have potential implications for the clinical management of CI recipients with tinnitus, in whom it may be advisable to monitor sleep problems so that they can be addressed where appropriate. Further research is needed to investigate the mechanisms and causal links behind insomnia and tinnitus-related symptoms in this population. Future studies should also investigate the feasibility and effectiveness of night time use of CIs to alleviate tinnitus-related insomnia. The potential impact of insomnia on the quality of life of CI users with tinnitus highlights the importance of including sleep measures in future evaluations of the effectiveness of cochlear implantation for the alleviation of tinnitus.

**Key words:** Clinical impact, Cochlear implantation, Deafness, Psychological disorders, Severe-profound hearing loss, Sleep difficulties, Tinnitus burden, Tinnitus distress, Tinnitus handicap, Tinnitus intervention, Tinnitus management, Tinnitus therapy.

(Ear & Hearing 2021;42;235–243)

**INTRODUCTION**

Tinnitus is a perception of sounds in the ears or head that do not come from an external source (Turnel et al. 2014; National Institute for Health and Care Excellence 2020). The management of tinnitus in people who are profoundly deaf has been identified by patients and clinicians as one of priorities for further research (Hall et al. 2013). Tinnitus appears to be highly prevalent in individuals with severe-profound hearing loss. Recent epidemiological data suggest that at least 50% of people who are eligible to receive a cochlear implant (CI) experience tinnitus (Pierzycki et al. 2016), but the prevalence reported across different studies suggests it can be as high as 80% on average (Baguley & Atlas 2007; Andersson et al. 2009; Pan et al. 2009; Amoodi et al. 2011). While the primary clinical purpose of cochlear implantation is to improve the ability to understand speech, recent systematic reviews suggest that cochlear implantation can be also associated with the alleviation of tinnitus and the burden it imposes (Ramakers et al. 2015; Zenner et al. 2017).

The symptoms contributing to the perceived burden from tinnitus and the extent to which those symptoms are alleviated by CI use can vary between patients. However, a large proportion of CI users (about 75%) report difficulties with sleep which can be as prevalent in candidates for implantation and more likely to occur in those with tinnitus (Pierzycki et al. 2016). The alleviation of tinnitus resulting from CI use arises primarily when it is switched on and stimulating the auditory nerve (Zeng et al. 2011). Similarly, some CI users may experience difficulties with sleep due to the presence of tinnitus when their CI is switched off at night time (Chadha et al. 2009). This experience is illustrated clearly when CI users are asked to plot changes in the perceived severity of their tinnitus during the day relative to when their implant is switched on and off (Fig. 1).

There is a large body of evidence suggesting that sleep difficulties can be a significant contributor to the perceived emotional distress from tinnitus in general tinnitus population (Tyler & Baker 1983; McKenna 2000; Crönlein et al. 2007; Langguth 2011; Crönlein et al. 2016; Koning 2019). Recent reviews suggest that sleep difficulties may be prevalent in up to 80% of people with tinnitus (Asnis et al. 2018), consistent with the large prevalence of sleep difficulties found in CI users (75%) or potential candidates for implantation (82%) found in epidemiological studies (Pierzycki et al. 2016). However, the mechanisms...
behind tinnitus-related sleep difficulties are not well understood with recent studies suggesting the importance of psychological symptoms such as anxiety (Crönlein et al. 2016), or the intensity of the tinnitus percept itself as the factors affecting sleep in people with tinnitus (Koning 2019). Moreover, available evidence does not allow establishing the clinical importance of tinnitus-related sleep difficulties due to the large variability or inadequate use of insomnia assessments that do not allow a clinical diagnosis (Asnis et al. 2018). For example, while some studies suggest that tinnitus-related difficulties with sleep can be experienced in the absence of a sleep-related disorder (Crönlein et al. 2007), other suggest the presence of undiagnosed insomnia among tinnitus patients (Miguel et al. 2014). Therefore, the unanswered question about the sleep difficulties reported by adult CI users is whether these difficulties are of sufficient importance to reach a clinical diagnosis of insomnia and warrant clinical intervention.

Tinnitus-related handicap has been found to be associated with increased anxiety and depression in CI users with tinnitus (Andersson et al. 2009; Olze et al. 2011; Kloostra et al. 2015). Prospective studies with patients undergoing cochlear implantation suggest only slight improvements in their anxiety and depression symptoms despite significant reduction of tinnitus-related distress as a result of implantation (Olze et al. 2011; Brüggemann et al. 2017). Similarly, the evidence from epidemiological studies suggests that the prevalence of emotionally distressing tinnitus among CI users, which may have been associated with anxiety and depression symptoms, could be as high as 41% compared to 63% among potential candidates to receive a CI (Pierzycki et al. 2016). However, anxiety and depression are also major risk factors for developing insomnia (LeBlanc et al. 2009). Therefore, the reported emotional distress from tinnitus in CI users may have been also associated with the high prevalence of self-reported difficulties with sleep, which would be compatible with the known association between tinnitus distress and insomnia found in the general tinnitus population and recent cognitive-behavioral models of tinnitus distress (McKenna et al. 2014). Thus, not only is it important to explore the extent of clinical insomnia among CI users with tinnitus but also the links between the insomnia, anxiety, and depression symptoms in this population. The present study aimed to determine: (1) the prevalence and nature of insomnia symptoms and (2) the associations between insomnia, anxiety, and depression symptoms, and tinnitus handicap in adult CI users.

Fig. 1. Severity of tinnitus-related problems during the day. Thick lines show “tinnitus problems at their worst” reported by three adult cochlear implant users from the Nottingham clinic (A–C). Tinnitus problems become more severe at night time, coinciding with switching cochlear implants off.
MATERIALS AND METHODS

Participants
A cross-sectional design was used to gather information about the prevalence of tinnitus, related clinical symptoms, and patient demographic data among a population of adult CI users. The study was advertised to all adult patients managed by the Nottingham Auditory Implant Programme (N = 645), a large provider of cochlear implantation services in the United Kingdom. A cohort of 128 patients responded to postal invitations (response rate of 20%), of whom 127 gave information about the presence of tinnitus and were included in the study. The study obtained ethical approval from the South East Coast – Surrey National Research Ethics Services Committee.

Self-Report Measures of Tinnitus and Sleep Difficulties
Table 1 shows the self-reported measures of tinnitus and sleep difficulties. All participants were asked about whether they experience tinnitus (“presence”). Those who reported having tinnitus were also asked to rate the frequency of occurrence of their tinnitus (“persistence”), and how much it worried, annoyed, or upset them at its worst (“emotional distress”). All participants, regardless of tinnitus presence, were asked to report whether they had difficulties falling or staying asleep (“sleep difficulties”). The questions and response options about tinnitus and sleep difficulties were the same as those used in the UK Biobank study (Sudlow et al. 2015), and similar to assessments of tinnitus-related emotional distress and sleep problems included in many tinnitus questionnaires (Kuk et al. 1990; Newman et al. 1996; Meikle et al. 2012; Tyler et al. 2014).

The responses of participants identified as currently having tinnitus were used to categorize their tinnitus as “infrequent” or “frequent” in terms of persistence, and “slight” or “upsetting” in terms of tinnitus-related emotional distress (Table 2). All participants were also categorized as having difficulties with sleep that were either “rare” or “usual.” These categories were the same as those used in our previous study characterizing tinnitus and sleep difficulties in adult CI users using the UK Biobank resource (Pierzycki et al. 2016).

Participants with tinnitus were also asked to complete the Tinnitus Handicap Inventory (THI) (Newman et al. 1996), a standard questionnaire used as a measure of tinnitus severity in clinical settings and tinnitus studies with CI users (Hoare et al. 2012; Ramakers et al. 2015). The THI consists of 25 items each asking the participant to rate the impact of their tinnitus on a specific aspect of daily function using a three-point scale “yes,” “no,” and “sometimes.” The participant’s responses were used to compute a mean global score ranging from 0 to 100, and used as a validated measure of their tinnitus-related handicap (Anderson et al. 2009). The global score was used because it includes the contributions of THI items relating to anxiety, depression, and sleep, and previous research suggests that the THI should be used as a unifactorial measure of tinnitus distress (Baguley & Anderson 2003).

Clinical Measures of Anxiety, Depression, and Insomnia
All participants were asked to complete standard diagnostic questionnaires to assess the presence of anxiety and depression symptoms using the Hospital Anxiety and Depression Scale (HADS) (Zigmond & Snaith 1983), and the presence of insomnia symptoms using the Insomnia Severity Index (ISI) (Bastien et al. 2001). The ISI questionnaire was used due to its short timeframe for the assessment of symptoms (last two weeks) which was similar to that used in the assessment of the anxiety and depression symptoms in the HADS questionnaire (last week) and allowed to minimize potential recall bias in reporting the symptoms. The standard cutoff criteria (Table 2) for the respective summary scores on the HADS and ISI questionnaires were used to maximize the specificity when categorizing participants into those who either had normal or abnormal clinical anxiety or depressive symptoms, and those with normal

TABLE 1. UK Biobank questions used in the present study

| ID   | Question and Response Options                                                                                                      |
|------|----------------------------------------------------------------------------------------------------------------------------------|
| H11  | Do you get or have you had noises (such as ringing or buzzing) in your head or in one or both ears that lasts for more than five minutes at a time? |
|      | a) Yes, now most or all of the time                                                                                               |
|      | b) Yes, now a lot of the time                                                                                                      |
|      | c) Yes, now some of the time                                                                                                       |
|      | d) Yes, but not now, but have in the past                                                                                          |
|      | e) No, never                                                                                                                      |
|      | f) Do not know                                                                                                                     |
|      | g) Prefer not to answer                                                                                                            |
| H11A | How much do these noises worry, annoy or upset you when they are at their worst?                                                   |
|      | a) Severely                                                                                                                        |
|      | b) Moderately                                                                                                                      |
|      | c) Slightly                                                                                                                        |
|      | d) Not at all                                                                                                                       |
|      | e) Do not know                                                                                                                     |
|      | f) Prefer not to answer                                                                                                            |
| SL2  | Do you have trouble falling asleep at night or do you wake up in the middle of the night?                                        |
|      | a) Never/rarely                                                                                                                    |
|      | b) Sometimes                                                                                                                       |
|      | c) Usually                                                                                                                         |
|      | d) Prefer not to answer                                                                                                            |

TABLE 2. Definitions of outcomes

| Outcome                        | Category       | Questions                      | Response         |
|--------------------------------|----------------|-------------------------------|------------------|
| Tinnitus presence              | (UK Biobank)   | No                            | Ticked (d) or (e) |
| Tinnitus persistence           | (UK Biobank)   | Yes                           | Ticked (a), (b) or (c) |
| Tinnitus emotional distress    | (UK Biobank)   | Infrequent                    | Ticked (c)       |
| Sleep difficulties             | (UK Biobank)   | Frequent                      | Ticked (a) or (b) |
| Sleep difficulties             | (UK Biobank)   | Slight                        | Ticked (c) or (d) |
| Sleep difficulties             | (UK Biobank)   | Upsetting                     | Ticked (a)       |
| Clinical anxiety               | (HADS)         | Normal                        | Score 0–7        |
| Clinical depression            | (HADS)         | Abnormal                      | Score 8–21       |
| Clinical insomnia              | (ISI)          | Normal                        | Score 0–7        |
or abnormal clinical insomnia symptoms (Zigmond & Snaith 1983; Bastien et al. 2001).

**Data Analysis**

Descriptive statistics were used to summarize participant characteristics in the tinnitus and no tinnitus groups. Responses “Prefer not to answer” or “Do not know” to any questions were treated as missing data. Linear regression models were used to compare the groups on their HADS anxiety and depression and ISI scores. A multivariable model was used to test for associations between the THI, HADS anxiety and depression, and ISI scores in the tinnitus group, and the interaction between the HADS anxiety or depression score and the ISI score. The relationships between the binary categories defined by the UK Biobank questions and the standard clinical diagnostic tools (HADS and ISI) were analyzed using logistic regression models. All regression models controlled for sex, age, and their interaction. Multivariable regression models were used to test the relative influence (marginal effects) between the tinnitus handicap and anxiety, depression and insomnia symptoms because these symptoms may have occurred together and be related to each other in a given patient. The use of regression models also allowed estimating the marginal effects while controlling for age, sex, and their interaction. Group differences in HADS and ISI item scores were explored using post-hoc independent samples t-tests. Correction for multiple comparisons was performed using the Holm–Bonferroni method at a 0.05 level. The data were analyzed using R statistical package. Results were considered statistically significant if \( p < 0.05 \).

**RESULTS**

**Participant Characteristics**

Table 3 lists the characteristics of participants in the tinnitus and no tinnitus groups. About 53% of CI users (n = 67) reported experiencing tinnitus, a similar proportion to that found in the UK Biobank population (50%) (Pierzycki et al. 2016). The majority of participants with tinnitus reported tinnitus onset before cochlear implantation surgery (84%), and smaller proportions reported tinnitus onset after the surgery and some time before (5%) or after (11%) the first CI activation. The average THI score in the tinnitus group was 21.14 (standard deviation = 21.51), with about 79% of participants having scores indicative of no or mild tinnitus handicap and 21% indicative of moderate or severe tinnitus handicap (Newman et al. 1998). Nearly, all participants (96%) were unilateral CI users. The sample comprised participants who were predominantly users of Cochlear Ltd. (71%) and Advanced Bionics Corp. CIs (27%) and several participants used devices from Med-El Corp. (2%). However, the distribution of device makes was almost identical between the tinnitus and no tinnitus groups (Table 3). These two groups were also similar in terms of their sex \( (p = 0.37) \), age \( (p = 0.29) \), duration of deafness \( (p = 0.49) \) and duration of CI use \( (p = 0.99) \).

**Self-Report Measures of Tinnitus and Sleep Difficulties**

Table 4 lists the outcomes on the self-report measures. The UK Biobank self-report measures suggested that about 54% of participants had persistent tinnitus and 41% reported emotional distress due to their tinnitus. A large proportion of all CI users (63%) reported experiencing difficulties with sleep. Logistic regression showed significant associations between tinnitus persistence and tinnitus-related emotional distress \( (p = 0.015) \); odds ratio \( [OR] = 4.19 \), 95% confidence interval \( [\text{conf. int.}] = 1.33 \) to 13.22). Sleep difficulties were not significantly associated with tinnitus persistence \( (p = 0.37) \) or emotional distress \( (p = 0.10) \), but were more likely to occur in CI users with tinnitus than those without \( (p = 0.01); \ OR = 2.84, 95\% \text{ conf. int.} 1.28 \) to 6.27).

**Impact of Tinnitus on Clinical Symptoms**

Table 4 shows the prevalence of clinical symptoms in the tinnitus and no tinnitus groups. Table 5 shows descriptive and statistical comparisons between the groups in terms of their mean scores on the HADS and ISI, and the proportions with abnormal clinical anxiety, depression, and insomnia symptoms. About 42% of CI users with tinnitus reported abnormal anxiety symptoms on HADS, and were significantly more likely to have abnormal anxiety symptoms compared to those without tinnitus \( (19\%; p = 0.004; \text{Fig. 2}) \). Abnormal depression symptoms were also significantly more likely to occur in those with tinnitus \( (14\%) \) than in those without \( (4\%; p = 0.032) \). Clinical insomnia was found in 41% of CI users with tinnitus, and was significantly more likely to occur compared to those without tinnitus \( (21\%; p = 0.040; \text{Fig. 3}) \). The results of the regression models also showed that the scores on the HADS anxiety and depression questionnaire and the ISI questionnaire were significantly different between the tinnitus and no tinnitus groups (Table 5).

---

**TABLE 3. Demographics of the sample**

| Characteristic                  | No Tinnitus | Tinnitus |
|---------------------------------|-------------|----------|
| All participants                | 60          | 67       |
| Male sex                        | 28          | 26       |
| Unilateral CI users             | 57          | 65       |
| CI make                         |             |          |
| Cochlear Ltd.                   | 42          | 46       |
| Advanced Bionics                | 15          | 28       |
| Med-El                          | 1           | 2        |
| Missing                         | 2           | 1        |
| Tinnitus onset                  |             |          |
| Before CI surgery               | —           | 54       |
| After CI surgery, before        | —           | 3        |
| activation                      | —           | 7        |
| After CI surgery, after         | —           | 3        |
| activation                      | —           |          |
| Missing                         | —           | 4        |
| Tinnitus handicap (THI score)*   | —           |          |
| No (0–16)                       | —           | 37       |
| Mild (19–36)                    | —           | 13       |
| Moderate (38–56)                | —           | 8        |
| Severe (58–100)                 | —           | 5        |
| Missing                         | —           | 4        |

| Characteristic                  | N  | SD   | N  | SD   |
|---------------------------------|----|------|----|------|
| Age (yrs)                       | 57.80 | 22.32 | 53.93 | 18.98 |
| Duration of deafness (yrs)      | 15.03 | 16.71 | 13.04 | 14.71 |
| Time since CI activation (yrs)  | 7.17  | 6.24  | 7.18  | 6.84  |
| THI score                       | —   | —    | 21.14 | 21.51 |

Missing data were excluded when calculating percentages.

CI, cochlear implant; SD, standard deviation; THI, Tinnitus Handicap Inventory.
TABLE 4. Self-reported characteristics of tinnitus and sleep difficulties assessed with the UK Biobank questions, and clinical symptoms of anxiety and depression assessed with HADS, and insomnia assessed with ISI

| Characteristic            | No Tinnitus | Tinnitus | Tinnitus vs. No Tinnitus |
|---------------------------|-------------|----------|-------------------------|
|                           | N   | %   | N   | %   | β      | 95% Conf. Int. | p   |
| Tinnitus presence         |     |     |     |     |        |                 |     |
| Past/never                | 60  | 47  | —   | —   | —      | 1.81, 95% conf. int. 0.25 to 3.37 | <0.001 |
| Current                   | —   | —   | 67  | 53  | —      | —                 |     |
| Tinnitus persistence      |     |     |     |     |        |                 |     |
| Infrequent                | —   | —   | 31  | 46  | —      | —                 |     |
| Frequent                  | —   | —   | 36  | 54  | —      | —                 |     |
| Missing                   | —   | —   | 0   | —   | —      | —                 |     |
| Tinnitus emotional distress|     |     |     |     |        |                 |     |
| Slight                    | —   | —   | 39  | 59  | —      | —                 |     |
| Upsetting                 | —   | —   | 27  | 41  | —      | —                 |     |
| Missing                   | —   | —   | 1   | —   | —      | —                 |     |
| Sleep difficulties        |     |     |     |     |        |                 |     |
| Rare                      | 28  | 49  | 18  | 27  | —      | —                 |     |
| Usual                     | 29  | 51  | 49  | 73  | —      | —                 |     |
| Missing                   | 3   | 0   | 0   | —   | —      | —                 |     |
| Clinical anxiety          |     |     |     |     |        |                 |     |
| Normal                    | 47  | 81  | 38  | 58  | —      | —                 |     |
| Abnormal                  | 11  | 19  | 28  | 42  | —      | —                 |     |
| Missing                   | 2   | 0   | 1   | —   | —      | —                 |     |
| Clinical depression       |     |     |     |     |        |                 |     |
| Normal                    | 55  | 96  | 56  | 86  | —      | —                 |     |
| Abnormal                  | 2   | 4   | 9   | 14  | —      | —                 |     |
| Missing                   | 3   | 0   | 2   | —   | —      | —                 |     |
| Clinical insomnia         |     |     |     |     |        |                 |     |
| Normal                    | 34  | 79  | 35  | 59  | —      | —                 |     |
| Abnormal                  | 9   | 21  | 24  | 41  | —      | —                 |     |
| Missing                   | 17  | 4   | 8   | —   | —      | —                 |     |

Missing data were excluded when calculating percentages.
HADS, Hospital Anxiety and Depression Scale; ISI, Insomnia Severity Index.

A comparison of single item scores on the HADS questionnaire showed significant differences between the groups on four out of seven ISI items including self-reported difficulty falling asleep, but these differences were not significant after correction for multiple comparisons (see Table S3, Supplemental Digital Content S1-S3, http://links.lww.com/EANDH/A668).

Figure 4 summarizes schematically the associations between tinnitus handicap measured with the THI, the HADS anxiety and depression scores, and ISI insomnia scores tested with the multivariable model in CI users with tinnitus. Tinnitus handicap scores were significantly associated with clinical depression scores ($p = 0.002; \beta = 4.20, 95\%$ conf. int. 1.67 to 6.74) but not with anxiety scores ($p = 0.080; \beta = -2.15, 95\%$ conf. int. -4.50 to 0.21). The clinical insomnia scores were also significantly associated with tinnitus handicap scores ($p = 0.028; \beta = 1.81, 95\%$ conf. int. 0.25 to 3.37), and significant interactions were observed between the ISI insomnia scores and both the HADS anxiety ($p = 0.012; \beta = 0.38, 95\%$ conf. int. 0.09 to 0.66) and depression scores ($p < 0.001; \beta = -0.53, 95\%$ conf. int. -0.80 to -0.25).

### DISCUSSION

The present study aimed to determine the prevalence of clinical insomnia among adult CI users, and to characterize associations between their clinical insomnia, anxiety, depression symptoms, and their tinnitus-related handicap. Clinically abnormal insomnia symptoms were found in about 32% of CI users, but the prevalence of those symptoms in CI users with tinnitus (41%) was significantly higher and nearly double that found in those without tinnitus (21%). Clinically abnormal anxiety symptoms were more prevalent (31%) than those of depression (9%), but both were also more likely to co-occur with tinnitus. Tinnitus-related handicap was significantly associated with clinical insomnia and depression symptoms, and the effect of insomnia on the level of perceived handicap varied based on the level of clinical anxiety and depression (Fig. 4).

### Domains of Tinnitus Burden in Cochlear Implant Users

About a half of CI users (53%) experienced tinnitus consistent with previous findings suggesting that complete suppression of tinnitus occurs in only about a half of CI recipients

---

**TABLE 5. Results from linear and logistic regression modeling of group differences in mean scores from standard clinical diagnostic tools and proportions with clinically abnormal anxiety, depression, and insomnia symptoms**

| Outcome score          | No Tinnitus | Tinnitus | Tinnitus vs. No Tinnitus |
|------------------------|-------------|----------|-------------------------|
|                        | Mean | SD | Mean | SD | β      | 95% Conf. Int. | p   |
| HADS anxiety           | 4.59 | 3.71 | 7.26 | 4.66 | 2.59 | 1.13 to 4.06 | <0.001 |
| HADS depression        | 2.61 | 2.76 | 3.83 | 3.22 | 1.40 | 0.34 to 2.46 | 0.011 |
| ISI                    | 4.44 | 5.53 | 7.64 | 6.14 | 3.25 | 0.91 to 5.60 | 0.008 |

| Outcome category       | No Tinnitus | Tinnitus | Tinnitus vs. No Tinnitus |
|------------------------|-------------|----------|-------------------------|
|                        | %    | 95% Conf. Int. | %    | 95% Conf. Int. | OR | 95% Conf. Int. | p   |
| Clinical anxiety (HADS)| 18.97 | 10.93 to 30.85 | 42.42 | 31.24 to 54.44 | 3.50 | 1.49 to 8.22 | 0.004 |
| Clinical depression (HADS) | 3.51 | 0.97 to 11.92 | 13.85 | 7.46 to 24.27 | 6.18 | 1.17 to 32.82 | 0.032 |
| Clinical insomnia (ISI) | 20.93 | 11.42 to 35.21 | 40.68 | 29.09 to 53.41 | 2.60 | 1.04 to 6.45 | 0.040 |

β, linear regression coefficient; Conf. Int., confidence interval; HADS, Hospital Anxiety and Depression Scale; ISI, Insomnia Severity Index; OR, odds ratio; SD, standard deviation.

---

Copyright © 2020 Wolters Kluwer Health, Inc. Unauthorized reproduction of this article is prohibited.
A significant difference between the groups on the logistic regression (Table 5). A novel finding of the present study was the presence of clinically abnormal insomnia symptoms in about a third of CI users, and that these symptoms were far more likely to occur in CI users with tinnitus. The severity of insomnia symptoms was assessed using the ISI, a clinical measure used for detecting and assessing the impact of insomnia (Bastien et al. 2001; Gagnon et al. 2013), and this severity was also found to be associated with tinnitus-related handicap. These findings are in agreement with the presence and association of clinical insomnia with the severity of tinnitus found in the general population (Miguel et al. 2014; Schecklmann et al. 2015; Crönlein et al. 2016; Asnis et al. 2018), and reinforce the importance and clinical relevance of screening for insomnia symptoms when assessing the impact of tinnitus in CI recipients.

Fig. 2. Proportion of clinically abnormal anxiety (A) and depression (B) symptoms on the Hospital Anxiety and Depression Scale in participants with and without tinnitus. Error bars show 95% confidence intervals for the proportions. Asterisks indicate a significant difference between the groups on the logistic regression (Table 5).

Clinical Impact of Tinnitus-Related Burden

A novel finding of the present study was the presence of clinically abnormal insomnia symptoms in about a third of CI users, and that these symptoms were far more likely to occur in CI users with tinnitus. The severity of insomnia symptoms was assessed using the ISI, a clinical measure used for detecting and assessing the impact of insomnia (Bastien et al. 2001; Gagnon et al. 2013), and this severity was also found to be associated with tinnitus-related handicap. These findings are in agreement with the presence and association of clinical insomnia with the severity of tinnitus found in the general population (Miguel et al. 2014; Schecklmann et al. 2015; Crönlein et al. 2016; Asnis et al. 2018), and reinforce the importance and clinical relevance of screening for insomnia symptoms when assessing the impact of tinnitus in CI recipients.

Fig. 3. Proportion of self-reported sleep difficulties using the UK Biobank question (A) and clinically abnormal insomnia symptoms on the Insomnia Severity Index scores (B) in participants with and without tinnitus. Error bars show 95% confidence intervals for the proportions. Asterisks indicate a significant difference between the groups on the logistic regression (Table 5).
nitus-related complaint reported by both tinnitus patients and the observations that difficulties with sleep are the major tin-

having an impact on their quality of life that was noticeable to sleep patterns, and the perception that their sleep problems were

Reported insomnia symptoms also appeared to be significant that these patients may be more susceptible to developing an functioning. The combination of greater difficulties with fall-

(29.8) were similar to those found in the present (21.14) and other studies (Kloostra et al. 2015; Ramakers et al. 2015). Andersson et al. (2009) found significant associations between THI score and HADS anxiety (Pearson product-moment correlation of .57) and depression scores (.54), and between HADS anxiety and depression scores (.58). The Pearson correlation analysis on the present data has also suggested significant, albeit slightly weaker correlations between THI and HADS anxiety (.42) and depression scores (.41), and similar correlation between HADS anxiety and depression scores (.59). However, the results of the present study suggested there was no significant effect of clinical anxiety on the perceived tinnitus-related handicap in CI users with tinnitus which may have been connected with the fact that the multivariable regression model estimated the marginal effects of all symptoms on tinnitus.

The current model of associations between clinical symp-
toms and tinnitus-related handicap suggests that clinical anxiety may not be a significant contributor to the tinnitus handicap after controlling for clinical insomnia, and thus the increased anxiety in CI users with tinnitus may be driven by the elevated insomnia symptoms. Significant interactions between clinical insomnia and anxiety support this observation. However, the effect of clinical insomnia on tinnitus handicap varied based on the clinical depression levels suggesting that the impact of tinnitus and related insomnia should be monitored together with psychological disorders that CI recipients might experience (Brüggemann et al. 2017).

The exploratory analysis of ISI questionnaire responses showed that, on average, CI users with tinnitus experience a greater interference of their sleep problems with their daily functioning. The combination of greater difficulties with falling asleep and greater interference with daily activities suggests that these patients may be more susceptible to developing an insomnia disorder (American Psychiatric Association 2013). Reported insomnia symptoms also appeared to be significant enough to contribute to the greater dissatisfaction with their sleep patterns, and the perception that their sleep problems were having an impact on their quality of life that was noticeable to others. Taken together, the present findings are consistent with the observations that difficulties with sleep are the major tinnitus-related complaint reported by both tinnitus patients and their significant others (Hall et al. 2018a), and have the potential to negatively impact quality of life, physical health, and daily activities (Bolge et al. 2009).

**Implications for Future Studies**

Information about the presence of anxiety, depression, and insomnia symptoms before implantation was not available in the present study, and it is not clear whether these symptoms changed as a result of undergoing cochlear implantation or affected the perceived tinnitus outcomes. Further prospective studies are needed to investigate the mechanisms and factors behind the causes of abnormal clinical symptoms, and such studies should investigate insomnia, anxiety, and depression symptoms to adequately characterize and assess the clinical importance of any residual tinnitus-related symptoms after cochlear implantation.

Despite the potential impact of tinnitus on sleep due to CIs being typically switched off at night time (Chadha et al. 2009), and known contribution of insomnia symptoms to poorer quality of life (Bolge et al. 2009), the number of studies reporting effects of cochlear implantation on tinnitus-related difficulties with sleep is limited (Di Nardo et al. 2007; Brüggemann et al. 2017). Recent efforts to standardize the reporting of results from clinical trials of tinnitus interventions have identified sleep quality as one of a set of core outcomes that should be measured when evaluating the effects of sound-based interventions for tinnitus (Hall et al. 2018b, 2019). The present findings support the inclusion of sleep-related measures in evaluations of the effectiveness of cochlear implantation for the alleviation of tinnitus and in studies seeking to predict tinnitus outcomes following cochlear implantation.

**Implications for Clinical Management**

It is not known whether and how many CI users access healthcare services to manage their sleep difficulties and insomnia, but the present results suggest that CI users with tinnitus might benefit from the management of insomnia symptoms. Previous studies have suggested that evidence of the presence of psychological disorders, including those of anxiety and depression, among cochlear implantation candidates and CI recipients with tinnitus, is sufficient to justify monitoring psychological symptoms in these patient groups and including the management of those symptoms in the routine care pathway (Andersson et al. 2009; Olze et al. 2011; Kloostra et al. 2015; Brüggemann et al. 2017). Clinically abnormal insomnia identified by the current study highlights the importance of also screening for insomnia symptoms, both to assess their clinical impact and to inform the ongoing management of CI users with tinnitus (Miguel et al. 2014; Assnis et al. 2018).

There is robust evidence available suggesting that specific types of cognitive behavioral therapy (CBT) can be effective in treating tinnitus and insomnia (for a review see McKenna & Daniel 2006; Martinez-Devesa et al. 2010; Cima et al. 2012; Geiger-Brown et al. 2015), as well as anxiety and depression disorders (Twomey et al. 2015; Carpenter et al. 2018). Current trials suggest that CBT is an effective intervention for the management of tinnitus-related insomnia (Andersson et al. 2005; Jasper et al. 2014; Weise et al. 2016; Beukes et al. 2017; Marks et al. 2019). However, it is not clear whether CI users would be willing to undergo new therapies to treat their tinnitus-related sleep problems in addition to the therapies they may already receive to manage any adverse effects associated with their
profound hearing loss. However, it is possible that a specific form of CBT could be devised for use in patients who find their tinnitus and related symptoms particularly bothersome (Anderson et al. 2009), particularly where such a therapy could alleviate more than one factor contributing to tinnitus-related handicap, for example, clinically abnormal depression and insomnia symptoms.

The potential benefits of electrical stimulation with a CI on sleep throughout the night have been explored previously (Velluti et al. 2010). However, the present results suggest that difficulties in falling asleep are the main contributor to clinical insomnia in CI users with tinnitus. Therefore, a potentially simple management option might be to advise these patients to use their CI when trying to fall asleep to promote tinnitus suppression. However, two related practical aspects may require further consideration. First, nearly all of our participants (95%) reported that they do not use their CIs at night time, mainly because they were advised to take their CI off before going to sleep or were not aware that CI use might help with their sleep. The small proportion of those who used their CIs at night reported doing so occasionally and primarily to be able to hear during night (e.g., their children and partners, or alarms), but only in some instances to alleviate their tinnitus and address difficulties with sleep. While these observations suggest that there may be potential benefits from night time CI use in some patients, further research is needed to develop specific guidance for patients and clinicians on how to best support such use while avoiding discomfort or damage to the device, and to evaluate the effect of night time use on tinnitus-related insomnia and quality of life. Second, previous studies have shown that residual inhibition of tinnitus is also possible in individual CI users (Osaki et al. 2005; Chang & Zeng 2012; Arts et al. 2015), and perhaps it could support the management of tinnitus at the point they are trying to fall asleep. However, systematic studies of residual inhibition following CI stimulation are needed to identify the patient groups in whom it would be possible to elicit reliably, the factors responsible for supporting sustained inhibition and ultimately whether it would be effective in managing the patient’s tinnitus and related difficulties with sleep.

ACKNOWLEDGMENTS

The authors would like to thank the patients for their time and willingness to take part in the study. The authors would also like to thank Tracey Twomey and Susan Johnson, and the staff of Nottingham Auditory Implant Programme for their support with conducting the study. The authors would also like to thank Derek Hoare and Kathryn Fackrell for helpful discussions on the choice of tinnitus assessments and their interpretation.

This project was supported by a grant from the Nottingham Hospitals Charity and the infrastructure funding from the National Institute for Health Research. This paper presents independent research funded by the National Institute for Health Research (NIHR). The views expressed are those of the author(s) and not necessarily those of the NHS, the NIHR or the Department of Health and Social Care. P.T.K.’s institution has received research grants from a manufacturer of cochlear implants, Cochlear Europe Ltd. R.H.P. received a travel grant from a manufacturer of cochlear implants, Oticon Medical. The authors have no conflicts of interest to disclose.

Address for correspondence: Robert H. Pierzycki, NIHR Nottingham Biomedical Research Centre, Ropewalk House, 113 The Ropewalk, Nottingham NG1 5DU, UK. E-mail: robert.pierzycki@nottingham.ac.uk

Received July 25, 2019; accepted April 28, 2020.

REFERENCES

American Psychiatric Association. (2013). Diagnostic and Statistical Manual of Mental Disorders: DSM-5. (5th ed.). Arlington, VA: American Psychiatric Association.

Amoody, H. A., Mick, P. T., Shipp, D. B., Friesen, L. M., Nedzelski, J. M., Chen, J. M. & Lin, V. Y. Y. (2011). The effects of unilateral cochlear implantation on the tinnitus handicap inventory and the influence on quality of life. Laryngoscope, 121, 1536–1540.

Andersson, G., Freijad, A., Baguley, D. M., & Idrizbegovic, E. (2009). Tinnitus distress, anxiety, depression, and hearing problems among cochlear implant patients with tinnitus. J Am Acad Audiol, 20, 315–319.

Andersson, G., Porsaeus, D., Wiklund, M., Kaldö, V., & Larsen, H. C. (2005). Treatment of tinnitus in the elderly: A controlled trial of cognitive behavior therapy. Int J Audiol, 44, 671–675.

Arts, R. A., George, E. L., Chenuault, M. N., & Stokroos, R. J. (2015). Optimizing intracochlear electrical stimulation to suppress tinnitus. Ear Hear, 36, 125–135.

Asnis, G. M., Majeed, K., Henderson, M. A., Sylvester, C., Thomas, M., & De La Garza, R. I. (2018). An examination of the relationship between insomnia and tinnitus: A review and recommendations. Clin Med Insights: Psychiatry, 9, 177957318781078.

Baguley, D. M., & Andersson, G. (2003). Factor analysis of the Tinnitus Handicap Inventory. Am J Audiol, 12, 31–34.

Baguley, D. M., & Atlas, M. D. (2007). Cochlear implants and tinnitus. Prog Brain Res, 166, 347–355.

Bastien, C. H., Vallières, A., & Morin, C. M. (2001). Validation of the Insomnia Severity Index as an outcome measure for insomnia research. Sleep Med, 2, 297–307.

Beekes, E. W., Allen, P. M., Manchaiah, V., Baguley, D. M., & Andersson, G. (2017). Internet-based intervention for tinnitus: Outcome of a single-group open trial. J Am Acad Audiol, 28, 340–351.

Bolge, S. C., Doan, J. F., Kannan, H., & Baran, R. W. (2009). Association of insomnia with quality of life, work productivity, and activity impairment. Qual Life Res, 18, 415–422.

Brüggemann, P., Szczepczek, A. J., Klee, K., Gräbel, S., Mazurek, B., & Olze, H. (2017). In patients undergoing cochlear implantation, psychological burden affects tinnitus and the overall outcome of auditory rehabilitation. Front Hum Neurosci, 11, 226.

Carpenter, J. K., Andrews, L. A., Witschaft, S. M., Powers, M. B., Smits, J. A. J., & Hofmann, S. G. (2018). Cognitive behavioral therapy for anxiety and related disorders: A meta-analysis of randomized placebo-controlled trials. Depress Anxiety, 35, 502–514.

Chadha, N. K., Gordon, K. A., James, A. L., & Papsin, B. C. (2009). Tinnitus is prevalent in children with cochlear implants. Int J Pediatr Otalaryngol, 73, 671–675.

Chang, J. E., & Zeng, F. G. (2012). Tinnitus suppression by electric stimulation of the auditory nerve. Front Syst Neurosci, 6, 19.

Cima, R. F., Maes, I. H., Joore, M. A., Scheyen, D. J. W. M., Refaie, A. E., Baguley, D. M., Anteunis, L. J. C., van Breukelen, G. J. P., & Vlaeyen, J. W. S. (2012). Specialised treatment based on cognitive behaviour therapy versus usual care for tinnitus: A randomised controlled trial. Lancet, 379, 1951–1959.

Crönlein, T., Langguth, B., Geisler, P., & Hajak, G. (2007). Tinnitus and insomnia. Prog Brain Res, 166, 227–233.

Crönlein, T., Langguth, B., Pregler, M., Kreuzer, P. M., Wetter, T. C., & Schecklmann, M. (2016). Insomnia in patients with chronic tinnitus: Cognitive and emotional distress as moderator variables. J Psychosom Res, 83, 65–68.

Di Nardo, W., Cantore, I., Cianfrone, F., Melillo, P., Scorpeacci, A., & Puludetti, G. (2007). Tinnitus modifications after cochlear implantation. Eur Arch Otorhinolaryngol, 264, 1145–1149.

Gagnon, C., Belanger, L., Ivers, H., & Morin, C. M. (2013). Validation of the insomnia severity index in primary care. J Am Board Fam Med, 26, 701–710.

Geiger-Brown, J. M., Rogers, V. E., Liu, W., Ludeman, E. M., Downton, K. D., & Diaz-Abad, M. (2015). Cognitive behavioral therapy in persons with comorbid insomnia: A meta-analysis. Sleep Med Rev, 23, 54–67.

Hall, D. A., Fackrell, K., Li, A. B., Thavayogan, R., Smith, S., Kennedy, V., Tinoco, C., Rodrigues, E. D., Campello, P., Martins, T. D., Lourenço, V. M., Ribeiro, D., & Haider, H. F. (2018a). A narrative synthesis of research evidence for tinnitus-related complaints as reported by patients and their significant others. Health Qual Life Outcomes, 16, 61.

Copyright © 2020 Wolters Kluwer Health, Inc. Unauthorized reproduction of this article is prohibited.
Hall, D. A., Hibbert, A., Smith, H., Haider, H. F., Londero, A., Mazurek, B., & Fackrell, K.; Core Outcome Measures in Tinnitus (COMiT) initiative. (2019). One size does not fit all: Developing common standards for outcomes in early-phase clinical trials of sound-, psychology-, and pharmacology-based interventions for chronic subjective tinnitus in adults. Trends Hear, 23, 2331216518824827.

Hall, D. A., Mohamm, N., Firkins, L., Fenton, M., & Stockdale, D. (2013). Identifying and prioritizing unmet research questions for people with tinnitus: The James Lind Alliance Tinnitus Priority Setting Partnership. Clin Invest, 3, 21–28.

Hall, D. A., Smith, H., Hibbert, A., Colley, V., Haider, H. F., Horobin, A., Londero, A., Mazurek, B., Thacker, B., & Fackrell, K.; Core Outcome Measures in Tinnitus (COMiT) initiative. (2018b). The COMiT ID study: Developing core outcome domains sets for clinical trials of sound-, psychology-, and pharmacology-based interventions for chronic subjective tinnitus in adults. Trends Hear, 22, 2331216518814384.

Hoare, D. J., Gander, P. E., Collins, L., Smith, S., & Hall, D. A. (2012). Management of tinnitus in English NHS audiology departments: An evaluation of current practice. J Eval Clin Pract, 18, 326–334.

Jasper, K., Weise, C., Conrad, I., Andersson, G., Hiller, W., & Kleinstäuber, M. (2014). Internet-based guided self-help versus group cognitive behavioral therapy for chronic tinnitus: A randomized controlled trial. Psychother Psychosom, 83, 234–246.

Kloostra, F. J., Arnold, R., Hofman, R., & Van Dijk, P. (2015). Changes in tinnitus after cochlear implantation and its relation with psychological functioning. Audiol Neurootol, 20, 81–89.

Koning, H. M. (2019). Sleep disturbances associated with tinnitus: Reduce the maximal intensity of tinnitus. Int Tinnitus J, 23, 64–68.

Kuk, F. K., Tyler, R. S., Russell, D., & Jordan, H. (1990). The psychometric properties of a tinnitus handicap questionnaire. Ear Hear, 11, 434–445.

Langhurst, B. (2011). A review of tinnitus symptoms beyond “ringing in the ears”: A call to action. Curr Med Res Opin, 27, 1635–1643.

LeBlanc, M., Mérette, C., Savard, J., Ivers, H., Baillargeon, L., & Morin, C. (2011). A review of tinnitus symptoms beyond “ringing in the ears”: A call to action. Curr Med Res Opin, 27, 1635–1643.

Langhurst, B. (2011). A review of tinnitus symptoms beyond “ringing in the ears”: A call to action. Curr Med Res Opin, 27, 1635–1643.

LeBlanc, M., Mérette, C., Savard, J., Ivers, H., Baillargeon, L., & Morin, C. (2011). A review of tinnitus symptoms beyond “ringing in the ears”: A call to action. Curr Med Res Opin, 27, 1635–1643.

Miguel, G. S., yaremchuk, K., Roth, T., & Peterson, E. (2014). The effect of cognitive behavioural therapy for anxiety and depression in primary care: A meta-analysis. Fam Pract, 32, 3–15.

Tyler, R. S. (1994). Advantages of disadvantages expected and reported by cochlear implant patients. Am J Audiol, 3, 153–160.

Zeng, F. G., Tang, Q., Dimitrijevic, A., Starr, A., Larky, J., & BLEVINS, N. H. (2011). Tinnitus suppression by low-rate electric stimulation and its electrophysiological mechanisms. Hear Res, 277, 61–66.

Zenner, H. P., Delb, W., Kröner-Herwig, B., Jäger, B., Ruehl, L., Biesinger, E., Seidler, H., & Langguth, B. (2017). A multidisciplinary systematic review of the treatment for chronic idiopathic tinnitus. Eur Arch Otorhino- laryngol, 274, 2079–2091.

Zigmond, A. S., & Snaith, R. P. (1983). The Hospital Anxiety and Depression Scale. Acta Psychiatr Scand, 67, 361–370.