THE EFFECT OF TINNITUS ON HEALTH-RELATED QUALITY OF LIFE OUTCOMES IN ADULT COCHLEAR IMPLANT RECIPIENTS

by

ELMIEN OPPERMAN

A dissertation submitted in fulfilment of the requirement for the degree

MA AUDIOLOGY

In the Department of Speech-Language Pathology and Audiology

FACULTY OF HUMANITIES
UNIVERSITY OF PRETORIA

SUPERVISOR:
Dr Talita le Roux

CO SUPERVISOR:
Prof Robert H. Eikelboom

February 2020

Elmien Opperman
Department of Speech-Language Pathology and Audiology
University of Pretoria
Pretoria
South Africa

elmieno@vodamail.co.za

ACKNOWLEDGEMENTS

Eph. 2:10 “For we are his workmanship, created in Christ Jesus for good works, which God prepared beforehand, that we should walk in them.” All the glory to my heavenly Father for the privilege and opportunity to attempt this work and through Whose grace it could be completed. **Php. 4:13** “I can do all things through Christ who gives me strength.”

To Dr. le Roux: My supervisor, mentor and ‘sane keeper’ during this process. Thank you for your very ‘human’ approach to this work and for your general regard of life happening outside of academics. Thank your believing in me and encouraging me to step outside of my comfort zone. It has been a privilege to learn from and work under your guidance for the past two years. The time, effort and expertise that you put into this project is much appreciated.

To Prof. Eikelboom: It has been a privilege to have you as a supervisor and to work under your expert guidance. Thank you for your invaluable advice, time and effort, amidst a very busy schedule, that went into this work.

To Mr. Andries Masenge: Thank you for being a statistical hero. Your patient and thorough explanation of, at first, very foreign terms has moulded the information yielded by this study into so much more than just numbers. Thank you for always being willing to help and for never shying away from last minute stats runs. Your time and input is greatly appreciated.

To ESIA: A sincere thank you to the Ear Science Institute Australia for making this study possible. Your diligent collection of data and gracious willingness to share this, allowed for this study to happen. Your input and collaboration are acknowledged and appreciated.

To my parents and sister: Thank you for being a constant source of support, encouragement and love during this entire process. Thank you for being the compass that subtly guides me, my inspiration to reach great heights and my comfort when I occasionally falter. I am abundantly blessed with you. Mom and Dad, without you this would not have been possible. I cannot thank you enough for allowing me the privilege of this opportunity and for constantly praying for and believing in me to see it through. Karli, thank you for being the best friend that I didn’t have to choose. I am so thankful for every sisterly moment of encouragement, understanding and much needed laughter.

To truly amazing friends: A sincere thank you to trusted old friends and surprising new friends for each of your timely encouragement, distraction, support, love and light. Your footprints are etched in so many life paths journeyed together and I am thankful for this one to be added to the list. Your presence and friendship are forever cherished.

CONTENTS

LIST OF TABLES

LIST OF FIGURES

RESEARCH OUTPUTS

Parts of this thesis have been presented at the following conferences:

1. Opperman, E., Le Roux, T., Eikelboom, R.H., The effect of tinnitus on health-related quality of life outcomes in adult cochlear implant recipients. Presented at *6th Humanities Postgraduate Conference*, University of Pretoria, Pretoria (October 2018)

2. Opperman, E., Le Roux, T., Eikelboom, R.H., The effect of tinnitus on health-related quality of life outcomes in adult cochlear implant recipients. Presented at *34th World Congress of Audiology*, Cape Town International Convention Centre, Cape Town (October 2018)

3. Opperman, E., Le Roux, T., Eikelboom, R.H., The effect of tinnitus on health-related quality of life outcomes in adult cochlear implant recipients. Presented at *4th World Congress on Cochlear Implants in Emerging Countries*, Cape Town International Convention Centre, Cape Town (November 2018)

4. Opperman, E., Le Roux, T., Eikelboom, R.H., The effect of tinnitus on health-related quality of life outcomes in adult cochlear implant recipients. Presented at *Speech-Language and Audiology research day*, University of Pretoria, Pretoria (August 2019)

ABSTRACT

The objective of this study was to describe the influence of tinnitus distress on quality of life (QoL) outcomes in adult cochlear implant (CI) recipients who experience tinnitus, and to investigate the prognostic significance of tinnitus distress over time.

A retrospective, longitudinal study of 210 adult (≥18 years) CI recipients implanted between 2001 and 2017 was conducted. Data on hearing-related QoL, using the *Abbreviated Profile of Hearing Aid Benefit* (APHAB) and tinnitus distress, using the *Tinnitus Reaction Questionnaire* (TRQ) were captured preoperatively as well as at 6-months, 12-months and >24-month postoperatively. The effect of tinnitus distress on hearing-related QoL outcomes over time was determined. Furthermore, 13 potential predictive factors were identified from the retrospective dataset, including demographic, hearing loss, CI, speech perception and tinnitus related factors. Multiple regression analyses were performed to identify variables that influence hearing-related QoL outcomes over time.

Lower tinnitus distress and younger age at implantation were the only two out of 13 possible predictor variables that were identified as significant predictors of better hearing-related QoL in adult CI recipients. A general trend of statistically significant ($p<0.01$) tinnitus relief was evident from the preoperative interval to the 6-months, 12-months and >24-months postoperative intervals, confirming significant relief in tinnitus distress up to more than two years post-implantation. Within this dataset, higher levels of tinnitus distress were associated with poorer hearing-related QoL outcomes, as confirmed by the negative correlation between tinnitus distress and hearing-related QoL.

This study contributes to a better understanding of the complex influence that multifactorial variables has upon the hearing-related QoL outcomes of adult CI recipients. This enables clinicians to provide evidence-based preoperative counselling combined with postoperative rehabilitation to adult CI recipients and their families. Not only was tinnitus distress confirmed as a predictive factor for hearing-related QoL in this study, but also the association between residual tinnitus distress and hearing-related QoL. These results emphasize the importance of identification, counselling and timely monitoring of adult CI recipients who experience tinnitus.

KEY WORDS

Adult cochlear implantation

Cochlear implant

Quality of life

Tinnitus

Tinnitus distress

ABBREVIATIONS

APHAB: Abbreviated Profile of Hearing Aid Benefit

TRQ: Tinnitus Reaction Questionnaire

ESIA: Ear Science Institute Australia

THI: Tinnitus Handicap Inventory

TQ: Tinnitus Questionnaire

HIU3: Health Utility Index

SF36: Short-Form Health Survey

QoL: Quality of Life

CI: Cochlear Implant

HL: Hearing Loss

CHAPTER 1

INTRODUCTION

1.1 Background

Tinnitus can be defined as a sound sensation in the head or ears in the absence of an external stimulus (Searchfield, 2014). Alternatively tinnitus is also described as an auditory phantom perception of sound, which resembles ringing, roaring, buzzing, hissing, humming, whistling or cricket-like sounds typically in the frequency range of 6-8kHz (Henry et al., 2008; Reavis et al., 2012; Sedley et al., 2016).

Multiple theories on the tinnitus mechanism have been considered in research, but due to its heterogeneous nature, the complex mechanism of tinnitus cannot be adequately explained by any particular hypothesis (Chung & Lee, 2016). Tinnitus is seen as a symptom rather than a disease entity and can therefore be prescribed to a variety of underlying conditions (Han, Lee, Kim, Lim, & Shin, 2009). Noise induced hearing loss is the most common cause of tinnitus (Van de Heyning, Gilles, Rabau, & Van Rompaey, 2015), but outer hair cell degeneration within the auditory peripheral system, auditory plasticity, increased excitation of central auditory structures within the auditory pathway, together with the limbic and somatosensory automatic nervous system are all involved in the pathogenesis of tinnitus (Chung & Lee, 2016). At present there is no definite cure for tinnitus due to the poorly understood pathophysiology of tinnitus (Aazh, Landgrebe, Danesh, & Moore, 2019). The negative effect of tinnitus on many aspects of a patient’s everyday life, including hearing, concentration, emotions and sleep, can successfully be treated with medication (Elgandy et al., 2018). However, the treatment of tinnitus itself is a different scenario. For the greater majority of cases, no surgery or medication have been approved and treatment consequently comes down to patient centred counselling strategies (Elgandy et al., 2018). Tinnitus specific care can be divided into information (understanding tinnitus), talking therapies (different individual counselling options), sound (external sound, hearing aids and implantable devices) and group support (Pryce et al., 2018).

Tinnitus is prevalent in approximately 70-90% of adults with hearing loss (Olze et al, 2011). In adult cochlear implant (CI) recipients, preoperative tinnitus prevalence range from 67%-100%, with a median of 80% (Baguley & Atlas, 2007). Four in five patients with severe to profound sensorineural hearing loss who were implanted, report tinnitus preoperatively (Baguley & Atlas, 2007). This association between tinnitus and hearing loss seems to increase the perceived severity of the tinnitus symptom (Savastano, 2008; Searchfield, 2014). When the brain is being deprived of auditory input, brain pathway reorganization often leads to the adaption of the function and structures of the auditory pathways resulting in an increased awareness of tinnitus (Del Bo & Ambrosetti, 2007). Many individuals experience tinnitus but are not bothered by their perceived tinnitus and subsequently do not seek medical help, whereas for other patients it can cause debilitating problems such as insomnia, frustration, depression and anxiety which has an impact on quality of life (QoL) (McCormack et al., 2016; Nondhal et al., 2007). In a recent systematic review it was indicated that 3% to 30.9% of individuals who experience tinnitus, report their tinnitus to be bothersome (McCormack et al., 2016). Tinnitus tends to be perceived as bothersome when it interferes with concentration, prevents or hinders sleep, makes it difficult to hear conversational speech and decreases social enjoyment (Bauer, 2018). For those individuals who perceive tinnitus as bothersome, the perception of the tinnitus sound is very disturbing because of maladaptive psychological responses (Cima, 2018). Discrepancies within how bothersome tinnitus is perceived as by an individual, can be ascribed to the individual's attention to tinnitus (Bauer, 2018). Furthermore the level of tinnitus annoyance is significantly associated with tinnitus loudness (Hashir & Richard, 2018) as well as existing depressive symptoms within the individual (Aazh et al., 2019). The way in which tinnitus is perceived and interpreted is confined to an individual's subjective perceptual and emotional experience (Cima, 2018). Tinnitus was listed as one of the 60 minor complaints described by adult CI recipients after CI surgery (Farinetti et al., 2014) and the impact of tinnitus was rated as the top-ranking concern for 28% of adult CI recipients following CI surgery (Gomersall et al., 2019).

Only a limited number of studies conducted in recent years investigated possible factors that relate to changes in the perception of tinnitus post CI (Ramakers et al., 2018). More extensive knowledge on the probability of a change in perceived tinnitus post CI will positively affect both the diagnosis and prognosis (Collins et al., 2015). This broadened knowledge will lead to more accurate referral and treatment commencement decisions within the diagnostic setting, while the planning of long-term lifestyle and therapeutic decisions of the prognostic setting will also be improved (Collins et al., 2015).

1.2 Suppressive effects of cochlear implantation on tinnitus

The use of amplification to suppress tinnitus has become a widespread tinnitus management tool since the late 1970's, which led to various studies exploring the link between cochlear implantation and tinnitus (Baguley & Atlas., 2007; Brüggemann et al., 2017; Knopke et al., 2017; Ramos-Marcías et al., 2018; Vesterager., 1997). Even though cochlear implantation is primarily performed in order to manage severe-profound hearing loss, tinnitus suppression is experienced as a beneficial secondary effect by 25%-72% of CI recipients (Baguley & Atlas., 2007; Quaranta et al., 2004; Ramakers et al., 2015; Knopke et al., 2017; Olze et al., 2016; Knopke et al., 2016). Also, it has been confirmed that cochlear implantation has a positive effect on the annoyance level, intensity and duration of tinnitus (Miyamoto & Bichey, 2003).

Uncertainty still exists about the exact mechanism underlying the suppressive effect of cochlear implantation on tinnitus (Olze et al., 2011). Electrical stimulation of the auditory nerve and acoustic masking are explored as possible explanations for this suppressive effect by various authors (Olze et al., 2011; Baguley & Atlas., 2007; Summerfield & Marshall., 1995; Mo et al., 2005). A recent study suggested three possible scenarios explaining the mechanism which associates tinnitus suppression with cochlear implantation (Knopke et al., 2017). Firstly, following implantation, the auditory improvement that is perceived, allows for the CI recipient to focus on sounds other than tinnitus. Secondly, the improvement in the QoL of a CI recipient after implantation leads to an overall stress decrease, which also positively affects the tinnitus stress loop. Thirdly, the electrical stimulation of the auditory nerve after cochlear implantation brings about plastic changes in the auditory system that reduce the perception of tinnitus. Irrespective, further evidence is needed to determine if and how the mentioned scenarios contribute to the reduction of tinnitus (Knopke et al., 2017).

There are three possible outcomes when considering the effect of a CI upon tinnitus. The first is for tinnitus to reduce after cochlear implantation, secondly it is possible for no significant change in tinnitus to be noticed and lastly there is a risk for newly induced tinnitus or for the worsening of existing tinnitus after cochlear implantation (Quaranta et al., 2004). It is of utmost importance that CI candidates should have a thorough understanding of the effect of cochlear implantation on tinnitus prior to implantation and all possible tinnitus outcomes should therefore be transparently included in the informed consent (Quaranta et al., 2004; Bovo et al., 2011). Insufficient attention is often paid to those cases in which tinnitus worsened after cochlear implantation (Tyler et al., 2009). In a study by Tyler et al. (2009), 11 of 91 (12%) patients who did not report tinnitus preoperatively developed tinnitus as a result of cochlear implantation. In a systematic review of 18 studies published between 1990 and 2006, only four studies reported on the prevalence of worsening or initiated tinnitus post-implantation (Hazell, McKinney, & Aleksy, 1995; Kou, Shipp, & Nedzelski, 1994; Miyamoto, Wynne, McKnight, & Bichey, 1997; R S Tyler & Kelsy, 1990). Using the *Tinnitus Handicap Inventory (THI)*, Bovo et al. (2011) reported that in a sample of 36 adult CI recipients who experienced tinnitus prior to cochlear implantation, 78% reported either tinnitus loudness reduction or total loudness suppression after implantation. In addition, a reduction in tinnitus annoyance scores was indicated for 75% of these CI recipients (Bovo, Ciorba, & Martini, 2011). Olze et al. (2011) used the *Tinnitus Questionnaire (TQ)* to confirm that the number of patients considered having high level tinnitus prior to cochlear implantation decreased from 23% to 13% after implantation, while the overall TQ score of 64% of patients showed a significant reduction after implantation, indicating a relief in tinnitus. In addition, out of the sample of 39 adult CI patients who reported tinnitus before cochlear implantation, 22 reported a decrease in tinnitus after implantation, while three CI recipients experienced that their tinnitus completely disappeared and 14 CI recipients reported that their tinnitus was unaffected (Olze, et al., 2011). In a follow-up study, Olze et al. (2012) investigated the influence of a second CI on the severity of tinnitus and results indicated that tinnitus severity decreased after the initial CI and decreased even more after the second CI. Furthermore, the number of CI recipients experiencing tinnitus prior to implantation decreased from 28 to 22 after the initial CI with an even further decrease to 17 subsequent to the second CI (Olze, Szczepek., et al. 2012). Knopke et al. (2017) also used the *TQ* to explore the effect of a CI on tinnitus over time. In their study a significant decrease in the TQ score was evident, indicating tinnitus relief already six months post-implantation with this level of tinnitus suppression continuing for the complete duration of the 24-month follow-up period (Knopke et al., 2017). Moreover, the total number of patients who experienced severe tinnitus prior to CI systematically lessened over time, resulting in a perceived decrease in tinnitus for seven patients at the 24 months post-implantation follow-up period (Knopke et al., 2017). Another longitudinal study on unilateral hearing loss confirmed a substantial improvement in tinnitus already 3 months after cochlear implantation which then stabilized with a constant tinnitus score at 6-, 12- and 36 months after the fitting (Mertens et al., 2016). In addition, a recent study also supported the suppressive effect of cochlear implantation on tinnitus by confirming a significant reduction in average tinnitus related distress scores after cochlear implantation (Brüggemann et al., 2017). The reduction of this score implies that cochlear implantation has a noteworthy effect on the hearing problems, sleep disorders, emotional burden and psychosomatic complaints that are associated with tinnitus (Brüggemann et al., 2017). More than half of the participants with single sided deafness testified to tinnitus suppression being the primary benefit perceived after their CI (Merten et al., 2016; Ramos-Marcías et al., 2018).

1.3 The influence of tinnitus on quality of life

A number of studies confirmed that cochlear implantation does not only provide the benefit of improved hearing abilities for CI recipients, but that it also leads to the improvement of

QoL (Knopke et al., 2017; Olze et al., 2011; Olze et al., 2016, 2012; Knopke et al., 2016). Patients who live with a hearing loss experience a level of psychological burden that is higher than that of the general normal hearing population (Brüggemann et al., 2017). Treating hearing loss with a CI leads to a significant increase in the QoL of these CI recipients (Contrera et al., 2016).

A number of generic and disease specific QoL questionnaires has been used throughout literature to assess changes in QoL brought on by a CI (Loeffler et al., 2010). For CI recipients, health-related QoL can be defined as a multi-dimensional concept used to symbolize the comprehensive effect that cochlear implantation has on the self-esteem, social life and everyday activities of the CI recipient (Loeffler et al., 2010). Disease specific QoL outcomes however represents a patient’s perception on a specific health problem (Loeffler et al., 2010). Since disease specific QoL outcome measures are strictly relevant to a particular disease, hearing-related QoL outcome measures, for example, specifically report the effect of a hearing impairment on the daily activities and lifestyle of the patient (Loeffler et al., 2010). Whether health-related QoL or more disease specific hearing-related QoL, the term QoL is linked to the emotional, social and physical well-being of individuals, including their ability to function in the ordinary tasks of living (Loeffler et al, 2010). Therefore, QoL has become a standard outcome measure to assess the impact that lasting hearing loss and its resultant management have on the personal well-being of CI recipients as well (Capretta & Moberly, 2016; King et al., 2014; Zaidman-Zait & Smith, 2010). Cochlear implantation does not only impact hearing and audiological outcomes like speech perception abilities, but also the broader spectrum of physical, social and emotional well-being (Loeffler et al., 2010). Hence, in addition to standard speech perception testing, QoL has become a widespread outcome measure to quantify and monitor CI outcomes.

A wide variety of factors have been identified to positively influence QoL outcomes in CI recipients, namely better speech understanding abilities (Sladen et al., 2017), shorter duration of deafness (Maillet et al., 1995; Hirschfelder et al., 2008), younger age at implantation (Chung et al., 2012; Farinetti et al., 2014), higher socio-economic status (Hawthorne et al, 2004), longer duration of CI use (Hirschfelder et al., 2008), bilateral implantation (Härkönen et al., 2015; le Roux et al., 2017) and attendance of mainstream schooling (le Roux et al., 2017). Only recently, an association between tinnitus and QoL outcomes in adult CI recipients has been confirmed (Knopke et al., 2016, 2017; Olze et al., 2016; Olze et al., 2011; Ramos-Marcías et al., 2018; Ramos et al., 2013; le Roux et al., 2017).

Evidence suggests that tinnitus may cause stress levels similar in severity to those of other chronic health problems, such as sleep apnoea with insomnia and chronic sinusitis (Chandra, Epstein, & Fishman, 2009; Malouff, Schutte, & Zucker, 2011). The neural activity associated with tinnitus related distress is similar to that of pain or depression and therefore tinnitus can be conceptualized as a chronic stressor (von Leupoldt et al., 2009; Malouff, Schutte, and Zucker, 2011; Mobascher et al., 2009). Brain imaging research revealed that, in the case of tinnitus, aberrant neural activity is observed in both central auditory pathways as well as non-auditory brain structures (Alonso-Valerdi et al., 2017). In the latter the involvement of the frontal lobe and limbic system, which are responsible for emotional and attentional regulation, are especially noticeable (Alonso-Valerdi et al., 2017). It seems that the brain is wired to decode a persistent loud noise, perceived as tinnitus, as a factor to be upset about

(Sanders, 2004). Patients who experience tinnitus are especially subject to mood disorders, anxiety and psychosomatic illnesses and clinicians acknowledge the fact that patients who experience the additional burden of psychological illnesses present with poorer QoL outcomes than those only handicapped by the physical (Brüggemann et al., 2017). In a study by Andersson et al. (2009) the perceived extent of tinnitus handicap was determined in 151 adult CI recipients by using three validated measures, including the *Tinnitus Handicap Inventory*, the *Hospital Anxiety and Depression Scale* and the *Gothenburg Profile.* These were utilized to measure the all-encompassing effects of tinnitus, anxiety and depression and hearing problems on each other (Andersson et al., 2009). Results indicated that an increase in anxiety, depression and hearing problems correlated with an increase in perceived tinnitus (Andersson, Freijd, Baguley, & Idrizbegoviz, 2009). Tinnitus was also indicated as the primary cause of 25% of the anxiety, depression and hearing problems that persisted post-implantation (Andersson et al., 2009). Olze et al. (2011) indicated that adults who experience tinnitus before cochlear implantation display poor coping strategies with regards to living with their tinnitus after implantation, as well as signs of more significant depressive symptoms. Furthermore, the experience of residual tinnitus after implantation can be linked to higher levels of perceived stress, more prominent depressive symptoms and generalized anxiety (Andersson et al., 2009; Olz et al., 2012). Furthermore, Olze et al. (2011) indicated that a high level of tinnitus impairment was associated with lower health-related QoL scores before and after cochlear implantation and confirmed negative correlations between QoL and stress, depression and anxiety.

Even though pre- and post-implantation data on health-related QoL outcomes of patients with tinnitus is limited (Olze et al., 2011), evidence suggests that the health-related QoL of CI recipients is affected by tinnitus. Olze et al. (2011) specifically confirmed the association between tinnitus impairment and poorer health-related QoL. Le Roux et al. (2017) also confirmed that a history of tinnitus prior to cochlear implantation was strongly predictive of poorer health-related QoL outcomes in adult CI recipients. Similarly, a recent multicultural, longitudinal study reported that tinnitus prior to cochlear implantation was also indicated as a strong predictor of poorer QoL outcomes in adult CI recipients (Lenarz et al., 2017). A significant negative correlation was also found between tinnitus related distress and health-related QoL at both the 6- and 12-months post-implantation intervals in a recent study by Knopke et al. (2017), where the experience of tinnitus preoperatively was the main inclusion criteria for bilaterally deafened patients. This correlation suggests that the health-related QoL of CI recipients are negatively influenced by tinnitus related emotional and cognitive distress together with tinnitus related auditory difficulties (Knopke et al., 2017). It can be expected that tinnitus therapy post cochlear implantation would lead to a further decrease in tinnitus related distress followed by an increase in health-related QoL, based on the confirmed negative correlation between tinnitus and QoL (Knopke et al., 2017).

Taking into account the strong association between the symptoms of anxiety and depression and those of tinnitus, it is not unreasonable to conclude that tinnitus related distress symptoms can lead to a decrease in the perceived benefit of cochlear implantation (Brüggemann et al., 2017). The significance of tinnitus as a hindrance in the auditory rehabilitation of CI recipients should therefore not be underestimated (Knopke et al., 2017).

1.4 Problem statement

A wide variety of individual and interacting factors influence the level of benefit that any particular CI recipient experience and result in a large variability of outcomes. Therefore, the ability to predict outcomes for individual CI candidates will arise from an increased knowledge of the causes of this variation (Brüggemann et al., 2017). Available evidence suggests that the effects of tinnitus negatively influence QoL and can even counterbalance the positive effects of cochlear implantation (Brüggemann et al., 2017; Olze et al., 2016; Knopke et al., 2016; Olze et a.l, 2011; le Roux et al., 2017; Summerfield et al., 2006; Ramos et al., 2013; Lenarz et al., 2017; Knopke et al., 2017). Therefore, the significance of tinnitus as a predictive factor for QoL outcomes in CI recipients should be investigated. What also needs further exploration is the lasting effect of tinnitus on QoL outcomes over time as well as the sustainability of the supressing effect of a CI on tinnitus and the effect thereof on QoL. This study therefore aimed to answer the research question: *What is the effect of tinnitus distress on the QoL outcomes in adult CI recipients over time?*

CHAPTER 2

METHODOLOGY

2.1 Research aim

The main aim of this study was to describe the influence of tinnitus distress on QoL outcomes in adult CI recipients who experience tinnitus, and to investigate the prognostic significance of tinnitus distress over time.

2.2 Research design

This study employed a descriptive research design, as there was no manipulation of the variables (Haynes & Johnson, 2009) and the researcher had no control over the variables (Kothari, 2004). The characteristics of an observed phenomenon was identified and described, without changing the situation under investigation (Leedy & Ormrod, 2010).

Since the variables of this study were measured in a numerical way, quantifying the subjective answers, as represented by the relevant outcome measures, a quantitative study design was followed (Leedy & Ormrod, 2010). The quantitative nature of the study design was also evident in the research being specific and the variables clearly defined and recognized (Kumar, 2014).

Furthermore, a longitudinal study design was followed, since the same variables were observed over an extended period of time (Babbie, 2016) in order to establish a relation pattern (Kumar, 2014). The fact that all the study participants were adult CI recipients deem this study a cohort study, as all of the participants formed a sub-group of the population with a common characteristic (Kumar, 2014). Within this specific sub-group, change over time was studied (Babbie, 2016).

Considering the reference period, this was a retrospective study as research was conducted on already available data (Kumar, 2014). Retrospective cohort studies typically recruit a specific group of participants and measure predictor variables from past data (Haynes & Johnson, 2009).

2.3 Ethical considerations

The current research was conducted within the framework of the *South African Guidelines for Good Practice in the Conduct of Clinical Trials with Human Participants in South Africa (2006)* and the *Ethics in Health Research: Principles, Structures and Processes (2004)* was adhered to during the course of this study. These guiding principles ensured acceptable conduct, protection of the rights and welfare of research participants and reflected basic ethical values concerning justice and participant respect (South African Medical Research Council, 2004). The individual principles presented in these documents are listed and discussed below as they were applied to the current research.

Table 2.1. Ethical principles applied to formulation of research design, participant selection and data collection and analysis procedures (South African Medical Research Council, 2004; South African National Health Act, 2007)

Guiding principle	**Application to research**
Respect and dignity: One of the primary concerns in health research involving human participants is the respect for dignity, safety and wellbeing of the participants.	The retrospective nature of the research ensured that there was no active participation and therefore exposure to unusual stress, expectations and loss of self-esteem related to the research process were avoided.
Informed consent: Persons on whom research is to be conducted have the right to be informed of the purpose of the research, methods and procedures to be followed or used during the research, potential or real harm and risks involved in participation and the extent to which confidentiality and privacy will be maintained.	Since this research followed a retrospective research design, no active participation was required from adult CI recipients. Prior to cochlear implantation, all adult CI recipients were requested to grant consent that their de-identified data may be used for quality control and research purposes without renewed consent being obtained for each research project (Appendix A). Consequently, each participant's right to privacy was protected at all times by treating data with strict confidentiality. The manager of the participating CI program signed a letter of consent, stating that permission was given that the specific data required for the purpose of this research anonymously be made available to the researcher (Appendix B).
Privacy and confidentiality: Both the research participant's right to privacy and confidentiality must be protected at all times. Privacy is concerned with personal record access while confidentiality refers to already disclosed personal information. The researcher must be sure that where personal information on a research participant is collected, stored, used or destroyed, this is done in ways that respect the privacy and confidentiality of the participants and any agreements made between the participants and the community.	Identifying information was excluded from the study and data was presented anonymously for the purpose of data-analysis. Participants were assigned an alphanumeric code which was used for data processing causing the participant identity to be unknown, even to the researcher, which ensured confidentiality and anonymity.

Inclusion and exclusion criteria: The inclusion, exclusion, selection and recruitment of research participants must be based on scientific principles. No person may be unjustly excluded on the basis of any form of discrimination.	The original mass of retrospective data was filtered to only include adult CI recipients who had preoperative hearing-related QoL outcome data available, as this was imperative to monitor the change in outcomes over time. For a smaller subset of data, the initial dataset was further filtered to exclusively include those participants who had both preoperative hearing-related QoL and tinnitus distress data available. Hence, the change of tinnitus distress as well as hearing-related QoL over time could have been compared and the possible interaction between these key variables could have been investigated. Irrespective, adult CI recipients from the complete range of demographical, educational and communication environments were included in these sifted groups.
Ethical clearance: Prior to the commencement of a study, approval should be obtained from the local research ethics committee. A researcher involved in research on human participants is obligated to submit research proposals to an accredited research ethics committee for approval.	Prior to the commencement of data collection, ethical clearance was obtained from *Research Ethics Committee of the Faculty of Humanities*, University of Pretoria (Appendix C). A plagiarism declaration (Appendix D) was signed by the researcher to confirm that the research was the original work of the researcher and that all possible attempts were made to avoid plagiarism.
Relevance: Research must be relevant to the broader health needs of the country as well as to the individual needs of those who suffer from the concerns and diseases that are studied.	The rational for this research was carefully considered in order to contribute to evidence-based pre- and postoperative service delivery to adult CI recipients and their families.
Release of findings Researchers are obligated to publicize research results, whether positive or negative in a competent and timely manner. All results that have scientific merit should be published in an ethical manner.	This research study was conducted with the aim to publish research findings in an international peer-reviewed journal. A research article was compiled and submitted the International Journal of Audiology (Appendix E). A research dissertation was compiled and will be made available online and in hard copy in the library of the University of Pretoria.
Storage of data	Upon the completion of the study, all relevant data will be stored in both hard and soft copy and will be archived at the Department of Speech-Language Pathology and Audiology, University of Pretoria for a period of fifteen years.

2.4 Participants

A retrospective dataset of 345 adult (≥18 years) CI recipients, implanted between 2001 and 2017 at the *Ear Science Institute Australia – Ear Science Clinic,* was reviewed for the purpose of this study. The final study sample consisted of 210 adult CI recipients who, according to the inclusion criteria, had preoperative *Tinnitus Reaction Questionnaire* (TRQ) and *Abbreviated Profile of Hearing Aid Benefit* (APHAB) scores available. A non-probability, convenience sampling technique was used to obtain participants for this study. Non-probability sampling is a sampling technique where the sample is gathered through a process that does not give the whole population equal chances of being included as participants (Etikan, 2016). Convenience sampling was used as this sampling method places more emphasis on generalizability by ensuring that the knowledge obtained from the participants is representative of the population from which the sample was drawn (Etikan, 2016). The quantitative nature of the research also served to support the convenience sampling technique choice (Etikan, 2016). Participants were recruited from the *Ear Science Institute Australia – Ear Science Clinic.*

The following inclusion criteria were specified for CI participants:

- Participants should be 18 years of age or older at the time of data collection at the *Ear Science Institute Australia – Ear Science Clinic*
- Participants should be cochlear implant recipients (unilaterally or bilaterally implanted) and receive CI programming and intervention services from the *Ear Science Institute Australia – Ear Science Clinic*

- Only adult CI recipients with available preoperative hearing-related QoL and tinnitus distress outcome data should be included

Demographic and clinical characteristics of the 210 adult CI recipients are described (Table 2.2).

Table 2.2. Characteristics of study population

Demographical characteristics	*% (n)*	*Clinical characteristics*	*% (n)*
Gender		Onset of hearing loss	
Male	49.5 (104/210)	Prelingual	18.1 (38/210)
Female	50.5 (106/210)	Postlingual	90.5 (172/210)
Chronological age at data interval (years)		Course of hearing loss onset	
3 months postoperatively (n=160)		Sudden	7.8 (16/206)
Mean (SD)	65.4 (14.2)	Progressive	92.23 (190/206)
Range	25.5 - 94.2		
		Balance concerns preoperatively	
12 months postoperatively (n=126)		Yes	30 (63/210)
Mean (SD)	66.3 (13.3)	No	70 (147/210)
Range	26.3 - 92.2		
		Duration of hearing loss prior to implant (years) (n=200)	
>24 months postoperatively (n=104)		Mean (SD)	30.4 (19.07)
Mean (SD)	67.9 (13.28)	Range	0.0 - 79.0
Range	27.7 - 92.3		
		First ear implanted	
		Left	49.5 (104/210)
		Right	50.5 (106/210)
		Age at (first) implant (years) (*n*=210)	
		Mean (SD)	62.9 (15.6)
		Range	20.6 - 93.8
		Bilateral implantation	
		12 months postoperatively	2.9 (6/210)
		>24 months postoperatively	15.2 (32/210)

2.5 Data collection tools

The retrospective dataset utilized in this study contained demographic, CI, hearing loss and tinnitus related data, as well as data from two validated questionnaires including the TRQ and the APHAB. During the reference period these questionnaires were routinely completed for all adult CI recipients preoperatively, as well as at 6-, 12- and >24-months postoperative intervals.

Demographic, CI and hearing loss related data are routinely captured on a database for all adult CI recipients from the Hearing Implants Clinic of the ESIA. Hence, data on the following variables were retrieved from the existing database and used for the purposes of this study: gender, chronological age, age at implant, etiology of hearing loss, onset of hearing loss, age at diagnosis of hearing loss/deafness, duration of deafness prior to CI, duration of CI use, age at CI and number of CI devices.

2.5.1 Tinnitus Reaction Questionnaire

The TRQ (Appendix F) is a 26-item questionnaire that was developed to measure the psychological distress associated with tinnitus (Wilson et al., 1991) and was classified among one of the most frequently used questionnaires for measuring tinnitus distress by a systematic review of 18 studies exploring the impact of tinnitus (Tegg-Quinn et al., 2016). The validity and reliability of the TRQ as a measurement tool for tinnitus severity has been established (Wilson et al., 1991). As indicated by Chronbach's alpha the TRQ has a high internal consistency of 0. 96 as well as a very good test-retest reliability of 0.88 (Wilson et al., 1991). Furthermore, the TRQ is also considered as a valid measuring tool for psychological distress related to tinnitus based on the evidence of its moderate to high correlations with anxiety and depression measures (Wilson et al., 1991). In this study, the TRQ was used as a subjective, self-report measure to assess the level of perceived distress experienced by adult CI recipients with tinnitus and to consequently quantify the amount of distress experienced by the recipients. Previous studies have successfully utilised the TRQ to report on subjective tinnitus related distress as experienced by the CI recipient (Távora-Vieira et al., 2013, 2015). The TRQ has also been translated into numerous languages (Andersson, 2002), but was used in its original English format for the purpose of this study.

2.5.2 Abbreviated Profile of Hearing Aid Benefit

In order to measure hearing-related QoL outcomes over time, adult CI recipients completed the *Abbreviated Profile of Hearing Aid Benefit* (APHAB) preoperatively and at fixed postoperative intervals. The APHAB is a clinical instrument and generic self-report measure that quantifies the disability associated with a hearing loss (HL), as well as the relief achieved with amplification (Cox & Alexander, 1995). In a recent systematic review and meta-analysis that examined the impact that hearing-assistive devices has on the health-related QoL of adults with single-sided deafness (Kitterick, Lucas, & Smith, 2015), the APHAB was specifically referred to as a disease-specific measure of health-related QoL. The most frequently adopted measure of disease-specific health-related QoL in this review was the APHAB, as it was utilized in 15 studies (Kitterick et al., 2015). Some studies also refer to the APHAB as a measure of subjective benefit and/ or effectiveness of hearing-assistive devices (House, Kutz Jr., Chung, & Fisher, 2010; Lin et al., 2006; Moore & Popelka, 2013).Furthermore, even though the APHAB in its original format was designed as a questionnaire for hearing aid users, it has been utilized in a number of studies to document subjective patient reports regarding hearing with

CIs (Dillon et al., 2018; Kloostra, Arnold, Hofman, & Van Dijk, 2015; Litovsky, Parkinson, Arcaroli, & Sammeth, 2006; Ramos-Macías et al., 2016; Santa Maria, Domville-Lewis, Sucher, Chester-Browne, & Atlas, 2013; Skarzynski, Lorens, Piotrowska, & Anderson, 2006; Sladen, Gifford, et al., 2017; Wackym, Runge-Samuelson, Firszt, Alkaf, & Burg, 2007). In studies related to adult cochlear implantation specifically, the APHAB is referred to as a measure of QoL (Dillon et al., 2018), a measure of health-related QoL (Ramos-Macías et al., 2016) and a measure of self-perceived hearing-related QoL (Sladen et al., 2017). In addition, the APHAB is also referred to as a audiology-specific example of a disease-specific health-related QoL measure (Abrams et al., 2005).

Most of the information that is utilized to communicate with and function within the environment, comes through the important sense of hearing (Redfors et al. 2014). It has been confirmed that an impairment of hearing has implications for general QoL (Chia et al, 2007; Dalton et al, 2003; Fisher et al, 2009). Within the APHAB design, the term 'disability' is defined as the effect that the hearing impairment has on the individual's auditory functioning in daily life (Cox & Alexander, 1995). Considering that a disability within the hearing sense has implications for general QoL ((Chia et al, 2007; Dalton et al, 2003; Fisher et al, 2009; Redfors et al., 2014) and that the APHAB measures this perceived disability (Cox & Alexander, 1995), it is reasonable to link what the APHAB measures to hearing-related QoL. In spite of the fact that the APHAB is frequently linked to health-related QoL, the APHAB will be referred to as a measure of hearing-related QoL for the purpose of this study.

The APHAB consists of 24 items, divided into four subcategories (ease of communication, background noise, reverberation and aversiveness). Each sub-category consists of six items to be scored on a 7-level scale that ranges from A - Always (99%) to G - Never (1%) for both unaided as well as aided experiences. For the purpose of this study the unaided experiences were presented as the preoperative score while the 6-, 12- and >24-months postoperative scores all represented aided (with CI) experiences. Speech communication scores in favourable, reverberant and noisy environments are depicted by the APHAB inventory (Cox & Alexander, 1995). The internal consistency reliability values of the APHAB, as indicated by Cronbach's alpha, ranges from 0.78 to 0.87, which is fairly high (Cox & Alexander., 1995). Moreover, a 90% and 95% critical difference has been found for each subscale and response mode of the APHAB (Cox & Alexander., 1995). Reliability has thus been confirmed for the APHAB as a hearing-related QoL outcome measure that quantifies the disability associated with hearing loss, as well as the relief achieved with amplification (either hearing aids or cochlear implantation) (Cox & Alexander., 1995).

2.6 Data collection procedures

As part of the standard pre- and postoperative protocol, adult CI recipients from the *Ear Science Institute Australia - Ear Science Clinic* completed the *APHAB* as an outcome measure for hearing-related QoL and the *TRQ* as a measure of tinnitus distress. Along with a number of general tinnitus questions (Appendix H), *TRQ* and *APHAB* data were captured for adult CI recipients preoperatively and at fixed postoperative intervals (including 3-, 6-, 12-, 24-, 36- and >36 months postoperative intervals). A number of databases were used by the *Ear Science Institute Australia - Ear Science Clinic* to capture patient data. Captured data were then exported into an Excel sheet to manipulate the data into a workable format. Upon attaining this retrospective, routinely captured data, an electronic database was developed to systematically sort and clean the retrospective data. Permission to access this already captured demographic, CI, hearing loss, tinnitus, APHAB and TRQ data of CI recipients who meet the inclusion criteria of this study have been obtained from the manager of the Ear Science Institute Australia – Ear Science Clinic (Appendix B).

2.7 Data analysis

Due to the retrospective nature of this study and the inevitable incidence of missing data when collecting these in a clinical setting, data for all dependent and independent variables were not available for each individual CI recipient at each time interval. As a result, data points were combined in order to minimize missing data. Postoperative intervals were combined and reduced to only the 6-, 12- and >24-months postoperative intervals. To justify these combinations, the Wilcoxon signed rank test was performed to test the difference between each of the time intervals. Where intervals did not differ statistically at a 5% level, they were combined and the average value between the interval points were used.

Commercially available statistical software packages (SAS version 9.4 and IBM SPSS version 25) were used for the analysis. The outcome variable in this study was the hearing-related QoL of adult CI recipients as measured by APHAB scores. Explanatory variables included demographical factors (gender, chronological age), HL related factors (course of HL, onset of HL, balance concerns, duration of HL before CI), CI related factors (duration of CI use, age at first CI, bilateral implantation, first ear implanted), speech perception factors (consonant-nucleus-consonant word scores, consonant-nucleus-consonant phoneme scores) and tinnitus related factors (*Tinnitus Reaction Questionnaire* score representing tinnitus distress). These variables were subdivided into categorical and continuous variables.

Descriptive statistics were utilized to define the test population in terms of demographical, CI and hearing loss characteristics (Table 2.1). Data on tinnitus distress and speech perception scores were also explored by means of descriptive statistics.

The paired sample t-test was performed to determine if statistical significant differences existed between the respective intervals for the overall APHAB scores, the APHAB sub-domain scores and the TRQ scores.

Data analysis for the APHAB: Answers to the 24 statements of the APHAB were scored by transforming answer categories (A-G) as follows: Always (A)=99%, almost always (B)=87%, generally (C)=75%, half-the-time (D)=50%, occasionally (E)=25%, seldom (F)=12% and never (G)=1% (Cox & Alexander 1995). This guidance percentage is provided on the APHAB to help the user decide which level to choose based on the percentage of time that the statement is true for the individual At each time interval, scores for each of the four subdomains of the APHAB were computed by adding together the 6-item scores of each subdomain and dividing it by the number of completed questions. Non-responses were processed as missing values. An overall APHAB average score was then also calculated for the four subdomains together. The questionnaire mostly consists out of negative descriptors and reversed scoring was applied for questions that were positive descriptors. Therefore, a higher score was representative of a high portion of perceived difficulties and consequently a lower hearing-related QoL.

Data analysis for the TRQ: The overall scoring method of the TRQ comprised of adding together the score numbers selected by the respondent for the 26 questions, obtaining a total score ranging between 0 to 104 (Wilson et al., 1991). All the questions were rated on a five-point rating scale ranging from 0 (not at all) to 4 (almost all of the time). Due to all statements being negative descriptors, a higher total score is associated with a higher level of tinnitus induced psychological distress. A total TRQ score out of 104 was captured for each CI recipient who filled out the TRQ at each respective time interval.

The extent of a relationship between to characteristics can be determined by means of the Spearman’s rank order correlation (Leedy & Ormrod., 2010). This correlation is a statistical measure of the strength of the monotonic relationship between paired data (Artusi, Verderio, and Marubini, 2002). The Spearman’s rank order correlation calculates a coefficient which measures the strength and direction of the association between two continuous variables. Spearman’s correlation coefficients were used to assess possible associations between tinnitus distress (TRQ scores) and hearing-related QoL (APHAB overall and sub-domain scores) over time. The calculated coefficients of the analysis represented the statistical significance of the relationship between tinnitus distress and hearing-related QoL. This test was chosen because it is a non-parametric test with free test distribution and is therefore not affected by the normal distribution of parameters.

The statistical method of determining the specific relationship existing between variables is known as a regression analysis (Babbie, 2016). The relationships among the involved variables are represented in the form of a regression equation (Babbie, 2016). Due to the dependent variable in this study being simultaneously affected by several independent variables a multiple regression analysis was utilized (Babbie, 2016). Multiple linear regression analysis was used for the prediction of hearing-related QoL outcomes in adult CI recipients. Twenty multiple linear regression models were constructed to investigate the influence of the 13 categorical and continuous predictors on hearing-related QoL scores over time. The influence of the 13 identified potential predictor variables on hearing-related QoL scores at a specific point in time was determined. Similar multiple linear regression analyses were conducted at all four time intervals. In order to investigate which variables were responsible for the change in hearing-related QoL scores from the pre-implant interval to each of the three postoperative intervals respectively, repeated measure analyses/ANOVA were also performed. These models included only the predictors found to be significant according to the multiple linear regression analysis.

Due to the relatively large sample size of this study and the specificity of the research question, it was decided to make use of a more conservative p-value of 0.01 to indicate statistical significance. This reduced the chance of false positives while simultaneously increasing the trustworthiness of any significant results obtained.

2.8 Reliability and validity

The success of drawing meaningful conclusions from research data is influenced greatly by the reliability and validity of the measurement tools used (Leedy & Ormrod, 2010). Validity can be defined as the degree to which the measurement tool measures what it is intended to measure while reliability represents the consistency with which a measuring tool yields unchanged results in the case of an unchanged measurement entity (Leedy & Ormrod, 2010). Otherwise described, validity is about the closeness of what is believed to be measured to what was intended to be measured, while reliability portrays how far a specific test will produce similar results in different circumstances, supposing nothing else have changed. The meticulousness of the research process and the trustworthiness of research findings are exhibited by reliability and validity (Giltinane, 2013).

In the current study, reliability and validity were ensured in the following ways:

- Data were obtained using two validated measures (the TRQ and the APHAB).
- Validity was ensured by analyzing a large sample size of de-identified data in an attempt to yield results that are representative of the adult CI recipient population.
- All participants completed the same two validated questionnaires at the same set intervals, thus ensuring reliability.

CHAPTER 3

RESEARCH ARTICLE: THE EFFECT OF TINNITUS ON HEARING-RELATED QUALITY OF LIFE OUTCOMES IN ADULT COCHLEAR IMPLANT RECIPIENTS

Authors: Elmien Opperman, Talita le Roux , Robert H. Eikelboom, Andries Masenge

Journal: International Journal of Audiology
Submission: TIJA-2019-05-0204 (under review)
Proof of submission: Appendix E

3.1 ABSTRACT

Objective: To describe the effect of tinnitus distress on the hearing-related quality of life (QoL) outcomes of adult cochlear implant (CI) recipients over time.

***Design**:* A retrospective, longitudinal study of adult CI recipients was conducted. Data on hearing-related QoL, using the *Abbreviated Profile of Hearing Aid Benefit* (APHAB) and tinnitus distress, using the *Tinnitus Reaction Questionnaire* (TRQ) were captured preoperatively as well as at 6-months, 12-months and >24-month postoperatively. The effect of tinnitus distress on hearing-related QoL outcomes over time was determined. Furthermore, 13 potential predictive factors, were identified from the retrospective dataset, including demographic, hearing loss, CI, speech perception and tinnitus related factors. Multiple regression analyses were performed to identify variables that influence hearing-related QoL outcomes over time.

Study sample: The study sample included 210 adult (≥18 years) CI recipients implanted between 2001 and 2017.

***Results**:* Lower tinnitus distress and younger age at implantation were strong predictors of better hearing-related QoL in adult CI recipients. A significant relief in tinnitus distress up to two years post-implantation was confirmed, as well as a negative correlation between tinnitus distress and hearing-related QoL.

Conclusion: Tinnitus distress negatively affects the hearing-related QoL outcomes of adult CI recipients.

3.2 Introduction

Subjective tinnitus can be defined as a sound sensation perceived in the head or ears in the absence of an external stimulus (Searchfield, 2014). In spite of being aware of this sound sensation, many people reporting tinnitus are not bothered by it and subsequently do not seek medical assistance, whereas for others it can cause debilitating problems such as insomnia, frustration, depression and anxiety (McCormack et al., 2016; Nondhal et al., 2007).

Multiple theories on the tinnitus mechanism have been considered in research, but due to its heterogeneous nature the complex mechanism of tinnitus cannot be adequately explained by any particular hypothesis (Chung & Lee, 2016). Tinnitus is seen as a symptom rather than a disease entity and can therefore be prescribed to a variety of underlying conditions (Han et al., 2009). At present there is no definite cure for tinnitus due to the poorly understood pathophysiology of tinnitus (Aazh et al., 2019).

Tinnitus is prevalent in approximately 70-90% of adults with hearing loss (Olze et al., 2011). In adult cochlear implant (CI) recipients, preoperative tinnitus prevalence range from 67%-100% with a mean of 80% (Baguley & Atlas., 2007). Evidently, four in five patients with severe to profound sensorineural hearing loss report tinnitus preoperatively (Baguley & Atlas, 2007). The impact of tinnitus as a potential difficulty with the implant was rated as the top-ranking concern for 28% of adult recipients following CI surgery (Gomersall et al., 2019). Even though cochlear implantation is primarily performed in order to manage severe-profound hearing loss, tinnitus suppression is experienced as a beneficial secondary effect by 25%-72% of CI recipients (Quaranta et al., 2004; Baguley & Atlas., 2007; Ramakers et al., 2015; Knopke et al., 2016; Olze et al., 2016; Knopke et al., 2017;). However, there is a risk for newly induced tinnitus or for the worsening of existing tinnitus after cochlear implantation (Quaranta et al., 2004). Therefore CI candidates should have a thorough understanding of the effect of cochlear implantation on tinnitus prior to implantation and all possible tinnitus outcomes should be transparently included in the informed consent (Quaranta et al., 2004; Bovo et al., 2011).

A number of studies confirmed that cochlear implantation does not only provide the benefit of improved hearing abilities for CI recipients, but that it also leads to the improvement of quality of life (QoL) (Knopke et al., 2017; Olze et al., 2011; Olze et al., 2016, 2012; Knopke et al., 2016). A number of generic and disease specific QoL questionnaires has been used throughout literature to assess changes in QoL brought on by a CI (Loeffler et al., 2010). For CI recipients, health-related QoL can be defined as a multi-dimensional concept used to symbolize the comprehensive effect that cochlear implantation has on the self-esteem, social life and everyday activities of the CI recipient (Loeffler et al., 2010). Disease specific QoL outcomes however represents a patient’s perception on a specific health problem (Loeffler et al., 2010). Since disease specific QoL outcome measures are strictly relevant to a particular disease, hearing-related QoL outcome measures, for example, specifically report the effect of a hearing impairment on the daily activities and lifestyle of the patient (Loeffler et al., 2010). Whether health-related QoL or more disease specific hearing-related QoL, the term QoL is linked to the emotional, social and physical well-being of individuals, including their ability to function in the ordinary tasks of living (Loeffler et al, 2010). Therefore, QoL has become a standard outcome measure to assess the impact that lasting hearing loss and its resultant management have on the personal well-being of CI recipients as well (Capretta & Moberly, 2016; King et al., 2014; Zaidman-Zait & Smith, 2010). A wide variety of factors have been identified to positively influence QoL in CI recipients, namely better speech understanding abilities (Sladen et al., 2017a) , shorter duration of deafness (Maillet et al., 1995; Hirschfelder et al, 2008), younger age at implantation (Chung et al., 2012; Farinetti et al., 2014), higher socio-economic status (Hawthorne et al., 2004), longer duration of CI use (Hirschfelder et al., 2008), bilateral implantation (Härkönen et al., 2015; le Roux et al., 2017) and attendance of mainstream schooling (le Roux et al., 2017).

Even though pre- and post-implantation data on QoL outcomes of patients with tinnitus is limited (Olze et al., 2011), evidence suggests that health-related QoL of CI recipients is affected by tinnitus. Olze et al (2011) specifically confirmed the association between tinnitus impairment and lower health-related QoL. Both le Roux et al (2017) and Lenarz et al (2017) recently confirmed that patient report of tinnitus before implantation was strongly predictive of reduced QoL outcomes in adult CI recipients. A significant negative correlation was also found between tinnitus related distress and health-related QoL at both the 6- and 12-months post-implantation intervals in a recent study by Knopke et al (2017), where the experience of tinnitus preoperatively was the main inclusion criteria for bilaterally deafened patients. Tinnitus was indicated as the primary cause for 25% of the anxiety, depression and hearing problems that persisted post-implantation in unilaterally implanted adults (Andersson et al., 2009). Furthermore, the experience of residual tinnitus after implantation can also be linked to higher levels of perceived stress, poorer coping strategies, more prominent depressive symptoms and generalized anxiety (Andersson et al., 2009; Olze et al., 2012). The significance of tinnitus as a hindrance in the auditory rehabilitation of CI recipients should therefore not be underestimated (Knopke et al., 2017).

A wide variety of individual and interacting factors influence the level of benefit that any particular CI recipient experience and results in a large variability of outcomes. Therefore, the ability to predict outcomes for individual CI candidates will arise from an increased knowledge of the causes of this variation (Brüggemann et al., 2017). The role of tinnitus as a predictive factor for QoL outcomes should therefore be investigated as available evidence has suggested that the effects of tinnitus negatively influenced QoL and can even counterbalance the positive effects of cochlear implantation (Brüggemann et al., 2017; Olze et al., 2016; Knopke et al., 2016; Olze et al., 2011; le Roux et al., 2017; Summerfield et al., 2006; Ramos et al., 2013; Lenarz et al., 2017; Knopke et al., 2017). What also needs further exploration is the lasting effect of tinnitus on hearing-related QoL over time as well as the sustainability of the tinnitus supressing effect of a CI and the effect thereof on hearing-related QoL. This study, therefore, aimed to describe the influence of tinnitus distress on hearing-related QoL outcomes in adult CI recipients who experience tinnitus, and to investigate the prognostic significance of tinnitus distress over time.

3.3 Method

Institutional ethical clearance was obtained prior to the analyses of retrospective data.

3.3.1 Study population

A retrospective dataset of 345 adult (≥18 years) CI recipients, implanted between 2001 and 2017 at the *Ear Science Institute Australia – Ear Science Clinic,* was reviewed for the purpose of this study. During the reference period hearing-related QoL, tinnitus distress and speech perception outcome data were routinely captured for all adult CI recipients preoperatively, as well as at 6-, 12- and >24-months postoperative intervals. Preoperative hearing-related QoL and tinnitus distress outcome data were prerequisites for inclusion. The final study sample comprised of 210 adult CI recipients for whom the demographic characteristics are described (Table 3.1). Based on available hearing-related QoL and tinnitus distress outcome data, the study population included at the postoperative intervals decreased from the baseline of 210 participants to 176, 126 and 104 participants at the 6-, 12- and >24-months postoperative intervals respectively. At the end of the >24-months postoperative interval, most of the adult CI recipients in this dataset (84.8%) were still unilateral CI users.

Table 3.1. Characteristics of study population

Demographical characteristics	*% (n)*	*Clinical characteristics*	*% (n)*
Gender		Onset of hearing loss	
Male	49.5 (104/210)	Prelingual	18.1 (38/210)
Female	50.5 (106/210)	Postlingual	90.5 (172/210)
Chronological age at data interval (years)		Course of hearing loss onset	
3 months postoperatively (n=160)		Sudden	7.8 (16/206)
Mean (SD)	65.4 (14.2)	Progressive	92.23 (190/206)
Range	25.5 - 94.2		
		Balance concerns preoperatively	
12 months postoperatively (n=126)		Yes	30 (63/210)
Mean (SD)	66.3 (13.3)	No	70 (147/210)
Range	26.3 - 92.2		
		Duration of hearing loss prior to implant (years) (n=200)	
>24 months postoperatively (n=104)		Mean (SD)	30.4 (19.07)
Mean (SD)	67.9 (13.28)	Range	0.0 - 79.0
Range	27.7 - 92.3		
		First ear implanted	
		Left	49.5 (104/210)
		Right	50.5 (106/210)
		Age at (first) implant (years) (*n*=210)	
		Mean (SD)	62.9 (15.6)
		Range	20.6 - 93.8
		Bilateral implantation	
		12 months postoperatively	2.9 (6/210)
		>24 months postoperatively	15.2 (32/210)

3.3.2 Data collection

As part of the standard pre- and postoperative protocol, adult CI recipients completed the *APHAB* as an outcome measure for hearing-related QoL and the *TRQ* as a measure of tinnitus distress. *TRQ* and *APHAB* data were captured for adult CI recipients preoperatively and at fixed postoperative intervals (including 3, 6, 12, 24, 36 and >36 months postoperative intervals).

3.3.3 Description of variables

3.3.3.1 Outcome variables

In order to measure hearing-related QoL outcomes over time, adult CI recipients completed the *Abbreviated Profile of Hearing Aid Benefit* (APHAB) preoperatively and at fixed postoperative intervals. The APHAB is a clinical instrument and generic self-report measure that quantifies the disability associated with a hearing loss (HL), as well as the relief achieved with amplification (Cox & Alexander, 1995). In a recent systematic review and meta-analysis that examined the impact that hearing-assistive devices has on the health-related QoL of adults with single-sided deafness (Kitterick et al., 2015), the APHAB was specifically referred to as a disease-specific measure of health-related QoL. The most frequently adopted measure of disease-specific health-related QoL in this review was the APHAB, as it was utilized in 15 studies (Kitterick et al., 2015). Some studies also refer to the APHAB as a measure of subjective benefit and/ or effectiveness of hearing-assistive devices (House et al., 2010; Lin et al., 2006; Moore & Popelka, 2013). Furthermore, even though the APHAB in its original format was designed as a questionnaire for hearing aid users, it has been utilized in a number of studies to document subjective patient reports regarding hearing with CIs (Dillon et al., 2018; Kloostra et al., 2015; Ramos-Macías et al., 2016; Sladen et al., 2017; Skarzynski et al., 2006). In studies related to adult cochlear implantation specifically, the APHAB is referred to as a measure of QoL (Dillon et al., 2018), a measure of health-related QoL (Ramos-Macías et al., 2016) and a measure of self-perceived hearing-related QoL (Sladen et al., 2017). In addition, the APHAB is also referred to as a audiology-specific example of a disease-specific health-related QoL measure (Abrams et al., 2005).

Most of the information that is utilized to communicate with and function within the environment, comes through the important sense of hearing (Redfors et al., 2014). It has been confirmed that an impairment of hearing has implications for general QoL (Chia et al., 2007; Dalton et al., 2003; Fisher et al., 2009). Within the APHAB design, the term 'disability' is defined as the effect that the hearing impairment has on the individual's auditory functioning in daily life (Cox & Alexander, 1995). Considering that a disability within the hearing sense has implications for general QoL (Chia et al., 2007; Dalton et al., 2003; Fischer et al., 2009; Redfors et al., 2014) and that the APHAB measures this perceived disability (Cox & Alexander, 1995), it is reasonable to link what the APHAB measures to hearing-related QoL. In spite of the fact that the APHAB is frequently linked to health-related QoL, the APHAB will be referred to as a measure of hearing-related QoL for the purpose of this study.

The APHAB consists of 24 questions, divided into four sub-domains (ease of communication, background noise, reverberation and aversiveness). Answers to the 24 statements of the APHAB were converted to a total as well as four sub-domain scores as per survey design (Cox & Alexander, 1995). The questionnaire mostly consists out of negative descriptors and reversed scoring was applied for questions that were positive descriptors. Therefore, a higher score was representative of a greater portion of perceived difficulties and consequently a lower hearing-related QoL. For data analysis, scores for each of the four APHAB sub-domains, as well as the total APHAB score (overall hearing-related QoL), were considered as continuous outcome variables.

3.3.3.2 Explanatory variables

Data regarding demographical and clinical characteristics (Table 3.1), together with tinnitus characteristics (Table 3.2) of the study sample were collected retrospectively. From the retrospective data set 13 potential predictor variables were identified and described as either categorical or continuous variables. These possible predictive factors included demographic (gender, chronological age at interval), hearing loss (onset of hearing loss, course of hearing loss, balance concerns, duration of hearing loss before implant), CI (age at implant, first ear implanted, bilateral implantation, duration of CI use at interval), speech perception (CNC word scores, CNC phoneme scores) and tinnitus related factors (TRQ score).

The *Tinnitus Reaction Questionnaire* (TRQ) is a valid and reliable 26-item questionnaire that was developed to measure the psychological distress associated with tinnitus (Wilson et al., 1991). This study utilized the TRQ as a subjective, self-report measure to assess and quantify the level of perceived stress experienced by adult CI recipients with tinnitus. As per the TRQ protocol the score numbers, rated on a 5 point scale ranging from 0 (not at all) – 4 (almost all of the time) by the respondent for the 26 questions, were totalled to represent a score out of 104 (Wilson et al., 1991). Due to all statements being negative descriptors, a higher total score is associated with a higher level of tinnitus induced psychological distress. Previous studies have successfully utilised the TRQ to report on subjective tinnitus related distress as experienced by the CI recipient (Távora-Vieira et al., 2013, 2015).

3.3.4 Statistical analysis

With this study being of retrospective nature and the inevitable incidence of missing data when collecting these in a clinical setting, data for all dependent and independent variables were not available for each individual CI recipient at each time interval. As a result, data points were combined in order to minimize missing data. Consequently, postoperative intervals were combined and reduced to only the 6-, 12- and >24-months postoperative intervals. To justify these combinations, the Wilcoxon signed rank test was performed to test the difference between each of the time intervals. Where the intervals did not differ statistically at a 5% level, they were combined and the average value between the interval points were used.

Commercially available statistical software packages (SAS version 9.4 and IBM SPSS version 25) were used for the analysis. Descriptive statistics were used to describe the study population in terms of demographical, CI and hearing loss characteristics (Table 3.1). Data on tinnitus distress (Table 3.2) and speech perception scores were also explored by means of descriptive statistics.

The Paired sample t-test was performed to determine if statistical significant differences existed between the respective intervals for the overall APHAB scores, the APHAB sub-domain scores and the TRQ scores.

Spearman's correlation coefficients were used to assess possible associations between tinnitus distress (TRQ scores) and hearing-related QoL (APHAB overall and sub-domain scores) over time. This test was chosen because it is a non-parametric test with free test distribution and is therefore suitable for analysis of data that is not normally distributed.

By using multiple linear regression analyses, hearing-related QoL outcomes in adult CI recipients were predicted. Twenty multiple linear regression models were built to explore the effect of the 13 predictor variables on hearing-related QoL scores over time. Predictor variables included demographic (gender, chronological age at interval), hearing loss (onset of hearing loss, course of hearing loss, balance concerns, duration of hearing loss before implant), CI (age at implant, first ear implanted, bilateral implantation, duration of CI use at interval), speech perception (CNC word scores, CNC phoneme scores) and tinnitus related factors (TRQ score). Similar multiple linear regression analyses were conducted at all four time intervals. Using these models, the influence of the 13 possible predictor variables of hearing-related QoL were determined at specific points in time. In order to investigate which individual variables were responsible for the change in hearing-related QoL scores from the pre-implant interval to each of the three postoperative intervals respectively, repeated measure analyses/ANOVA, were also performed. These models included only the predictors found to be significant according to the multiple linear regression analyses.

Due to the relatively large sample size of this study and the specificity of the research question, it was decided to make use of a more conservative p-value of 0.01 to indicate statistical significance. This reduced the chance of false positives/ type I error of incorrectly rejecting the null hypothesis, while simultaneously increasing the accuracy of any significant results obtained.

3.4 Results

3.4.1 Hearing-related quality of life outcome profile

All postoperative APHAB total and sub-domain scores were lower than the preoperative scores, indicating positive hearing-related QoL outcomes (Table 3.2). Background noise and reverberation APHAB sub-domains indicated the highest mean scores across time intervals while the aversiveness APHAB sub-domain had the lowest mean scores across time intervals.

The Paired sample t-test was conducted to determine whether the differences between the APHAB scores at the various time intervals were significant. Overall APHAB scores, as well as scores for all four APHAB sub-domains showed an improved hearing-related QoL from the preoperative time interval to each of the three postoperative time intervals. It is evident that there was a statistically significant decrease ($p < 0.01$) in the mean overall APHAB scores from the preoperative time interval to the 6 months (mean = 38; SD = 15.1; n = 176), 12 months (mean = 36.4; SD = 15.2 n = 126) and >24 months (mean = 40.2; SD = 17.3; n = 104) postoperative intervals. The background noise and reverberation APHAB sub-domains had statistically significant ($p<0.01$) higher mean scores compared to the other sub-domains at the preoperative interval as well as all postoperative intervals. Aversiveness APHAB sub-domain portrayed mean scores that were statistically significantly ($p<0.01$) lower than all other sub-domains preoperatively and statistically significantly ($p<0.01$) lower than the reverberation and background noise sub-domains at the 6-month, 12-month and >24- month postoperative intervals.

Table 3.2. Hearing-related quality of life scores depicted from APHAB results

Symbol	*Time interval*		*Overall APHAB*	*Ease of communication sub-domain*	*Background noise sub-domain*	*Reverberation sub-domain*	*Aversiveness sub-domain*
A	*Preoperatively*	Mean (SD)	61 (16.5) $^{(A,B)(A,C)(A,D)}$ *n*=210	59.3 (25.5) $^{(A,B)(A,C)(A,D)}$ *n*=210	76.9 (16.7) $^{(A,B)(A,C)(A,D)}$ *n*=210	75.7 (20.7) $^{(A,B)(A,C)(A,D)}$ *n*=210	32.1 (26.7) $^{(A,B)(A,C)(A,D)}$ *n*=210
		Range	9.0 - 98.4	1.0 – 99.0	20.6 – 99.0	8.3 – 99.0	1.0 – 99.0
B	*6-months postoperatively*	Mean (SD)	38 (15.1)$^{(B,C)}$ *n*=176	28.1 (17.9) *n*=161	53.11 (20.8)$^{(B,C)}$ *n*=161	53.2 (22.34) *n*=161	25.9 (21.1) *n*=161
		Range	10.9 - 78.6	2.8 - 87.0	6.8 - 99	8.7 - 99.0	1.0 - 97.0
C	*12-months postoperatively*	Mean (SD)	36.4 (15.2) *n*=126	24.9 (18.1) *n*=127	48.5 (19.8)$^{(C,D)}$ *n*=127	47.7 (20.5) *n*=127	24.9 (19.61) *n*=127
		Range	8.5 - 72.3	1.0 - 78.7	2.8 - 99.0	6.5 - 99.0	1.0 - 97,0
D	*>24-months postoperatively*	Mean (SD)	40.2 (17.3) *n*=104	29.5 (21.9) *n*=104	53.7 (20.86) *n*=104	54.9 (25.2) *n*=104	24.7 (19.5) *n*=104
		Range	8.6 - 80.9	1.0 - 99.0	10.2 - 99.0	10.5 - 99.0	1.0 - 75.0

Symbol superscripts represent time intervals which present with a statistically significant difference between them (p <0.01)

3.4.2 Tinnitus profile

Almost half (49.52%) of the adult CI recipients in this study sample reported tinnitus distress preoperatively, while 39.36% still experienced tinnitus distress >24 months postoperatively. When compared to previous studies (Baguley & Atlas, 2007; Olze, Szczepek, Haupt, Zirke, et al., 2011), the preoperative tinnitus prevalence in this study is lower and may largely be due to the relatively large sample size included in this study. The low mean score is a result of the inclusion of the TRQ scores for all adult CI recipients who reported experiencing tinnitus, but reported no associated distress by means of the TRQ, subsequently scoring a 0 on the TRQ and thus lowering the mean scores. According to the Paired sample t-test, a general trend of statistically significant (p<0.01) tinnitus relief is evident from the preoperative interval to the 6-month (mean = 5.9; SD = 12.8; n = 150), 12-month (mean = 5.4; SD = 12.2; n = 113) and >24-month (mean = 6.3; SD = 14.8; n = 89) postoperative intervals.

Table 3.3. Tinnitus Reaction Questionnaire scores

					p-value			
Time interval	*n*	*Mean (SD)*	*Range*	*Median*		*2*	*3*	*4*
1.Pre-operatively	210	13.2 (21.5)	0 - 101	1				
2. 6-months postoperatively	150	5.9 (12.8)	0 - 67	0	0.000*			
3. 12-montsh postoperatively	113	5.4 (12.2)	0 - 65	0	0.000*	0.074		
4. >24-montsh postoperatively	89	6.3 (14.8)	0 - 99	0	0.002*		0.496	

** Significant: p <0.01*

3.4.3 Associations between hearing-related quality of life ratings and tinnitus distress

Spearman's correlation coefficients were used to assess possible associations between TRQ and APHAB scores at each time interval. Visual assessment of scatterplots (Figure 3.1) shows that the relationship between hearing-related QoL outcomes and tinnitus distress is monotonic. Twelve months postoperatively, there was a significant positive correlation between TRQ and overall APHAB scores ($r = 0.28$, $p < 0.01$), implying that higher levels of tinnitus distress are associated with poorer hearing-related QoL outcomes. TRQ scores were also positively correlated with APHAB scores for the *aversiveness* sub-domain preoperatively ($r = 0.30$, $p < 0.01$), 12 months ($r = 0.34$, $p < 0.01$) and >24 months ($r = 0.30$, $p < 0.01$) postoperatively.

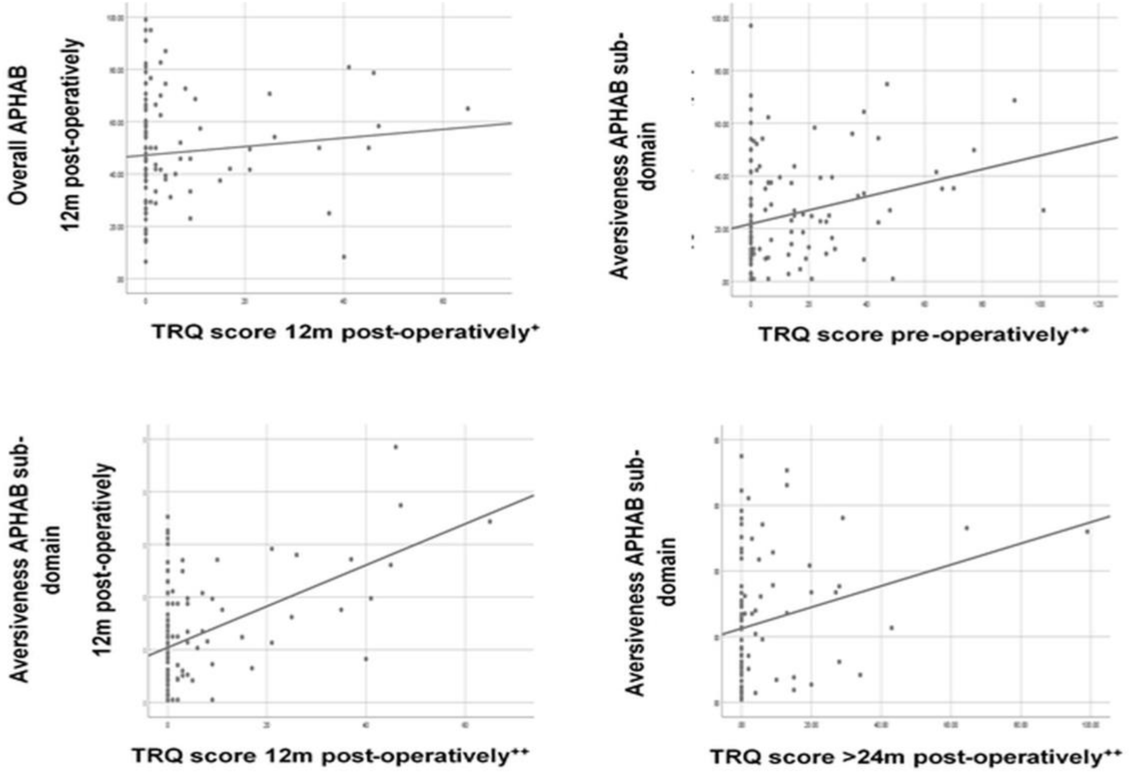


Figure 3.1. Scatter plot representing the significant associations between hearing-related quality of life (APHAB scores) and tinnitus distress (TRQ scores) across time intervals.
Presented is 12 months postoperative overall APHAB versus 12 months postoperative TRQ score, 12 months postoperative aversiveness sub-domain versus preoperative TRQ score, 12 months postoperative aversiveness sub-domain versus 12 months postoperative TRQ score and lastly >24 months postoperative aversiveness sub-domain versus >24 months postoperative TRQ score

**Significant: p <0.01*
+ r=0.10-0.29; small correlation
++ r=0.30-0.49; medium correlation
+++ r=0.50-1.00; large correlation

3.4.4 Multiple regression analysis

Twenty multiple linear regression models were run of which only four were significant. Furthermore, only two out of the possible 13 predictor variables were found to be significant predictors for hearing-related QoL (Table 3.4), namely tinnitus distress and age at implant. Multiple linear regression was performed to examine the simultaneous effect of multiple predictors on the outcome variables. Preoperatively, better APHAB ease of communication and reverberation sub-domain scores were predicted by lower tinnitus distress and a younger age at cochlear implantation (for reverberation only). At 12-months postoperative, a better

APHAB total score was predicted by a young age at implantation and lower TRQ scores, and a better APHAB aversiveness sub-domain score was predicted by lower TRQ distress. However, the determination coefficients (R2) showed that 26% or less of the variations in outcome measures can be explained by the models.

Table 3.4. Multiple linear regression analysis results

Outcome variable	*Predictors (individual variables of significance)*	*Parameter estimates*	*p-value*	*Pr > F (model p-value)*	*R^2*	*df*	*Sum of squares*
Overall APHAB 12-months postoperative (n=103)	Age at implant	0.27	0.0087*	0.0017*	0.21	7	4876.352
	TRQ score 12 months postoperative	0.39	0.0005*				
Ease of communication APHAB sub-domain Preoperative (n=135)	Age at implant	0.54	<0.0001*	0.0019*	0.21	11	18313.968
	TRQ score preoperative	0.26	0.0008*				
Reverberation APHAB sub-domain Preoperative (n=135)	Age at implant	0.42	<0.0001*	0.0017*	0.21	11	1141.630
Aversiveness APHAB sub-domain 12-months postoperative (n=103)	TRQ score 12-months postoperative	0.78	0.0019*	0.0001*	0.26	7	5081.749

** Significant: p <0.01*
df: degrees of freedom
Pr>F: p-value of the F-test (with F-test testing the significance of the model)
R^2: determination coefficient

3.5 Discussion

In this study the positive effect that cochlear implantation has on tinnitus distress was confirmed by improved hearing-related QoL outcomes post-implantation. The most significant improvement in hearing-related QoL was seen at 6-months post-implantation, the same time interval that showed the most significant tinnitus relief. Tinnitus distress has also been identified as a strong predictor for poorer hearing-related QoL outcomes. Study results also confirmed a negative correlation between perceived tinnitus distress hearing-related QoL outcomes. In addition, this study also identified younger age at implantation as a strong predictor for better hearing-related QoL.

For overall APHAB scores a statistically significant decrease was seen up to one year post-implantation, with no significant change thereafter. The most significant improvement in hearing-related QoL outcomes in the present study was seen at the 6-month postoperative interval for both the overall APHAB and all four sub-domains. This study has confirmed previous findings of a significant improvement in health-related QoL scores between pre- and post-implantation, indicating a relief in perceived difficulties associated with hearing loss over time (Knopke et al., 2017). For overall APHAB scores, a statistically significant decrease was seen up to one year post-implantation, with no significant change thereafter. Lenarz et al (2017), using the *Health Utilities Index 3* (HUI3), also showed a stabilization of QoL outcomes after one year of implantation in 291 unilaterally implanted adolescent/adult CI recipients. The most significant improvement in hearing-related QoL outcomes in the present study was seen at the 6-month postoperative interval for both the overall APHAB and all four sub-domains. Contrera et al (2016), using the *Short-Form Health Survey* (SF-36) as a generic QoL outcome measure also confirmed that the most significant improvement in QoL for postlingual unilaterally implanted adult (≥50 years) CI recipients, was seen at the 6-month postoperative interval, with improvement continuing up to one year post-implantation. Knopke et al (2017), using the *Nijmegen Cochlear Implant Questionnaire* as CI-specific health-related QoL measure, similarly confirmed 6 months postoperatively as the time interval with the most significant health-related QoL increase with this significant increase continuing up to two years post-implantation. However, a recent multicentre study involving unilaterally implanted adult CI recipients, found a significant improvement in QoL outcomes only at the one year post-implantation interval when using the HUI3 (Ramos-Marcías et al., 2018).

Study results identified *background noise* and *reverberation* as the APHAB sub-domains with which adult CI recipients experience the greatest problems as reflected by the highest mean scores across time intervals. Furthermore, these two sub-domains were proved statistically different from both the *ease of communication* and *aversiveness* sub-domains at all intervals. These observations of greater difficulty with speech perception in noise, as marked by the relatively high final scores, may be explained by CI limitations as the majority (84.8%) of the study population was still implanted unilaterally at the >24 months postoperative time interval (Arnold & Baumgärtel, 2018; Badajoz-Davila et al., 2018). Contrary to this, as per the lowest mean scores, *aversiveness* was identified as the sub-domain in which the least problems were experienced. The *aversiveness* sub-domain was found significantly different from all other sub-domains preoperatively, and significantly different from the *background noise* and *reverberation* sub-domains at all postoperative intervals.

Overall, the tinnitus profile of the adult CI recipients in this study showed a significant decrease in tinnitus distress at all three postoperative intervals compared to the preoperative state. However, there was no significant improvement after 6 months implantation. Ramos-Marcías et al (2018) similarly found a significant decline in *Tinnitus Handicap Inventory* (THI) scores of adult CI recipients at one year after CI activation compared to preoperative scores. Also using the THI, Kim et al (2016) showed a tinnitus reduction in 40% of adult CI recipients

6 months post-implantation. Knopke et al (2017), using the *Tinnitus Questionnaire* (TQ)*,* found significant decreases in tinnitus distress between consecutive time intervals up to two years post-implantation.

This present study also serves to confirm the positive effect that a CI can have on the tinnitus distress of these adult CI recipients. It shows the positive effect that a CI has on reducing tinnitus distress together with the increase in hearing-related QoL as previously shown by others. Tinnitus reduction has often been identified by CI recipients with single-sided deafness as the primary benefit of their CI (Mertens et al., 2016; Ramos-Marcías et al., 2018; Galvin et al., 2018). This evidence has contributed to the consideration of a CI as an appropriate, cost effective and worthwhile treatment option for patients who experience tinnitus (Ramos-Marcías et al., 2018; Elgandy et al., 2018). Gomersall et al (2019) reported that more awareness of tinnitus during switch off periods was one of the main reasons behind improved CI use.

A small negative correlation between perceived tinnitus distress and hearing-related QoL outcomes was shown for adult CI recipients in this study sample. This finding is in line with those of others who explored QoL (Brüggemann et al., 2017, 2016) and health-related QoL outcomes (Knopke et al., 2017; Olze, Gräbel, et al., 2012).

In addition, tinnitus distress was identified as a strong predictor of poorer hearing-related QoL not only preoperatively, but also 12 months postoperatively when controlling for many confounding factors including speech perception outcomes. Preoperatively, better (lower) scores for *ease of communication* and *reverberation* APHAB sub-domains were predicted by lower tinnitus distress. At 12 months postoperatively, a better (lower) APHAB total score and a better (lower) APHAB *aversiveness* sub-domain score were predicted by a lower TRQ score. Out of all 13 potential predictors, tinnitus distress was identified as a significant predictor of hearing-related QoL outcomes in three of the four significant models. Previously, using the NCIQ and HUI3 as QoL outcome measures respectively, both le Roux et al (2017) and Lenarz et al (2017) identified preoperative tinnitus as a significant prognostic indicator for reduced QoL outcomes in adult CI recipients. However, this present study adds to existing literature by confirming that both preoperative tinnitus and residual tinnitus post CI was predictive of poorer QoL outcomes. Contrary to expectations, speech perception testing outcomes were not identified as a predictor for QoL outcomes in this dataset.

An additional finding from this study was that *aversiveness* was associated with tinnitus distress, as TRQ scores correlated positively with APHAB scores for this specific sub-domain preoperatively as well as 12 and >24 months postoperatively. This association was confirmed by the identification of tinnitus distress as a significant predictive factor for poorer hearing-related QoL within the *aversiveness* APHAB sub-domain. The aversiveness of sound in CI users, however, are suggested by the current study results to be linked to the experience of tinnitus additional to a hearing problem. The aforementioned low aversiveness scores (indicating better hearing-related QoL) observed in this study can be explained by the fact that only half (49.52%) of the study sample reported tinnitus distress preoperatively. Moreover, that the aversiveness score reduces over time can be attributed to the similarly noted tinnitus reduction proceeding over time in this study. To corroborate this statement, Olze et al (2011) utilized the brief *COPE* to measure the coping behaviour of 43 adult CI patients in unpleasant situations and found a linear correlation between evasive coping (denial, self-blame, venting) and tinnitus. A CI recipient's negative reaction towards environmental sounds are quantified by the APHAB *aversiveness* sub-domain (Cox & Alexander, 1995). The link between tinnitus and this specific sub-domain therefore indicated that adult CI recipients who experience tinnitus distress are more likely to perceive the described environmental sounds as uncomfortably loud in their everyday lives. A further explanation for this phenomenon may be ascribed to the co-occurrence of tinnitus and hyperacusis (Pienkowski, 2019). Four out of 10 individuals who experience tinnitus also experience some form of hyperacusis (Baguley, 2018). Additionally, hyperacusis can also be a possible explanation for both the uncomfortable loudness (Tyler et al., 2015) as well as the avoidance of sounds (Aazh et al., 2014) accredited to the experience of tinnitus in this study.

The emotional and cognitive burden brought on by tinnitus, adds to the already higher psychological burden that adults with a hearing loss face resulting in poorer QoL outcomes (Brüggemann et al., 2017). Reports have stressed the fact that perceived tinnitus distress should be taken into account when considering prospective CI candidates. The negative effect that residual tinnitus distress has on hearing-related QoL should therefore not be underestimated and potential and existing CI recipients who experience tinnitus distress should thus be earmarked for counselling and timely monitoring. An evidence-based prediction model of CI outcomes will allow clinicians to counsel CI recipients preoperatively on realistic expectations regarding tinnitus recovery and adjust treatment and lifestyle strategies to foster an increased chance of tinnitus recovery postoperatively (Ramakers et al., 2018). The feasibility of including tinnitus screening as part of the standard assessment protocol for CI candidacy should be considered, in order to identify those at risk for tinnitus distress, facilitate more accurate prediction of outcomes and to earmark cases in which tinnitus relief is the primary motivation for cochlear implantation. Postoperative counselling and rehabilitation services should be tailored according to the unique needs of each individual and their families and therefore additional support services in terms of tinnitus specialities should be available to CI recipients as required, either through the core team or through additional access (Müller & Raine., 2013). Close collaboration between CI and tinnitus specialities will offer a more integrated treatment and rehabilitation approach to CI recipients and address the need for comprehensive psychosomatic care throughout the entire CI process (Brüggemann et al., 2017; Harris et al., 2011).

In addition to tinnitus distress, younger age at implantation was also indicated in this study as a strong predictor for better hearing-related QoL outcomes. While Farinetti et al (2014) supports this finding, a number of studies found no association between age at implantation and QoL (Sladenet al., 2017; Lenarz et al., 2017; Copeland & Pillsbury, 2004; le Roux et al., 2017; Garcia et al., 2018; Capretta & Moberly, 2016).

This current study explored one of the largest datasets on tinnitus and hearing-related QoL to date. Even though the TRQ and APHAB are not considered the ultimate and most recent measurement tools for tinnitus and QoL respectively, study results add to an increased understanding of the factors that influence hearing-related QoL outcomes in adult CI recipients. Prognostication should be prioritized by CI programs in order to predict CI outcomes with certainty (Black et al., 2011). The importance of standardized, routine documentation of outcome data should be highlighted, as such continuous, uniform collection of QoL outcome data may also contribute to determining the impact of postoperative rehabilitative strategies on a CI recipient’s perceived benefit from the device.

In addition to TRQ scores, or another suitable measure of tinnitus distress, the inclusion of descriptive information on tinnitus in future CI studies, may contribute to the understanding of a complicated issue experienced by CI recipients and the effect that it has on the QoL of these CI recipients.

3.6 Conclusion

In adult CI recipients, less tinnitus distress and a younger age at cochlear implantation were strongly predictive of better hearing-related QoL outcomes. Moreover, study results provided evidence of a lowering in tinnitus distress over time as a result of cochlear implantation and also confirmed a small negative correlation between tinnitus distress and hearing-related QoL. Suitable preoperative counselling and postoperative rehabilitation should be prioritized for all CI recipients who experience tinnitus.

3.7 Acknowledgements

The authors would like to acknowledge the *Ear Science Institute Australia-Ear Science Clinic* for the provision of data used for the purpose of this study.

CHAPTER 4

GENERAL DISCUSSION, CLINICAL IMPLICATION AND CONCLUSION

The emotional and cognitive burden brought on by tinnitus, adds to the already higher psychological burden that adults with a hearing loss carry resulting in poorer QoL outcomes (Brüggemann et al., 2017). Research have stressed the fact that perceived tinnitus distress should be taken into account by clinicians when considering prospective CI candidates (Gomersall et al., 2019). The negative effect that residual tinnitus distress has on hearing-related QoL should therefore not be underestimated and potential and existing CI recipients who experience tinnitus distress should thus be earmarked for counselling and timely monitoring. An evidence-based prediction model of CI outcomes will allow clinicians to counsel CI recipients preoperatively on realistic expectations regarding tinnitus recovery and adjust treatment and lifestyle strategies to foster an increased chance of tinnitus recovery postoperatively (Ramakers et al., 2018). The feasibility of including tinnitus screening as part of the standard assessment protocol for CI candidacy should be considered, in order to identify those at risk for tinnitus distress, facilitate more accurate prediction of outcomes and to earmark cases in which tinnitus relief is the primary motivation for cochlear implantation. Postoperative counselling and rehabilitation services should be tailored according to the unique needs of each individual and their families and therefore additional support services in terms of tinnitus specialities should be available to CI recipients as required, either through the core team or through additional access (Müller & Raine., 2013). Close collaboration between CI and tinnitus specialities will offer a more integrated treatment and rehabilitation approach to CI recipients and address the need for comprehensive psychosomatic care throughout the entire CI process (Brüggemann et al., 2017; Harris et al., 2011). The significance of tinnitus as a predictive factor for hearing-related QoL outcomes in CI recipients was investigated in this study, together with the lasting effect of tinnitus on hearing-related QoL over time. In addition, the sustainability of the supressing effect of a CI on tinnitus and the effect thereof on hearing-related QoL were explored.

4.1 Overview of research findings

This study has confirmed previous findings of a significant improvement in hearing-related QoL outcomes between pre- and post-implantation, indicating a relief in perceived difficulties associated with hearing loss over time (Knopke et al., 2017). For overall APHAB scores, a statistically significant decrease was seen up to one year post-implantation, with no significant change thereafter. Lenarz et al. (2017), using the HUI3, also showed a stabilization of health-related QoL outcomes after one year of implantation in 291 unilaterally implanted adolescent/adult CI recipients.

Study results identified *background noise* and *reverberation* as the APHAB sub-domains that adult CI recipients experience the greatest problems with as reflected by the highest mean scores across time intervals. Contrary to this, *aversiveness* was identified as the sub-domain in which the least problems were experienced. Furthermore, *background noise* and *reverberation* scores were proven to be statistically higher and *aversiveness* scores proven to be statistically lower compared to all other APHAB sub-domain scores. As indicated by Arnold and Baumgärtel. (2018) and Badajoz-Davila et al. (2018), background noise and reverberation is a general problem that most people with hearing loss (and in essence CI recipients) struggle with. These observations of greater difficulty with speech perception in noise, as marked by the relatively high final scores, may be explained by CI limitations as the majority (84.8%) of the study population was still implanted unilaterally at the >24 months postoperative time interval (Arnold & Baumgärtel, 2018; Badajoz-Davila et al., 2018).

Overall, the tinnitus profile of the adult CI recipients in this study showed a significant decrease in tinnitus distress at all three postoperative intervals compared to the preoperative state. However, there is no significant improvement after 6 months post-implantation. Similarly, Ramos-Marcías et al. (2018) confirmed a significant decline in *Tinnitus Handicap Inventory* (THI) scores of adult CI recipients at 1 year after CI activation compared to preoperative scores. Also using the THI, Kim et al. (2016) indicated a reduction in tinnitus in 40% of adult CI recipients 6 months postoperatively. Knopke et al. (2017), using the *Tinnitus Questionnaire* (TQ), found significant decreases in tinnitus distress between consecutive time intervals up to two years post-implantation.

Furthermore, this present study also serves to confirm the positive effect that a CI can have on the tinnitus distress of these adults. It shows the positive effect that a CI has on reducing tinnitus distress and improving hearing-related QoL. Tinnitus reduction has often been identified by CI recipients with single-sided deafness as the primary benefit of their CI (Mertens et al., 2016; Ramos-Marcías et al., 2018; Galvin et al., 2018). This evidence has contributed to the consideration of cochlear implantation as an appropriate, cost effective and worthwhile treatment option for patients who experience tinnitus (Ramos-Marcías et al., 2018; Elgandy et al., 2018). Gomersall et al. (2019) reported that a greater awareness of tinnitus during switch off periods was one of the main reasons behind improved CI use.

Study results indicated a small negative correlation between perceived tinnitus distress and improved hearing-related QoL outcomes for adult CI recipients in this study sample. The nature of the relationship between these two variables confirms that greater tinnitus distress will lead to a poorer hearing-related QoL. This negative correlation was confirmed by Brüggemann et al. (2016) who indicated that tinnitus distress had a negative effect on the emotional stress, somatic symptoms and hearing problem subscales used to compute the mental health of patients (Brüggemann et al., 2016). The tinnitus related emotional and cognitive distress as well as tinnitus related auditory difficulties that persisted post CI negatively influenced the QoL of CI recipients as confirmed by the significant negative correlation found between the TQ score and all NCIQ subscales (Knopke et al., 2017). Thus the reduction of tinnitus related distress coincide with an increase in a CI recipient's QoL (Knopke et al., 2016, 2017; Olze et al., 2016).

Tinnitus distress was identified as a strong predictor of poorer hearing-related QoL, not only preoperatively, but also 12 months postoperatively when controlling for many cofounders, including speech perception. Out of all 13 potential predictors, tinnitus distress was identified as a significant predictor of hearing-related QoL outcomes in three of the four significant models. Previously, using the NCIQ and HUI3 as QoL outcome measures respectively, both le Roux et al. (2017) and Lenarz et al. (2017) identified preoperative tinnitus as a significant prognostic indicator for reduced health-related QoL outcomes in adult CI recipients. However, this present study adds to existing literature by confirming that both a history of tinnitus prior to CI and residual tinnitus existing post CI was predictive of poorer hearing-related QoL. Contrary to expectation, speech perception testing outcomes were not confirmed as a prognostic factor for hearing-related QoL outcomes in this dataset.

An additional finding from this study was that *aversiveness* was identified as being associated with tinnitus distress. This association was confirmed with the identification of tinnitus distress as a significant predictive factor for poorer hearing-related QoL within the *aversiveness* APHAB sub-domain. The aversiveness of sound in CI users, however, are suggested by the current study results to be linked to the experience of tinnitus additional to a hearing problem. Lower average scores for the *aversiveness* APHAB sub-domain (indicating better hearing-related QoL) observed in this study, can be explained by the fact that only half (49.52%) of the study sample reported tinnitus distress preoperatively. Moreover, the aversiveness score reducing over time can be attributed to the similarly noted tinnitus suppression proceeding over time in this study. To corroborate this statement, Olze et al. (2011) utilized the brief *COPE* to measure the coping behaviour of 43 adult CI patients in unpleasant situations and found a linear correlation between evasive coping (denial, self-blame, venting) and tinnitus. A CI recipient's negative reaction towards environmental sounds are quantified by the APHAB *aversiveness* sub-domain (Cox & Alexander, 1995). The link between tinnitus and this specific sub-domain therefore indicated that adult CI recipients who experience tinnitus distress are more likely to perceive the described environmental sounds as uncomfortably loud in their everyday lives. A further explanation for this phenomenon may be ascribed to the co-occurrence of tinnitus and hyperacusis (Pienkowski, 2019). Four out of 10 individuals who experience tinnitus also experience some form of hyperacusis (Baguley, 2018). Additionally, hyperacusis can also be a possible explanation for both the uncomfortable loudness (Tyler et al., 2015) as well as the avoidance of sounds (Aazh et al., 2014) accredited to the experience of tinnitus in this study.

In addition to tinnitus distress, younger age at implantation was also indicated in this study as a strong predictor for better hearing-related QoL outcomes. While Farinetti et al. (2014) supports this finding, a number of studies found no association between age at implantation and hearing-related QoL outcomes (Sladenet al., 2017; Lenarz et al., 2017; Copeland & Pillsbury., 2004; le Roux et al., 2017; Garcia et al., 2018; Capretta & Moberly, 2016).

Prognostication should be prioritized by both individual CI teams as well as CI programs in order to predict CI outcomes with certainty (Black et al., 2011). The importance of standardized, routine documentation of outcome data should be highlighted as such continuous, uniform collection of hearing-related QoL outcome data may also contribute to determining the impact of postoperative rehabilitative strategies on a CI recipient's perceived benefit from the device. In addition to TRQ scores, the inclusion of descriptive information on tinnitus in future CI studies, may contribute to the understanding of a complicated issue experienced by CI recipients and the effect that it has on the hearing-related QoL of these CI recipients.

4.2 Strengths and limitations

Strengths and limitations of this study was identified by conducting a critical evaluation of study methods and findings.

4.2.1 Study strengths

Even though the data used in this study was of a retrospective nature, the actual data were initially captured in real time for adult CI recipients of the Ear Science Institute Australia – Ear Science Clinic, eliminating recall bias.

With a study sample consisting of 210 adult CI recipients, this current study explored one of the largest datasets on tinnitus and hearing-related QoL in CI recipients to date. This larger sample more closely approximated the CI population and yielding more reliable results with greater precision.

Study findings contributed to the research field concerned with hearing-related QoL and tinnitus in CI recipients that is currently made up of a limited number of available studies. Not only was the suppressive effect of a CI for tinnitus confirmed and tinnitus distress identified as a predictor for hearing-related QoL outcomes in adult CI recipients, but this was done over time. Long term interval data were available which allowed for multiple regression analyses at various points in time as to study hearing-related QoL predictor factors for adult CI recipients at consecutive data points. Both Le Roux et al. (2017) and Lenarz et al. (2017) recently confirmed that patient report of tinnitus prior to cochlear implantation was strongly predictive of reduced QoL outcomes in adult CI recipients. However, to the researcher's knowledge, this study was the first of its kind to identify residual tinnitus distress post-implantation as a predictive factor for poorer hearing-related QoL.

An extensive range of possible predictive factors were identified from the retrospective dataset and included as independent variables in the regression models. This study thus tested for the possible influence of 13 predictor variables on hearing-related QoL outcomes in adult CI recipients.

4.2.2 Study limitations

Due to the retrospective nature of this study and the inevitable incidence of missing data when collecting these in a clinical setting, data for all variables were not available for each individual CI recipient at each time interval. To minimize missing data, interval data points were combined as described in the data analysis section. To further account for missing data, average scores at the respective time intervals were used rather than specific individual scores tracked over time. As a result of this, it was not possible to track specific, individual CI recipients over time and determine the exact number of participants for whom tinnitus decreased, worsened, or initiated following implantation.

Data was initially collected as part of a standard clinical protocol at *ESIA*. Thus, when questionnaire data was collected (TRQ and APHAB) it was not anonymous, being part of the clinical protocols for assessment of implant recipients. Some bias may have been introduced into the questionnaire responses as a result of this, as recipients may have provided more positive than true answers to meet what they may have thought were the expectations of the clinicians.

Possible scenarios of tinnitus relief post CI include that of auditory improvement, allowing for the patient to focus on sounds other than tinnitus, as well as the speculation that plastic changes in the auditory system, brought on by electrical stimulation of the auditory nerve after implantation, reduces the perception of tinnitus (Knopke et al., 2017). Considering this, it would have been interesting to study the difference in effect of bilateral and unilateral CI on tinnitus distress specifically. Bilateral implantation could however not be statistically validated as a predictor of hearing-related QoL due to the small number of bilaterally implanted recipients within the study sample.

As per the inclusion criteria, only adult CI recipients who had preoperative TRQ and APHAB scores available, were included as study participants in this current study. This led to the inclusion of multiple zero TRQ scores for all those who self-reported a tinnitus sensation but reported no associated distress. Even though this caused relatively low TRQ mean scores, it ensured that no tinnitus experiencing participants from the dataset were excluded from this study.

Of all the clinical measuring tools available for tinnitus, the use of the TRQ has not been very common over the last decade (Harris et al., 2011). However, in a systematic review of studies between 1996 to 2014, the TRQ was reported to be the most frequently used tool to measure tinnitus distress specifically (Tegg-Quinn et al., 2016). Hearing-related QoL outcomes in this study were measured by the APHAB. Even though the APHAB in its original format was designed as a questionnaire for hearing aid users, it has been utilized in a number of studies to document subjective patient reports regarding hearing with CIs (Dillon et al., 2018; Kloostra et al., 2015; Ramos-Macías et al., 2016; Sladen et al., 2017; Skarzynski et al., 2006). In spite of the fact that the APHAB is frequently linked to health-related QoL outcomes in studies related to hearing-assistive devices (including CIs), more recently developed disease-specific health-related QoL measures (such as the *Nijmegen Cochlear Implant Questionnaire*) are preferred for adult CI recipients.

Linear regression models in this study presented with determination coefficients (R^2) ranging between 21% and 26%. These determination coefficients indicate that less than a third (33%) of the variation in the hearing-related QoL outcomes observed in the data was accounted for by the specified models. This implies that hearing-related QoL outcomes in adult CI recipients are determined by many more single or interacting factors that were not included in these models.

4.3 Clinical implications

It is of great importance that all possible tinnitus changes following a CI is explained to the CI recipients as well as transparently included in patient informed consent (Bovo et al., 2011). Insufficient attention has often been paid to those cases in which tinnitus worsened after cochlear implantation (Tyler et al., 2009). Evidence has shown that CI recipients who harbour realistic outcome expectations has a better QoL with their CI (Harris et al., 2016). Preoperative, individualized counselling around both tinnitus and CI outcomes are needed to ascertain a full understanding of the CI process as well as to foster realistic outcome expectations (Parikh et al., 2017). The prognostic factors identified in this study lends supporting evidence to tinnitus distress outcomes to be included in patient consent to warrant it being transparent and openly informative. Results from this study report on the effect of tinnitus distress and identified prognostic factors over time which can aid CI teams in providing CI recipients with realistic long-term expectations.

The adverse effect that residual tinnitus has on the hearing-related QoL of CI recipients is not to be overlooked and CI recipients, both potential and existing, who experience tinnitus distress should be earmarked for counselling and timely monitoring. Evidence ascribed a great deal of postoperative anxiety and depression to the experience of residual tinnitus (Andersson et al., 2009) and moreover suggested tinnitus as a hindrance to the conventional auditory rehabilitation process for CI recipients (Knopke et al., 2017). Study findings contribute to a better understanding of the factors influencing hearing-related QoL outcomes in adult CI recipients, allowing clinicians to adjust treatment to foster an increased chance of tinnitus recovery postoperatively (Ramakers et al., 2018). Adult CI recipients will only be able to set evidence-based expectations for themselves when they are guided by professionals who are able to distinguish between factors that will affect CI outcomes both favourably and unfavourably. Auditory rehabilitation as well as postoperative counselling services rendered to this unique group of CI recipients should include access to additional tinnitus support services as required individually (Müller & Raine, 2013). Close collaboration between CI and tinnitus specialities will offer a more integrated treatment and rehabilitation approach to CI recipients and address the need for comprehensive psychosomatic care throughout the entire CI process (Brüggemann et al., 2017; Harris et al., 2011).

Proven by this study was the negative effect that residual tinnitus distress has on hearing-related QoL outcomes. This emphasizes the importance of the identification, counselling and timely monitoring of CI recipients who experience tinnitus pre- and postoperatively in order for clinicians to provide a comprehensive service delivery to this unique group of CI recipients. It is clear that tinnitus distress is an ailment that should be taken into account for every individual considered for a CI. The inclusion of tinnitus screening in CI candidacy considerations may facilitate a more accurate prediction of outcomes post CI. A candidacy criteria of this comprehensive nature could also assist in ensuring that a costly CI device is only allocated to a recipient who are sure to experience the maximum benefit thereof.

The treatment of tinnitus itself and the treatment of a patient’s reaction to tinnitus should be differentiated. Tinnitus can have a negative effect on many aspects of a patient’s everyday life including hearing, concentration, emotions and sleep of which the reactions to these can successfully be treated with medication (Elgandy et al., 2018). However, the treatment of tinnitus itself is a different scenario. For the greater majority of cases, no surgery or medication have been approved and treatment consequently comes down to patient centred counselling strategies (Elgandy et al., 2018). This study not only confirmed the suppressive effect that a CI has on tinnitus, but also identified tinnitus distress as a predictive factor of poorer hearing-related QoL outcomes up to one year post-implantation. These results suggest that even though the physical treatment of tinnitus can be successful to an extent, it is essentially limited and the need for additional treatment beyond the physical is emphasised. It is suggested that additional, tinnitus specific care can be divided into information (understanding tinnitus), talking therapies (different individual counselling options), sound (external sound, hearing aids and implantable devices) and group support (Pryce et al., 2018). With a complex condition like tinnitus, where no independent treatment has been proven effective, the emphasis on patient preference is imperative throughout the therapy plan and decision making process (Pryce et al., 2018). The clinician should therefore guide the patient with tinnitus through all the possible therapy choices to arrive at a therapy choice that is in line with the patient’s desired and informed preference (Pryce et al., 2018; Stacey et al., 2017).

The clinical relevance of reduced tinnitus distress post-implantation is highlighted by improved hearing-related QoL outcomes portrayed by CI recipients who experience a relief in tinnitus distress post-implantation. Tinnitus can negatively influence hearing, concentration, emotions and sleep (Elgandy et al., 2018) and lead to anxiety, depression (Andersson et al., 2009) and even a decreased perceived CI benefit (Brüggemann et al., 2017). Considering this, it can be assumed that reduced tinnitus distress post-implantation will have the opposite effect, leading to less hearing-, concentration-, sleep- and emotional disturbances, greater perceived benefit from the CI and also improved QoL outcomes, as corroborated by this and multiple other studies (Contrera et al., 2016; Knopke et al., 2017; Lenarz et al., 2017; Ramos-Marcías et al., 2018).

Literature search during this study once again brought to light the large variety of outcome measures used for both tinnitus and hearing-related QoL. The use of standardized, valid and reliable questionnaires at set follow up intervals by various CI facilities as a mean of collecting both tinnitus and hearing-related QoL data could ensure compatible data that can be effectively collected across CI programs. Such continuous, uniform collection of hearing-related QoL outcome data may also contribute to determine the impact of postoperative rehabilitative strategies upon a CI recipient's perceived benefit from the device.

4.4 Future research perspectives

Predicting factors of tinnitus outcomes include tinnitus severity (continuity, awareness and loudness of the tinnitus), the preoperative auditory steady state response and the level of depression experienced (Hoekstra et al., 2014; Kim et al., 2016). A deeper understanding of the factors that are associated with tinnitus severity could increase the effectiveness of care provided to those patients who experience tinnitus (Hoekstra et al., 2014). Future studies should therefore focus on the influence of variables such as tinnitus type, loudness, pitch, awareness, and pulsatality on perceived tinnitus outcomes.

Prospective, longitudinal future research with regards to the interaction between tinnitus and CI should be conducted. This type of research will yield valuable information as it will allow for specific individuals to be to be tracked over time, eliminating retrospective recall bias as well as the inevitable occurrence of relatively large portions of missing data in retrospective studies. Prospective longitudinal studies are needed to gather and present information on the changes in tinnitus for each specific CI recipient over time. This will allow for a better understanding into the complex interaction between a recipient's tinnitus and CI, which varies from person to person.

Even though a variety of tinnitus treatment types with varying evidence to support efficacy is found throughout literature (Zenner et al., 2017), to the researcher's knowledge there is no set referral pathway for the treatment of tinnitus in CI recipients. Investigation into the current practice for tinnitus rehabilitation, support and treatment used for CI recipients is required in order to establish tinnitus referral pathways with access to a variety of treatment options within this pathway. Furthermore, research measuring the outcomes of tinnitus rehabilitation is lacking (Henry, 2016). In order to determine the effectiveness of tinnitus treatments as well as to narrow treatment options down to viable methods, prospective, longitudinal research should investigate the effect of rehabilitation and treatment services on tinnitus outcomes.

4.5 Conclusion

Less tinnitus distress and a younger age at cochlear implantation have been identified as strong predictors of better hearing-related QoL outcomes in adult CI recipients. Lower tinnitus distress and younger age at implantation were the only two out of 13 possible predictor variables that were identified as significant predictors of better hearing-related QoL in adult CI recipients. Moreover, study results provided evidence of a lowering in tinnitus distress together with an improvement of hearing-related QoL over time as a result of cochlear implantation, with 6 months postoperatively identified as the interval which presented the most significant change. The *background noise* and *reverberation* APHAB sub-domains were those in which the most handicap were experienced, with the a*versiveness* sub-domain presenting the least experienced handicap. A negative correlation between tinnitus distress and hearing-related QoL were confirmed, implying that higher levels of tinnitus distress are associated with poorer hearing-related QoL outcomes.

The negative effect that both pre- and postoperative tinnitus has on the hearing-related QoL outcomes of CI recipients was highlighted by this study. Furthermore, supporting evidence of the suppressive effect that a CI has on tinnitus was provided. This study contributed to a better understanding of the factors influencing hearing-related QoL outcomes in adult CI recipients, enabling clinicians to provide suitable preoperative counselling and postoperative rehabilitation which should be prioritized for all CI recipients who experience tinnitus.

REFERENCES

Aazh, H., Landgrebe, M., Danesh, A. A., & Moore, B. C. J. (2019). Cognitive Behavioral Therapy For Alleviating The Distress Caused By Tinnitus, Hyperacusis And Misophonia: Current Perspectives. *Psychology Research and Behavior Management*, *12*, 991–1002. https://doi.org/10.2147/PRBM.S179138

Aazh, H., McFerran, D., Salvi, R., Prasher, D., Jasterboff, M., & Jaterboff, P. (2014). Insights from the first international conference on hyperacusis: Causes, evaluation, diagnosis and treatment. *Noise & Health*, *16*(69), 123–126.

Alonso-Valerdi, L. M., Ibarra-Zarate, D. I., Tavira-Sánchez, F. J., Ramírez-Mendoza, R. A., & Recuero, M. (2017). Electroencephalographic evaluation of acoustic therapies for the treatment of chronic and refractory tinnitus. *BMC Ear, Nose and Throat Disorders*, *17*(1), 1–16. https://doi.org/10.1186/s12901-017-0042-z

Andersson, G. (2002). Psychological aspects of tunnitus and the application of cognitive-behavioral therapy. *Clinical Psychology Review*, *22*, 977–990. Retrieved from internal-pdf:/Andersson 2002.pdf

Andersson, G., Freijd, A., Baguley, D., & Idrizbegovic, E. (2009). Tinnitus distress, anxiety, depression, and hearing problems among cochlear implant patients with tinnitus. *Journal of the American Academy of Audiology*, *20*(5), 315–319. https://doi.org/10.3766/jaaa.20.5.5

Arnold, L., & Baumgärtel, R. (2018). Improving performance of unilateral CI users. *Journal of Hearing Science*, *8*(2), 115.

Artusi, R., Verderio, P., & Marubini, E. (2002). Bravais-Pearson and Spearman correlation coefficients: Meaning, test of hypothesis and confidence interval. *International Journal of Biological Markers*, *17*(2), 148–151. https://doi.org/10.5301/JBM.2008.2127

Babbie, E. R. (2016). *The practice of social research*. *Cengage Learning* (14th ed.). Boston, MA: Cengage Learning.

Badajoz-Davila, J., Buchholz, J., & Van-Hoesel, R. (2018). Effect of noise and reverberation on speech intelligibility in cochlear implant recipients considering realistic sound environments. *Journal of Hearing Science*, *8*(2), 100.

Baguley, D. M. (2018). *Hyperacusis and Disorders of Soind Intolerance: Clinical and Research Perspectives*. San Diego: Plural Publishing.

Baguley, D. M., & Atlas, M. D. (2007). Cochlear implants and tinnitus. *Progress in Brain Research*, *166*, 347–355. https://doi.org/10.1016/S0079-6123(07)66033-6

Bauer, C. A. (2018). Tinnitus. *New England Journal of Medicine*, *378*(13), 1224–1231. https://doi.org/10.1056/NEJMcp1506631

Bovo, R., Ciorba, A., & Martini, A. (2011). Tinnitus and cochlear implants. *Auris Nasus Larynx*, *38*(1), 14–20. https://doi.org/10.1016/j.anl.2010.05.003

Brüggemann, P., Szczepek, 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. *Frontiers in Human Neuroscience*, *11*(May), 1–13. https://doi.org/10.3389/fnhum.2017.00226

Brüggemann, P., Szczepek, A. J., Rose, M., McKenna, L., Olze, H., & Mazurek, B. (2016). Impact of Multiple Factors on the Degree of Tinnitus Distress. *Frontiers in Human Neuroscience*, *10*(June), 1–11. https://doi.org/10.3389/fnhum.2016.00341

Capretta, N. R., & Moberly, A. C. (2016). Does quality of life depend on speech recognition performance for adult cochlear implant users? *The Laryngoscope*, *126*(3), 699–706.

https://doi.org/10.1002/lary.25525

Chandra, R. K., Epstein, V. A., & Fishman, A. J. (2009). Prevalence of depression and antidepressant use in an otolaryngology patient population. *Otolaryngology - Head and Neck Surgery*, *141*(1), 136–138. https://doi.org/10.1016/j.otohns.2009.03.030

Chia, E.-M., Wang, J. J., Rochtchina, E., Cumming, R. R., Newall, P., & Mitchell, P. (2007). Hearing Impairment and Health-Related Quality of Life: The Blue Mountains Hearing Study. *Ear and Hearing*, *28*(2). Retrieved from https://journals.lww.com/ear-hearing/Fulltext/2007/04000/Hearing_Impairment_and_Health_Related_Quality_of.6.aspx

Chung, J., Chueng, K., Shipp, D., Friesen, L., Chen, J., Nedzelski, J. M., & Lin, V. Y. W. (2012). Unilateral Multi-Channel Cochlear Implantation Results in Significant Improvement in Quality of Life. *Otology & Neurotology*, *33*(4), 566–571.

Chung, J. H., & Lee, S. H. (2016). The Pathophysiologic Mechanism of Tinnitus. *Hanyang Medical Reviews*, *36*(2), 81. https://doi.org/10.7599/hmr.2016.36.2.81

Cima, R. F. F. (2018). Bothersome tinnitus: Cognitive behavioral perspectives. *Hno*, *66*(5), 369–374. https://doi.org/10.1007/s00106-018-0502-9

Collins, G. S., Reitsma, J. B., Altman, D. G., & Moons, K. G. M. (2015). Transparent reporting of a multivariable prediction model for individual prognosis or diagnosis (TRIPOD): The TRIPOD Statement. *European Urology*, *67*(6), 1142–1151. https://doi.org/10.1016/j.eururo.2014.11.025

Contrera, K. J., Betz, J., Li, L., Blake, C. R., Sung, Y. K., Choi, J. S., & Lin, F. R. (2016). Quality of life after intervention with a cochlear implant or hearing aid. *Laryngoscope*, *126*(9), 2110–2115. https://doi.org/10.1002/lary.25848

Copeland, B. J., & Pillsbury, H. C. (2004). Cochlear Implantation for the Treatment of Deafness. *Annual Review of Medicine*, *55*(1), 157–167. https://doi.org/10.1146/annurev.med.55.091902.105251

Cox, R M, & Alexander, G. C. (1995). The abbreviated profile of hearing aid benefit. *Ear and Hearing*, *16*(2), 176–186. https://doi.org/10.1097/00003446-199504000-00005

Cox, Robyn M, & Alexander, G. C. (1995). The Abbreviated Profile of Hearing Aid Benefit. *Ear and Hearing*, *17*(1), 31–48. https://doi.org/10.1097/00003446-199504000-00005

Dalton, D. S., Cruickshanks, K. J., Klein, B. E. K., Klein, R., Wiley, T. L., & Nondahl, D. M. (2003). The Impact of Hearing Loss on Quality of Life in Older Adults. *The Gerontologist*, *43*(5), 661–668. https://doi.org/10.1093/geront/43.5.661

Dillon, M. T., Buss, E., Rooth, M. A., King, E. R., Deres, E. J., Buchman, C. A., … Brown, K. D. (2018). Effect of Cochlear Implantation on Quality of Life in Adults with Unilateral Hearing Loss. *Audiology & Neuro-Otology*, *22*(4–5), 259–271. Retrieved from http://search.ebscohost.com/login.aspx?direct=true&db=eoah&AN=44391734&site=ehost-live&scope=site

Elgandy, M. S., Tyler, R., Dunn, C., Hansen, M., & Gantz, B. (2018). A Unilateral Cochlear Implant for Tinnitus. *International Tinnitus Journal*, *22*(2), 128–132. https://doi.org/10.5935/0946-5448.20180022

Etikan, I. (2016). Comparison of Convenience Sampling and Purposive Sampling. *American Journal of Theoretical and Applied Statistics*, *5*(1), 1. https://doi.org/10.11648/j.ajtas.20160501.11

Farinetti, A., Ben Gharbia, D., Mancini, J., Roman, S., Nicollas, R., & Triglia, J. M. (2014). Cochlear implant complications in 403 patients: Comparative study of adults and children and review of the literature. *European Annals of Otorhinolaryngology, Head* *and Neck Diseases*, *131*(3), 177–182. https://doi.org/10.1016/j.anorl.2013.05.005

Fischer, M. E., Cruickshanks, K. J., Klein, B. E. K., Klein, R., Schubert, C. R., & Wiley, T. L. (2009). Multiple sensory impairment and quality of life. *Ophthalmic Epidemiology*, *16*(6), 346–353. https://doi.org/10.3109/09286580903312236

Galvin, J. J., Fu, Q., Wilkinson, E. P., Mills, D., Hagan, S. C., Lupo, J. E., … Shannon, R. V. (2018). Benefits of Cochlear Implantation for Single-Sided Deafness : Data From the House Clinic-University of Southern California-University of California , Los Angeles Clinical Trial. *Ear and Hearing*, 1–16.

Garcia, L., Zuriñe, I., Ane, M., Mercedes, U., & Xabier, F. (2018). Cochlear implantation in the elderly : outcomes , long-term evolution , and predictive factors. *European Archives of Oto-Rhino-Laryngology*, *275*(4), 913–922. https://doi.org/10.1007/s00405-018-4910-y

Giltinane, C. L. (2013). Reliability and validity in research, *20*(Cook 1999), 39–44. https://doi.org/10.7748/ns2013.06.27.41.35.e7565

Gomersall, P. A., Baguley, D. M., & Carlyon, R. P. (2019). A Cross-Sectional Questionnaire Study of Tinnitus Awareness and Impact in a Population of Adult Cochlear Implant Users. *Ear and Hearing*, *40*(1), 135–142.

Han, B., Lee, H., Kim, T., Lim, J., & Shin, K. (2009). Tinnitus: Characteristics, causes, mechanisms, and treatments. *Journal of Clinical Neurotology*, *5*, 11–19.

Härkönen, K., Kivekäs, I., Rautiainen, M., Kotti, V., Sivonen, V., & Vasama, J.-P. (2015). Sequential bilateral cochlear implantation improves working performance, quality of life, and quality of hearing. *Acta Oto-Laryngologica*, *6489*(October 2014), 1–7. https://doi.org/10.3109/00016489.2014.990056

Harris, F., Parker, R., Fields, S., Frewin, B., & Baguley, D. M. (2011a). Identifying and treating persistent tinnitus in CI users. *Cochlear Implants International*, *12 Suppl 2*, S33-5. https://doi.org/10.1179/146701011x13074645127432

Harris, F., Parker, R., Fields, S., Frewin, B., & Baguley, D. M. (2011b). Identifying and treating persistent tinnitus in CI users. *Cochlear Implants International*, *12*(s2), S33–S35. https://doi.org/10.1179/146701011X13074645127432

Harris, M. S., Capretta, N. R., Henning, S. C., Feeney, L., Pitt, M. A., & Moberly, A. C. (2016). Postoperative Rehabilitation Strategies Used by Adults With Cochlear Implants: A Pilot Study. *Laryngoscope Investigative Otolaryngology*, *1*(3), 42–48. https://doi.org/10.1002/lio2.20

Hashir, A., & Richard, S. (2018). The Relationship between Severity of Hearing Loss and Subjective Tinnitus Loudness among Patients Seen in a Specialist Tinnitus and Hyperacusis Therapy Clinic in UK. *American Journal of Audiology*, *30*(8), 712–719.

Hawthorne, G., Hogan, A., Giles, E., Stewart, M., Kethel, L., White, K., … Taylor, A. (2004). Evaluating the health-related quality of life effects of cochlear implants: a prospective study of an adult cochlear implant program. *International Journal of Audiology*, *43*(4), 183–192. https://doi.org/10.1080/14992020400050026

Haynes, W. O., & Johnson, C. E. (2009). *Understanding research and evidence-based practice in communication disorders: A primer for students and practitioners* (1st ed.). Pearson.

Hazell, J. W. P., McKinney, C. J., & Aleksy, W. (1995). Mechanism of tinnitus in profound deafness. *Annals of Otology, Rhinology and Laryngology*, *166*, 418–420.

Henry, J. A. (2016). “measurement” of Tinnitus. *Otology and Neurotology*, *37*(8), e276–e285. https://doi.org/10.1097/MAO.0000000000001070

Henry, J. A., Zaugg, T. L., Meyers, P. J., & Schechter, M. A. (2008). Using Therapeutic Sound With Progressive Audiologic Tinnitus Management. *Trends in Amplification*, *12*(3), 188–

209. Retrieved from http://search.ebscohost.com/login.aspx?direct=true&db=rzh&AN=105780919&site=ehost-live

Hirschfelder, A., Grabel, S., & Olze, H. (2008). The impact of cochlear implantation on quality of life: The role of audiologic performance and variables. *Otolaryngology–Head and Neck Surgery*, *138*(3), 357–362. https://doi.org/https://doi.org/10.1016/j.otohns.2007.10.019

Hoekstra, C. E. L., Wesdorp, F. M., & van Zanten, G. A. (2014). Socio-demographic, health, and tinnitus related variables affecting tinnitus severity. *Ear and Hearing*, *35*(5), 544–554. https://doi.org/10.1097/AUD.0000000000000045

House, J. W., Kutz Jr., J. W., Chung, J., & Fisher, L. M. (2010). Bone-anchored hearing aid subjective benefit for unilateral deafness. *The Laryngoscope*, *120*(3), 601–607. https://doi.org/10.1002/lary.20802

Kim, D. K., Moon, I. S., Lim, H. J., Yoo, S. Y., Heo, K. W., Bae, S. C., … Park, S. N. (2016). Prospective, Multicenter Study on Tinnitus Changes after Cochlear Implantation. *Audiology and Neurotology*, *21*(3), 165–171. https://doi.org/10.1159/000445164

King, N., Nahm, E. a, Liberatos, P., Shi, Q., & Kim, A. H. (2014). A new comprehensive cochlear implant questionnaire for measuring quality of life after sequential bilateral cochlear implantation. *Otology & Neurotology : Official Publication of the American Otological Society, American Neurotology Society [and] European Academy of Otology and Neurotology*, *35*(3), 407–413. https://doi.org/10.1097/MAO.0000000000000229

Kitterick, P. T., Lucas, L., & Smith, S. N. (2015). Improving Health-Related Quality of Life in Single-Sided Deafness : A Systematic Review and Meta-Analysis. *Audiology & Neurotology*, *20*(suppl 1), 79–86. https://doi.org/10.1159/000380753

Kloostra, F. J. ., Arnold, R., Hofman, R., & Van Dijk, P. (2015). Changes in Tinnitus after Cochlear Implantation and Its Relation with Psychological Functioning. *Audiology & Neurotology*, *20*, 81–89. https://doi.org/10.1159/000365959

Knopke, S., Gräbel, S., Förster-Ruhrmann, U., Mazurek, B., Szczepek, A. J., & Olze, H. (2016). Impact of cochlear implantation on quality of life and mental comorbidity in patients aged 80 years. *Laryngoscope*, *126*(12), 2811–2816. https://doi.org/10.1002/lary.25993

Knopke, S., Szczepek, A. J., Häussler, S. M., Gräbel, S., & Olze, H. (2017). Cochlear implantation of bilaterally deafened patients with tinnitus induces sustained decrease of tinnitus-related distress. *Frontiers in Neurology*, *8*(APR). https://doi.org/10.3389/fneur.2017.00158

Kou, B. S., Shipp, D. B., & Nedzelski, J. M. (1994). Subjective benefits reported by adult Nucleus 22-channel cochlear implant users. *Journal of Otolaryngology*, *23*(1), 8–14.

Kumar, R. (2014). *Research methodology : a step-by-step guide for beginners* (Fourth edi). Los Angeles : SAGE,.

le Roux, T., Vinck, B., Butler, I., Louw, L., Nauta, L., Schlesinger, D., & Swanepoel, D. W. (2017). Predictors of health-related quality of life in adult cochlear implant recipients in South Africa. *International Journal of Audiology*, *2027*, 0–8. https://doi.org/10.1080/14992027.2016.1227482

le Roux, Talita, Vinck, B., Butler, I., Louw, L., Nauta, L., Schlesinger, D., & Swanepoel, D. W. (2017). Predictors of health-related quality of life in adult cochlear implant recipients in South Africa. *International Journal of Audiology*, *56*(1), 16–23. https://doi.org/10.1080/14992027.2016.1227482

Leedy, P. D., & Ormrod, J. E. (2010). *Practical Research: Planning and Design*. *Practical*

Research - Planning & Design.

Lenarz, T., Muller, L., Czerniejewska-Wolska, H., Varela, H. V., Dotú, C. O., Durko, M., … Wyss, J. (2017). Patient-Related Benefits for Adults with Cochlear Implantation: A Multicultural Longitudinal Observational Study. *Audiology and Neurotology*, *22*(2), 61–73. https://doi.org/10.1159/000477533

Lin, L.-M., Bowditch, S., Anderson, M. J., May, B., Cox, K. M., & Niparko, J. K. (2006). Amplification in the Rehabilitation of Unilateral Deafness: Speech in Noise and Directional Hearing Effects with Bone-Anchored Hearing and Contralateral Routing of Signal Amplification. *Otology & Neurotology*, *27*(2). Retrieved from https://journals.lww.com/otology-neurotology/Fulltext/2006/02000/Amplification_in_the_Rehabilitation_of_Unilateral.7.aspx

Litovsky, R., Parkinson, A., Arcaroli, J., & Sammeth, C. (2006). Simultaneous Bilateral Cochlear Implantation in Adults: A Multicenter Clinical Study. *Ear and Hearing*, *27*(6), 714–731. https://doi.org/10.1097/01.aud.0000246816.50820.42.Simultaneous

Loeffler, C., Aschendorff, A., Burger, T., Kroeger, S., Laszig, R., & Arndt, S. (2010). Quality of Life Measurements after Cochlear Implantation. *The Open Otorhinolaryngology Journal*, *4*, 47–54. https://doi.org/10.2174/1874428101004010047

Maillet, C., Tyler, R., & Jordan, H. (1995). Change in the quality of life of adult cochlear implant patients. *The Annals of Otology, Rhinology & Laryngology. Supplement*, *165*, 31–48.

Malouff, J. M., Schutte, N. S., & Zucker, L. A. (2011). Tinnitus-related Distress: A Review of Recent Findings. *Current Psychiatry Reports*, *13*(1), 31–36. https://doi.org/10.1007/s11920-010-0163-1

McCormack, A., Edmondson-Jones, M., Somerset, S., & Hall, D. (2016). A systematic review of the reporting of tinnitus prevalence and severity. *Hearing Research*, *337*, 70–79. https://doi.org/10.1016/j.heares.2016.05.009

Mertens, G., De Bodt, M., & Van de Heyning, P. (2016). Cochlear implantation as a long-term treatment for ipsilateral incapacitating tinnitus in subjects with unilateral hearing loss up to 10 years. *Hearing Research*, *331*, 1–6. https://doi.org/10.1016/j.heares.2015.09.016

Miyamoto, R. T., & Bichey, B. G. (2003). Cochlear implantation for tinnitus suppression. *Otolaryngologic Clinics of North America*, *36*(2), 345—352. https://doi.org/10.1016/s0030-6665(02)00165-2

Miyamoto, R. T., Wynne, M. K., McKnight, C., & Bichey, B. (1997). Electrical suppression of tinnitus via cochlear implants. *International Tinnitus Journal*, *3*, 35–38.

Mobascher, A., Brinkmeyer, J., Warbrick, T., Musso, F., Wittsack, H. J., Saleh, A., … Winterer, G. (2009). Laser-evoked potential P2 single-trial amplitudes covary with the fMRI BOLD response in the medial pain system and interconnected subcortical structures. *NeuroImage*, *45*(3), 917–926. https://doi.org/10.1016/j.neuroimage.2008.12.051

Moore, B. C. J., & Popelka, G. R. (2013). Preliminary comparison of bone-anchored hearing instruments and a dental device as treatments for unilateral hearing loss. *International Journal of Audiology*, *52*(10), 678–686. https://doi.org/10.3109/14992027.2013.809483

Müller, J., & Raine, C. H. (2013). Quality standards for cochlear implantation in children and young adults. *Cochlear Implants International*, *14 Suppl 2*, 13–20. https://doi.org/10.1179/1467010013Z.00000000099

Nondhal, D. M., Cruickshanks, K. J., Dalton, D. S., Klein, B. E. K., Klein, R., Schubert, C. R., … Wiley, T. L. (2007). The Impact of Tinnitus on Quality of Life in Older Adults. *Journal of the American Academy of Audiology*, *18*(3), 257–266.

Olze, H., Gräbel, S., Haupt, H., Förster, U., & Mazurek, B. (2012). Extra Benefit of a Second Cochlear Implant With Respect to Health-Related Quality of Life and Tinnitus. *Otology & Neurotology*, *33*(7), 1169–1175. https://doi.org/10.1097/MAO.0b013e31825e799f

Olze, H., Knopke, S., Gräbel, S., & Szczepek, A. J. (2016). Rapid Positive Influence of Cochlear Implantation on the Quality of Life in Adults 70 Years and Older. *Audiology and Neurotology*, *21*(1), 43–47. https://doi.org/10.1159/000448354

Olze, H., Szczepek, A. ., Haupt, H., Zirke, N., Graebel, S., & Mazurek, B. (2011). The Impact of Cochlear Implantation on Tinnitus, Stress and Quality of Life in Postlingually Deafened Patients. *Audiology and Neurotology*, *17*(1).

Olze, H., Szczepek, A. ., Haupt, H., Zirke, N., Graebel, S., & Mazurek, B. (2012). The Impact of Cochlear Implantation on Tinnitus, Stress and Quality of Life in Postlingually Deafened Patients. *Audiology & Neurotology*, *17*(1), 2–11. https://doi.org/10.1159/000323847

Olze, H., Szczepek, A. J., Haupt, H., Förster, U., Zirke, N., Gräbel, S., & Mazurek, B. (2011). Cochlear implantation has a positive influence on quality of life, tinnitus, and psychological comorbidity. *Laryngoscope*, *121*(10), 2220–2227. https://doi.org/10.1002/lary.22145

Parikh, S. R., Machleder, D. J., Chobot-Rodd, J., Girouard, K., Shanske, A., Stern, E., … Dinces, E. (2017). Building a Multidisciplinary Cochlear Implant Team. *Einstein Journal of Biology and Medicine*, *21*(1), 19. https://doi.org/10.23861/ejbm200421456

Pienkowski, M. (2019). Rationale and Efficacy of Sound Therapies for Tinnitus and Hyperacusis. *Neuroscience*, *407*(January), 120–134. https://doi.org/10.1016/j.neuroscience.2018.09.012

Pryce, H., Durand, M.-A., Hall, A., Shaw, R., Culhane, B.-A., Swift, S., … Chilvers, K. (2018). The development of a decision aid for tinnitus. *International Journal of Audiology*, *0*(0), 1–6. https://doi.org/10.1080/14992027.2018.1468093

Quaranta, N., Wagstaff, S., & Baguley, D. M. (2004). Tinnitus and cochlear implantation, *43*, 245–251.

Ramakers, G. J., Van Zon, A., Stegeman, I., & Grolman, W. (2015). The effect of cochlear implantation on tinnitus in patients with bilateral hearing loss: A systematic review. *Laryngoscope*, *125*(11), 2584–2592. https://doi.org/10.1002/lary.25370

Ramakers, G., van Zanten, G., Thormeer, H., Stokroos, R., Heymans, M., & Stegman, I. (2018). Development and internal validation of a multivariable prediction model for tinnitus recovery following unilateral cochlear implantation: a cross-sectional. *BMJ Open*, 1–9. https://doi.org/10.1136/bmjopen-2017-021068

Ramos-Macías, Á., Falcón González, J. C., Borkoski-Barreiro, S. A., Ramos de Miguel, Á., Batista, D. S., & Pérez Plasencia, D. (2016). Health-related quality of life in adult cochlear implant users: A descriptive observational study. *Audiology & Neurotology*, *21*(Suppl 1), 36–42. https://doi.org/10.1159/000448353

Ramos-Marcías, A., Falcón-González, J. C., Rodríguez, M. M., Pérez, C. M., García-Ibáñez, L., Cenjor, E. C., … Killian, M. (2018). One-Year Results for Patients with Unilateral Hearing Loss and Accompanying Severe Tinnitus and Hyperacusis Treated with a Cochlear Implant. *Audiology and Neurotology*, *23*(1), 8–19. https://doi.org/10.1159/000488755

Ramos, A., Guerra-Jiménez, G., Rodriguez, C., Borkoski, S., Falcón, J. C., & Perez, D. (2013). Cochlear implants in adults over 60: A study of communicative benefits and the impact on quality of life. *Cochlear Implants International*, *14*(5), 241–245. https://doi.org/10.1179/1754762812Y.0000000028

Ramos, Á., Guerra-Jiménez, G., Rodriguez, C., Borkoski, S., Falcón, J. C., & Perez, D. (2013). Cochlear implants in adults over 60: A study of communicative benefits and the impact on quality of life. *Cochlear Implants International*, *14*(5), 241–245. https://doi.org/10.1179/1754762812Y.0000000028

Reavis, K. M., Rothholtz, V. S., Tang, Q., Carroll, J. A., Djalilian, H., & Zeng, F. G. (2012). Temporary suppression of tinnitus by modulated sounds. *JARO - Journal of the Association for Research in Otolaryngology*, *13*(4), 561–571. https://doi.org/10.1007/s10162-012-0331-6

Redfors, Y. D., Olaison, S., Karlsson, J., Hellgren, J., & Möller, C. (2014). Hearing-related, health-related quality of life in patients who have undergone otosclerosis surgery: A long-term follow-up study. *International Journal of Audiology*, *2027*(April), 1–7. https://doi.org/10.3109/14992027.2014.948220

Santa Maria, P. L., Domville-Lewis, C., Sucher, C. M., Chester-Browne, R., & Atlas, M. D. (2013). Hearing preservation surgery for cochlear implantation--hearing and quality of life after 2 years. *Otology & Neurotology : Official Publication of the American Otological Society, American Neurotology Society [and] European Academy of Otology and Neurotology*, *34*(3), 526–531. https://doi.org/10.1097/MAO.0b013e318281e0c9

Savastano, M. (2008). Tinnitus with or without hearing loss: are its characteristics different? *European Archives of Oto-Rhino-Laryngology*, *265*(11), 1295–1300. https://doi.org/10.1007/s00405-008-0630-z

Searchfield, G. D. (2014). Tinnitus what and where: An ecological framework. *Frontiers in Neurology*, *5*(DEC), 1–11. https://doi.org/10.3389/fneur.2014.00271

Sedley, W., Friston, K. J., Gander, P. E., Kumar, S., & Griffiths, T. D. (2016). An Integrative Tinnitus Model Based on Sensory Precision. *Trends in Neurosciences*, *39*(12), 799–812. https://doi.org/10.1016/j.tins.2016.10.004

Skarzynski, H., Lorens, A., Piotrowska, A., & Anderson, I. (2006). Partial deafness cochlear implantation provides benefit to a new population of individuals with hearing loss. *Acta Oto-Laryngologica*, *126*(9), 934–940. https://doi.org/10.1080/00016480600606632

Sladen, D. P., Gifford, R. H., Haynes, D., Kelsall, D., Benson, A., Lewis, K., … Driscoll, C. L. (2017). Evaluation of a revised indication for determining adult cochlear implant candidacy. *Laryngoscope*, *127*(10), 2368–2374. https://doi.org/10.1002/lary.26513

Sladen, D. P., Peterson, A., Schmitt, M., Olund, A., Teece, K., Dowling, B., … Driscoll, C. L. (2017). Health-related quality of life outcomes following adult cochlear implantation: A prospective cohort study. *Cochlear Implants International*, *18*(3), 130–135. https://doi.org/10.1080/14670100.2017.1293203

South African Medical Research Counsil. (2004). Ethics in Health Research: Principles, Structures and Processes. *Health (San Francisco)*, *97*(850), 1–67.

South African National Health Act. (2007).

Stacey, D., Légaré, F., Lewis, K., Barry, M. J., Bennett, C. L., Eden, K. B., … Trevena, L. (2017). Decision aids for people facing health treatment or screening decisions. *Cochrane Database of Systematic Reviews*, (10). https://doi.org/10.1002/14651858.cd001431.pub5

Summerfield, Q. A., Barton, G. R., Toner, J., McAnallen, C., Proops, D., Harries, C., … Pringle, M. (2006). Self-reported benefits from successive bilateral cochlear implantation in post-lingually deafened adults: randomised controlled trial. *International Journal of*

Audiology, *45 Suppl 1*(Supplement 1), S99-107. https://doi.org/10.1080/14992020600783079

Távora-Vieira, D., Marino, R., Acharya, A., & Rajan, G. P. (2015). The impact of cochlear implantation on speech understanding, subjective hearing performance, and tinnitus perception in patients with unilateral severe to profound hearing loss. *Otology & Neurotology: Official Publication Of The American Otological Society, American Neurotology Society [And] European Academy Of Otology And Neurotology*, *36*(3), 430–436. https://doi.org/10.1097/MAO.0000000000000707

Távora-Vieira, D., Marino, R., Krishnaswamy, J., Kuthbutheen, J., & Rajan, G. P. (2013). Cochlear implantation for unilateral deafness with and without tinnitus: A case series. *Laryngoscope*, *123*(5), 1251–1255. https://doi.org/10.1002/lary.23764

Tegg-Quinn, S., Bennett, R. J., Eikelboom, R. H., & Baguley, D. M. (2016). The impact of tinnitus upon cognition in adults: A systematic review. *International Journal of Audiology*, *2027*(August), 1–8. https://doi.org/10.1080/14992027.2016.1185168

Tyler, R S, & Kelsy, D. (1990). Advantages and disadvantages reported by some of the better cochlear implant patients. *American Journal of Otology*, *11*(4), 282–289.

Tyler, Richard S, Coelho, C., Pan, T., Ji, H., Gehringer, A. K., & Gogel, S. A. (2009). Changes in the Tinnitus Handicap Questionnaire After Cochlear Implantation. *American Journal of Audiology*, *18*(2), 144–151. https://doi.org/10.1044/1059-0889(2009/07-0042).Changes

Tyler, Richard S, Pienkowski, M., Roncancio, E. R., Jin Jun, H., Brozoski, T., Dauman, N., … Moore, B. C. H. (2015). A Review of Hyperacusis and Future Directions: Part I. Definitions and Manifestations. *American Journal of Audiology*, *23*(4), 402–419. https://doi.org/10.1044/2014

Van de Heyning, P., Gilles, A., Rabau, S., & Van Rompaey, V. (2015). Subjective tinnitus assessment and treatment in clinical practice: the necessity of personalized medicine. *Current Opinion in Otolaryngol Head Neck Surgery*, *23*, 369–375.

Vesterager, V. (1997). Fortnightly review: tinnitus investigation and management. *Bmj*, *314*(7082), 728–728. https://doi.org/10.1136/bmj.314.7082.728

von Leupoldt, A., Sommer, T., Kegat, S., Baumann, H. J., Klose, H., Dahme, B., & Büchel, C. (2009). Dyspnea and pain share emotion-related brain network. *NeuroImage*, *48*(1), 200–206. https://doi.org/10.1016/j.neuroimage.2009.06.015

Wackym, P. A., Runge-Samuelson, C. L., Firszt, J. B., Alkaf, F. M., & Burg, L. S. (2007). More challenging speech-perception tasks demonstrate binaural benefit in bilateral cochlear implant users. *Ear and Hearing*, *28*, 80S-85S. https://doi.org/10.1097/AUD.0b013e3180315117

Wilson, Peter H. Henry, Jane. Bowen, Maitland. Haralambous, G. (1991). Tinnitus research questionare Psychometric Properties of a Measure of Distress Associated with Tinnitus.pdf. *Journal of Speech and Hearing Research*, *34*(1), 197–201. https://doi.org/10.1044/jshr.3401.197.

Wilson, P. H., Henry, J., Bowen, M., & Haralambous, G. (1991). Tinnitus Reaction Questionnaire: Psychometric Properties of a Measure of Distress Associated With Tinnitus. *Journal of Speech and Hearing Research*, *34*, 197–201.

Zaidman-Zait, A., & Smith, M. (2010). Quality of Life Among Cochlear Implant Recipients. *International Encyclopedia of Rehabilitation*. Retrieved from http://cirrie.buffalo.edu/encyclopedia/en/article/293/

Zenner, H.-P., Delb, W., Kröner-Herwig, B., Jäger, B., Peroz, I., Hesse, G., … Langguth, B.

(2017). A multidisciplinary systematic review of the treatment for chronic idiopathic tinnitus. *European Archives of Oto-Rhino-Laryngology*, *274*(5), 2079–2091. https://doi.org/10.1007/s00405-016-4401-y

APPENDICES

Appendix A: Patient consent

Implant - Client Details Form

Title: Dr Mr Mrs Ms Miss Date of Birth: ______________________________

Surname: ______________________________ First Names: ______________________________

Address: ____

Suburb: ______________________________ Post code: ______________________________

Phone No: ______________________________ Mobile No: ______________________________

Email: ______________________________ Preferred Contact Method: ___________________

Emergency Contact Name: __________________ Phone: ___________________________________

Emergency Contact Relationship: ____

Medicare No: _________________________ Ref No: __________ Expiry: __________________

Health Insurance Fund: __________________ Membership No: _________________ Ref No: _______

Pension: ____________________________________ Expiry: _____________________________

DVA No: ________________________ Expiry: _____________________________ WHITE / GOLD

Australian Hearing Member: Yes / No If Yes, AH No.: _______________ Expiry:__________

General Practitioner Name: ____

General Practitioner Address: ____

Audiologist Name: ________________________ Practice Address: ______________________________

How did you hear about the ESIA Hearing Implant Centre? (Please Circle)

ENT Specialist

General Practitioner

Neurologist

Friend / Relative

Speech Pathologist

Yellow Pages

Internet

Other (please specify) ____

Lions Club / Member

Office of Hearing Services

Newspaper

Ear Science Institute Australia

PRIVACY ACT 1988
PATIENT CONSENT TO COLLECT AND DISCLOSE INFORMATION

The Privacy Act 1988 requires medical practitioners to obtain consent from their patients to collect, use and disclose that patient's personal information.

Collection
This means we will collect information that is necessary to properly advise and treat you. Such necessary information may include:

- Full medical history
- Family medical history
- Ethnicity
- Contact Details
- Medicare/private health fund details
- Genetic information; and
- Billing/account details.

The information will normally be collected directly from you. There may be occasions where we will need to obtain information from other sources, for example:

- Other medical practitioners, such as former GPS and specialists
- Other health care providers such as physiotherapists, occupational therapists, psychologists, pharmacists, dentists, nurses; and
- Hospital and day surgery units.

Both our practice staff and the medical practitioners may participate in the collection of this information. In emergency situations we may need to collect personal information from relatives or other sources where we are unable to obtain your prior express consent.

Use and Disclosure
With your consent, the practice staff will use and disclose your information for purposes such as:

- Account keeping and billing purposes
- Referral to another medical practitioner or health care provider
- Sending of specimens, such as blood samples for analysis
- Referral to a hospital for treatment and/or advice
- Advice on treatment options
- The management of our practice
- Quality assurance, practice accreditation and complaint handling
- To meet our obligations of notification to our medical defence organisations or insurers
- To prevent or lessen a serious threat to an individual's life, health or safety; and
- Where legally required to do so, such as producing records to court, mandatory reporting of child abuse or the notification of diagnosis of certain communicable diseases.
- To enable the Ear Science Institute Australia to send to you a periodic newsletter which contains educational information relating to ear and hearing disorders and other information (or requests) which may be of interest to you, unless you tell us not to do so. **NO** ☐
- To enable the ESIA to use your non-identifiable information for research purposes. **NO** ☐

Access
You are entitled to access your own health records at any time convenient to both yourself and the practice. Access can be denied where:

- To provide access would create a serious threat to life or health
- There is a legal impediment to access
- The access would unreasonably impact on the privacy of another
- Your request is frivolous
- The information relates to anticipated or actual legal proceedings and you would not be entitled to access the information in those proceedings; and
- In the interests of national security.

We ask that, where possible, your request be in writing. We may impose a charge for photocopying or for staff time involved in the processing of your request. Where you dispute the accuracy of the information we have recorded you are entitled to correct the information. It is our practice policy that we will take all steps to record all of your corrections and place them with your file but will not erase the original record.

Consent
I provide my consent for the Ear Science Institute Australia to collect, use and disclose my personal information as outlined above.
I understand that I am entitled to access my own health records except where access would be denied as outlined above.
I understand that I may withdraw my consent as to the use and disclosure of my personal information (except when legal obligations must be met).

Patient Name:____________________________ Patient Signed:____________________ Date:___________

Witness Name:___________________________ Witness Signed:___________________ Date:___________

Appendix B: Signed agreement letter

LIONS
HEARING
CLINIC

17 August 2017

Dr Talita le Roux
Department of Speech Language Pathology and Audiology
University of Pretoria
Talita.LeRoux@up.ac.za

Dear Talita

As Manager of the Ear Science Institute – Ear Science Clinic, I grant permission for de-identified data from a selection of our cochlear implant patients be provided to you for our collaborative study on tinnitus and quality of life of cochlear implants recipients. The data will not include patient names, contact information or any other identifiable information.

We will provide these data with your agreement that these are used in accordance with ethical guidelines of your institution. Furthermore, these data are to be used for this specific project, to be accessible only by researchers named on your institution's ethics approval, that the source of these data are appropriately acknowledged in any reports or publications, and that at least one researcher from ESIA be a co-author on any forthcoming academic publications. We also request a copy of the project's ethics application and institutional approval.

Please indicate your agreement to these conditions, by signing and dating the bottom of this letter, and returning a copy to us by email or fax.

I look forward to a fruitful collaboration on this project.

[Signed]

Ms Lize Coetzee

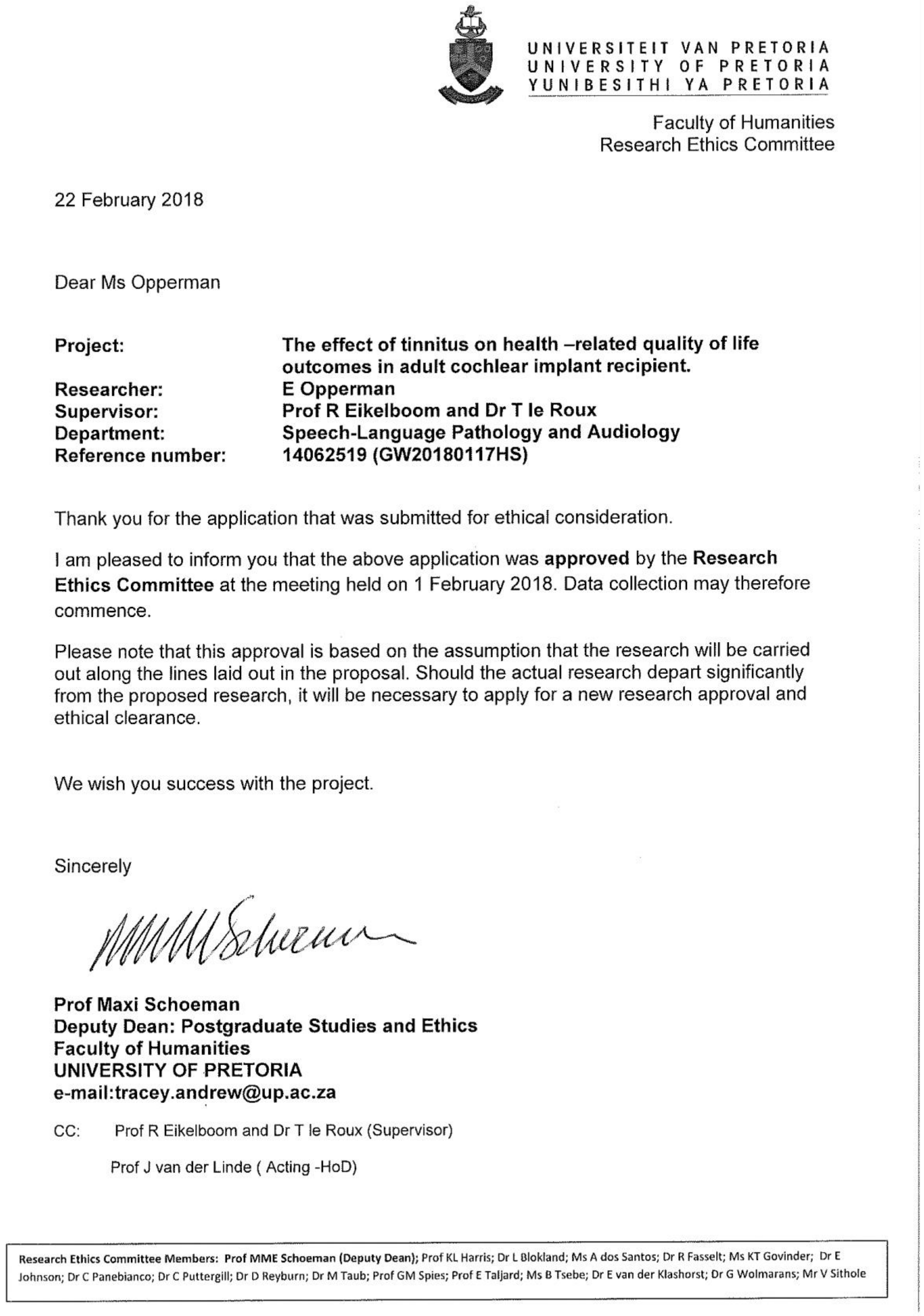
I hereby agree to accept the conditions as described above:

2017 | 08 | 21

Dr Talita le Roux   Date

Lions Hearing Clinic | 1800 054 667 | www.lionshearing.org.au | info@lionshearing.org.au | ABN 48 804 903 003

Appendix C: Approval of ethical clearance



UNIVERSITEIT VAN PRETORIA
UNIVERSITY OF PRETORIA
YUNIBESITHI YA PRETORIA

Faculty of Humanities
Research Ethics Committee

22 February 2018

Dear Ms Opperman

Project:	**The effect of tinnitus on health –related quality of life outcomes in adult cochlear implant recipient.**
Researcher:	**E Opperman**
Supervisor:	**Prof R Eikelboom and Dr T le Roux**
Department:	**Speech-Language Pathology and Audiology**
Reference number:	**14062519 (GW20180117HS)**

Thank you for the application that was submitted for ethical consideration.

I am pleased to inform you that the above application was **approved** by the **Research Ethics Committee** at the meeting held on 1 February 2018. Data collection may therefore commence.

Please note that this approval is based on the assumption that the research will be carried out along the lines laid out in the proposal. Should the actual research depart significantly from the proposed research, it will be necessary to apply for a new research approval and ethical clearance.

We wish you success with the project.

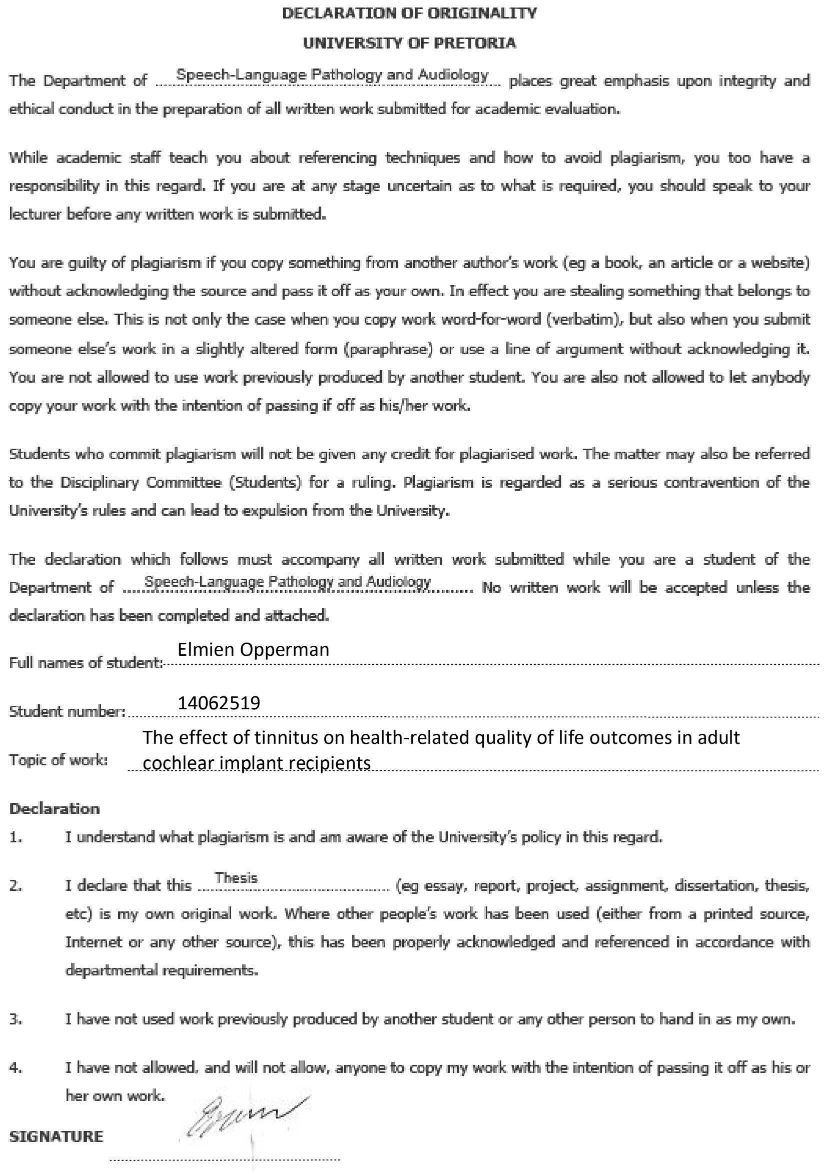
Sincerely

Prof Maxi Schoeman
Deputy Dean: Postgraduate Studies and Ethics
Faculty of Humanities
UNIVERSITY OF PRETORIA
e-mail:tracey.andrew@up.ac.za

CC: Prof R Eikelboom and Dr T le Roux (Supervisor)

Prof J van der Linde (Acting -HoD)

Appendix D: Declaration of originality



DECLARATION OF ORIGINALITY

UNIVERSITY OF PRETORIA

The Department of Speech-Language Pathology and Audiology places great emphasis upon integrity and ethical conduct in the preparation of all written work submitted for academic evaluation.

While academic staff teach you about referencing techniques and how to avoid plagiarism, you too have a responsibility in this regard. If you are at any stage uncertain as to what is required, you should speak to your lecturer before any written work is submitted.

You are guilty of plagiarism if you copy something from another author's work (eg a book, an article or a website) without acknowledging the source and pass it off as your own. In effect you are stealing something that belongs to someone else. This is not only the case when you copy work word-for-word (verbatim), but also when you submit someone else's work in a slightly altered form (paraphrase) or use a line of argument without acknowledging it. You are not allowed to use work previously produced by another student. You are also not allowed to let anybody copy your work with the intention of passing if off as his/her work.

Students who commit plagiarism will not be given any credit for plagiarised work. The matter may also be referred to the Disciplinary Committee (Students) for a ruling. Plagiarism is regarded as a serious contravention of the University's rules and can lead to expulsion from the University.

The declaration which follows must accompany all written work submitted while you are a student of the Department of Speech-Language Pathology and Audiology. No written work will be accepted unless the declaration has been completed and attached.

Full names of student: Elmien Opperman

Student number: 14062519

Topic of work: The effect of tinnitus on health-related quality of life outcomes in adult cochlear implant recipients

Declaration

1. I understand what plagiarism is and am aware of the University's policy in this regard.
2. I declare that this Thesis (eg essay, report, project, assignment, dissertation, thesis, etc) is my own original work. Where other people's work has been used (either from a printed source, Internet or any other source), this has been properly acknowledged and referenced in accordance with departmental requirements.
3. I have not used work previously produced by another student or any other person to hand in as my own.
4. I have not allowed, and will not allow, anyone to copy my work with the intention of passing it off as his or her own work.

SIGNATURE ....

Appendix E: Proof of submission of article

MS: The effect of tinnitus on health-related quality of life outcomes in adult cochlear implant recipients
MS#: TIJA-2019-05-0204

31-May-2019

Dear Dr. le Roux:

This letter will acknowledge the successful online submission of the above listed manuscript to the International Journal of Audiology. The manuscript will soon be forwarded to an associate editor to oversee the review and obtain editorial comments from expert reviewers. Should you have questions, feel free to contact the editorial office (editor.ija@up.ac.za). Please reference the manuscript number in any correspondence. You can also view the status of your manuscript at any time by checking your Author Center after logging in to https://mc.manuscriptcentral.com/tija.

It is the goal of the International Journal of Audiology to provide each manuscript with a comprehensive and expeditious peer review. You will be contacted upon completion of the initial review.

Thank you for considering IJA for your submission.

Sincerely,

De Wet Swanepoel, Ph.D.
Editor-in-Chief
International Journal of Audiology

Appendix F: Tinnitus Reaction Questionnaire

For Client

Tinnitus Reaction Questionnaire (TRQ)

Name Date Completed:

This questionnaire is designed to find out what sort of effects tinnitus has had on your lifestyle, general well-being, etc. Some of the effects below may apply to you, some may not. Please answer **all** questions by circling the number that best reflects how your tinnitus has affected you **over the past week**.

	Not at all	A little of the time	Some of the time	A good deal of the time	Almost all of the time
1. My tinnitus has made me unhappy.	0	1	2	3	4
2. My tinnitus has made me feel tense.	0	1	2	3	4
3. My tinnitus has made me feel irritable.	0	1	2	3	4
4. My tinnitus has made me feel angry.	0	1	2	3	4
5. My tinnitus has led me to cry.	0	1	2	3	4
6. My tinnitus has led me to avoid quiet situations.	0	1	2	3	4
7. My tinnitus has made me feel less interested in going out.	0	1	2	3	4
8. My tinnitus has made me feel depressed.	0	1	2	3	4
9. My tinnitus has made me feel annoyed.	0	1	2	3	4
10. My tinnitus has made me feel confused.	0	1	2	3	4
11. My tinnitus has "driven me crazy".	0	1	2	3	4
12. My tinnitus has interfered with my enjoyment of life.	0	1	2	3	4
13. My tinnitus has made it hard for me to concentrate.	0	1	2	3	4
14. My tinnitus has made it hard for me to relax.	0	1	2	3	4
15. My tinnitus has made me feel distressed.	0	1	2	3	4
16. My tinnitus has made me feel helpless.	0	1	2	3	4
17. My tinnitus has made me feel frustrated with things.	0	1	2	3	4
18. My tinnitus has interfered with my ability to work.	0	1	2	3	4
19. My tinnitus has led me to despair.	0	1	2	3	4
20. My tinnitus has led me to avoid noisy situations.	0	1	2	3	4
21. My tinnitus has led me to avoid social situations.	0	1	2	3	4
22. My tinnitus has made me feel hopeless about the future.	0	1	2	3	4
23. My tinnitus has interfered with my sleep.	0	1	2	3	4
24. My tinnitus has led me to think about suicide.	0	1	2	3	4
25. My tinnitus has made me feel panicky.	0	1	2	3	4
26. My tinnitus has made me feel tormented.	0	1	2	3	4
Total					

Wilson et al. 1991

Appendix G: Abbreviated Profile of Hearing Aid Benefit

A

ABBREVIATED PROFILE OF HEARING AID BENEFIT

NAME: ____ ☐ Male ☐ Female TODAY'S DATE: ___/___/___
Last *First*

INSTRUCTIONS: Please circle the answers that come closest to your everyday experience. Notice that each choice includes a percentage. You can use this to help you decide on your answer. For example, if a statement is true about 75% of the time, circle "C" for that item. If you have not experienced the situation we describe, try to think of a similar situation that you have been in and respond for that situation. If you have no idea, leave that item blank.

A Always (99%)
B Almost Always (87%)
C Generally (75%)
D Half-the-time (50%)
E Occasionally (25%)
F Seldom (12%)
G Never (1%)

	Without Hearing Aid	With Hearing Aid
1. When I am in a crowded grocery store, talking with the cashier, I can follow the conversation.	A B C D E F G	A B C D E F G
2. I miss a lot of information when I'm listening to a lecture.	A B C D E F G	A B C D E F G
3. Unexpected sounds, like a smoke detector or alarm bell are uncomfortable.	A B C D E F G	A B C D E F G
4. I have difficulty hearing a conversation when I'm with one of my family at home.	A B C D E F G	A B C D E F G
5. I have trouble understanding the dialogue in a movie or at the theater.	A B C D E F G	A B C D E F G
6. When I am listening to the news on the car radio, and family members are talking, I have trouble hearing the news.	A B C D E F G	A B C D E F G
7. When I'm at the dinner table with several people, and am trying to have a conversation with one person, understanding speech is difficult.	A B C D E F G	A B C D E F G
8. Traffic noises are too loud.	A B C D E F G	A B C D E F G
9. When I am talking with someone across a large empty room, I understand the words.	A B C D E F G	A B C D E F G
10. When I am in a small office, interviewing or answering questions, I have difficulty following the conversation.	A B C D E F G	A B C D E F G
11. When I am in a theater watching a movie or play, and the people around me are whispering and rustling paper wrappers, I can still make out the dialogue.	A B C D E F G	A B C D E F G
12. When I am having a quiet conversation with a friend, I have difficulty understanding.	A B C D E F G	A B C D E F G

(Continued on back)

A Always (99%)
B Almost Always (87%)
C Generally (75%)
D Half-the-time (50%)
E Occasionally (25%)
F Seldom (12%)
G Never (1%)

	Without Hearing Aids	With Hearing Aids
13. The sounds of running water, such as a toilet or shower, are uncomfortably loud.	A B C D E F G	A B C D E F G
14. When a speaker is addressing a small group, and everyone is listening quietly, I have to strain to understand.	A B C D E F G	A B C D E F G
15. When I'm in a quiet conversation with my doctor in an examination room, it is hard to follow the conversation.	A B C D E F G	A B C D E F G
16. I can understand conversations even when several people are talking.	A B C D E F G	A B C D E F G
17. The sounds of construction work are uncomfortably loud.	A B C D E F G	A B C D E F G
18. It's hard for me to understand what is being said at lectures or church services.	A B C D E F G	A B C D E F G
19. I can communicate with others when we are in a crowd.	A B C D E F G	A B C D E F G
20. The sound of a fire engine siren close by is so loud that I need to cover my ears.	A B C D E F G	A B C D E F G
21. I can follow the words of a sermon when listening to a religious service.	A B C D E F G	A B C D E F G
22. The sound of screeching tires is uncomfortably loud.	A B C D E F G	A B C D E F G
23. I have to ask people to repeat themselves in one-on-one conversation in a quiet room.	A B C D E F G	A B C D E F G
24. I have trouble understanding others when an air conditioner or fan is on.	A B C D E F G	A B C D E F G

Please fill out these additional items.

HEARING AID EXPERIENCE:	**DAILY HEARING AID USE**	**DEGREE OF HEARING DIFFICULTY (without wearing a hearing aid):**
☐ None ☐ Less than 6 weeks ☐ 6 weeks to 11 months ☐ 1 to 10 years ☐ Over 10 years	☐ None ☐ Less than 1 hour per day ☐ 1 to 4 hours per day ☐ 4 to 8 hours per day ☐ 8 to 16 hours per day	☐ None ☐ Mild ☐ Moderate ☐ Moderately-Severe ☐ Severe

HARL
Hearing Aid Research Lab

Appendix H: General tinnitus questions

Name: ____ Date:_______________________________________

General questions regarding tinnitus (please fill in the required information or mark the applicable option)

Are you currently experiencing tinnitus or have experienced tinnitus in the past month?	Yes	No					
When did you first experience your tinnitus?							
How did you perceive the beginning?	Gradual	Abrupt					
Where do you experience the tinnitus? [choose the most suitable answer]	ONLY in my right ear	ONLY in my left ear	In my head	In both ears equally	In both ears but worse in my right ear	In both ears but worse in my left ear	Unsure
My tinnitus is	Intermittent (comes and goes)	Constant (is there all the time)					
My tinnitus	Stays at the same volume	Changes in volume (goes softer and louder)					
Describe the loudness of your tinnitus using a scale from 1-10	[scale 1 to 10]						
Does your tinnitus pulse in time with your heartbeat?	Yes	No					
How often are you aware of your tinnitus during awake times?	All of the time	Most of the time	Some of the time	Hardly ever			