Investigating the Impact of Hearing Aid Use and Auditory Training on Cognition, Mood, and Social Interaction in Older Adults with

Hearing Loss

A thesis submitted for the degree of Doctor of Philosophy

By

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Abstract

Sensorineural hearing loss (SNHL) is the most common sensory deficit among adults. SNHL results from damage to any part of the inner ear or the neural pathways to the human brain, diminishing brainpower and imposing an extra detrimental workload on the brain. Some of the psychosocial consequences of this condition include difficulty in understanding speech, depression and social isolation. There is no clinical way to predict the onset of the disease in advance, however, imaging of the inner ear may help to detect the disease and to rule out any congenital, infectious, inflammatory or tumoural pathology.

The first study presented in this thesis assessed the efficacy of the simultaneous use of hearing aids and auditory training for improving cognition and psychosocial function in adults with hearing loss, and the relationships between hearing loss, speech perception and cognition. This was a crossover trial which targeted 40 men and women between 50 and 90 years of age with either mild or moderate symmetric sensorineural hearing loss. None of these adults were current hearing aid users. Consented, willing participants underwent a 6-month intensive face-to-face auditory training (active control), and were assigned in random order to receive hearing aid (intervention) for either the first 3 or last 3 months of the 6-month auditory training program. Correlations and structural equation modelling suggested that several cognitive domains were associated with speech perception at baseline. Hearing aid use reduced problems with communication, but there were no significant improvements in speech perception, social interaction or cognition associated with hearing aid use. During this short-term study, the effect of hearing aids and auditory training for improving depressive symptoms was significant. The protocol for this registered clinical trial, with identifier NCT03112850, was published in the Journal of Medical Internet Research (JMIR) Research Protocols (2017) and a paper summarising the results has been submitted to Clinical Interventions in Aging for publication.

The second study in this thesis was a Magnetic Resonance Imaging (MRI) study, which was planned to investigate the extent to which hearing loss can cause damage and other changes in regions of the brain beyond those involved in auditory processing. Only the initial baseline comparison of nine (9) long-term and eighteen (18) first-time hearing aid users has been included in this thesis because this trial is on-going. When the degree of hearing loss was controlled, no significant difference was found between long-term and first-time hearing aid users in terms of cognition, speech perception, hearing problems, mood and social interaction. However, the neuroimaging experiment, which involves a combination of auditory and sensory tasks to test whether long-term hearing aid use is associated with changes in brain function, has already provided interesting results. The initial MRI analysis (for one long-term hearing aid user) has shown that the neuroimaging experiment designed for this study has the ability to detect differences in how the brain responds to different stimuli in the auditory cortex.

In conclusion, this thesis demonstrated relationships between hearing loss, speech perception and cognition, and the hearing intervention provided evidence of reduced depressive symptoms. The small sample size meant that the study was underpowered. A full-scale hearing loss intervention and neuroimaging trial has been planned to test the neural, cognitive and psychosocial efficacy of hearing aid use in adults with post-lingual SNHL. The study protocol for this second registered clinical trial, with identifier ACTRN12617001616369, is included in this thesis as a paper which has been accepted for publication in JMIR Research Protocols (2018).

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Declaration

I declare that this thesis contains no material which has been accepted for the award of any other degree or diploma. To the best of my knowledge, the thesis contains no work previously published or written by another author unless due reference is made in the text. Where the work is based on joint research or publications, the relative contributions of the respective authors are disclosed in the text.

Signed:

Dowson

Date: 5th April 2019

Contribution to Jointly Authored Papers

The candidate would like to acknowledge the help of all-co-authors who contributed to the papers included in this thesis. All co-authors have given approval for the relevant papers to be included as part of this dissertation. The author indication forms are provided in the appendices.

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List of Published Papers Incorporated in this Thesis

Nkyekyer J, Meyer D, Blamey PJ, Pipingas A, Bhar S. Investigating the Impact of Hearing Aid Use and Auditory Training on Cognition, Depressive Symptoms, and Social Interaction in Adults With Hearing Loss: Protocol for a Crossover Trial. JMIR Res Protoc. 2018 Mar 23;7(3):e85. doi: 10.2196/resprot.8936. PubMed PMID: 29572201.

Hughes ME, **Nkyekyer J**, Innes-Brown H, Rossell SL, Sly D, Bhar S, Pipingas A, Hennessy A, Meyer D. The neural, cognitive and psychosocial effects of hearing aid use in older adults with post-lingual sensorineural hearing loss: A protocol for a prospective cohort study JMIR Research Protocols. (forthcoming/in press) DOI: <u>10.2196/resprot.9916</u> URL: <u>http://preprints.jmir.org/preprint/9916</u>

Submitted Paper Incorporated in this Thesis

Nkyekyer J, Meyer D, Pipingas A, Reed NS. The Cognitive and Psychosocial Effects of Auditory Training and Hearing Aids in Adults with Hearing Loss. Clinical Interventions in Aging. Submitted for Publication on September 13, 2018.

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List of Abbreviations

ACC	Anterior Cingulate Cortex
APHAB	Abbreviated Profile of Hearing Aid Benefit
AV	Aversiveness of Sound
BN	Background Noise
CANTAB	Cambridge Neurological Test Automated Battery
CHP	Centre for Human Psychopharmacology
CI	Confidence Interval
CNC	Consonant-Vowel Nucleus-Consonant
CON	Control
CSF	Cerebrospinal Fluid
DASS	Depression, Anxiety and Stress Scale
DCAL	Deafness Cognition and Language
dB	Decibel
EC	Ease of Communication
ENT	Ear Nose and Throat
ERP	Event Related Potential
ESRC	Economic and Social Research Council
GDS	Geriatric Depression Scale
ITG	Inferior Temporal Gyrus
JMIR	Journal of Medical Internet Research
kHz	Kilohertz
КТН	Kungliga Tekniska Högskolan
LACE	Listening and Communication Enhancement
LOF	Liberty Open-Fit
MAT	Matched

MCI	Mild Cognitive Impairment
MIS	Mismatched
MRI	Magnetic Resonance Imaging
MTG	Middle Temporal Gyrus
MMSE	Mini-Mental State Examination
MMRM	Mixed Model Repeated Measures
NART	National Adult Reading Test
NAL-NL	National Acoustics Laboratory
NOS	No Sound
РТА	Pure-Tone Average
PET	Positron Emission Tomography
RMQ	ReadMyQuips
ROC	Receiver Operator Characteristic
RV	Effects of Reverberation
SD	Standard Deviation
SPMSQ	Short Portable Mental Status Questionnaire
SNHL	Sensorineural Hearing Loss
SNR	Signal-to-Noise Ratio
SPT	Speech Perception Test
STC	Superior Temporal Cortex
STG	Superior Temporal Gyrus
SUCCAB	Swinburne University Computerized Assessment Battery
VVLT	Visual Verbal Learning Test
WAI	Working Alliance Inventory
WAIS-IV	The Wechsler Adult Intelligence Scale – Fourth Edition
WHO	World Health Organization

List of Appendices

Appendix A: Research Protocol Paper for Crossover Study

Appendix B: Research Protocol Paper for MRI Study

Appendix C: Results Paper and Supplementary Data for Crossover Study

Appendix D: Additional Descriptive Statistics for Demographic Questionnaire Crossover Study

Appendix E: Completer Analysis Table

Appendix F: Author Indication Forms

Appendix G: Ethics Documentation

Appendix H: Questionnaire for Crossover Study

Appendix I: The Abbreviated Profile of Hearing Aid Benefit Questionnaire

Appendix J: Screening Questionnaire for Crossover Study

Prelude

The number of people worldwide with hearing impairment exceeds six hundred (600) million and this number is expected to rise with the aging population. Some estimates suggest that up to two-thirds of older adults with hearing impairment do not use hearing aids. In addition, even when hearing aids are fitted, some patients struggle to hear speech clearly in noisy environments. The importance of this problem goes beyond the hearing difficulties associated with hearing loss. When someone loses their hearing, the neural connections in the brain that respond to sound, are reorganised. Recently, a connection between hearing loss and decline in cognitive function has been reported. Scientists have suggested that even mild levels of hearing loss increase the long-term risk of cognitive decline and depression, and that an intervention as simple as hearing aids could improve a patient's hearing, thereby reducing these risks. Hearing loss is also known to be a risk factor for social isolation.

The present study investigates whether wearing hearing aids improves the impact of auditory training on cognition, depressive symptoms and social interaction in adults with sensorineural hearing loss (SNHL). Some of the psychosocial consequences of age-related hearing loss include difficulty in understanding speech. The effectiveness of hearing aids and auditory training for improving depression and social interaction will therefore be evaluated using an online speech perception test (SPT).

Chapter 1 provides an introduction to the phenomena of SNHL. This chapter will review the global burden, prevalence and severity of disabling hearing loss. The number of adults who suffer from hearing loss worldwide is likely to increase rapidly as the population ages. Age-related hearing loss involves permanent damage at the cellular level of the auditory system, and is often referred to as SNHL. Further, this chapter will discuss the different categories of age-related hearing loss, provide perspectives into the risk factors associated with the progression of SNHL, and the expected impact of SNHL on cognitive functioning and the quality of life of adults. Chapter 1 will conclude by focusing on the main types of rehabilitation intervention available for treating adults with hearing loss.

Chapter 2 explains the rationale for the study. SNHL is neither correctable by surgical nor pharmacologic interventions. Timely detection and diagnosis is paramount to its treatment and management. There is evidence that SNHL is associated with Page 22 of 309

cognitive decline, depression, social isolation and incident dementia. Neuroimaging studies have also found that SNHL may cause parts of the brain to atrophy. The mechanistic pathways explaining the relationship between hearing impairment and cognitive functioning will be discussed. Explanation on how the communicative brain adapts to auditory and visual stimuli in both normal and hearing impaired adults, and the brain structural changes that occur as a consequence of aging, will also be discussed. The aims of this study and the hypotheses to be tested will be motivated in the above discussion.

Chapter 3 describes the aims, hypotheses and detailed methodology for the first study, also known as Crossover Study. The research methodology has also been published in the Journal of Medical Internet Research (JMIR) Research Protocols (2018), and the draft manuscript submitted for publication is included in this thesis in Appendix A.

Chapter 4 will present the statistical analyses and results for the Crossover Study, summarizing the study findings and suggesting avenues for further research in the Discussion. It will also discuss the limitations of this study. The results have been accepted for publication in Clinical Interventions in Aging and the draft manuscript is included in Appendix C. Results of the Crossover Study have suggested that hearing treatment may take longer than 6 months to affect cognition. Therefore, the second pilot study, also termed Magnetic Resonance Imaging (MRI) Study, involves a comparison of participants who have never used hearing aids with long-term users of hearing aids, in order to determine whether long term hearing aid usage relates to cognition, a person's mood, social interaction, speech perception, and hearing satisfaction level, after controlling for level of hearing loss.

Chapter 5 presents the aims, hypotheses, and methods for the MRI Study and Chapter 6 presents the baseline results. A neuroimaging experiment has been planned as part of the MRI Study in order to investigate the impact of hearing aid use on brain activity. Preliminary results from this study suggest that the planned MRI experiment can indeed detect brain changes in the human auditory cortex, as was expected.

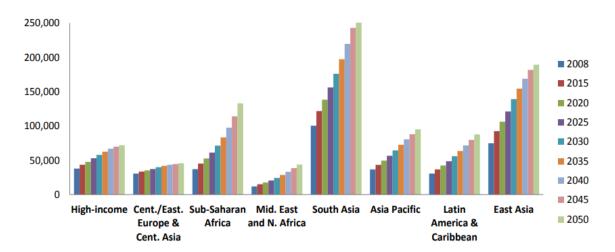
Chapter 7 is the concluding chapter that summarizes the findings of both the Crossover and the MRI Studies, and then considers the future implications for aural rehabilitation. One of our findings from the Crossover Study suggests that management of hearing loss may reduce depression and improve the life conditions of adults. However, depressive symptoms can be a part of the clinical presentation of dementia, suggesting that the effective management of hearing loss may also help to reduce the incidence of dementia. Recognition of hearing loss as a risk factor for dementia is relatively new requiring further investigation.

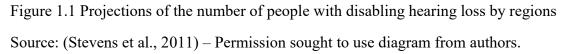
In conclusion, the findings of these studies have provided the motivation needed to proceed with a full-scale, randomized hearing loss intervention and a neuroimaging study, with cognitive outcomes measured after short-term as well as after long-term hearing aid use. The protocol for this study has been published in JMIR Research Protocols (2018) and the draft manuscript which was submitted for publication has been included in Appendix B. This may be the first prospective cohort randomized controlled trial to test the neural, cognitive and psychosocial efficacy of hearing aid use in adults with post-lingual SNHL.

1 Introduction and Background Theory

1.1 Prevalence of Disabling Hearing Loss

According to the World Health Organization (WHO), disabling hearing loss affects approximately 466 million people globally and its prevalence will increase as the world population ages [1, 2] (See Figure 1.1). Disabling hearing loss is defined as a permanent unaided hearing loss – in the better ear and averaged over frequencies of 0.5, 1, 2 and 4 kilohertz (kHz) – of more than of 40 decibel (dB) in adults and 30 dB in children [2]; this condition has a profound impact on interpersonal communication, psychosocial well-being, quality of life and economic independence.





There are likely to be rapid increases in disabling hearing loss for South Asia, East Asia, and Sub-Sahara Africa in the future, as shown in Figure 1.1. Relatively slower but still substantial is the growth of hearing loss predicted in the Asia Pacific, Latin America and Caribbean. In Australia for instance, there are one in six people affected by hearing loss and, with the ageing population, this number is expected to increase to one in four by 2050 [3]. Also in the United States, several population-based studies estimate hearing loss prevalence at 42-47% in one or both ears [1, 4, 5]. A study in the United Kingdom predicts that in 20 years there will be an increase in hearing loss of almost 50%, from 11 million people in 2015 to 15.6 million people in 2035. A similar study estimates that more than one in five people over the age of 50 (20.1%) have disabling hearing loss, as well as almost half of all people over the age of 70 (44.4%) [6].

One of the factors which have contributed to the upward trend seen in estimates of the global prevalence of disabling hearing impairment is the increasing prevalence of age-related hearing loss, also known as SNHL. Another is improvement in the technology available for the early detection and diagnosis of hearing impairment [7]. The World Health Organisation (WHO) [6] has identified hearing loss as an important target for health promotion in the elderly, and a leading cause of non-fatal disease burden in the older population [8, 9]. It has become the third most common chronic health condition faced by older adults, exceeding 90% in individuals over 80 years of age.

1.2 Classification and Severity of Hearing Loss

Hearing loss can be classified by type (i.e. sensorineural, conductive, or mixed), configuration (e.g., flat, sloping), and severity (e.g., mild, moderate, severe, or profound). Hearing losses between 26 and 40 dB are considered mild, between 41 and 55 dB moderate, between 56 and 70 dB moderately severe, between 71 and 90 dB severe, and above 91 dB as profound [10].

With mild hearing loss, soft noises are not heard and understanding speech is difficult in a loud environment. For moderate hearing loss, soft and moderately loud noises are not heard and understanding speech becomes very difficult if background noise is present. Adults with severe or profound hearing loss most likely have a long-standing hearing loss which is likely to be aggravated by age.

The consequences of long-standing hearing loss tend to be different from those associated with a recent-onset of hearing loss [11]. Severe to profound hearing impairment is most commonly the result of cochlear lesions with the consequence that the individual can hear little or nothing from the affected ear or ears. More severe impairment up to total deafness which can arise from cochlear lesions, leads to increased communication difficulties and very little auditory recognition of speech, which may result in severe psychological problems in adults [12, 13].

Research studies have shown that untreated hearing loss can have a profound effect on mental state. Adults with hearing loss are likely to experience a myriad of mental and emotional issues such as anger, depression, anxiety, loneliness, frustration, and decreased cognitive functioning. A study by the National Council on Aging examined more than 2300 people with hearing loss, and found that those with hearing loss were 50 percent more likely to experience depression. In addition, hearing-impaired adults are significantly more likely to experience emotional distress and social engagement restrictions, directly due to their hearing impairment, reduced ordinary social activities, increased relational problems with family and friends, and greater emotional difficulties at work among others [14].

Within the inner ear, SNHL is the most common sensory deficit among older adults [15]. SNHL can be caused by infection, trauma, prolonged exposure to environmental noise, exposure to a range of chemicals and drugs and a number of vascular and metabolic conditions that result in damage to the inner ear [16]. There is no clinically proven method to predict the onset of SNHL, as its occurrence is generally slow and progressive, affecting both ears equally [17]. This type of hearing loss cannot be medically treated [18-21]. Noise-induced hearing loss also poses a significant public health problem. Approximately 10% of United States adults (22 million) between 20 and 69 years of age have permanent hearing loss due to exposure to loud noise at work or during leisure activities [22].

1.2.1 Age-related Sensory Hearing Loss or Presbycusis

There is a general consensus that SNHL or Presbycusis is the result of various types of physiological degeneration, plus the accumulated effects of noise exposure, medical disorders and their treatment, as well as hereditary susceptibility [15]. The hallmarks of Presbycusis include reduced audibility of high frequencies, reduced speech understanding, specifically in noise and reverberant environments, interference with the perception of rapid changes in speech, and impaired sound source localization [23].

Results from audiometric tests and temporal bone pathology have classified Presbycusis into six categories namely: sensory, neural, metabolic, cochlear conductive, mixed and intermediate presbycusis [24] (as summarized in Table 1.1). Among these, stria/metabolic presbycusis is the most common form of presbycusis [25].

Type of Presbycusis	Criteria
Sensory	Atrophy of organ of Corti and auditorynerve in the basal end of the cochlea, andis manifested by abrupt high-tone hearinglosses
Neural	Loss of 50% or more of the cochlear neurons as compared to the mean number of cochlear neurons for neonates
Stria/Metabolic	Loss of stria tissue cells in apical and middle turns of cochlea (e.g., atrophy of stria vascularis)
Cochlear conductive	Changes in physical properties of cochlea, loss of elasticity in basilar membrane
Mixed	Presence of significant pathologic change in more than one structure
Intermediate	Cochlear changes do not reach significant levels in any structure, and the audiometric profile of cochlear conductive presbycusis is not met

Table 1.1 Classification of six types of presbycusis

Notes: Adapted from: Schuknecht HF et al. [26]

1.2.2 Pathophysiology of SNHL

There are a number of pathophysiological processes underlying age related changes in the auditory system. The auditory system acts to channel and transduce sound pressure waves into electrophysiological signals that can then be localized and interpreted by the higher cortical centres [27]. A number of stages are involved in this process (See Figure 1.2).

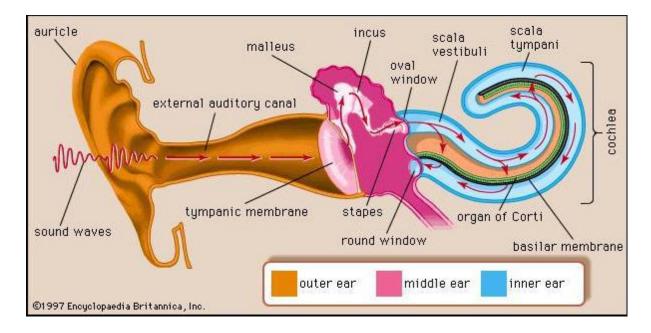


Figure 1.2 Structure of the human ear – The stages in the hearing pathway

Adapted from : Ballachanda B. [28]

1.2.2.1 The External Ear and Associated Changes

The external part of the ear collects sound waves and directs them into the tympanic membrane. This part of the ear consists of the pinna or auricle, and external auditory canal. The pinna has vestigial muscles which increase the efficiency with which sound is collected in the ear, and channel it into the ear canal [29].

In the external ear, the following age-related changes occur: 1) the production of excessively large amounts of cerumen, coupled with inadequate epithelial migration, which often results in impacted cerumen [30]; 2) hair growth in and around the ear canal; 3) collapsed ear canal resulting in artificial air-bone gaps during audiometric testing [28, 31]; 4) changes in the physical properties of the skin, including atrophy, loss of elasticity and dehydration making it prone to trauma and breakdown [28]; 5) enlargement of the pinnae which may affect the acoustic properties of the ear [32].

1.2.2.2 The Middle Ear and Associated Changes

The middle ear is an air filled space, and is connected to the back of the nose by a long, thin tube called the Eustachian tube. The middle ear also houses the tympanic membrane, more commonly referred to as the ear drum. Sound is conducted from the tympanic membrane to the inner ear by three bones (ossicles): the malleus; incus; and stapes. In the middle ear, the following age related changes occur: 1) the tympanic membrane thickens, appears duller and loses elasticity [33, 34]; 2) thinning and calcification of the cartilaginous incudomalleal and incudostapedial joints [34]; 3) atrophy and degeneration of the fibres of the middle ear muscles of the ossicular ligaments [33]; and 4) the ossification and calcification of both the Eustachian tube cartilage and ossicles [35].

1.2.2.3 The Inner Ear and Associated Changes

The entire inner ear is vulnerable to the effects of ageing [36]. In the inner ear, sound is transmitted from the outer and middle ear to the cochlea, via the mechanical motion of the middle ear ossicles against the oval window [29]. This initiates the process of hearing by the transduction of mechanical energy into trains of nerve impulses. There are progressive degenerations of several functional components of the inner ear, including: sensory, stria, neural, and supportive cells within the cochlea (as indicated in Table 1.1).

Loss of inner hair cells and ganglion cells is observed at the base of the cochlea [37, 38]. The decrease in hair cell population is greatest in adults over 70 years of age. There is also an overall blood supply change which reduces auditory functionality by affecting the arteries that oxygenate the auditory system, along with decrease in vascularization in the layers of the stria vascularis. This decrease in vascularization limits blood flow and affects metabolic processes that maintain the various cochlea potentials [38].

1.2.2.4 Other Medical Conditions Contributing to Age Related Hearing Loss

Other medical conditions which contribute to hearing loss in older adults include excessive exposure to occupational or recreational noise, genetic factors, acoustic neuroma, and trauma. Also, a number of systemic diseases such as hypertension [39], diabetes mellitus [40], plasma hyper-viscosity [41], atherosclerosis [42], hyperlipidaemia [43], metabolic bone disease [44], hypothyroidism [45], and Alzheimer's disease [46] potentially contribute to increasing hearing loss with age.

How the individual copes with their hearing loss depends on several factors such as early versus late onset, the progressive nature of the loss (either gradual or sudden), the severity of the loss, communication demands, and personality [47]. In the long term however, adults who develop clinically significant hearing loss may also develop changes in how they use their brain for listening in daily life, and this may lead to permanent changes in brain activity [48]. These changes may include mild cognitive impairment (MCI) or various types of dementia.

1.2.3 The Impact of Hearing Loss on Aging

Age contributes to changes in both hearing and memory, and hearing loss can have serious widespread health implications in terms of promoting healthy ageing. The consequences of untreated hearing loss are not obvious, but they can have psychophysical, cognitive, and psychosocial impacts [49].

Aging is defined as the biological process of growing old and intrinsic and extrinsic factors, as well as their interactions, influence the degree and rate at which our hearing ages [50]. The most important consequence of the decline in hearing sensitivity with aging is difficulty understanding speech. Also aging can negatively impact the range of processes required for speech perception [51]. The occurrence of age-related sensory hearing loss can also be influenced by environmental factors such as noise. Difficulties arise when elderly listeners must follow conversational speech in adverse listening conditions, including noise and reverberation [23]. Reverberation is the prolongation of sound in an enclosed room, making reverberant environments notably difficult for elderly listeners [19]. Age-related hearing loss is exacerbated in conditions that combine reverberation and noise [52-54].

Several studies have attempted to document the impact of untreated hearing loss and results of these studies have shown significantly higher rates of depression, anxiety, and other psychosocial disorders [55]. The impact of hearing loss in older adults is farreaching and also includes the following: communication difficulties, social isolation, decline in physical functioning, and decreased quality of life [56, 57]. According to the World Health Organisation, quality of life is defined as "an individual's perception of his/her own projection in life, within the context of culture and value systems in which one lives, and in relation to his/her objectives, expectations, patterns and concerns" [58]. Therefore, the impact of untreated hearing loss cannot be ignored.

For instance, in epidemiologic studies, sensory deficits have been linked with accelerated cognitive decline and earlier onset of dementia [59]. An association between sensory impairment and the diagnosis of dementia, although recognized for a long time, has not been the focus of concerted research, with only small numbers of underpowered Page **31** of **309**

and heterogeneous studies published [60]. A widely reported meta-analysis carried out by Lin [61] found that a mild sensorineural hearing loss of 25 dB had an effect on cognitive scores approximately equivalent to seven years of aging. An independent and linear correlation between hearing loss and the risk of developing incident dementia was also demonstrated [59, 61]. When compared to individuals with normal hearing, a patient with a mild, moderate or severe hearing loss had a two-, three-, or five-fold increase in the likelihood of developing incident dementia, respectively [61]. More recently, hearing loss has been grouped with the midlife risk factors for dementia, and evidence suggests that it continues to increase dementia risk in later life. A striking finding from a recent large-scale population study has revealed a strong statistical connection between the appearance and degree of hearing loss with dementia [5]. Specifically in this study, results indicated that individuals with mild hearing loss were twice as likely to develop dementia as those with normal hearing, those with moderate hearing loss were three times more likely to do so, and those with severe hearing loss had five times the risk of developing dementia.

Dementia is the greatest global challenge for health and social care in the 21st century [62]. The annual 2015 global cost of dementia was estimated to be US\$818 billion [63, 64]. Globally, about 47 million people were living with dementia in 2015. With advancing age, this figure is expected to increase to 66 million by 2030, and 131 million by 2050 [65]. Studies have shown that sensorineural hearing loss complicates dementia in a number of ways as it confuses diagnosis and interferes with rehabilitation support [66]. Currently, over 321,600 Australians have dementia, with approximately one person being diagnosed every 6 minutes - which equates to 1,700 new cases per week. By 2050, this figure is expected to reach 7,400 new cases per week [67]. In New South Wales hospitals, the average cost of care per diagnosis was \$7,720 for a patient with dementia versus \$5,010 for a patient without dementia [68]. These generally higher care costs are predicted to see spending related to dementia exceed that of any other health condition by the 2060's [67]. To put some perspective on the total health and residential care costs of this disease, a 2004 report from Access Economics, modelling the impact of delaying onset of Alzheimer's (the most common form of dementia), found that a 50% reduction in new cases each year from 2005 (equivalent to delaying onset by about 5 years), would result in 48.7% fewer cases by 2050, equivalent to an estimated \$105 billion in cumulative savings. Just a 5% reduction would provide cumulative savings of \$10.3 billion over the same period. An estimated 57% of these savings were predicted to be in the health and residential care sectors [69].

Although the risk of hearing loss increases with age, it is often ignored during the diagnosis and treatment of cognitive and memory disorders in elderly patients [70]. It is important to note that hearing loss is an individual experience, and that how the individual copes with hearing loss will depend on several factors such as early versus late onset, the progressive nature of the loss (either gradual or sudden), the severity of the loss, communication demands, and personality [47]. Therefore, using hearing loss as a screening tool would undoubtedly lead to more appropriate diagnosis and treatment as well as significantly better outcomes for individuals with cognitive impairments.

1.2.3.1 Aging, Auditory and Cognitive Functioning

Over an adult life span, there are gradual and age-related losses in cognitive processing. A wealth of evidence has suggested that older adults have more trouble learning new information, exhibit less efficient reasoning skills, are slower to respond on all types of cognitive tasks, and are more susceptible to disruption from interfering information than younger adults [71, 72].

Cognitive function is an intellectual process by which one becomes aware of, perceives, or comprehends ideas. It encompasses all aspects of perception, memory, thinking, reasoning and awareness. Changes in cognitive function are common in normal ageing and occur across the life-span. Along with physical decline, decline in cognitive function is a hallmark of ageing and is predictive of mortality [73]. Considering the fact that cognitive function is an intellectual process that involves all aspects of perception, thinking, reasoning, evaluating, recollecting, etc., hearing impairments could impact negatively on several domains of ageing such as social engagement, activity, vitality and physical mobility.

Among older adults, a broad spectrum of cognitive capability exists with dementia at one extreme and normal cognitive function at the other. With an anticipated exponential expansion of the population that will develop dementia and the consequent costs to society, it is increasingly important to investigate the factors that promote optimal cognitive function in old age [74].

The cognitive domains that show the greatest declines with age include selective attention, working memory, long term memory, perception and sensory function, spatial function and executive function.

Attention: Attention is a basic but complex cognitive process, involved in virtually all other cognitive domains, except when task performance has become habitual or automatic. For attentional tasks that require dividing or switching of attention among multiple tasks, older adults exhibit significant impairments [75]. They show impairments on those tasks that require flexible control of attention, such as driving, an activity that, for many people, is essential to independence.

Working Memory: Working memory is defined as the cognitive system that stores information in an accessible state that allows temporary storage and manipulation of several facts or thoughts to enable solving a problem or performing complex mental tasks [76]. In working memory, task-relevant information can be maintained while complex cognitive tasks, such as speech understanding in adverse conditions, are performed. Working memory is the fundamental source of age-related deficits in a variety of every day cognitive tasks, such as decision-making, problem-solving, and the planning of goal-directed behaviours which require the integration and reorganization of information from a variety of sources [77-79]. Researchers have also shown that there are changes in the activity of frontal lobes responsible for working memory in adults with deterioration in cognitive function [78].

Working memory capacity varies between individuals. It is highly associated with executive functions such as inhibition - the process involved in preventing irrelevant information from entering working memory [80], and attention - the process of selecting and limiting the amount of information entering or remaining in working memory [81]. In a review of different models of working memory [81], it was concluded that many described models fitted the following generic description: working memory is those mechanisms or processes that are involved in the control, regulation, and active maintenance of task-relevant information in the service of complex cognition, including novel as well as familiar, skilled tasks.

The working memory model for Ease of Language Understanding [82, 83] proposes that under favourable listening conditions, language input can be rapidly and implicitly matched to stored phonological representations in long-term memory, whereas under suboptimal conditions, it is more likely that this matching process may

fail. This implies that under taxing conditions, language understanding may be a function of explicit cognitive capacity; whereas under less taxing conditions it may not. Individual differences in working memory, which are commonly measured using complex span tests, can predict performance on challenging linguistic tasks such as language comprehension, vocabulary learning, speech perception, and dichotic listening. Individual differences can be explained in terms of mental resources that can be divided up among processing and storage components in working memory. There are also several possible specific underlying mechanisms that explain the predictive power of complex span tests. These include individual differences in the ability to inhibit irrelevant information [80, 84], to divide/control attention [85], to selectively attend to target information [86], and to effectively retrieve items from the long-term store [87].

For persons with hearing loss, perceived listening effort may indicate the degree to which limited working memory resources are allocated to perceptual processing [88]. Higher levels of perceived effort may indicate fewer resources for information storage, suggesting that listeners who are hard of hearing would be poorer than listeners with normal hearing on complex auditory tasks involving storage. Results reported by Rabbitt [89] also suggest that listeners who are hard of hearing allocate more information processing resources to the task of initially perceiving the speech input, leaving fewer resources for subsequent recall.

Long Term Memory: Many older adults complain of increased memory lapses as they age, and studies published have attempted to distinguish memory declines attributable to normal ageing from those that are indicative of pathological ageing, particularly Alzheimer's disease [90, 91]. Long-term memory, unlike short-term and working memory, requires retrieval of information that is being maintained in an active state. Ageing affects memory for specific events or experiences that occurred in the past [92], such as remembering context or source information, for example: where or when something was heard or read, or even whether something actually happened or was just thought about which is referred to as "reality monitoring" [93]. In situations like this, encoding and retrieving specific or peripheral details about a prior event may be particularly demanding of attentional resources, and good cues for the retrieval of such information may often be lacking. *Perception and Sensory Function:* Declining sensory and perceptual abilities have important implications for the everyday lives of older adults. Perception is viewed as a set of processes that occurs prior to cognition [94]. With this view, studies have controlled sensory and perceptual deficits when conducting cognitive experiments in older adults, and have demonstrated that a significant proportion of age-related variance in several cognitive tasks can be accounted for by hearing and vision loss. Visual impairments can limit mobility and interact with attentional deficits to make driving a particularly hazardous activity [95].

Spatial Function: Spatial function can be defined as the perception and processing of spatial properties such as direction, distance, location, shape, size, relative position, and orientation. In the scientific literature, spatial function is referred as visuospatial function due to the visual nature of the assessment tasks. Research suggests that spatial function is necessary for navigation and direction, and is also relevant to everyday tasks such as reaching for objects or reading an analogue clock face as it involves the use of memory, attention and spatial orientation [96]. The construct of spatial function can be further divided according to the frame of reference. Egocentric frames of reference consider the position of an object in relation to the self, whereas an allocentric frame of reference considers an object. This can be exemplified by contrasting the experience of reading a map (allocentric) compared with driving through the streets (egocentric). It has been proposed that allocentric, orientation-free representations are stored in long term memory and interact with the egocentric system which updates relations to objects from the self-orientation [97].

Assessing spatial function in the elderly poses some difficulties because many popular tasks that purport to measure spatial function also require other cognitive abilities and Drag and Bieliauskas [96] suggests that it is difficult to attribute performance specifically to visuospatial competence. In general, the more complex a task, the more likely it is that multiple cognitive functions may be required. Well-validated tasks such as the Visual Spatial Learning Test, Wechsler Adult Intelligence Scales (WAIS) Block Design, Clock Drawing and the Rey-Osterrieth Complex Figure, which all have a substantial spatial component, do demonstrate significant decline with age [98].

The Visual Spatial Learning Test requires participants to recall the positions of various abstract designs within a 6x4 grid. The task shows decline in the elderly, with progressively less information being recognized or recalled with increasing age. Retention in the delayed task remains similar [98], indicating a deficit in encoding into memory rather than retrieval of stored information. The performance of a group of patients with dementia, predominantly Alzheimer's disease, was compared to a control group and results showed that dementia patients performed poorly in comparison and made a greater number of intrusion errors (false positives) [99]. The WAIS Block Design Subtest is known to show a decline in performance from around midlife, with a considerable impairment exhibited by later life [100]. For this task, a variation in performance is also observed, with older people demonstrating greater diversity of test scores than younger people. This suggests that some individuals decline more than others on this task. The Rey-Osterrieth Complex Figure taps into visuospatial perception and memory as well as spatial constructional ability. There is a copy condition where the figure is directly copied, as well as immediate and delayed memory conditions, where the figure is drawn from memory and performance in all of these conditions declines with age [101]. This task also requires planning and problem solving and therefore the age-related decline cannot be presumed to be entirely a spatial deficit as executive functions might also play a role. Studies have suggested that Clock drawing is very sensitive to cognitive decline, particularly abnormal decline and this task has also been demonstrated to be better at discriminating Mild Cognitive Impairment (MCI) and Alzheimer's dementia patients from the normal elderly [102, 103]. Performance on clock drawing has been shown to be predictive of later cognitive deterioration [104] and this task also correlates with executive functions and other cognitive abilities [105].

Other less commonly used spatial tasks have demonstrated significant agerelated decline in performance. In a study by Uttl and Graf [106], museum and office settings were used to examine age-related changes in episodic spatial memory. A first experiment required participants to recall on a map particular items in the museum setting. The office setting included a relocation test, and participants were required to physically replace items within the office. It was observed that the older group performed more poorly than the younger group. In another example by Maki and colleagues [107], a visual-spatial memory test was developed which involved remembering the location of numbered circles on the screen and entering them in sequential order. Results showed impairment in visuospatial function in patients with MCI, with even greater impairment observed in dementia patients. From these examples, it is evident that age-related performance decrements can be observed in a wide variety of spatial tasks and evidence suggests that visuospatial function may actually be more susceptible to aging than other cognitive functions despite the difficulty in isolating the spatial component of any given test,.

Further, in a series of three experiments, two groups of participants (young vs old) were tested on verbal and visuospatial tasks, including processing speed, memory span and learning [108]. In all the three conditions, the older participants performed more poorly than the younger participants and even more poorly on the visuospatial tasks as compared with verbal tasks. Another study by Haaland and colleagues [109] demonstrated a more rapid deterioration of visuospatial function using the Visual Reproduction task of the Wechsler Memory Scale III when compared to the Logical Memory task.

Spatial working memory may be more susceptible to aging than other spatial functions due to additional ageing effects on working memory. In adults, there is a slowing of response and a decrease in accuracy in mental imagery tasks and this is mediated by declines in working memory rather than sensorimotor speed [110]. This may suggest that spatial working memory may be particularly useful in research on cognitive aging. For instance in the above studies it may be argued that the greater decline in the visuospatial tasks is due to task complexity rather than a particular deficit in spatial ability. Simpler tasks however might do better at isolating spatial cognition. The spatial task that is used in this study, Spatial Working Memory, has been demonstrated to be highly sensitive to cognitive decline [111]. In this task, participants are required to memorise patterns of white squares in a 4x4 grid. This task exercises working memory for spatial information, with a low requirement for manual dexterity or other cognitive functions and it is interesting to note that in normal adults, this task showed the steepest gradient for change with age for both accuracy and speed of response.

Executive Function: Executive function is defined as the coordination and regulation of cognitive performance. It includes a range of behaviours including

intentionality, interference management, inhibition, planning and social regulation [112]. Jurado and colleague [113] states that executive abilities allow people to shift their mind set quickly and adapt to diverse situations while at the same time inhibiting inappropriate behaviours. Executive function enables individuals to create a plan, initiate its execution, and persevere on the task at hand until its completion, and it mediates the ability to organize one's thoughts in a goal-directed way. They also argue that "executive function" does not appear to be a unitary system, referring to four different modalities namely: attentional control, planning, set shifting and verbal fluency.

Miyake and colleagues [114] identify three separable functions namely mental set shifting, information updating and monitoring, and inhibition, that are frequently considered in the scientific literature. Set shifting is defined as the process of changing focus between multiple tasks or mental sets. Information monitoring and updating refers to information in working memory. It maintains task-relevant information and it actively manipulates it, evaluating incoming information and revising existing contents. Inhibition is defined as the ability to inhibit behavioural responses that are dominant or automatic, when the need arises. These three functions were clearly distinguished from each other but also shared some commonality, with moderately high correlations among them in a factor analysis [114]. Impairment in executive functions can be observed in patients with frontal lobe damage, who exhibit "dysexecutive syndrome" and whose skills in planning, organization, reasoning and/or decision making may be disrupted [115]. An age-related decline in performance on executive tasks has also been observed in updating and inhibition, and non-significantly in shifting across an age range of 20-81 years, and a relationship between these variables and processing speed, in addition to the relationship with age has also been observed [116]. Also, age-related decline has been observed in other executive function tests, namely, the Wisconsin Card Sorting Test, which assesses set shifting or switching; fluency tasks including letter and category fluency; and the Tower of London test, which measures planning [117]. Executive tasks tend to have low internal reliability and test-retest reliability, and it has been demonstrated that these functions are associated with activities of daily living, and so may reflect an elderly person's capacity for independent living [113].

1.2.3.2 Cognitive Mechanisms in Speech Understanding

There are four processes involved in auditory functioning namely: 1) hearing, the detection of sound; 2) listening, the process of intentional and attentional hearing; 3) comprehending, the extraction of meaning and information that follows listening; and 4) communicating, which refers to an interactive and bidirectional way of exchanging meaning and information [118, 119]. Auditory processing is fundamental to all these functions whilst listening, comprehending and communicating also depend to a great extent on cognitive processing. Speech comprehension involves a sequence of processes, ranging from acoustically-driven bottom-up processing (such as detection of auditory information) to cognitively-driven top-down processing (such as interpretation of speech signals with the help of prior knowledge, experience, and language proficiency) [82, 83, 119, 120]. According to research, speech perception can be successfully achieved by bottom-up hearing but in noisy or adverse listening conditions, bottom-up hearing is difficult because the acoustic signal becomes distorted and/or less audible.

A number of cognitive functions are related to general speech understanding, including speed of information processing and lexical access, phonological processing skills, and working memory capacity [83, 121-123]. These studies have shown that these functions are important because they are related to the accessing of information from semantic long-term memory. Studies have also shown that memory for speech heard in noise is worse than in quiet, even when the to-be-remembered speech stimuli are recognized accurately [89, 124-132]. One common explanation of this finding is that listening in challenging situations, such as with reduced hearing sensitivity and in the presence of noise, requires more effort than in easy listening situations (such as in quiet) [133]. Having a hearing impairment would lead to less efficient bottom-up processing, and therefore more top-down processing would be recruited in order to achieve successful listening.

1.2.3.3 Processing Speed and its Impact on Cognitive Ageing

Processing speed is defined as the general slowing in cognitive ability which affects performance in all other cognitive domains [134]. For nearly a century, it has been reported that cognitive speed is reduced with increasing age and the speed with which cognitive processes can be carried out is known to begin to deteriorate from the early twenties [134]. The effects of cognitive slowing can be observed in simple tasks that assess response time, such as a computerized reaction time task where participants push a button in response to a target stimulus, or a choice reaction time task in which participants push one of two or more buttons in response to different target stimuli. Response time and choice response time tasks are reported to show decrements with increasing age in computerized batteries [111] such as the Cambridge Neurological Test Automated Battery (CANTAB) [135] and Cogstate [136]. These batteries have also demonstrated slower response times. For instance, the Coding and Symbol Search tasks of the WAIS have demonstrated that a significant speed component is sensitive to age.

Processing speed is known to occur through two mechanisms, namely the limited time mechanism and the simultaneity mechanism [134]. The limited time mechanism suggests that accuracy may be affected when there is a time limit for processing. Later mental operations cannot be completed because earlier operations have taken too long, and time to complete the cognition runs out. With the simultaneity mechanism, the products of early processing may be lost by the time that later processing is completed. In a large study by Finkel and colleagues [137], it was determined that processing speed could account for most of the variation in cognitive performance as well as the acceleration of cognitive decline in later years. Another study reported that processing speed was the best indicator of age-related changes in spatial function and memory, although not verbal ability [138].

Two broad categories of cognitive change are known to occur with normal aging. The first is an increase in general knowledge and know-how, i.e., vocabulary and other acquired knowledge and this can be referred to as crystalized abilities [139]. The other is a decline in cognitive performance, such as deterioration in memory, spatial abilities, reasoning and mental speed [140], and this can be referred to as fluid abilities. A study by Bäckman and colleagues [141] describe a pattern of cognitive aging whereby tasks which are highly automatized, have limited speed demands, or depend on prior experience are little affected. On the other hand, tasks that require new learning, speed, and mental flexibility are greatly affected.

Memory loss is due to processes involved with encoding memories rather than retrieving them, and research supports the notion that knowledge increases with age and experience. For instance, data from a large longitudinal study of cognition throughout adulthood indicated that there was an increase in semantic memory (vocabulary and general knowledge) from middle adulthood up until early old-age (55-65 years), and a decrease in older old-age (70-80 years) [142]. A similar study observed that semantic representation (in this case, knowledge about the categories or attributes of items) was preserved in old age, despite slower responses [143]. In a longitudinal study, crystalized abilities, as measured by the National Adult Reading Test (NART), remained stable after seven years of follow up in elderly participants [139]. Interestingly however, in normal aging, forgetting rates are stable across the lifespan [144].

During the aging process, whilst some functions do improve, other mental faculties show clear decline with age. To be specific, performance impairment is evident in cognitive speed, memory, executive function and spatial abilities, among others. But there is still some debate regarding the nature of the impairments. Some authors have argued that there is evidence of a single general factor underlying cognitive decline [98, 140] and this is thought to be processing speed. Other research has shown decrements in specific areas in addition to processing speed. Pipingas and colleagues [111] have demonstrated that different cognitive functions decline at different rates, with the greatest decline observed in tasks assessing spatial working memory and contextual memory. Cognitive decline becomes most apparent in the elderly, however a reduction in performance can be observed from early adulthood [111, 145]. Cross-sectional studies have noted cognitive decline to be linear and mild throughout adulthood, but becoming steeper after 70 years of age [146]. In longitudinal studies however, cognitive decline does not appear to be as steep, and Salthouse [140] has suggested that this might be due to practice effects. A general reduction in mental processing speed may present as poorer performance in tasks which are more complex than those described above, thus affecting performance in accuracy as well as response time. Salthouse [134] addressed the processing speed theory more comprehensively in their influential paper, contending that processing speed does manifest as a simple slowing and may therefore affect other cognitive functions as well. These cognitive functions include memory and executive function. This occurs through two mechanisms, namely the limited time mechanism and the simultaneity mechanism. The limited time mechanism is suggested to explain that accuracy may be affected when there is a time limit for processing. In the simultaneity mechanism however, "the products of early processing may be lost by the time that later processing is completed". That is, by not being able to concurrently access earlier and later processes, errors may occur and the effects of this would be observed in tasks of working memory.

There is other research work that supports the processing speed theory. For instance, in a large study by Finkel [137], it was determined that processing speed could account for most of the variation in cognitive performance as well as the acceleration of cognitive decline in later years. It was also noted in this study that a significant proportion of the genetic influences on cognitive ability were mediated by genetic factors that affected processing speed. Further, Eckert [147] reported that processing speed was the best indicator of age-related changes in spatial function and memory, although not verbal ability. It has also been argued that the reverse might be true, since many other functions underpin performance on a processing speed task [147]. An example of this is the trail making "Connections" task which requires the coordination of many cognitive processes, such as stimulus perception, working memory, decision making, motor planning and praxis, and performance evaluation.

1.2.3.4 Processing Speed and its Impact on the Brain

Data from neuroimaging studies provide evidence of the nature of age-related processing speed changes. For instance, structural changes in both grey matter and white matter have the potential to impact processing speed. Grey matter loss could contribute to cognitive slowing because it could impair the quality of neural signals and increase noise, which may slow recognition and response processes [147]. Loss of myelination (white matter) could also slow rates of signal conduction along neural pathways, thereby slowing processing speeds. White matter lesions and brain atrophy are known to be associated with cognitive decline. In an MRI investigation of people with cerebral small vessel disease, the extent of white matter lesions was associated with the level of cognitive decline in processing speed and executive function [148]. Similarly, longitudinal association between baseline periventricular white matter hyper intensities and the reduction of processing speed has been observed [149]. This relationship was maintained longitudinally over three years, with poorer cognitive performance being associated with an increasing volume of white matter lesions.

Research has noted that cognitive slowing may also be attributed to a decrease in the efficiency of neural networks, or cortical connectivity. For instance, cortical networks were examined in 342 healthy elderly people using diffusion tensor imaging [150]. The investigators observed that global as opposed to local network efficiency was associated with processing speed in the Digit Symbol Coding and Trail Making A tasks, and concluded that many types of lesion may produce a reduction in processing speed because processing speed was global. Despite the general cognitive slowing that is a well-established corollary of age, it is apparent that other functions also decline and this cannot be wholly explained by cognitive slowing. With the physical and cognitive effects of senility, elderly people, especially those with impaired hearing, may need rehabilitation support for improving their quality of life.

1.2.4 The Impact of Age-Related Hearing Loss on Speech Perception

Research suggests that there are four processes required for effective communication. These include hearing as a means to access the auditory world as a passive function, listening both attentionally and intentionally (requiring mental effort), comprehension to decipher the meaning, intent and requirement of the perceived information, and communication, which is the transfer of information between two or more listeners [118]. Wingfield and colleague [151] suggest that in everyday conversations, speech rates range between 140-180 words per minute. This implies that the human brain must identify each individual word as it arrives. Speech is then processed to identify the relationships between the individual words such as actions, objects, and who is involved. Speech is then integrated with prior knowledge and new information is received simultaneously. If this process does not occur as expected, memory is engaged and a backlog of processing is created. The individual still needs to remember new information as older information is being processed [152].

1.2.4.1 Speech Perception in Noise

Research suggests that understanding speech in noisy environments is a complex task as it requires perception through peripheral hearing, and processing in the central auditory system for cognitive use by the brain [153]. Adults suffering from age-related hearing loss often experience difficulty in understanding speech in challenging listening environments. According to Moore [154], the speech-to-noise ratio has to be higher in hearing loss sufferers as spatial separation of the speech and interference is impaired. Normal hearing adults' use their temporal and spectral volume dips to identify speech in competing background noise. Due to loudness recruitment which reduces dynamic range, these dips cannot be distinguished in adults with SNHL. If the intense part of a sentence is comfortably loud, softer parts may become inaudible. Speech perception becomes challenging as some parts in a sentence cannot be heard and processed [154]. According to Moore [154], SNHL impairs the understanding of speech in sound as hearing impaired adults cannot distinguish between spectral and temporal volume dips in competing background noise.

1.2.4.2 Speech Perception in Quiet

Research has shown that damage to the cochlear structures affects the perception of pitch, timbre, and loudness [155]. In relation to loudness, people with SNHL experience exaggerated perception of sound levels and this results in an overall reduction in dynamic range [154]. As a result, sounds that fluctuate in amplitude such as speech or music are exaggerated and impairment of the outer hair cells of the human ear decreases its capability to amplify its tasked frequency [155]. Adults with SNHL may then perceive the same sound at a different pitch in each ear which makes the cochlea lose its capacity to distinguish between different sound frequencies. And even when sound and noise have different frequencies, the auditory system is still unable to differentiate between them, thus affecting speech intelligibility adversely [155].

1.3 Rehabilitation Interventions for Adults with Hearing Loss

Very few adults with hearing impairment are candidates for a medical, pharmacological, or surgical intervention such as cochlear implants to address their agerelated hearing impairment. Interventions therefore focus on aural rehabilitation. The first step after diagnosis of SNHL is to restore audibility of sound with hearing aids, hearing assistance technology, and communication programs [156]. Hearing aids amplify sounds to levels that the wearer can perceive, assistive listening devices facilitate access to auditory information [157], and communication/auditory programs (either group based or individualized) for older adults with hearing impairment target the improvement of speech perception and/or communication management [158].

1.3.1 The Role of Hearing Aids

The basic function of hearing aids is acoustic amplification of sound signals with the aim of restoring the audibility of sounds, thus helping to improve speech perception [159]. Hearing aids amplify sound to a level that the wearer can perceive. They can be made to fit in the ear or behind the ear, can be of different sizes, can be used unilaterally or bilaterally, and can contain different signal processing features (See Figure 1.3).



Figure 1.3 Examples of the three major types of currently available hearing aids -Behind-the Ear Hearing Aid, In-the-Ear Hearing Aid, and a Completely-In-the-Canal Hearing Aid (from left-to-right)

Adapted from: (Starkey.com)

All currently available hearing aids include the same basic components listed in Table 1.2. The majority of hearing aids fitted to new users in Australia use digital signal processing.

Component	Function
Microphone	To convert -sound signal into an electric signal
Amplifier	To increase the strength of the electrical signal
Loudspeaker	To convert electric signal back to a sound signal
Coupler	To send the amplified sound signal toward the tympanic membrane
Battery	Disposable or rechargeable

Table 1.2 Basic components of currently available hearing aids

Notes: Adapted from: Laplante-Lévesque A. et al. [156]

Hearing aids are the main clinical intervention for adults with sensorineural hearing loss and have been shown to mitigate the impact of unmanaged hearing loss on cognitive decline and quality of life [157, 160, 161]. A systematic review survey [162], which evaluated the social and economic costs of hearing impairment, has shown that the use of hearing aids causes significant improvement in the quality of life of hearing impaired people. Preliminary evidence has suggested that hearing aids may improve cognitive abilities and the social, emotional, psychological, and physical well-being of

people [159, 161, 163, 164]. For individuals already diagnosed with dementia for instance, hearing aid use can reduce the number of problem behaviours reported by caregivers [165, 166]. Recent evidence from a longitudinal study has also suggested that central auditory processing dysfunction may be an antecedent of Alzheimer's disease [167]. Several large studies have investigated the benefits of hearing aids in elderly populations, with reported improvements in quality of life [168, 169], general health, mental health [169], social and emotional function [161, 169-171], symptoms of depression [19, 169, 170] and cognitive function [172].

A study has also examined the effects of hearing aid use by older adults on a broad range of cognitive functions, such as information processing speed, memory, and verbal fluency. Individual differences in working-memory capacity and verbal information-processing speed may correlate with language processing performance and speech understanding [173]. Therefore, hearing-impaired adults may sometimes miss information in acoustically demanding everyday life situations even when using hearing aids, as they have to guess and fill in words to get the message and this processing is cognitively demanding [123]. Although hearing loss makes listening in adverse conditions more cognitively demanding [94], which can affect speech understanding, research examining the effects of hearing aid use on a broad range of specific cognitive functions (such as information processing speed and memory), has suggested that hearing aids could improve cognitive abilities and reduce listening effort [163, 174, 175]. Other research reporting the cognitive and psychological benefits of using hearing aids in elderly people has shown that the effects are greatest in the early periods of use [21]. Findings of these research studies suggest that the effects of hearing aids can be seen within one month of use [169] and can still be demonstrated after one year of use [170].

However, not all people with some measurable form of hearing loss are candidates for continued hearing aid use [176] and the process of hearing aid adoption still remains complex [177]. A proposed model of the adoption of a hearing aid solution is displayed in Figure 1.4.

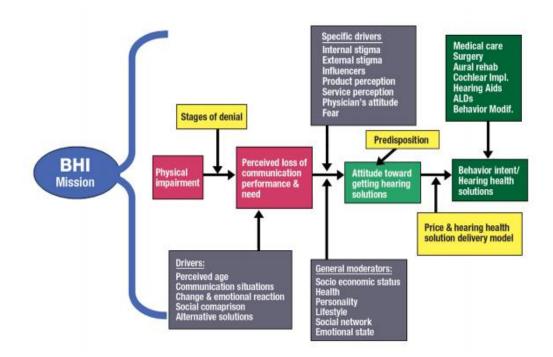


Figure 1.4 Hearing solution adoption model

Adapted from: Kochkin S. [177] – Permission sought to use diagram from author.

BHI: Better Hearing Institute.

As shown in Figure 1.4, hearing aid adoption is intimately related to degree of hearing loss, lifestyle, need, as well as many other moderating variables. These variables include attitudes toward wearing hearing aids, perceptions of the efficacy and value of hearing aids, perceptions of the appearance of people with hearing aids, internal and external stigma, hearing loss coping mechanisms, communication with others, stress associated with hearing loss, activity level, severity of hearing loss, level of social interaction and denial of hearing loss, among others [177]. Thus, for a person to seek out a hearing solution, a number of concurrent events must occur, both perceptually and in reality. The individual must first recognize his or her hearing loss, and recognize that the hearing loss causes them problems which are sufficiently disruptive to their quality of life or that of their family. Also, the individual's search for a solution must result in the formation of a reasonable probability that the problem will be sufficiently addressed and that the solution will be of good value. In the US for instance, hearing aid adoption continues to increase slowly (now 1 in 4 people with hearing loss), and less than 1 in 10 people with mild hearing loss use amplification, while 4 in 10 people with moderate-to-severe hearing loss use amplification for their hearing loss. In general, the average age for first time use of a hearing aid in a suitable

individual is 74 years, with an average of 10 years of significant hearing loss prior to fitting [178].

1.3.1.1 The Effects of Hearing Aids on Speech Perception, Brain and Cognition Function

To ensure that the auditory signals received in the ear are sufficient to compensate for the loss in hearing, hearing aids are designed to increase sound in different frequency regions. The hearing aid alters and amplifies the sound signal and the modified signal is processed in the auditory system. The comprehension of sound relies both on the quality of the sound signal and the effective processing of the signal received by the human brain. The brain (and cognitive function) plays an important role in the rehabilitation of hearing loss, as it is responsible for the biological coding, integration and use of the information perceived [179].

Choi and colleagues [180] investigated whether cognitive functions involving speech in background noise could be improved by the use of hearing aids in older adults. Results indicated that the use of hearing aids in hearing impaired people positively affected the input of auditory signals into the central auditory system. The authors also found that hearing intervention assisted the degenerated cognitive function associated with hearing loss.

Technological advances in hearing aids have focussed more on improving the signal-to-noise ratio of speech and a study by Sarampalis and colleagues [129] has shown that the noise reduction function of hearing aids reduces the cognitive load required to listen to speech. This study also showed that additional cognitive resources became available, which improved speech performance on a secondary task. The authors of the same research study reported that, when study participants were involved in two simultaneous tasks, a competition for brain resources resulted. The more cognitively demanding task used a greater share of the allocated resources, which decreased what was available for the other task. This resulted in changes in performance on both tasks. The presence of background noise in the experiments was shown to have a negative effect on listening and cognitive activities. The authors concluded that the increase in signal-to-noise ratio (SNR) achieved through hearing aids not only improved speech intelligibility, but also reduced listening effort [129], and that, if hearing aids were able to reduce listening effort, they could theoretically also reduce cognitive

overload. The question of whether this reduction in cognitive overload leads to a reduction in cognitive decline still remains unknown, and this needs further investigation.

1.3.2 Auditory Training

Auditory training is the use of instruction, drill, or practice, designed to increase the amount of information that hearing contributes to a person's total perception [181]. The main goal of auditory training in adults with sensorineural hearing loss is to improve speech perception in noise [182]. Historically, auditory training has been provided in a face-to-face setting that centred on a range of auditory skills included detection. discrimination, identification, and comprehension. Training often incorporated both drill-like activities described as analytic therapy activities, and paragraph comprehension activities which were synthetic in nature. Thus auditory training may be either analytic, synthetic or a combination of the two. Analytic training involves mastery of the building blocks of speech, such as syllables and words; synthetic training emphasizes cognitive skills and global comprehension of the sentence and/or message. While the outcomes of analytic training remain mixed, synthetic training or a combination approach is known to improve sentence recognition and overall communication [183]. For both activities, the auditory skills that were trained used various stimuli such as syllabi, words, phrases, sentences, and continuous discourse [184].

A fundamental assumption of any auditory training program is that the skills learned within the program will generalize or transfer to untrained stimuli and/or to everyday listening situations [182]. Research suggests that the possibility that a new hearing aid user could be trained or retrained to use "bottom-up" or "top-down" auditory processing skills is rooted in the recognition that the auditory system of a patient acquiring hearing aids has probably been deprived of normal auditory input for several years [182]. Auditory training regimens using principles of perceptual learning are adaptable through a hierarchy of listening tasks, provide immediate feedback to users, employ both auditory and visual/orthographic cues, and expose listeners to multiple talkers.

Particularly for the elderly population, it is unrealistic to expect that they will be able to instantly and optimally synthesize the novel and partial auditory cues provided by new hearing aids without experience or training. Studies have shown that hearing aid devices alone do not always adequately compensate for sensory losses despite significant advances in digital technology [184, 185]. Therefore, in aural rehabilitation, auditory training is necessary to augment the benefit from hearing aids in the hope that participants will assimilate their improved hearing with listening, comprehension and successful communication strategies [184]. For example, a person with a hearing-impairment who is fitted with a new hearing aid may benefit from instruction and practice in recognizing sounds through the aid. Research has also suggested that new hearing aid users show greater benefit from auditory training than experienced hearing aid users [185].

Auditory training also shares processes in common with cognitive training for improving working memory, attention and communication [173]. Recent studies of an auditory-based cognitive training program which combined auditory perceptual training with increased memory demands (Brain Fitness; Posit Science) have suggested generalized improvements in non-trained tests of memory, attention and speed of processing in adults [186], and an improved neural timing and speech perception in noise [153]. These studies have shown that auditory training can produce prolonged cognitive performance improvements [187, 188] and improve speech understanding [189-191]. Benefits of auditory training for people with hearing loss in terms of improved speech understanding are best achieved if an integrated auditory-cognitive training approach is adopted [173].

Evidence of the effectiveness of auditory training also comes from the field of neuroscience. The human brain is not hardwired; it has the ability to change in response to experience. Structural and physiological changes are induced in the brain as a consequence of training and learning. This positive feature, termed "plasticity," is retained throughout the lifespan, even in adults [192]. Plasticity changes have been documented using behavioural approaches, as well as imaging and electrophysiological techniques. Auditory training is designed to exploit the plasticity of the brain in response to structured stimulation. Auditory training improves hearing aid outcomes and maximizes the use of individual's residual hearing [184].

The concept of auditory rehabilitation is not new and has for many years been the centrepiece of care for hearing-impaired individuals, because it conquers the challenges of everyday listening by giving the brain the information it needs to make sense of what someone is saying in situations where it is difficult to hear. Today however, auditory training is routine practice only with paediatric clients who receive rehabilitation services and with clients who receive cochlear implants [193]. The popularity of auditory training has further declined in recent years and the focus of research has been shifted to improving wearable amplification such as hearing aids. Professionals tend not to provide auditory training because of the poor reimbursement and the time required. Yet access to auditory training is now readily available over the internet at no or very low cost. In fact, today, computerized auditory training is a reality. There are several commercially available auditory training programs: Listening and Communication Enhancement (LACE) and ReadMyQuips (RMQ) are two examples of online programs designed for adults with hearing loss [194]. LACE is a self-paced training program using a combination of analytic and synthetic approaches. Training includes listening in noise, listening to fast talkers, and listening in the presence of competing speech. In addition, speed of processing, use of contextual cues and memory tasks are targeted. Participants also receive helpful communication tips throughout the training period. Improvements in perceptual skills as well as cognitive skills have been documented [185, 187].

Auditory training relies on the assumption that neurons in the brain can reorganize and restructure following training or changes in sensory input [195-197]. A recent study has shown that auditory functions can be improved by stimulating these cognitive functions [198], and the benefits of training for people with hearing loss in terms of improved speech understanding in adverse conditions are best achieved if an integrated auditory-cognitive training approach is taken [199]. Further auditory training might have greater impacts on complex higher level executive skills such as memory updating or task switching. Studies [188, 200] comparing the performance of nonhearing aid users with hearing impaired individuals showed that performance of hearing aid users improved following auditory training on challenging measures of divided attention and working memory [201]. Similarly, Kuchinsky and colleagues [202] reported that adults with hearing loss improved over untrained individuals on a test of word recognition in noise and reaction time, and showed changes in pupillary responses that were indicative of a change in cognitive demand. Anderson and colleagues [203] also showed improved scores on tests of short-term memory and attention for individuals who had conducted auditory training as compared to untrained individuals.

1.3.2.1 Auditory Training Options for Adults with SNHL

Auditory training has historically been provided in a face-to-face setting that centers on a range of auditory skills including detection, discrimination, identification, and comprehension [184]..Recently, there is an increased recognition of the role of patient-centered care in aural rehabilitation [204] and the need for audiologists to adjust rehabilitation and service to particular needs. Adults with SNHL are often able to regain some lost auditory function with the help of hearing aids. However, hearing aids are not able to overcome auditory distortions such as impaired frequency resolution and speech understanding in noisy environments [205]. Therefore, there is an increase in research examining the potential of home-based auditory training for improving speech perception in adults with hearing loss.

Initial research reports beneficial effects of computer-delivered auditory training on speech perception in people with hearing loss [187]. These include Listening and Communication Enhancement (LACE) [206], Angel Sound [207, 208] and ReadMyQuips [206] allowing adults to train at home at their leisure and are selfdirected. Other adults however require more clinician-directed training such as Seeing and Hearing Speech [209-211], Speech Perception Assessment and Training System for the Hearing Impaired [212, 213] or Kungliga Tekniska Högskolan (KTH) Speech Tracking [214]. The LACE, Angel Sound, eARena, KTH Speech Tracking programs provide training only by means of auditory stimuli whereas others use both auditory plus visual training (Seeing and Hearing Speech and ReadMyQuips) options. These computer-based programs vary in availability of language, cost, targeted auditory skill(s), type of stimuli, and the number of speakers used during training.

Other auditory training options currently available include mobile smart auditory training applications for iPhone, iPad, Macintosh, and Android systems. Although the web applications incorporate evidence-based features related to auditory learning such as the use of feedback, opportunity to repeat a stimulus, or client selection of difficult training stimuli, there is no evidence-based research to support the actual use of the web-based applications. The exception to this is however is Angel Sound application which is derived from the computer training Angel Sound program. Research suggests

that the computerized programs are more extensive in comparison to mobile app programs. For instance, research base of computerized programs is also more extensive in comparison to mobile app programs [184].

Studies have further investigated the effects of the computerized auditory training programs such as the LACE software, on generalization to speech perception, self-report of communication difficulties, and cognition [183, 187, 188]. The results of these studies have often demonstrated the efficacy of auditory training, despite the computerized method of auditory training perhaps resulting in lower compliance with training protocols [215]. In addition, Saunders et al [182] found that LACE training did not result in improved outcomes over a standard-care hearing aid intervention on its own. Furthermore, according to research studies [216, 217], there are still a large number of outstanding questions on the benefits of auditory training, such as which aspects of auditory training protocols contribute to learning, how auditory training generalizes to benefits in everyday communication, how individual characteristics interact with training outcomes to identify candidacy for auditory training, and the identification of outcome measures that are appropriate and sufficiently sensitive.

1.4 Summary and Conclusion

Ageing is a natural consequence of the human condition and society is rapidly ageing. The number of people worldwide with hearing impairment currently exceeds 600 million [6] and this number is expected to rise with the aging population. Older age is significantly related to declines in auditory and cognitive function with public health implications. Some estimates suggest that up to two-thirds of older adults with hearing impairment do not use hearing aids [20]. Hearing aid devices alone do not always adequately compensate for sensory losses despite significant technological advances in digital technology [184] and even when hearing aids are fitted some patients struggle to hear speech clearly in noisy environments, making auditory training in conjunction with a hearing aid an attractive proposition. This proposition is explored in the Crossover Study as explained in the next two chapters.

2 Rationale for Crossover Study

This chapter discusses the rationale for the Crossover Study. In order to establish the aims and hypotheses used for this study, it provides an overview of the impact of age-related hearing loss on cognitive and brain structure and function. The effects of hearing loss on psychosocial factors such as social isolation and depression are also discussed in this chapter.

2.1 Overview

The downstream costs of untreated hearing loss are significant and yet to be completely understood. However, there is clearly a need to reduce risk factors for cognitive decline and accelerated onset of dementia as we age. A case-control study, conducted in 1989, reported that hearing loss among older adults was strongly associated with cognitive decline [218], with adverse effects on the older adult's performance of daily activities including driving and ambulation [59, 219-223]. This raised the intriguing hypothesis that age-related hearing loss may contribute to cognitive decline or incident dementia. However, the mechanism underlying cognitive decline associated with age-related hearing loss is not yet clear; nor is it established whether auditory rehabilitation strategies, such as hearing aids, can prevent or delay the onset of dementia [59].

Progress in this field was hindered due to the perception that hearing loss was an inconsequential part of ageing, and hence was likely to be inevitable. In the ensuing years, epidemiologic and longitudinal studies investigated this link among adults over a 6-year study with a sample of 1,984 community-dwelling individuals aged 70 to 79, and found that older people with hearing impairment had a 24% increased risk of a decline in cognitive function, experiencing a 30% to 40% higher rate of cognitive decline over time than those without hearing loss [59, 224, 225]. However, research has shown that, older age and microvascular pathology increase the risk of both dementia and SNHL, and might therefore confound the association between hearing loss and cognitive decline [62].

The proposed theories to explain the above association consider the effects of hearing loss on cognitive load and cognition reserve, effects of hearing impairment on brain structure and shared pathologic aetiology, social isolation and mood [223] (See Figure 2.1).

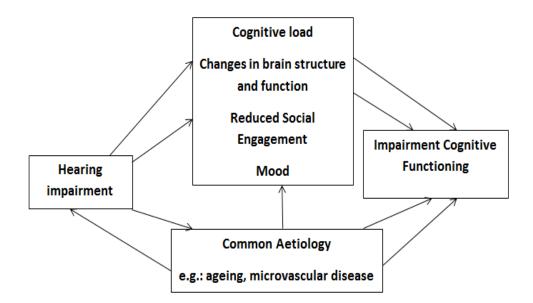


Figure 2.1 Conceptual model of the association of hearing impairment with cognitive functioning

Adapted from: Lin F. et al. [59, 220] - Permission sought to use diagram from authors.

As shown in Figure 2.1, the mechanisms by which hearing loss may impact cognition are thought to be associated with increased cognitive load, changes in brain structure, decreased social engagement and mood. In summary, hearing loss increases cognitive load on brain activity by diverting cognitive resources to process the degraded auditory signal, at the expense of other cognitive processes such as working memory. Also, a greater number of depressive symptoms are associated with cognitive and concentration disorders. Therefore, a better understanding of the aetiology behind the connection between hearing loss and cognitive decline could help lead to interventions that preserve cognitive function in hearing loss patients. The subsequent sections will describe the three hypothesized mechanistic pathways in more details.

2.1.1 Cognitive Load Hypothesis

Cognitive load is the brain activity needed to understand and recognize a voice, essentially it is the effort associated with constantly straining to understand [226]. For people with hearing impairment, greater cognitive resources are required for auditory perceptual processing to the detriment of other cognitive processes [131, 227, 228]. For an individual with hearing impairment, such a cognitive load would be a 'dual task', that is always present, and could, therefore, affect an individual's performance in usual activities and cognitive tasks [228]. Studies have demonstrated that hearing loss causes communication problems, especially in demanding listening situations, such as when speech is masked with noise or when competing talkers are present [118, 229, 230]. There is also a growing body of evidence suggesting that cognitive factors play an important role in these situations [231, 232]. Several studies have reported that the ageing process may influence both perceptual and cognitive functions. For instance, Tun and Wingfield [233] have shown that listening performance is predicted not only by individual differences in hearing ability but also by speed of processing, which underscores the combined role of age-related auditory and cognitive changes in spoken language. Baltes & Lindenberger [95] have found strong age associated links between cognitive and sensory functioning in individuals from 25 to 103 years of age, which they interpret as reflecting brain ageing. Furthermore, Wingfield [234] argued that two cognitive factors, cognitive slowing and age-related memory constraints, are of particular importance for auditory performance in elderly adults.

Another basic cognitive factor involved in speech understanding is attention [235] - the ability to selectively focus on a target talker while inhibiting competing information, or to divide attention to or switch attention between different talkers [236]. Research has addressed speech recognition with competing talkers and mainly focused on differences between younger and elderly listeners. These studies have demonstrated that older listeners performed worse than younger listeners, even when group differences in hearing loss were taken into account [237]. Everyday communication frequently presents situations with more than one talker speaking at a time and these situations may pose high attentional and memory demands on the listener. Therefore hearing impaired listeners may often experience extra difficulties with higher cognitive load.

A wealth of evidence has suggested that older adults have more trouble learning new information, exhibit less efficient reasoning skills, are slower to respond on all types of cognitive tasks, and are more susceptible to disruption from interfering information than younger adults [71, 72]. Also, research has shown that less cognitive reserve leads to earlier development of dementia. However, for adults who have cognitive reserve, it is possible to tolerate more neuropathology without cognitive and functional decline, and therefore develop dementia more slowly than people without this type of brain reserve [238].

2.1.2 A Shared Pathologic Etiology / Brain Atrophy

As a consequence of aging and hearing loss, there are morphological changes in auditory areas which are consistent with damage. Some theories exist which seek to explain why hearing loss might diminish brainpower and impose an extra, detrimental workload on the brain. One such theory is that hearing loss may cause parts of the brain to atrophy. A recent study has shown that hearing loss in older adults is associated with accelerated brain atrophy [48]. Brain atrophy occurs when there is damage to the connections between brain cells. The basis of the observed associations between hearing impairment and accelerated brain atrophy is unknown although one possibility is a shared neuropathological ageing process [239] leading to both cochlear and brain ageing [240]. Older adults suffering from brain atrophy associated with hearing loss will likely struggle to understand speech, as they have to work harder to listen to and absorb sound. There is also evidence that brain atrophy is correlated with the recruitment of compensatory mechanisms for auditory and language processing [241]. Researchers have also shown that this association may be related to alterations in the degree of neural activation provided by an impoverished auditory signal with subsequent structural changes in cortical reorganization and brain morphometry [242], but the mechanistic basis of the observed associations is unclear [48]. Brain tissue loss happens faster in older adults with hearing loss than it does for those with normal hearing [48].

Studies have also shown that SNHL can result from damage to any part of the inner ear or the neural pathways to the human brain [243], thus diminishing brainpower and imposing an extra detrimental workload on the brain. Imaging of the inner ear helps to detect the disease and to rule out any congenital, infectious, inflammatory or tumoural pathology. Techniques such as magnetic resonance imaging (MRI) provide supplementary information on the fine intralabyrinthine structures of the brain to narrow down the differential diagnosis of the disease [244].

Neuroimaging studies have linked hearing loss in old people with marked differences in brain structure and recent studies have analysed MRIs to establish this link [48, 242, 245-248]. One such study used functional MRI to examine brain activity while participants listened to sentences that varied in their grammatical complexity [242]. As it is well established that linguistically complex sentences rely on increased neural activity [249], the listeners with poorer hearing showed a smaller degree of change in their neural activity for the more complex sentences relative to the less Page 58 of 309

complex sentences. As expected this effect was observed in the auditory cortex, which is the first cortical waystation for acoustic information processing in the brain. However, the presence of a significant interaction between hearing ability and linguistic difficulty in the functional MRI data suggested that listeners' hearing ability did not only impact their sensory processing of auditory information, but also impacted higherlevel linguistic processes [242]. A second related study used structural MRI images to investigate the relationship between hearing ability and regional grey matter volume [242]. The results revealed that people with poorer hearing also had a lower grey matter volume in the auditory cortex and the findings suggested that decreased hearing ability has cascading consequences for the neural processes supporting both perception and cognition.

A longitudinal study has examined the link between hearing loss and brain mass change over time by analysing MRI scans of participants taken over up to 10 years. Results of this study showed a correlation between hearing loss and brain atrophy [48]. In analysing the MRIs from these participants, researchers also found that those with impaired hearing lost more than an additional cubic centimetre of brain tissue each year, compared with those with normal hearing. The most shrinkage occurred in particular regions, including the superior, middle, and inferior temporal gyri, brain structures responsible for processing sound, speech, memory and sensory integration. This shrinkage could potentially compromise the cognitive function, as studies have shown that the shrinkage of these regions is related to early stages of cognitive impairment and Alzheimer's disease.

A recent neuroimaging study [48] has found that people who have been diagnosed with hearing loss for at least seven years are more likely to have brains with smaller lateral temporal lobes, which are involved with retaining visual memories, processing and deriving meaning from sensory input, and storing new information. The basis of the observed associations between hearing impairment and accelerated brain atrophy is unknown although one possibility may be a shared neuropathological ageing process [239], leading to both cochlear and brain ageing. Other studies have also linked hearing loss with marked differences in brain structure and recent studies have analysed MRIs to establish this link [48, 242, 245-248].

2.1.2.1 Does hearing loss result in structural changes beyond the superior temporal cortex (STC)?

Many studies have characterized the effects of aging on the structure of the human brain, and in particular on the prefrontal cortex. However, it is not clear whether hearing loss also causes damage or other changes in regions beyond those involved in auditory processing [241].

Very recent neuroimaging studies have further investigated the role of the superior temporal cortex (STC) in auditory speech perception and its involvement in the processing of both auditory and visual speech cues (lip/speech reading) [250]. Existing evidence suggests that cross-modal plasticity can take place whereby superior temporal brain regions can become more responsive to visual cues when deprived of auditory inputs in both deaf and hearing people [251-253]. Cross modal plasticity refers to cortical areas that become under stimulated by their usual sensory inputs and are taken over by other modalities, such as the activation of auditory areas which process sign language or lip/speech reading [254].

Similar studies have shown that wearing hearing aids before cochlea implantation for patients with severe to profound hearing loss improves post-implantation speech understanding [255]. This suggests that even minimal stimulation tends to preserve auditory functions and areal specificity, and that hearing aids have a protective effect against deleterious plasticity such as visual take-over of auditory areas [256]. The recommendation from these studies is that a specific cognitive rehabilitation program could be adapted to speed up or optimize speech comprehension recovery in severe to profound hearing loss, however hearing impaired patients are also encouraged to wear hearing-aids as soon as diagnosed, before they start to adapt profoundly to their disability [251].

2.1.2.2 How the Communicative Brain adapts to Auditory and Visual Stimuli in Normal and Hearing Impaired Older Adults

Theories as to how auditory training and visual inputs to the brain converge on the same neural substrate have been described. For instance, neuroimaging studies have compared brain activity during language comprehension with brain activity during action or perception and have shown that there is an overlap in the brain areas that are active during both (a) reading of words associated with motion and (b) perception of motion [257, 258]. To further explore this theory, researchers have measured pupillary responses to single words that conveyed a sense of brightness (e.g. day) or darkness (e.g. night) or were neutral (e.g. house) and found that pupils were largest for words conveying darkness, of intermediate size for neutral words, and smallest for words conveying brightness, for both visually presented words and spoken words [259]. This experiment shows that word comprehension alone is sufficient to activate sensory and motor representation and can even trigger involuntary pupillary responses.

In people with normal hearing, communication is mainly achieved through verbal exchange and its written transcription, making communication difficult when hearing is lost [251]. This causes new modes of communication to develop and sign language (visual based communication) is one of these. Sign language processing and production uses visual modalities in the brain without any sound-based phonological correspondence. The left side of the human brain therefore shows highly preserved organization for language processing, independently of the input modality (audio or visuo-spatial).

The initial stages of speech processing in normal hearing adults involves analysis of basic speech sounds, including phoneme (speech sounds made by the mouth, e.g., spoon has 4 phonemes; s/p/oo/n) and acoustic processing [260], which occurs within the mid/posterior parts of the bilateral dorsal temporal lobe structures, including the superior temporal gyrus (STG), superior temporal sulcus and the planum temporale [261]. In their model of speech processing, Hickok and Poeppel suggest that subsequent higher-level processing, that includes motor (reproduction and planning) and memory (semantic and linguistic) processes, map the initial sensory and phonological output onto distinct dorsal and ventral neural pathways [261]. A left-lateralised dorsal articulatory motor network, that includes the inferior frontal, premotor, anterior insula and temporo-parietal cortices, maps the output onto articulatory representations; and a bilateral ventral pathway, that includes anterior and posterior portions of the middle and inferior temporal lobes (sulci and gyri), maps the output onto ventral lexical/semantic representations to facilitate understanding. Of key interest here is alteration of the brain structures that underlie speech processing in sensorineural hearing loss patients.

However, individuals with sensorineural hearing loss typically adapt to their altered aural predisposition by developing their lip-reading ability. In normal hearing older adults, lip and word reading broadly activate the abovementioned dorsal articulatory and spectro-temporal/phonological analysis networks, with the exception of the primary auditory cortices due to diminished auditory function [262]. Adults with SNHL engage a similar network, but exhibit greater amplitudes in the attendant structures, especially the prefrontal and premotor cortices, and recruit additional structures including the right posterior temporal lobe [251, 252, 263, 264] that is normally only activated by actual sounds [262].

This functional alteration is thought to stem from a loosening of associations between memory/phonological processes and viseme (visual aspects of phoneme pronunciation) processes as SNHL progresses [265] (i.e., altered functional connectivity), leading to these plastic brain changes. The phonological processing specialisation of left posterior temporal lobe appears to be preserved, while right lateral homologues that are predominantly involved in processing environmental sounds are repurposed to accommodate enhanced visual processing that aids lip-reading and phonological processing capabilities [251-253]. Furthermore, a right anterior part of the superior temporal gyrus that normally performs voice/speaker identification functions, is also repurposed for lip-reading, however this plastic alteration can be reversed by auditory rehabilitation [266].

In addition, functional MRI studies have explored the functional neural organization of seen speech in congenitally deaf native signers and hearing non-signers, by examining activation in the left middle and posterior portions of superior temporal cortex during silent speech reading. Results show a positive correlation between speech reading skill and activation in the middle/posterior superior temporal cortex in both signers and non-signers, and this finding indicates that activation in the left superior temporal regions for silent speech reading can be modulated by both hearing status and speechreading skill [253].

To understand changes that may occur during post-lingual deafness, similar functional MRI studies have compared brain networks for language and environmental sound processing between normal hearing controls and post-lingually deaf subjects. Results have shown that there are different areas of brain activation during tasks such as written rhyming tasks, lip-reading tasks, and environmental sound imagery tasks [252, 263, 264, 266, 267]. This shows that not having access to one sense can modify our interactions with the environment, and this in turn will produce brain reorganization.

2.1.3 Effects of Hearing Loss on Psychosocial Function - Social Isolation and Depression

Hearing loss is suggested to be causally associated with cognitive decline, possibly because social isolation and communication impairments caused by hearing loss can lead to loneliness and depression in older adults [268-271]. Social isolation and depression lead to a negative perception of one's own health and a decline in daily activities. A nationwide survey of 4,000 adults with hearing loss compiled by the National Council on Aging [55] found significantly higher rates of psychosocial disorders, including depression and anxiety, in individuals with untreated hearing loss. A number of studies, and organisations including The National Heart Foundation (Australia) and the World Health Organisation (WHO) have recognised that depression increases the likelihood of developing a chronic physical illness such as cardiovascular (heart) disease, coronary heart disease, and stroke. Another study has shown that those with hearing loss are at higher risk of developing depression [272].

SNHL affects not only physical, cognitive and emotional activities, but also social functioning. One's quality of life deteriorates with various symptoms such as social isolation and lowered self-esteem [273]. In addition, social isolation has been shown to be a predictor of mortality, psychiatric illness, and cognitive and functional decline in older adults [274-277]. Previous studies have implicated hearing loss in the development of social isolation in a sample of older Australians and senior citizens in Amsterdam [278, 279]. These studies have found that hearing impairment may be associated with poorer scores in social functioning.

In situations in which hearing is difficult, social gatherings may become difficult for adults, and relationships may suffer because of communication problems or even because activities once enjoyed together are no longer pleasant to the individual with hearing loss [280]. Long standing uncorrected hearing loss in the elderly may result in withdrawal from a variety of social activities, which in turn may affect quality of life as well as mental health and wellbeing. It may also give rise to feelings of loneliness and increased symptoms of depression, and adults with hearing impairment may not always be aware of all the consequences of their hearing loss [272].

Social isolation is well known as a risk factor for cognitive problems, and the document Towards a Dementia Prevention Policy for Australia: Implications of the

Current Evidence [281] published by the Dementia Collaborative Research Centres and Alzheimer's Australia, lists several measures of social engagement as being associated with a lower risk of dementia, including participating in more social activities, not feeling lonely, and being part of larger social networks. A recent report from the Economic and Social Research Council (ESRC) Deafness Cognition and Language Research Centre ("DCAL"), University College London, reads:

There are good theoretical reasons to support the 'social isolation' theory. The risk of dementia associated with hearing loss appears to increase only at thresholds greater than 25 decibels (dB), the threshold at which hearing loss begins to impact on verbal communication [5]. Similarly, it has been noted that those people who wear hearing aids do not demonstrate the same level of decline in cognitive function as those who do not [221]. Both of these suggest that it is the impact of hearing loss on communication, rather than a biological process, that leads to increased rates of dementia. (DCAL, n.d, p.14)

Social isolation and communication impairments caused by hearing loss [268, 269] often result in a negative perception of one's own health and a decline in daily activities, with associated declines in cognitive performance. Neuroanatomic studies [282] have subsequently demonstrated associations of loneliness and poor social networks with cognitive decline and dementia. Mechanisms that have been implicated in these associations include direct pathophysiologic effects of altered gene expression profiles or increased inflammation in lonely individuals [283]. Longitudinal studies have also suggested that social interaction might prevent or delay dementia, but there is an absence of evidence from intervention studies that social activity prevents cognitive decline or dementia. Compared with people without dementia however, people with dementia might be less motivated to engage socially or they may find more difficulty in organising activities, be embarrassed by their difficulties, or worried that they might be unable to manage previous activities or might get lost [62]. Studies have shown that depression is associated with hearing impairment [57]; it is both a risk factor and a prodromal of Alzheimer's disease, It occurs commonly in all types of dementias as well as in mild cognitive impairment [59]. There is also the hypothesis that hearing loss leads to depression which has been shown to contribute to dementia. These studies have shown a link between the number of depressive episodes and the risk of dementia, with more than 20% of people with dementia either having diagnosable depression at any one time or experiencing depressive symptoms. Depression reduces quality of life, exacerbates cognitive and functional impairment, and is associated with increased mortality [284]. Better understanding of the aetiology behind the connection between hearing loss and dementia could help lead to interventions that preserve cognitive function in patients with hearing loss.

Researchers have used structural MRI to examine the association between depressive symptoms and volumetric decline in grey matter over intervals as long as 9years in older adults, and have shown that depressive symptoms are associated with volume reduction in frontal and temporal brain regions, particularly with advancing age [285]. Other literature has linked late-life depression to dementia [286] and implicated hippocampal atrophy in Alzheimer disease [287]. If hearing loss is potentially contributing to the differences seen in the MRI scans, it is important to treat it before these structural changes take place in the brain, since untreated hearing loss in older adults has been shown to be associated with diminished cognitive function, poorer mental health, and social withdrawal.

2.2 Gaps in Research

Hearing loss is treatable and interventions exist and work, yet a significant number of people with hearing loss do not seek treatment. Despite its high prevalence and the consequences for health outcomes, hearing loss is still largely underdiagnosed and thus undertreated [20, 288-291]. People are generally slow to acquire hearing aids, and it often takes about 10 years for an individual to recognize that they have a hearing problem [292]. Long-term deprivation of auditory input may impact on cognition either directly, through impoverished input, or via effects of hearing loss on social isolation and depression [220, 293, 294].

Various studies have examined the effects of hearing aid use by older adults on a broad range of cognitive functions, such as information processing speed, memory, and verbal fluency. Other researchers have demonstrated the effects of hearing aid use on other factors related to cognition: improvements in social, emotional, psychological, and physical well-being [159, 161, 164, 295]. However, less than 25% of people who would benefit from hearing aids actually own them [20] and there is insufficient research clarifying the potential benefit of hearing aids for maintaining cognitive function.

Secondly, existing research in this area, attempting to describe the effects of hearing aids on cognition, always assessed global mental status rather than cognitive performance and often examined only a single measure of hearing [21, 163, 296], thus limiting the insights gained. These studies also lack data on the duration of hearing impairment, and loosely define hearing aid use as the self-reported use of a hearing aid in either or both ears. It is also unclear how hearing loss may affect performance on measures of cognition.

Thirdly, although the concept of auditory training is not new, its popularity has declined in recent years and only a small proportion of audiologists offer auditory training to patients with hearing impairment [215]. Also, limited auditory training effort has been directed towards adults with impaired hearing, and the focus of auditory training has historically been directed towards young children with profound or severe to profound hearing loss [183, 297]. Studies have investigated the effects of auditory training with laptops and computers, such as with the LACE software for its applicability and generalisation to improving speech perception, self-reporting of communication difficulties and cognition [183, 187, 188]. The results of these studies have demonstrated the efficacy of auditory training, despite the computerized method of auditory training perhaps resulting in lower compliance with training protocols [215]. In addition, Saunders et al. [182] found that LACE training did not result in improved outcomes over a standard-care hearing aid intervention on its own. Furthermore, according to research studies [216, 298], there are still a large number of outstanding questions on the benefits of auditory training, such as which aspects of auditory training protocols contribute to learning, how auditory training generalizes to benefits in everyday communication, how individual characteristics interact with training outcomes to identify candidacy for auditory training, and the identification of outcome measures that are appropriate and sufficiently sensitive.

Lastly, studies have used various techniques to assess structural brain changes as a consequence of hearing loss in older adults. However, outcomes from these techniques have been mixed. For instance, of those studies measuring brain morphometric changes in auditory cortices, two studies showed a positive correlation between hearing loss and reductions in grey matter volume [242, 246] whereas another two studies did not find a significant effect [245, 247]. Similarly, studies assessing the effects of hearing loss on the morphometry of other structures of the temporal lobe and the rest of the brain are also mixed and these studies lacked specificity when defining regions of interest. Some of these studies reported reduced grey matter in the superior temporal gyrus (STG), middle temporal gyrus (MTG), and inferior temporal gyrus (ITG) in patients with unilateral hearing loss [299] and similar discrepancies were also found when looking at results from the whole brain. Furthermore, studies of speech in noise [300] found that the reduction in activity in auditory areas of the brains of older individuals was accompanied by stronger recruitment of parietofrontal regions and that this additional recruitment correlated with performance. A further study [301] also showed that the volume of the left pars triangularis and the cortical thickness of the left superior frontal gyrus were positively correlated with performance in speech in noise testing. Grey matter volume in left auditory cortices was also found to be positively associated with word recognition skills, and negatively associated with activation in anterior cingulate cortex and middle frontal gyrus [302, 303]. From all these studies, it is evident that additional recruitment of frontal regions is observed when there is damage in auditory areas, and the amount of damage in temporal cortices and the recruitment of frontal regions predict behavioural performance. What is not known is whether this damage is the cause of compromised auditory processing, and the reliance on other cognitive resources, such as lip reading, to aid communication [241].

In trying to understand discrepancies in the observed effects of hearing loss on brain morphometry in previous research, the following facts are noteworthy:

- 1. The lack of specificity when defining brain regions of interest [241]
- 2. Since hearing loss tends to be greater for higher-frequency sounds, using the high-frequency component of hearing thresholds may provide more accurate estimations of the effects of hearing loss on neural structure [246]
- All the studies mentioned were observational. Thus the use of experimental studies, with hypothesis-driven definitions of regions of interest could shed some light on the mixed results found when measuring gray matter changes as a consequence of hearing loss [241].
- 4. Given the relationship between hearing ability and brain volume change, and the effects of hearing aids on cognitive function, no previous research has investigated whether improving hearing ability through the use of hearing aids

might help preserve (or even improve) either cortical health or cognitive ability [249].

2.3 Justification of Research

The early detection of SNHL and immediate attention to its management are of paramount importance to the outcomes of interventions. Recognition of hearing loss as a risk factor for dementia is relatively new [62]. Therefore, rather than waiting until mild cognitive impairment or dementia have been identified, earlier intervention using a health promotion approach to encourage help-seeking for hearing loss may be advantageous [304]. Research has shown that hearing aid devices alone do not always adequately compensate for sensory losses despite significant advances in digital technology [184]. Particularly for the elderly population, it is unrealistic to expect that they will be able to instantly and optimally synthesize the novel auditory cues provided by new hearing aids without experience or training. Therefore, auditory training is necessary for some patients to augment the benefit of improved hearing with the use of hearing aids by assisting them to integrate hearing with listening, comprehension and successful communication strategies.

One of the main barriers to treatment is health care providers' underestimation of the negative physical and emotional impact of hearing loss in the older adult [305]. Cost and perceived stigma associated with hearing aid use are other factors that impede the treatment of hearing loss [306]. Training interventions to improve cognitive performance have been developed in the past decade, and studies have revealed that cognitive training may minimize the effects of hearing loss on cognitive performance by improving memory, processing speed and executive function [307-311]. However, few studies have been designed to specifically look at the efficacy of the simultaneous use of hearing aids and individualized auditory training for improving cognitive performance in older adults.

Finally, there is evidence that age and hearing loss cause atrophy in auditory regions of the human brain, and this atrophy is correlated with the recruitment of compensatory mechanisms for auditory and language processing [241]. Structural neuroimaging, for example, frontotemporal dementia from Alzheimer's disease [312] may help to distinguish the common neurodegenerative causes of dementia.

2.4 Summary and Conclusion

Based on the rationale for the study, this thesis will consist of two pilot studies (Study 1 and Study 2). Subsequent chapters will discuss the motivation for these two studies, and present the aims, hypotheses, study methodology and findings for the studies. The thesis will conclude by summarizing the results for both studies and will discuss the future implications for aural rehabilitation.

3 Protocol for Crossover Study

This chapter presents an overview of the aims and method for the Crossover Study. It will begin by highlighting the motivation for this study, and then present the aims, hypotheses and other research questions under investigation, and the methodology used. The draft manuscript of the research methods for the study which was submitted for publication is included in Appendix A.

3.1 Motivation for Crossover Study

The onset of SNHL, damage of inner hair cells in the peripheral and central auditory system is associated with ageing. With the ageing of the world population, SNHL is expected to increase substantially in the future. Many studies [59, 272, 313] have indicated that as hearing loss worsens, psychological, social, emotional and cognitive functioning will deteriorate as well as communication and earning power. In particular, it is expected that treating hearing loss will contribute to the management of dementia [62]. Novel approaches are therefore urgently needed in order to improve outcomes of aural rehabilitation in adults with SNHL. The early detection of SNHL and immediate attention to its management are of paramount importance to its treatment [175]. Also, rather than waiting until mild cognitive impairment (MCI) or dementia has been identified, earlier intervention using a health promotion approach to encourage help-seeking for hearing loss is expected to be advantageous [304]. However, there are still a large number of outstanding questions regarding auditory rehabilitation.

There are two relatively common forms of aural rehabilitation. Hearing aids are the most common form of hearing rehabilitation, whereas auditory training was used prior to the invention of hearing aids. Auditory training can be defined as formal listening activities whose goal is to optimize the activity of speech perception [181]. Hearing aid devices alone do not always adequately compensate for sensory losses despite significant technological advances in digital technology [184]. Therefore, in aural rehabilitation, auditory training is necessary to augment the benefit of hearing aids in the hope that participants will assimilate their improved hearing with listening, comprehension and successful communication strategies. For example, a person with a hearing impairment who is fitted with a new hearing aid may benefit from instruction and practice in recognizing sounds through the aid. In particular, new hearing aid users show greater benefit from auditory training than experienced hearing aid users. Little however is known about how auditory training generalizes to benefits in everyday Page **70** of **309** communication, how individual characteristics interact with training outcomes to identify candidacy for auditory training, and the identification of outcome measures that are appropriate and sufficiently sensitive for testing the benefits of auditory training [216, 298].

3.2 Aims

The primary objective of the crossover study is to examine the efficacy of the simultaneous use of hearing aids and individualized face-to face auditory training for improving cognition, social interaction and depressive symptoms in comparison with auditory training on its own. The relationship of Speech Perception Test (SPT) with hearing loss and cognition will also be investigated. In addition, the effects of aural intervention on hearing difficulties will be investigated.

3.2.1 Hypotheses

This study is based on the following two primary hypotheses:

- 1. In adults with SNHL, hearing aids in combination with face-to-face auditory training will be more effective for improving cognition than face-to-face auditory training on its own.
- 2. In adults with SNHL, hearing aids in combination with face-to-face auditory training will be more effective for improving depression and social interaction than face-to-face auditory training on its own.

3.2.2 Other Supplementary Research Questions

In addition to these two hypotheses which are solely based on the primary aims in Section 3.2, this thesis will also investigate the following research questions:

- 1. What cognitive measures are associated with hearing loss and speech perception at baseline?
- 2. Is the relationship between speech perception and depression mediated by particular hearing problems?
- 3. How does hearing aid use affect speech perception?
- 4. How does hearing aid use affect hearing satisfaction?
- 5. How do auditory training and hearing aids affect speech tracking over time?

3.3 Methods

This section describes the recruitment process, study design the population under consideration, hearing loss interventions, sample size selection, measures and outcomes for the Crossover Study. The description of the statistical analysis is presented in Chapter 4.

3.3.1 Recruitment

Aged care facility managers were contacted by telephone to explain the study. If an aged care facility showed interest in the study, researchers visited the facility to provide the facility manager with more detailed written and oral information. If the facility manager consented to their facility's participation in the study, the study was advertised at the facility and promotional materials were distributed to all the residents inviting them to an information session. Participants from Swinburne University's Centre for Human Psychopharmacology (CHP) database were also contacted by the researchers, either by telephone or email to explain the study, and participants who expressed interest were invited to attend an information session.

At the information session, the researchers explained the purpose and significance of the study. At the same time, a pre-selection screening was conducted to identify participants who were willing to wear hearing aids and undergo auditory training to address their hearing loss. Selected participants were sent a Participant Information and Consent Form package that included detailed information on the study procedure, a consent form and a pre-paid return envelope. Once written consent was received, participants were invited to complete baseline measures before enrolment into the study. Recruitment commenced in December 2016 and ended in June 2017.

Based on a power analysis described later (See Section 3.3.11), forty (40) participants were recruited for this study. All participants provided informed consent to take part in the study. They were recruited from seven (7) independent living residential aged care accommodations and surrounding communities based in Melbourne.

3.3.2 Trial Design

This study involved a randomized crossover trial design. All participants underwent an individualized face-to-face auditory training program for a period of 6 months, and were randomly allocated to one of the following groups.

- Participants who were fitted with hearing aids only for the first 3 months of the auditory training program – *Immediate HA*
- Participants who were fitted with hearing aids only for the last 3 months of the auditory training program – *Delayed HA*

Participants were tested at baseline, and at three and six months for cognition, depressive symptoms, social interaction, and hearing satisfaction. A crossover design was chosen in order to allow each participant to serve as their own control [314]. *Immediate HA* participants were provided the option to withdraw from the study after 3 months if they decided to purchase hearing aids immediately, or at any other time. Similarly, *Delayed HA* participants were given the option of withdrawing from the study at any time. Since all participants received auditory training for the entire duration of the study to address their hearing loss, participants benefited from the study even when the hearing aid intervention was not in place or when they withdrew from the study.

3.3.3 Eligibility Criteria

To be eligible to participate in the study, participants had to satisfy the following criteria:

- 1) Be aged between 50 to 90 years
- 2) Have a good working knowledge of English
- 3) Have mild (26 to 40dB HL) or moderate (41 to 70 dB HL) symmetric sensorineural hearing loss, as measured by a pure-tone average (PTA) at threshold of 0.5 – 4 kHz in both ears
- 4) Never worn hearing aids previously
- 5) Willing to wear hearing aids for three months
- 6) Willing to undergo weekly auditory training for a period of six months
- Willing to undergo hearing tests and cognitive assessments at baseline, 3 months and at 6 months
- 8) Willing to provide written consent to participate in the study

3.3.4 Exclusion Criteria

Participants were excluded from the study if they had any significant visual impairment that would prevent reading or performing computer based tasks requiring colour recognition. Additionally, study participants with severe or profound hearing loss

were not eligible to take part in the study. Finally, participants with suspected cognitive impairment (defined as a score less or equal to 24) on the mini-mental state examination (MMSE) questionnaire were excluded.

3.3.5 Intervention

3.3.5.1 Fitting of hearing aids for Group A and Group B Participants

Participants were loaned and fitted with two Blamey Saunders hearing aids known as the Liberty Open-Fit (LOF). LOF is the current trade name used by the manufacturer for the model of hearing aid used in this study. The hearing aids were fitted for participants according to the Blamey and Saunders protocol. Explanation of the hearing aid usage, insertion of the aids and batteries along with a step-by-step guide on how to use the hearing aid were provided. To increase hearing aid compliance, support was provided post fitting (after 1 month) to make sure that each participant was progressing with his/her hearing aid. Counselling and other compliance-improving policies [315-317] were provided when participants received their new hearing aids. An automatic internet-based data logging function installed in the hearing aids was used to assess hours of hearing aid use.

3.3.5.2 Auditory Training

All participants enrolled into the study underwent weekly individualized face-toface auditory training for a period of 6 months. Over the 6 month period, each participant participated in 2 x 12-week individualised speech tracking programs. Participants living in supported accommodation attended their auditory training sessions at their place of residence, once per week for the 6 month period. Participants living independently in the community attended their auditory training sessions once per week at Swinburne University of Technology. Each auditory training session lasted for approximately 15 minutes.

The type of face-to-face auditory training intervention provided to participants was called Continuous Discourse Speech Tracking [318]. This type of auditory training program was considered for the Crossover Study instead of the computerized programs mainly because it involves interaction between the researcher and the participants, which is a vital component of real-life communication, and may improve compliance with the training sessions. In this process, the researcher articulated a sentence or phrase in a novel/short story, and the task of the participant was to repeat back verbatim the

sentence or phrase. If the repetition was correct, the researcher articulated the next phrase or sentence. If the repetition was incorrect, the researcher repeated the phrase or sentence, or a portion of it, or used other repair strategies, until the sentence or phrase was correctly repeated in its entirety. The procedure was timed for 15 minutes and scored by the number of words per minute correctly transmitted. Tracking rate was calculated as the number of words correctly repeated divided by the time elapsed.

This program was adopted also for this sample population because training materials could be tailored to the personal interests of participants. The materials chosen consisted of short stories which were long enough to last for each of the two 12 week program. A new story was started at the beginning of each 12 week program.

3.3.6 Outcome Measures

In this study cognitive performance was measured by the Swinburne University Computerized Assessment Battery (SUCCAB).

3.3.6.1 Swinburne University Computerized Assessment Battery (SUCCAB)

The SUCCAB is a validated computer based cognitive battery consisting of eight measures that were developed based on cognitive and neuroimaging literature, to focus on cognitive domains that were most likely to decline with increasing age [111]. Studies using this battery have shown cognitive changes sensitive to interventions in 5-16 weeks [319, 320]. Reliability and validity assessment has demonstrated that the SUCCAB is sensitive to ageing and intervention, and correlates strongly with memory subsets in The Wechsler Adult Intelligence Scale- Fourth Edition (WAIS-IV) [111, 319, 321].

The SUCCAB battery uses a simple 5 button interface and has been validated in other studies involving the elderly [322, 323]. The eight cognitive tests assessed by the SUCCAB provide measures for Simple and Choice Reaction Times, Immediate and Delayed Recognition Memory, Congruent and Incongruent Stroop colour-words, Spatial Working Memory and Contextual Memory [111].

Simple Reaction Time: A single white square was presented in the centre of the screen at random intervals. Participants responded as quickly as possible with a right button press.

Choice Reaction Time: Red squares and blue triangles were randomly presented in the centre of the screen, with a randomized delay. Participants responded as quickly as possible with a left/blue button press or right/red button press.

Immediate and Delayed Recognition Memory: Participants were initially shown a series of 40 abstract images that were presented on the screen for three seconds each, with no inter-stimulus interval. In the Immediate condition, a second series of 40 images followed, half of which had just been presented, the other half were new. Participants had to determine which images they had seen and respond with a left or right button press. The delayed condition used the remaining 20 images from the initial set randomized with another set of new images. These were presented as the last task of the test battery, approximately 40 minutes after the initial presentation. Again participants indicated with a left or right button press whether they recognized each image.

Stroop – Congruent and Incongruent: The words RED, YELLOW, GREEN, and BLUE were presented on the screen one at a time for 1.7 seconds with 0.5 seconds inter-stimulus interval. In the congruent condition the text was presented in the colour matching the written word and participants responded by pressing the matching coloured button. In the incongruent condition the colour of the word did not match. Participants ignored the written word and pressed the button corresponding to the colour of the text.

Spatial Working Memory: A 4x4 grid was presented on the screen, with six spaces filled with white squares, making a pattern. This was displayed for three seconds then the pattern disappeared. White squares then appeared one at a time in four of the spaces, for two seconds each. Participants responded with a yes or no button press, according to whether the square was in one of the spaces that matched the pattern. There were 14 different grid patterns presented, with a total of 56 responses elicited.

Contextual Working Memory: Photographs of 20 everyday items were presented one at a time at the top, bottom, left or right of the screen for three seconds with no inter-stimulus interval. Subjects were required to memorise where on the screen the objects were presented. On completion of the series, the pictures were presented again in the centre of the screen in randomized order. Participants responded with a top, bottom, left or right button press corresponding to the location of the original presentation.

A performance score for each task was calculated as the ratio of accuracy and reaction time. This approach took into account variations in accuracy and response time due to speed versus accuracy trade-offs in performance. The primary outcome cognitive measure was the Stroop Incongruent cognition measure. This measure is related to executive function which is defined as the brain-controlled functions that guide planning, solving problems, organizing and directing daily activities [324] Studies have observed age-related decline in executive function performance [116, 150, 325] and this study investigated whether this cognitive function is associated with hearing loss. The remaining cognition measures were regarded as secondary measures.

Other secondary measures included social interaction measured using the Berken-Syme Social Network Index and depressive symptoms measured using the Geriatric Depression Scale (GDS). The APHAB Inventory was used to measure the degree and type of hearing difficulty, with or without hearing aids.

3.3.6.2 Geriatric Depression Scale (GDS)

The GDS is a self-rating screening scale for measuring levels of depressive symptoms in elderly populations [326]. The short version of the GDS was used. [327]. The GDS has been found to be a reliable and valid measure of depressive symptoms [328], and to be highly correlated with other measures of such symptoms. The GDS was designed for older adults. Items are scored dichotomously (respondents answer "Yes" or "No" to fifteen items). Items assess non-somatic aspects of depression, thus allowing for discrimination between respondents with depressive symptom and those with medical problems. A cut-off GDS score of 7 indicates the presence of depression. Participants answered the 15-question GDS, together with other measures at baseline, after 3 months and then at 6 months, and it took approximately 5 minutes to complete the GDS (See Appendix H).

3.3.6.3 The Berkman-Syme Social Network Index

The Berkman-Syme Social Network Index [329] was used to assess participants' social interaction and connections with families and friends. Twelve (12) types of social relationships were assessed, namely relationships with a spouse, parents, parents-in-law, children, other close family members, close neighbours, friends, workmates,

schoolmates, fellow volunteers, members of groups without religious affiliation, and religious groups. While the Berkman-Syme Social Network Index is commonly used in epidemiological research [330], there have been no detailed assessments of its reliability. The originators of this index have however reported an overall reliability (Cronbach alpha) of .92 in a 14-week follow-up study of 245 first year university students [329]. This index relies on self-report and therefore its validity relies on the honesty of participants.

Participants answered the 12-question Berkman-Syme Social Network Index, together with other measures at baseline, after 3 months and then at 6 months, and it took approximately 5 minutes to complete this index (See Appendix H).

3.3.6.4 The Abbreviated Profile of Hearing Aid Benefit (APHAB)

The APHAB [331] is a self-assessment inventory which was answered by each participant in order to assess difficulty experienced with communication or noise in everyday listening situations. Participants answered the 24-item self-assessment APHAB inventory together with other measures at baseline, after 3 months and after 6 months, and it took approximately 10 minutes to complete this inventory (See Appendix I). Four scales of the APHAB were assessed namely:

- Ease of communication (EC)
- Effects of background noise (BN)
- Effects of reverberation (RV), such as listening to sounds across a large room
- Aversiveness of sound (AV), which looked at uncomfortable loudness of background sounds such as traffic and alarm bells

The APHAB inventory subscales exhibit acceptable reliability, with Cronbach's alpha's of .87 (EC), .83 (RV), .82 (BN) and .86 (AV) in unaided conditions, and test-retest correlation coefficients of .80, .65, .71, and .89 respectively [331]. Studies assessing hearing aid benefit using the APHAB have shown that in addition to audiological outcome measures obtained from objective testing, subjective benefits are of great importance. For instance, a study by Cox and colleagues have shown that [332] subjectively rated improvement in speech understanding, attributed to the hearing aid, accounts for less than 40% of the variance in satisfaction regarding the hearing aid. This result may suggest that user satisfaction is in fact also greatly impacted by other issues such as user expectations. To evaluate subjective benefits therefore, patient self-report Page **78** of **309**

surveys [333] or questionnaires such as the Glasgow hearing aid benefit profile [334] or the APHAB [331, 335] are generally used. Thus the APHAB was used in this study to report the amount of trouble participants are having with communication and noise in everyday situations.

All these outcomes were measured at baseline, after 3 months and after 6 months as explained in Table 3.1.

Time points		Pre-screening telephone call	Baseline assessment T ₀ < 24 days following	Study assessment T ₁ 3 month	Study assessment T ₂ 6 month
	Explain study	X ^a	screening	follow-up	follow-up
Enrolment	Screen eligibility criteria	X			
Assessments	Demographic Questionnaire, Audiometric testing, SPT ^b		Х	Х	Х
	SUCCAB ^c testing		Х	Х	Х
	$\mathrm{GDS}^{\mathrm{d}}$		Х	Х	Х
Outcome measures	Berken-Syme		Х	Х	Х
measures	APHAB ^e		Х	Х	Х
	Randomisation after completion of all baseline assessment		Х		
	Auditory training		<u>♦</u>		•
Interventions	Hearing Aid for Group A participants		•	•	
	Hearing Aid for Group B participants			•	

Table 3.1 SPIRIT diagram outlining schedule of enrolment, interventions and assessments for Crossover Study

Notes: ^aX: Task to be completed; ^bSPT: Speech Perception Test; ^cSUCCAB: Swinburne University Computerized Cognitive Assessment Battery; ^dGDS: Geriatric Depression Scale; ^eAPHAB: Abbreviated Profile of Hearing Aid Benefit. **SPIRIT: Standard Protocol Items: Recommendations for Interventional Trials**

3.3.7 Participant Timeline

Participant pre-screening and assessment took place at information sessions which were held at several independent living aged care facilities located in Melbourne and at Swinburne University of Technology. Independent living aged care facilities with existing relationships with Swinburne University of Technology were chosen. Participants attending information sessions at Swinburne University were individuals in the community who had expressed interest in assisting with research projects run by the University, and therefore provided their contact information to be stored in Swinburne's Centre for Human Psychopharmacology (CHP) database. After providing informed consent, eligible participants were randomized into two equal Groups *(Immediate HA and Delayed HA)* for the study described in Figure 3.1.

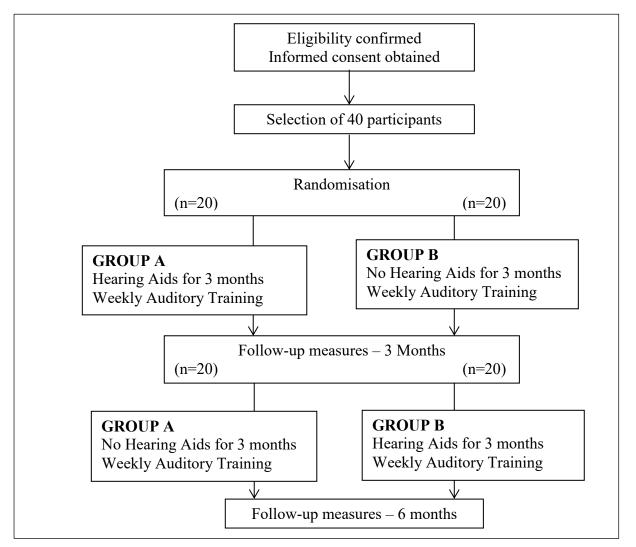


Figure 3.1 Participant flow diagram at baseline (full 40 participants enrolled in Crossover Study) Notes: Group A = Immediate HA; Group B = Delayed HA

3.3.8 Assignment of Interventions

Allocation: Groups were matched in terms of the degree of hearing loss (mild (26-40dB) or moderate (41-70dB)) with one member from each matched pair randomly assigned to *Immediate HA* and the other member of each matched pair assigned to *Delayed HA*. Allocation was performed using a system of envelopes prepared and opened by the researcher following recruitment, prior to treatment beginning.

Blinding: Given the nature of the intervention, this study was not blinded as both investigators and participants knew who was wearing hearing aids in each 3 month period.

3.3.9 Measures

3.3.9.1 Screening

All enrolled participants were screened for adequate cognitive functioning using the MMSE. Participants scoring 24 or lower on the MMSE were not eligible to participate in the study.

3.3.9.2 Hearing Assessments

Participants underwent the following hearing assessments:

- Otoscopy and tympanometry: Following otoscopy, all participants underwent tympanometry and acoustic reflex testing to assess the status of the middle ear.
- Pure tone audiometry in each ear: To understand the degree of hearing impairment, and classify participants according to the type of hearing loss, hearing threshold was measured at threshold frequencies 0.5, 1, 2, 3, 4 kHz in both ears. The choice of frequency to be tested corresponds to the amplification range of most modern hearing aids, and is consistent with capturing sensitivity at frequencies affected by sensorineural hearing loss and noise induced damage. Only participants with either mild or moderate symmetric sensorineural hearing loss were included in the study.
- Blamey Saunders Speech Perception Test (SPT): An online SPT (URL: https://apps.blameysaunders.com.au/clinic/wordtest/) was used in addition to the standard audiogram for the purpose of measuring hearing loss. The SPT is a validated measurement tool and consist of a monosyllabic word test used to characterise the form and degree of hearing loss [336]. The SPT was validated in an initial study of 39 people with known "good hearing" who did not use

hearing aids and 49 hearing aid users in the unaided condition [337].The distribution of SPT scores in the validation study showed 94% sensitivity and 98% specificity for hearing loss compared with 80% and 83% for the commonly used telephone digit screening test [338]. There were five (5) SPT evaluations altogether: The SPT was performed without hearing aids at baseline, after 3 months and then at 6 months for all participants included in the trial. It was also performed with hearing aids immediately after participants were fitted with hearing aids for the first time and at the end of 3 months of auditory training while wearing a hearing aid.

All hearing assessments were performed by the researcher and it took approximately 45 minutes to complete the hearing tests.

3.3.9.3 Paper-based Questionnaire

Participants completed a 15-minutes paper-based questionnaire in order to provide demographic information and information about participant psychosocial function (See Appendix H).

3.3.10 Working Alliance Inventory (WAI)

At the end of the 6 month auditory training program, after all examinations had been completed, both participants and the researcher completed a WAI [339], in order to evaluate the following: the quality of participant-researcher relationship, the collaborative nature of agreeing on tasks and goals of both auditory training and hearing aid compliance, and the outcome measures from auditory training provided to participants. Some randomized controlled trials have demonstrated that this evaluation was crucial for engaging, retaining and improving positive outcomes for study participants, and is vital for relationship-building [340, 341].

3.3.11 Power Analysis

Allowing for 5% significance, 80% power and a moderate effect size (f=0.25), G-Power 3.1.9.2 indicated that a repeated measures mixed effects design required a total sample size of 34 participants, split evenly between the two groups. Thus a total sample size of 40 participants (allowing for 10% attrition) was required. This is a very small sample size when all the secondary outcome measures are considered. Consequently this study must be regarded as a feasibility pilot study meant to test the study protocol and gather information needed to plan a trial large enough to detect a clinically meaningful effect.

3.4 Statistical Analysis

3.4.1 Baseline Comparison

Baseline comparison of the two groups was performed in terms of hearing loss, speech perception, hearing satisfaction, depression, social interaction, and cognition. To determine the magnitude of the difference between the two groups, descriptive statistics of each intervention group as randomized at baseline were reported. Also, appropriate chi-squared tests and independent sample t-tests were used to test for the significance of these differences. Outcome measures at baseline within each intervention group were also compared by estimating the effect sizes using Cohen's d. *P-Values* were reported here only as a guide, with effect sizes (Cohen's d) regarded as a more valid measure of group differences because of the small sample size. In accordance with the assumption of normality for independent samples t-tests, square root transformations were applied for some of the baseline measures where necessary.

3.4.2 Attrition Analysis

The attrition rates were compared for the two participant groups and a binary logistic regression model was developed in order to predict the probability (propensity) of attrition based on significant baseline predictors.

3.4.3 Baseline Correlations

Pearson correlations and structural equation modelling [342] were used to explore the relationships between hearing loss, speech perception, cognition and age, in order to address the first supplementary research question, "whether cognition was associated with hearing loss and speech perception at baseline". Fitting the structural model using maximum likelihood estimation, goodness of fit was evaluated using a chi-squared goodness of fit statistic.

3.4.4 Mediation Analysis between Outcome Variables

In addition to exploring the relationships between hearing loss, cognition and speech perception at baseline, at the end of the 6 month period of hearing intervention, the second supplementary research question was addressed, using a mediation analysis to test whether any of the APHAB measures, i.e. EC, BN, RV and AV mediated the relationship between hearing loss and depression. This analysis was important to further the understanding of the benefits of hearing loss intervention for improving depressive symptoms in a 6 month period. This analysis was also conducted using structural

equation modelling.

3.4.5 The Effects of Hearing Aids

The primary research questions for the Crossover Study investigated the effects of hearing aid use in combination with auditory training as opposed to auditory training on its own. In addition, supplementary research questions 3 and 4 (See Section 3.2.2) considered the effects of hearing aids on speech perception and perceived hearing satisfaction.

3.4.5.1 The Effects of Hearing Aid Usage on Hearing Problems and SPT – t-tests

Supplementary research questions 3 and 4 were addressed as described below. This study used the APHAB inventory to report on perceived hearing problems in different listening situations. Analysis of the aided and unaided scores from the APHAB questionnaire was used to determine if the benefit of hearing aids differed between the groups using independent sample t-tests In addition paired t-tests were used to evaluate the significance of any improvement in terms of hearing problems and speech perception, separately for each group.

3.4.5.2 The Effects of Hearing Aid Usage on all Outcome Measures – Cross-over Analysis

In this pilot study, a cross-over analysis was performed to determine whether hearing aids had any significant effects in comparison with auditory training on its own, addressing the primary research questions. A crossover design was used in order to allow each participant to serve as their own control, and to avoid the confounding effects of participant variables such as age and sex. This design was also chosen as it required lower sample sizes in order to meet the same criteria in terms of Type I and Type II errors. Crossover designs require a washout period to rule out any carry-over effects. A washout period was however impossible for this study so an analysis that tested for carry-over effects was performed.

In the cross-over analysis, a mixed model repeated measures (MMRM) intention to treat analysis was considered. This allowed participants with missing data to be incorporated in the analysis. A square root transformation was applied when the outcome measures exhibited obvious skewness. There was an adjustment for the propensity for attrition, for corresponding baseline outcome values and for age. In addition, there was an adjustment for baseline outcome measures that differed significantly between the two groups at baseline. The fixed effects considered were *Time (3 or 6 months), Hearing Aid Usage (Yes or No)* and a *Carry-over effect.* The carry-over effect was defined equal to one in the second 3 month period for participants who had used hearing aids in the previous 3 month period. Otherwise this carry-over measure was set to zero. The outcome measures were considered only at 3 months and 6 months.

3.4.6 The Effect of Auditory Training

The study assessed the effect of the auditory intervention provided to participants by tracking improvements in speech perception from auditory training over time in order to determine the overall effect of this intervention.

3.4.6.1 Speech Tracking Rates from Auditory Training

First, to analyse the speech tracking rates from the auditory training, the following "learning and forgetting" mathematical model, as described by Blamey and Alcantara, was used [181]:

$$R(t) = \frac{1 - \exp(-f(t - T))}{L/f}$$

where

- R (t) = tracking rate in words per minute at time t.
- L = learning rate per week, i.e. the increase in speech tracking rate after 1 week of auditory training
- f = forgetting rate per week, i.e. the reduction in speech tracking rate in between speech tracking sessions
- t is time in weeks, t>0
- T is a constant.

The parameters L, f and T, were estimated for each group over both 3 month periods separately. The L and f parameter estimates are valid measures of the cognitive processes, learning and forgetting, that may be affected by the use of hearing aids and/or auditory training. Research in auditory training has shown that the amount of training, the amount of learning, the generalization of skills (whether auditory training will improve communication in real-life situations as well as under artificial test conditions), and the degree of retention of skills are all inter-related [181]. This mathematical formula is therefore helpful for tracking improvements in auditory training over time.

3.4.6.2 Longitudinal Mixed Model Analysis for the Effect of Auditory Training

Secondly, combining all the data and ignoring any hearing aid effect, an analysis was performed in order to determine the overall effect of auditory training in this pilot trial. A square root transformation was applied when the outcome measures exhibited obvious skewness. The only fixed effect considered was time. The outcome measures were considered at baseline, 3 months and 6 months. Only people who completed all three assessments were included in the longitudinal mixed model analysis.

3.4.7 Compliance - Working Alliance Inventory (WAI)

The WAI was administered to participants at the end of the study, to assess the efficacy of the auditory training program for improving compliance and to address the fifth supplementary research question. The alliance scores for both participants and the researcher were compared for the two groups using nonparametric Mann-Whitney U because of skewness in the distributions. Also, the Wilcoxon Signed Ranks test was used to compare the alliance perceptions of the researcher and the participants.

3.5 Summary and Conclusion

This chapter has provided details of the methods and statistical analysis used for the Crossover Study. The next chapter will discuss the results for this study.

4 Results for Crossover Study

4.1 Introduction

The primary objective of this study was to conduct a pilot study to investigate the efficacy of the simultaneous use of hearing aids and individualized auditory training for improving cognition, depressive symptoms and social interaction in adults with SNHL and to test the following hypotheses.

- 1. In adults with SNHL, hearing aids in combination with face-to-face auditory training will be more efficient for improving cognition than face-to-face auditory training on its own.
- 2. In adults with SNHL, hearing aids in combination with face-to-face auditory training will be more efficient for improving depression and social interaction than face-to-face auditory training on its own.

In addition to the primary objective, exploratory analyses were performed to investigate the following supplementary research questions:

- 1. What cognitive measures are associated with hearing loss and speech perception at baseline?
- 2. Is the relationship between speech perception and depression mediated by particular hearing problems?
- 3. How does hearing aid use affect speech perception?
- 4. How does hearing aid use affect hearing satisfaction?
- 5. How do auditory training and hearing aids affect speech tracking over time?

The rationale for the study was based on the hypothesis that in adults with SNHL, using hearing aids for the first time in combination with individualized auditory training would be more effective for improving cognition, depressive symptoms and social interaction than auditory training on its own.

After ethics approval on July 22, 2016 (Swinburne's Human Research Ethics Committee protocol number SHR Project 2016/159) (See Appendix G), data collection commenced in December 2016 and was completed in June 2017. Figure 4.1 describes the flow of participants in this pilot study.

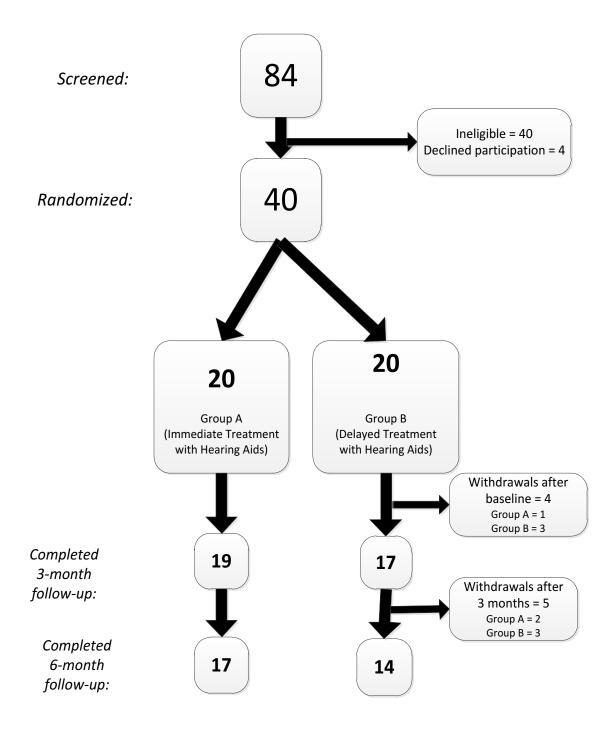


Figure 4.1 Participant eligibility, randomization and follow-up (end trial position with 9 participants dropped out)

Eighty four (84) individuals expressed interest in the study, attended the information sessions at Swinburne University of Technology, and were screened for eligibility. Of those screened, 54 (64.3%) participants were recruited from retirement

independent living villages while 30 (35.7%) participants were from surrounding communities. The study recruitment rate at the retirement independent living accommodation was two participants per week, and one participant per week for the community dwellers. The 5-minutes screening questionnaire asked about a variety of issues, such as perceived auditory ability, hearing difficulties in everyday life situations, participant's willingness to wear hearing aids and undergo auditory training (See Appendix J).

Table 4.1 shows reported prevalence (%) of some current Ear Nose and Throat (ENT) problems addressed in the screening questionnaire.

Current Problem	Overall Prevalence N (%)
Q1: Any hearing difficulty	68 (81.9)
Q1b: Duration of hearing difficulty, <10 years	35 (47.3)
Q1b: Duration of hearing difficulty,>=10 years	15 (20.3)
Q2: Conversation in background noise	65 (77.4)
Q3: Conversation in group	47 (56.0)
Q4: Loud sounds annoying	44 (52.4)
Q5: Hearing on right	41 (48.9)
Q6: Hearing on left	44 (52.4)

Table 4.1 Reported Prevalence of ENT symptoms

Notes: ENT: Ear Nose and Throat

A high proportion of potential study participants (81.9%) reported hearing loss. However, to identify those adults who could be included in the trial, participants were asked if they were willing to wear hearing aids and undergo auditory training. Eighty (95.2%) indicated their willingness to wear hearing aids, and 79 (94%) were prepared to undergo auditory training. Only participants who were both willing to wear hearing aids and prepared to undergo auditory training were invited to attend initial hearing assessments. Pure tone audiometry tests were carried out for all these potential participants. After screening, forty participants were found to be ineligible and four did not want to either wear hearing aids or undergo auditory training and therefore declined to participate in the study. In accordance with the screening, inclusion and exclusion criteria, the remaining forty (40) participants with either mild or moderate symmetric sensorineural hearing loss were randomly allocated -20 to *Immediate HA* and 20 to *Delayed HA* - to take part in the experimental study.

Overall 17 (85%) participants from *Immediate HA* and 14 (70%) participants from *Delayed HA* completed all measures of the study from baseline to six months (See Figure 4.1). Nine (22.5%) out of 40 participants withdrew from the study for the following reasons:

- Discomfort after wearing the hearing aids (2 participants)
- Health issues (2 participants)
- Personal reasons (2 participants)
- Inability to attend weekly auditory training sessions (3 participants).

4.2 Baseline Analysis

Table 4.2 displays the overall baseline characteristics of participants in the study with additional statistics provided in Appendix D. There were no significant differences between the groups at baseline, however, moderate to large effect sizes (Cohen's d) are indicated for the Contextual Recognition Memory task and Aversiveness of sound (AV) measure of the APHAB. The Contextual Recognition Memory cognition task is a measure of episodic memory. The AV scale quantifies negative reactions to (loud) environmental sounds.

Sections 4.2.1 to 4.2.6 will look at the result for each of the measures used in further detail.

Table 4.2 Baseline characteristics

Characteristics	Group A	Group B	Total	Test	p-	Cohen's d
Characteristics	n = 20	n = 20	n = 20 N = 40		value	Conen s u
Gender, n (%)						
Male	8 (40.0)	11 (55.0)	19 (47.5)	$x^{2}(1) = 0.002$	0.342	
Female	12 (60.0)	9 (45.0)	21 (52.5)	$\chi^2(1) = 0.902$	0.342	
Age, mean (SD)	75.9 (7.9)	76.5 (7.5)	76.2 (7.6)	t = 0.246	0.807	-0.08
MMSE, mean (SD)	28.4 (0.7)	28.5 (0.9)	28.5 (0.8)	t = 0.384	0.703	-0.12
Employment Status, n (%)						
Employed	2 (10.0)	5 (25.0)	7 (17.5)	$x^{2}(2) = 2,272$	0.251	
Retired	18 (90.0)	15 (75.0)	33 (82.5)	$\chi^2(3) = 3.273$	0.351	
Education, n (%)						
Primary/Secondary/TAFE	14 (70.0)	13 (65.0)	27 (67.5)	2(7) 4.254	0.750	
University Qualification	6 (30.0)	7 (35.0)	13 (32.5)	$\chi^2(7) = 4.254$	0.750	
Hearing Status, n (%)						
Reported Hearing Trouble	18 (90.0)	17 (85.0)	35 (87.5)	$\chi^2(1) = 0.229$	0.633	
Reported Perceived Tinnitus	9 (45.0)	5 (25.0)	14 (35.0)	$\chi^2(3) = 3.788$	0.285	

Characteristics	Group A n = 20	Group B n = 20	Total N = 40	Test Statistics	p- value	Cohen's d			
Hearing Loss (dBHL), mean (SD)	37.6 (7.6)	39.5 (11.3)	38.5 (9.6)	t = 0.623	0.537	-0.20			
Speech Perception Test, mean (SD)	119.5 (18.1)	111.2 (22.0)	115.4 (20.3)	t = 1.305	0.200	0.41			
SUCCAB Performance Cognition Measures (seconds), mean (SD)									
Simple Reaction Time	331.0 (45.4)	333.6 (47.1)	332.3 (45.7)	t = 0.181	0.858	-0.06			
Complex Reaction Time	204.9 (31.0)	203.2 (25.7)	204.1 (28.1)	t = 0.190	0.850	0.06			
Immediate Recognition Memory	67.7 (24.4)	65.2 (18.7)	66.4 (21.5)	t = 0.357	0.723	0.12			
Delayed Recognition Memory	64.8 (21.0)	58.6 (11.6)	61.7 (17.0)	t = 1.157	0.257	0.37			
Stroop Congruent	116.4 (17.5)	112.2 (19.5)	114.3 (18.4)	t = 0.715	0.479	0.23			
Stroop Incongruent	87.1 (29.1)	85.7 (20.7)	86.4 (24.0)	t = 0.169	0.867	0.06			
Spatial Working Memory	60.5 (21.9)	54.0 (16.6)	57.3 (19.5)	t = 1.058	0297	0.33			
Contextual Recognition Memory	73.3 (23.9)	59.9 (20.5)	66.6 (23.0)	t = 1.899	0.065	0.61			

Characteristics	Group A	Group B	Total	Test Statistics		Cohen's d				
Characteristics	n = 20 n = 20		N = 40	Test Statistics	p-value	Conen's u				
Hearing Problems, mean (SD)										
Ease Communication (EC)	26.0 (19.0)	26.2 (20.2)	26.1 (19.4)	t = 0.035	0.959	0.00				
Effects Reverberation (RV)	34.2 (12.9)	34.6 (14.0)	34.4 (13.3)	t = 0.098	0.922	-0.03				
Effects Background Noise (BN)	36.4 (13.5)	34.7 (17.0)	35.5 (15.2)	t = 0.366	0.717	-0.11				
Aversiveness (AV)	35.4 (22.5)	22.5 (19.0)	29.0 (25.6)	t = 1.955	0.058	0.09				
Psycho-Social Measures, mean (SD)										
Depression (GDS)	1.7 (1.8)	1.5 (1.5)	1.6 (1.6)	t = 0.380	.660	0.01				
Social Interaction	32.5 (11.3)	32.6 (12.6)	32.5 (11.8)	t = 0.040	.969	0.00				

Notes: dBHL: decibels Hearing Loss; GDS: Geriatric Depression Scale; MMSE: Mini-mental state examination (score out of 30); SUCCAB: Swinburne University Computerized Assessment Battery; Group A = Immediate HA; Group B = Delayed HA

4.2.1 4.2.1 Initial Hearing Assessments

The first test, an audiogram, was used to assess hearing threshold in each ear at frequencies 0.5, 1, 2, 4, 6 Hz in both ears. The bone conduction test was also performed for each ear at threshold frequencies 0.5, 1, 2, and 4 Hz. Audiometric air condition results were summarized as the pure-tone average (PTA) of the first four hearing thresholds 0.5, 1, 2 and 4 Hz, calculated for the better-hearing ear. The mean PTA for all 40 participants was 38.50 dB HL (SD: 9.565; range: 25 - 66). A total number of 21 (52.5%) reported as having mild symmetric sensorineural hearing loss and 19 (47.5%) participants reported as having moderate symmetric sensorineural hearing loss. The mean PTA for Immediate HA was 37.55 dB HL (SD: 7.63; range: 28 - 56) and the mean PTA for Delayed HA was 39.45 dB HL (SD: 11.29, range 25 - 66).

4.2.2 4.2.2 Evaluation of Speech Perception Test (SPT) as a Measure of Hearing Loss - Baseline

The online Blamey Saunders SPT [336] was used in addition to the standard audiograms for the purpose of measuring hearing loss. The SPT is a monosyllabic word test with 50 items that generate a display of information transmission for 50 vowels and 100 consonants to characterise the shape and degree of hearing loss, analogous to an audiogram. All 40 participants completed the SPT at baseline without hearing aids and their Phoneme scores (total score of vowels and consonants) were used as a measure of speech perception accuracy for each of the two participant groups (See Figure 4.2).

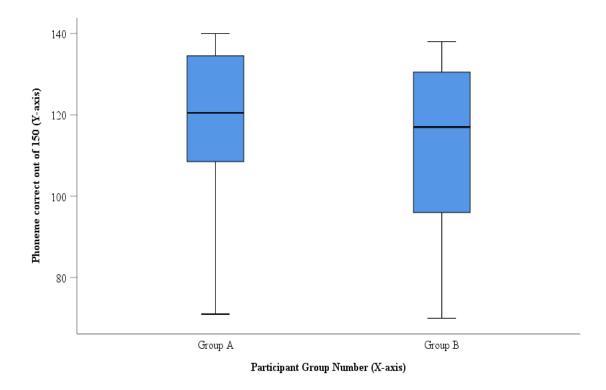


Figure 4.2 Boxplot representation of the distribution of phoneme score obtained from the Speech Perception Test for each participant group at baseline

Notes: Group A = Immediate HA; Group B = Delayed HA; The data shown are medians (thick horizontal line) and range (whiskers).

The mean Phoneme score for Immediate HA was 119.50 (SD: 18.06) and the mean phoneme score for Delayed HA was 111.20 (SD: 21.97). The distribution for both participant groups is negatively skewed. Table 4.2 shows no significant mean differences between the two groups.

4.2.3 The Abbreviated Profile of Hearing Aid Benefit at Baseline

At baseline, the study assessed how all 40 participants reported the percentage of problems for different listening situations in day-to-day life without hearing aids. The 24-item questionnaire was further categorised under four major subscales, each comprising six items, namely Ease of Communication (EC), Effects of Background Noise (BN), Effects of Reverberation (RV) and Aversiveness of Sound (AV). The percentage for each subscale was averaged to calculate the unaided score for each of the four subscales at baseline (See Figure 4.3). Using a 7-point scale, participants indicated

how often the statement was true for them. Each point on the scale provided a descriptor and an associated percentage of time.

1	Always	(99%)
2	Almost Always	(87%)
3	Generally	(75%)
4	Half-the-time	(50%)
5	Occasionally	(25%)
6	Seldom	(12%)
7	Never	(1%)

Table 4.3 7-point APHAB scale with assigned percentage values

Notes: APHAB: Abbreviated Profile of Hearing Aid Benefit

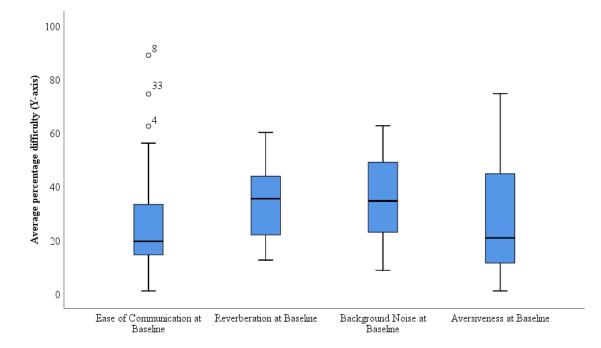


Figure 4.3 Boxplot representation of the distribution of unaided APHAB scores at baseline

Notes: The data shown are medians (thick horizontal line), range (whiskers) and outliers (open circles).

The distribution of unaided scores for EC, BN, RV and AV Scale for each of the participant groups at baseline is displayed in Figure 4.4. Table 4.2 shows no significant mean differences between the two groups for any of these four measures.

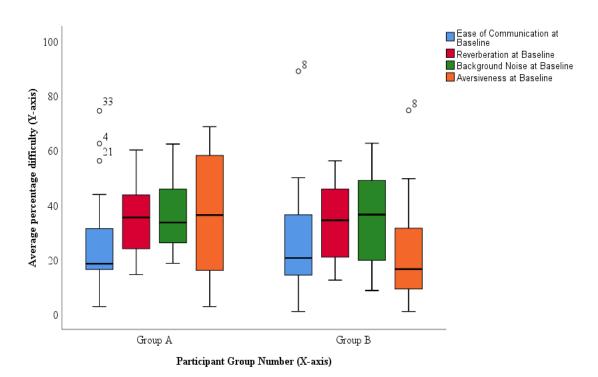




Figure 4.4 Boxplot representation of the distribution of unaided scores for the APHAB for each of the participant groups at baseline

Notes: Group A = Immediate HA; Group B = Delayed HA; The data shown are medians (thick horizontal line) range (whiskers), and outliers (open circles).

Based on reported percentage of problems for different listening situations in day-to-day life without hearing aids, the distribution for EC, RV, BN and AV for both participant groups is slightly positively skewed, especially in the case of Ease of Communication.

4.2.4 Depression Assessments at Baseline

At baseline, the GDS analysis revealed a mean score of 1.49 (range: 2 - 12; SD: 1.63). The distribution of GDS scores at baseline are shown in Figure 4.5 by participant group.

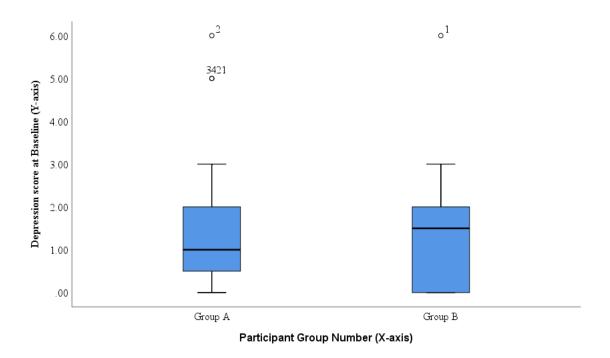


Figure 4.5 Boxplot representation of the distribution of the GDS score by participant group at baseline

Notes: Group A = Immediate HA; Group B = Delayed HA; The data shown are medians (thick horizontal line) and range (whiskers).

The mean GDS score for Immediate HA was 1.7 (SD: 1.78) and the mean GDS score for Delayed HA was 1.5 (SD: 1.54). The distribution for both participant groups is positively skewed.

4.2.5 Social Interaction Assessments at Baseline

The Berkman-Syme Social Network Index [329] was used to measure participants' social engagement and connections with families, friends, etc. The distribution of social index scores at baseline is shown by participant group in Figure 4.6.

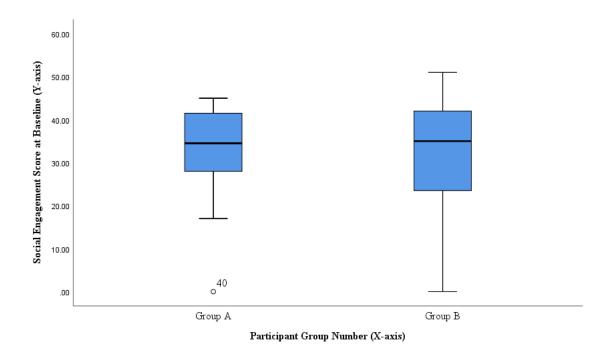


Figure 4.6 Boxplot representation of the distribution of the Berkman-Syme Social Network Index score by participant group at baseline

Notes: Group A = Immediate HA; Group B = Delayed HA; The data shown are medians (thick horizontal line) range (whiskers), and outliers (open circles).

The mean Berkman-Syme Social Network Index score for Immediate HA was 32.45 (SD: 11.29) and the mean score for Delayed HA was 32.60 (SD: 12.60). The distribution for both participant groups is negatively skewed.

4.2.6 Cognitive Outcomes at Baseline

The SUCCAB was administered at baseline as a primary measure to assess cognitive performance. For this study SUCCAB cognitive outcomes were response time and accuracy on the individual SUCCAB measure. The ratio of these two measures (Performance = Accuracy/Reaction Time) was used to obtain 8 SUCCAB Performance measures for cognition. Means, standard deviations, and t-test value for the group comparison of the baseline SUCCAB performance measures are shown in Table 4.2. In addition to t-tests, nonparametric Mann Whitney U tests were performed in order to compare the two groups, confirming no significant differences between the groups.

Based on the values obtained from two-sample t-test values and the Mann Whitney U z-values there is no significant difference in cognitive performance between *Group A* and *Group B* at baseline.

4.3 Attrition Analysis

The attrition rate was 15% for *Immediate HA* and 30% for *Delayed HA*. However, this difference was not significant (*Fisher Exact Test p-value* = 0.451). Also, no demographic variables were significantly associated with attrition and the only significant baseline predictor was performance cognition scores for contextual recognition memory. For every additional unit on the baseline contextual recognition memory (CRM) measure of performance, the odds of completion increased by 5.5% (95% CI: 1.0%, 10.2%) on average (See Table 4.4). This estimated model was used to produce an attrition propensity score (probability) for each participant.

SUCCAB Cognition Measure	В	S.E	Wald	df	Sig.	EXP (B)	95% C. (B)	I EXP
(seconds)							Lower	Upper
CRM	0.054	0.022	5.899	1	0.015	1.055	1.010	1.102
Constant	-1.898	1.309	2.103	1	0.147	0.150		

Table 4.4 Binary Logistic Regression Analysis of Attrition Rate

Notes: B: Constant; CI: Confidence Interval; CRM: Contextual Recognition Memory; df: Degrees of Freedom; EXP: Exponent; S.E: Standard Error; Sig.: Significance Level; Wald: F- distribution test

4.4 Correlation Analysis

4.4.1 Pearson Correlations between Baseline Values

Table 4.5 shows the relationship between all the cognitive and psychosocial measures, the APHAB measures (without hearing aids) with age and hearing impairment. As shown in this table, overall, there were significant correlations between most of the cognition measures, age and the SPT result at baseline. By contrast, the correlations between hearing loss and cognition were weaker. However, there was a significant negative correlation between Stroop Incongruent and this correlation was only slightly weaker when we controlled for age (partial correlation = -0.314).

There was a significant but weak positive correlation between the SPT result and two cognition measures (Simple Reaction Time and Spatial Working Memory), with stronger significant positive correlations for the Stroop Congruent and Contextual Recognition Memory cognition measures. Due to the negative effect of hearing loss on speech perception, we further investigated the relationship between speech perception and cognition at baseline. Also, due to the non-significant correlation between hearing loss and depression, we investigated the mediating role of the APHAB measures for this relationship.

Outcome Measures	Age (years)	Hearing Loss (PTA)	Speech Perception Test (SPT)
Age (years)	1.000	0.278	-0.443**
Hearing Loss (PTA)	0.278	1.000	-0.695**
Speech Perception Test (SPT)	-0.443**	-0.695**	1.000
Cognition: Simple Reaction Time (s)	-0.369*	-0.301	0.338*
Cognition: Complex Reaction Time (s)	-0.390*	114	0.223
Cognition: Immediate Recognition Memory (s)	-0.555**	-0.145	0.300
Cognition: Delayed Recognition Memory (s)	-0.500**	-0.040	0.279
Cognition: Stroop Congruent (s)	-0.400*	219	0.492**
Cognition: Stroop Incongruent (s)	-0.079	-0.323*	0.265
Cognition: Spatial Working Memory (s)	-0.325*	-0.153	0.393*
Cognition: Contextual Recognition Memory (s)	-0.522**	-0.083	0.405**
APHAB: SQRT Ease of Communication (EC)	0.129	0.404**	-0.578**
APHAB: Reverberation (RV)	0.122	0.297	-0.332*
APHAB: Background Noise (BN)	-0.121	0.226	-0.317*
APHAB: SQRT Aversiveness (AV)	0.081	-0.121	-0.170
SQRT Depression	0.014	0.057	-0.019
Social Interaction	-0.352*	-0.095	0.238

Table 4.5 Pearson correlations for baseline values without hearing aids

Notes: **. Correlation is significant at the 0.01 level (2-tailed); *. Correlation is significant at the 0.05 level (2-tailed); PTA: Pure tone average; SQRT: Square root; s: seconds

4.2.4 4.4.2 Structural equation modelling to illustrate the relationships between hearing loss, SPT and cognition

Figure 4.7 displays the association between hearing loss, unaided SPT and cognition, providing a good fit for the data (Chi-Squared = 40.67, df=35, p=.235). In this model cognition is measured as a latent variable and, although it is assumed that SPT and cognition are correlated, no assumption about the direction of this relationship is made. As expected, there were many significant correlations between the cognition measures. However, Stroop Incongruent was the only measure that was correlated with hearing loss, allowing this cognition measure to be separated from the other cognition measures in Figure 4.7. As explained previously this cognitive measure relates to executive functioning.

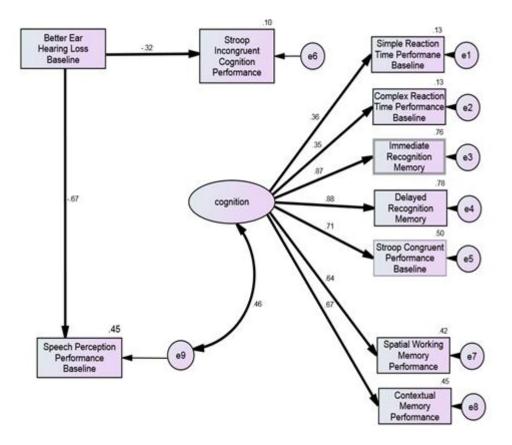


Figure 4.7 Structural equation model with R-Square values and standardised path coefficients for the relationship between hearing loss and cognition at baseline, with significant (P<.05) paths bolded.

4.4.3 Structural equation modelling to illustrate the relationships between hearing loss, SPT, hearing satisfaction and depression

Figure 4.8 displays the structural equation model of standardised path coefficients for the relationship between hearing loss and depressive symptoms. As Page **104** of **309**

shown in Figure 4.8, EC and BN scales at baseline mediate the relationship between the baseline speech perception result and depression at 6 months, with this model explaining 34% of the variation in the depression measure. This model also describes the covariance in the data well (Chi-Square = 4.406, df=5, p=.493). As shown in this model, there is no direct link between SPT and depression, suggesting a mediated relationship.

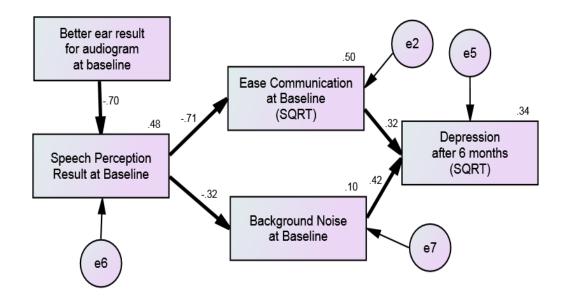


Figure 4.8 Structural equation model with R-Square values and standardised path coefficients for the relationship between hearing loss and depression after 6 months, with significant (P<.05) paths bolded.

4.5 The Objective and Subjective Outcome of Hearing Aid Use

The average daily hearing aid use for *Immediate HA* and *Delayed HA* as measured through objective data logged by the hearing aid for the 3 month period (when hearing aids were first fitted) was 4.6 hours and 5.25 hours respectively. However, there was a high proportion of missing data for this variable due to hardware and software issues making these results unreliable. The perceived benefit of wearing hearing aids for the 3 months as determined by the APHAB measure is discussed in the next sections.

4.5.1 Analysis of the Effects of Hearing Aids on SPT and Hearing Satisfaction – Immediate Effect

Table 4.6 displays the subjective effect of wearing hearing aids for 3 months as determined by the APHAB measure. There was a significant reduction in all problems

for Immediate HA except in the case of Aversiveness of Sound (AV) which increased. However, for Delayed HA there was a significant reduction only for the Effects of Reverberation (RV) scale, nearly significant reduction for Effects of Background Noise (BN) scale, when hearing aids were worn and there was again a significant increase in AV.

	Imme	ediate HA	Mean (S	D)	Delayed HA Mean (SD)			
Domain		N = 1	9		N = 14			
Domain	Baseline	3	t- p-		3	6	t-	p-
	Dasenne	months	value	value	months	months	value	value
EC	27.2	17.0	2.809	0.012	18.4	12.8	1.298	0.217
EC	(18.7)	(17.0)	2.009	0.012	(15.3)	(10.5)	1.290	0.217
RV	36.0	29.3	2.614	0.017	30.3	20.0	3.187	0.007
ΚV	(14.0)	(16.1)	2.014	+ 0.01/	(13.6)	(11.7)	5.107	0.007
BN	36.6	24.7	2.926	0.009	31.3	26.1	2.062	0.060
DIN	(13.9)	(16.5)	2.920	0.007	(15.0)	(13.3)		0.000
AV	36.4	48.1	2.275	0.035	14.3	37.2	3.357	0.005
21.0	(22.7)	(23.5)	2.275	0.055	(11.8)		5.557	0.005
SPT#	125.1	124.5	0.459	0.652	124.0	122.9	0.473	0.644
DI I II	(15.7)	(17.2)	0.707	0.052	(16.7)	(17.8)	0.775	0.011
SPT@	120.0	124.5	2.319	0.032	119.0	122.9	2.025	0 .065
51 1 @	(18.4)	(17.2)	2.317	0.032	(18.6)	(17.8)	2.023	0.003

Table 4.6 Outcome of perceived hearing aid benefit

Notes: AV: Aversiveness of Sound; BN: Effects of Background Noise; EC: Ease of Communication; RV: Effects of Reverberation; SPT#: Results with hearing aids only; SPT@: without hearing aids before and with hearing aids after 3 months; significant p values in bold.

As described in Table 4.6, SPTs were performed immediately after hearing aid fitting and again at the end of 3 months of auditory training and hearing aid usage (#).

The results showed no significant change for Immediate HA or Delayed HA. However, when SPT results without wearing hearing aids before and with hearing aids after 3 months of auditory training and hearing aid usage (@) were compared, there is a significant improvement for Immediate HA and nearly a significant improvement for Delayed HA.

SPT results without hearing aids (HA) and immediately after hearing aid fitting were also compared between the two groups and the results are displayed in Table 4.7.

Table 4.7 Outcome of hearing aid benefit with respect to SPT results when hearing aids are first fitted vs when hearing aids are removed

		Group A Mear	Group B Mean (SD)					
Time Period	N =20	at Baseline an months	N = 14 at 3 months and 6 months					
	Without	With	t-	p-	Without	With	t-	p-
	HAs	HAs	value	-	HAs	HAs	value	value
D 1'	119.5	124.9	2.02	0.07				
Baseline	(18.1)	(15.3)	3.03	.007				
2	121.5	124.5	1.22	202	119.0	124.0	2.012	0.065
3months	(18.4)	(17.2)	1.32	.203	(18.6)	(16.7)	2.012	0.065
(1					122.9	121.6	0.400	0.(24
6months					(17.8)	(21.8)	0.488	0.634

Notes: HA: Hearing aids; Group A = Immediate HA; Group B = Delayed HA; Significant p values in bold.

Interestingly there was significant immediate improvement in speech perception when hearing aids were first fitted for Immediate HA while the improvement in speech perception approached significance for Delayed HA. However, when the hearing aids were finally removed, at 3 months for Immediate HA and at 6 months for Delayed HA, the SPT results showed no significant change for either group, with or without hearing aids. The unaided SPT scores increased during the intervening auditory training period but the aided SPT scores remained fairly constant.

4.5.2 Mixed Model Cross-Over Analysis for the Effect of Hearing Aids – Long Term Effect

At the six month follow-up period, 9 (22.5%) out of 40 participants had withdrawn from the study for the following reasons: discomfort after wearing the hearing aids; health issues; personal reasons, inability to attend weekly auditory training sessions. Overall, 17 (85%) participants from the Immediate HA group and 14 (70%) participants from the Delayed HA group completed all measures of the study from baseline to six months. A mixed model cross-over analysis was completed in order to determine whether the hearing aids had a significant effect on cognition, the APHAB measures and the psychosocial measures. Only SPT measures without hearing aids (HA) were considered.

In addition, significant changes between the 3 months and 6 months assessments were tested while controlling for baseline levels. The carry-over effect was designed to detect any treatment order effect associated with hearing aid usage. The results showed significant improvements in depressive symptoms from 3 to 6 months with a moderate to large effect size (Cohen's d = 0.87). In addition, there was a significant deterioration in AV when hearing aids were worn. A significant carry-over effect for delayed recognition memory was also found, invalidating the results for this cognition measure.

Results of the analysis are displayed in Table 4.8.

Outcome	Time E	ffect	Hearing Ai	Carry-over Effect HA	
Measure	Coefficient (Std error)	Cohen's d	Coefficient (Std error)	Cohen's d	
Hearing Loss	-1.493 (2.034)	-0.30	2.660 (2.002)	0.54	3.271 (3.747)
Speech Perception Test (woHA)	3.423 (3.301)	0.43	738 (3.244)	-0.09	-4.018 (6.069)
SUCCAB Perfo	rmance Cognit	ion Measure	es (seconds)		
SRT	2.449 (14.342)	0.07	-9.656 (14.141)	-0.28	-13.768 (26.614)
CRT	-1.599 (7.483)	-0.09	-7.833 (7.390)	-0.45	-4.000 (14.090)
IREC	-1.675 (5.606)	-0.13	-7.469 (5.522)	-0.58	-6.958 (10.348)
DREC	6.337 (5.714)	0.47	-12.993 (5.632)*	-0.95	-22.280 (10.190)*
CStrp	1.951 (4.801)	0.17	-4.989 (4.683)	-0.44	-7.804 (8.598)
IStrp	6.057 (8.201)	0.35	-9.109 (8.138)	-0.52	-11.565 (15.800)
SWM	-5.381 (4.861)	-0.44	.179 (4.739)	0.01	-1.111 (7.076)
CMEM	3.411 (5.072)	0.27	.153 (4.953)	0.01	-4.869 (8.622)
Hearing Probler	ns				
SQRT (ECwoHA)	.077 (.480)	0.07	.065 (.476)	0.06	.084 (.900)
RV	951 (5.169)	-0.08	1.448 (5.075)	0.12	6.527 (9.243)

Table 4.8 Mixed model crossover analysis

Hearing Problems										
BN	2.957 (5.272)	0.23		780 (5.199)		-0.06	-1.495 (9.807)			
SQRT (Aversiveness)	472 (.558)	-0.3	34 1.38 (.54		-	1.01	1.432 (.987)			
Psycho-Social N	leasures	1		1						
SQRT(GDS)	469 (.230)*	469 (.230)*			- .090(.2 26)	-0.17	.056(.403)			
Social Interaction	-1.489 (3.261)	-0.19		-1.762 (3.146)	-0.06	.506 (5.238)			

Notes: *P<0.05; BN: Background Noise; CRT: Complex Reaction Time; CMEM: Contextual Recognition Memory; CStrp: Stroop Congruent; SQRT: Square root; DREC: Delayed Recognition Memory; ECwoHA: Ease of Communication without Hearing Aids; GDS: Geriatric Depression Scale; IREC: Immediate Recognition Memory; IStrp: Stroop Incongruent; RV: Reverberation of sound; SWM: Spatial Working Memory; SRT: Simple Reaction Time; Std: Standard; SUCCAB: Swinburne University Computerized Cognitive Assessment Battery; woHA: without Hearing Aids;

In addition to controlling for baseline outcome measures, we controlled for baseline scores for Contextual Recognition Memory and square root (SQRT) AV because there were large differences between the two groups on these variables at baseline. In addition, age and attrition probability were controlled for, in order to adjust for age effects and any attrition bias. In these analyses effect sizes (Cohen's d) were obtained by dividing the estimated coefficients by the residual standard deviation, as recommended by Feingold [344]. Confirming the results from Table 4.8, there was a significant increase in AV when a hearing aid was worn (Cohen's d = -1.01). There was a significant decline in Delayed Recognition Memory performance when hearing aids were used (Cohen's d = 0.95). There was also a narrowly significant carry-over effect in the case of delayed recognition memory, suggesting an unreliable result for Delayed Recognition Memory.

The improvement in depression from 3 to 6 months was significant with a moderate to large effect size (Cohen's d = 0.87). In particular, in a completer analysis (See Appendix E), it was found that after receiving auditory training for 3 months, and then wearing hearing aids while continuing with auditory training for an additional 3 months, the *Delayed HA* participants experienced a very significant reduction in depression levels over the second 3 month period. Clearly, it was only relatively large effect sizes that could be detected in this analysis due to the small sample size considered in this pilot study.

4.6 Auditory Training

4.6.1. Analysis of Speech Tracking from Auditory Training

Over the 6 month period of the auditory training program, each participant underwent two 12-week individualised speech tracking program, one with and one without hearing aids.

Table 4.9 shows the estimated parameters from speech tracking. Standard errors for these estimates were obtained using bootstrapped samples.

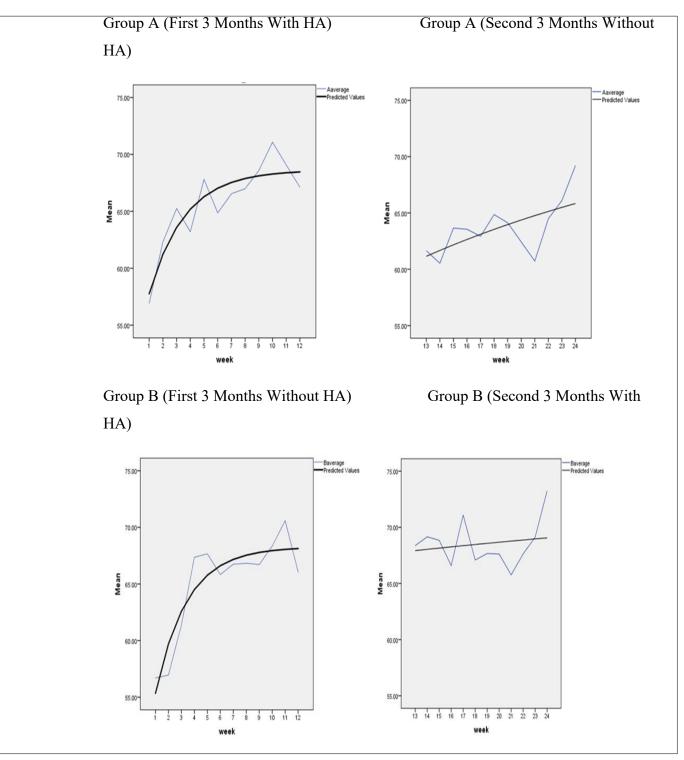
Condition	Gr	oup A	Group B		
Number of sessions per week	First 3 Months With HA	Second 3 Months Without HA	First 3 Month Without HA	Second 3 Month With HA	
Constant (T)	-3.803	-41.78	-3.046	-136.14	
	(5.22)	(56.45)	(2.92)	(174.6)	
Forgetting rate per	0.384	0.041 (.13)	0.412	0.018	
week (f)	(.212)		(.253)	(.210)	
Learning rate per	26.351	3.02	28.09	1.33	
week (L)	(14.03)	(8.29)	(16.84)	(14.35)	

Table 4.9 Estimated parameters (standard errors) derived from speech tracking data

Notes: HA: Hearing Aids; Significant Forgetting and Learning Rates in bold Group A = Immediate HA; Group B = Delayed HA

Fitted learning curves (with and without hearing aids) from the speech tracking are displayed in Figure 4.9. It was expected that it would be easier to learn to do speech tracking when participants used hearing aids than when they did not, and that using hearing aids during the week would mean that forgetting was slower. However, Table 4.9 suggests that forgetting and learning rates were significant only for the first three months for both groups. However, Figure 4.9 clearly shows a decline for Immediate HA when hearing aids were removed, but this decline was quickly reversed.

Table 4.9 also shows that there were no significant differences between Immediate and Delayed HA participants in either the first 3 months for all the three parameter estimates (i.e. T, f, and l) or in the second 3 months. There were however significant differences in all three parameter estimates between the first and the second 3 month periods for both participant groups.



Notes: Group A = Immediate HA; Group B = Delayed HA

Figure 4.9 Experimental data and learning curves derived from speech tracking sessions for Group A and Group B

4.6.2 Longitudinal Mixed Model Analysis for the Effect of Auditory Training

Table 4.10 presents a repeated measures analysis conducted using all three assessments, and ignoring any group effects to assess the effect of the 6 month auditory training program. Confirming the result in Table 4.8, there is indeed a significant time effect for depression. At 6 months depression levels were significantly lower than at 3 months. The large effect size for depression suggests that auditory training had an important effect on this variable. There are relatively large effects ($\eta 2 > .14$) for Spatial Working Memory and Immediate Recognition Memory. However, these effects were not significant.

Outcome Measure	Baseline	3 Months	6 Months	F-value	Den df	p-value	Effect Size (η2)
Hearing Loss	37.48	36.06	36.00	1.143	29	.158	.044
Hearing Problems	I		I	1			I
SQRT(ECwoHA)	4.216	4.319	4.319	.338	30	.565	.011
Reverberation	34.97	30.83	33.23	1.738	29	.194	.107
Background Noise	36.69	32.43	34.59	.977	30	.388	.063
SQRT (Aversiveness)	5.109	4.711	4.917	1.421	29	.258	.089
Psychosocial Facto	rs	<u> </u>	<u> </u>	<u> </u>	<u> </u>		
SQRT(depression)	1.071	1.220	.802	6.532	29	.005	.311
Social Interaction	34.97	34.23	33.77	.427	28	.657	.030
SUCCAB Perform	ance Cogni	tion Meas	sures (seco	onds)			
SRT	337.8	352.4	347.1	1.965	29	.158	.119
CRT	207.4	203.2	200.7	1.297	29	.289	.082
IREC	69.13	68.47	63.80	2.490	29	.101	.147
DREC	63.32	66.40	61.71	1.486	29	.243	.093
CStrp	116.3	113.1	111.6	1.965	29	.137	.064
IStrp	87.99	87.19	87.26	.01	29	.990	.001
SWM	58.58	66.63	59.83	3.219	29	.055	.182
CMEM	72.17	67.65	69.06	1.901	29	.168	.116

Table 4.10 Marginal means for repeated measures analysis

Notes: significant p values in bold; CRT: Complex Reaction Time; CMEM: Contextual Recognition Memory; CStrp: Stroop Congruent; df: Degrees of Freedom; DREC: Delayed Recognition Memory; ECwoHA: Ease of Communication without Hearing Aids; IREC: Immediate Recognition Memory; IStrp: Stroop Incongruent; SWM: Spatial Working Memory; SRT: Simple Reaction Time; SUCCAB: Swinburne University Computerized Cognitive Assessment Battery.

4.7 Group Comparison in terms of Working Alliance

The WAI was used as a tool for increasing compliance with the auditory training program. Mean working alliance scores provided by the researcher (MN = 6.34, SD = 0.574) were significantly higher (Z=3.322, p = 0.001) than for participants (MN = 5.62, SD = 1.054). However, there were no significant differences between the groups in terms of participants scores (Z=.060, p=.953) or researcher scores (Z=879, p=.399). This result means that it can be assumed that the working alliance was similar for the two groups.

4.8 Discussion – Summary of Findings for Crossover Study

The above results have provided answers for the following supplementary research questions as well as the primary research questions. We start by addressing the supplementary research questions.

- 1. What cognitive measures are associated with hearing loss and speech perception at baseline?
- 2. Is the relationship between speech perception and depression mediated by particular hearing problems?
- 3. How does hearing aid use affect speech perception?
- 4. How does hearing aid use affect hearing satisfaction?
- 5. How do auditory training and hearing aids affect speech tracking over time?

4.8.1 Supplementary Research Questions

Addressing the first supplementary research question (Q.1), the baseline results showed that there existed a relationship between cognition and speech perception, with better cognition performance in several domains in the case of participants with better speech perception. This finding replicates the well-established link observed between cognitive abilities and speech recognition performance in first time hearing aid users [123]. Also as expected, there were significant but weaker negative correlations between speech perception and the APHAB hearing problems. Contrary to expectation, there was only one significant correlation between hearing loss and cognition (Incongruent Stroop – the only measure relating to executive function), and only one significant correlation between hearing loss and problems identified with hearing (EC). As expected, greater hearing loss was associated with lower levels for the Incongruent Page **116** of **309** Stroop cognition measure and greater problems with ease of communication. In this study, the Incongruent Stroop cognition measure tested selective attention, that is, being able to focus on the colour of a print and supress the automatic word reading.

Studies have previously confirmed a relationship between auditory training and cognitive processes such as executive function [183, 345]. The significant correlation between cognition as measured by the Incongruent Stroop test and hearing loss (even when controlling for age) needs further investigation, as this result may suggest that tests of visual Incongruent Stroop capability could be an important addition to aural rehabilitative assessments [346].

No significant correlations were observed with hearing loss for social interaction or depression. However, the structural equation model used to address the second supplementary research question (Q.2) indicates that there is a significant relationship between speech perception and depression that is mediated by hearing problems related to ease of communication and background noise. Participants with speech perception experienced greater hearing problems which were associated with higher levels of depression.

Addressing the third supplementary research questions (Q.3), hearing aid use was associated with improved speech perception, increasing the audibility of sounds.

Addressing the fourth supplementary question (Q.4), increases in Aversiveness were also detected but this was expected [347].

Finally, addressing the fifth supplementary question (Q.5), there was no evidence to suggest that it is easier to learn speech tracking when participants use hearing aids than when they do not. This is a surprising result which may require further investigation. Further, an unexpected result was the fact that as depicted in Figure 4.9, there was similarity in the data for Immediate HA group and Delayed HA group during the first 3 months. This could imply that, in the first 3 months of the face-to-face auditory training program, all study participants were learning how to do a specific task rather than learning how to improve their understanding of speech. It could also be that it was learning by the researcher, about how to correct mistakes in the most efficient way during the speech tracking task, which could have resulted in increased tracking rates for both groups. This result will require further investigation.

4.8.2 The Effects of Hearing Aids and Auditory Training on Cognition and Psychosocial Function (Depression and Social Interaction)

This section will address the primary research questions. In the Crossover Study, no significant hearing aid effect was detected in the cross-over analysis, suggesting that hearing aids did not have any additional benefit over auditory training in terms of improved cognition and psycho-social function. An analysis was therefore performed in order to assess the impact of the auditory training (in conjunction with any hearing aid effects). Although there was no significant improvement in cognition or social interaction observed that could be related to the hearing interventions, there was significant improvement in depressive symptoms over the course of the study.

This result is consistent with previous studies suggesting that hearing aids reduce depression [21, 169]. Depression is associated with hearing impairment [348]; it is both a risk factor and a prodromal of Alzheimer's disease and is a common occurrence in all types of dementias as well as in mild cognitive impairment [349]. Having depression reduces quality of life, exacerbates cognitive and functional impairment, and is associated with increased mortality [284]. Therefore, our findings suggest that management of hearing loss has the potential to improve the quality of life for hearing impaired adults and may reduce the burden associated with dementia.

The findings for this study have been accepted for publication in a peer-review journal and the draft manuscript has been included in Appendix C of this thesis.

4.9 Limitations and Future Research

A first limitation of the Crossover Study was that, daily hours of hearing aid usage were not reliably assessed and could not therefore be included in the analysis. This was due to hardware and software issues in the data-logging function installed in the hearing aids. This means that it is impossible to determine to what extent some of the participants actually made use of their hearing aids outside of their auditory training sessions.

A second limitation of the Crossover Study was that, although auditory training significantly reduced depressive symptoms over the course of the study, this finding should be interpreted with caution. This is due to the fact that this conclusion could'nt be strongly supported due to lack of a control group to actually test the effect of auditory training on depressive symptoms, as this was not the main objective of the Crossover Study. A future randomized controlled hearing loss intervention study is needed to further investigate the effects of auditory training on depressive symptoms.

In addition, this study was underpowered given the small sample size and high attrition rate. Given the limitations of this study, the magnitude of the effects reported here should not be interpreted as would be the case for a fully powered trial [350]. The baseline results have provided the motivation needed to proceed with a full-scale, randomized hearing loss intervention and a longer neuroimaging study with cognitive outcomes measured in the short term as well as after at least 6 months of hearing aid use. This, to the best of my knowledge, may be the first prospective cohort randomized controlled trial to test the neural, cognitive and psychosocial efficacy of hearing aid use in adults with post-lingual sensorineural hearing loss. Pilot studies have already begun for this second investigation and the subsequent chapters of this thesis will discuss the research methodology and some of the baseline findings for this study (MRI Study).

5 Aims, Hypothesis and Methods for MRI Study

5.1 Motivation for MRI Study

The findings described in the Crossover Study show that while auditory interventions conducted over a 6 month period did not significantly improve cognition, there were specific tests of cognitive function in which subjects with better speech perception showed a better baseline performance. While a link between cognitive function and speech recognition performance has previously been empirically demonstrated [123, 201, 351], In order to develop a greater understanding of the specific interactions between hearing loss and changes in specific cognitive subsets, a fully-powered investigation is needed. This would be of particular value if underpinned by studies which are able to measure the changes in brain activity resulting from hearing aid use.

Secondly, a relationship between hearing loss interventions and cognitive processes such as executive function has previously been suggested [183, 345], and the baseline results of the Crossover Study demonstrated a significant negative correlation between cognition as measured by the Incongruent Stroop test and hearing loss, even when we controlled for age. However, because impairment on Stroop colour naming and interference tests appears to be a concomitant of normal ageing, caution should be exercised when interpreting the Stroop test results for older patients with suspected cerebral dysfunction [325].

In the Stroop task, participants are presented with colour names printed in a particular colour and they must name the colour while ignoring the written word, therefore requiring inhibition of a natural response. This cognition task is related to executive function - defined as the brain-controlled functions that guide various functions of the body such as planning, solving problems, organizing and directing the body to carry out daily activities [324]. Dementias, such as Alzheimer's disease, frontal dementia and other related dementias, lead to progressive decline in executive function as well as other thinking functions. It has also been shown that there is a decrease in executive function as people age [148, 352, 353] and that the neural changes that result in decline in executive function long enough to a conversation to be able to respond appropriately. Having cognitive control is a central aspect of many higher-level

cognitive functions, including attention, working memory and planning [354]. In addition to standard audiometric assessments, tests of visual Incongruent Stroop capabilities could be an important addition to aural rehabilitative assessments, and this needs further investigation [346].

In addition, the Crossover Study showed that hearing aid use increased the audibility of sounds for both participant groups and that a significant improvement in depressive symptoms was found as a result of the combined effect of auditory training and hearing aids. Previous studies have suggested that hearing aids reduced depression [21, 169]. Studies have shown that depression is associated with hearing impairment [348]; hearing loss is both a risk factor and a prodromal of dementia and is a common occurrence in all types of dementias as well as in mild cognitive impairment [349]. Having depression reduces quality of life, exacerbates cognitive and functional impairment, and is associated with increased mortality [284].

Recent evidence suggests that hearing loss increases the long-term risk of cognitive decline and depression in individuals who are cognitively intact and hearing impaired at baseline. The mechanism by which hearing loss increases the risk of developing cognitive decline is not well understood nor is the effect of interventions. To date, few experimental studies have tested if hearing loss interventions can improve the quality of life for adults or change the risk profile for dementia in adults with SNHL [62]. Study 2 has therefore been designed in order to address this gap in the literature.

Billings and colleagues in the year 2007 demonstrated continuing evidence that the signal-to-noise ratio (SNR) produced by hearing aids influences aided cortical potentials (P1-N1- P2) in a way that obscures the biological representation of hearing aid gain. A few pilot cases where altering frequency compression hearing aid parameters have improved audibility of a 4 kHz tone burst and improved detection of cortical evoked responses [355, 356]. When examining the effect of hearing aid amplification on plasticity, the presence or absence of change over time might reflect changes in signal alterations introduced by the hearing aid, within a single recording or between sessions. And these changes to the hearing aid prescription could be presumed to contribute to changes in the evoked neural responses [179]. However, further research is needed to explore appropriate test stimuli and presentation paradigms, in neuroimaging studies that seek to investigate whether hearing aids have any impact on brain activity.

A better understanding of the testing conditions and stimuli that yield the most valid measures is needed. Traditional presentations of speech stimuli, with tones or speech syllables being presented in isolation, interleaved with silent periods so the necessary average brain responses can be obtained, might not always be a comparable auditory experience to the running speech that is usually delivered to the brain by the hearing aid. For instance, Easwar and colleagues [357] evaluated the output levels of 10 different hearing aids for phonemes in isolation and in running speech to determine the effects of processing strategies on the output level of each. Their results suggested remarkable differences in sound level and hearing aid activation, depending on the method of stimulus presentation. This implies that different conclusions could be drawn for the same person, depending on the way in which the stimuli interact with the hearing aid. A more optimistic spin on this finding could be that it might be possible to use cortical activity to assess the effects of hearing aid fine-tuning, such as changes to hearing aid gain and frequency shaping, or other aspects of hearing aid signal processing such as frequency.

Another potential area of research may be to examine the interaction between onset and change responses evoked by the auditory cortex. This information may provide an objective quantification of the relationship between the onset of the processed signal versus changes within a between processed sounds [358]. The P1-N1-P2 cortical response is appropriate for this purpose because it is sensitive to the onset of sound as well as to acoustic changes within an ongoing sound [358, 359]. There is few published evidence examining the relationship between hearing aid signal processing in response to the onset of sound, and the dynamic changes in hearing aid circuitry that are triggered by the dynamic nature of the speech signal.

Tremblay and colleagues have demonstrated difference in the amount of pupil dilation among normal hearing participants listening to speech masked by fluctuating noise versus a single talker [179]. The authors posited that the degree of pupil dilation may reflect the additional cognitive load resulting from the more difficult listening task, and suggested that pupillometry may offer a viable objective measure of the benefits associated with specific hearing aid signal processing features such as digital noise

reduction. The authors also noted that successful use of hearing aids to improve human communication will ultimately depend on more than just brain measures. It is suggested that other factors that could contribute to aided speech understanding in noisy environments include device centred and patient centred variables. These variables include directional microphones, signal processing, gain settings, age, attention, motivation, biology, personality, and lifestyle.

Lastly, larger longitudinal studies, preferably examining the executive function of the brain through neuroimaging, are therefore needed to establish whether there does exist any causal association between hearing aid use and improved/retention of cognitive performance. Here, the MRI Studywill investigate the neural, cognitive and psychosocial efficacy of hearing aid use in both experienced and inexperienced hearing aid users with either mild or moderate SNHL.

5.2 Objective

The objective of the MRI Study is to use sensory integration and cognition tasks to investigate the effects of hearing aid usage on brain activity, cognitive and psychosocial function in older adults with mild or moderate symmetric sensorineural hearing loss. In particular, this research will attempt to monitor changes in cognition, and compensatory mechanisms for auditory and language processing in participants who are wearing hearing aids for the first time, and comparing these changes with those observed in long-term hearing aid users. The psychosocial effects of hearing aid use will also be investigated in these participants. This chapter describes the methods for a large scale longitudinal study which is beyond the scope of this thesis. Pilot data demonstrating the feasibility of this approach is presented in Chapter 6.

5.2.1 Hypotheses for MRI Study

A comparison of cognition test results and MRI scans of age, gender and hearing acuity matched subjects that are either long-term or first-time hearing aid users, is expected to show that initially, cognitive abilities will be less preserved in first-time hearing aid users than in long-term hearing aid users. However, over a 6 month period, it is expected that the wearing of hearing aids by first-time hearing aid users will quickly reduce this disadvantage. Preliminary results of this pilot study are reported in Chapter 6. In particular, it is expected that:

H1: Cognitive performance levels will initially be lower in participants with no hearing aid experience than in long-term hearing aid users, after controlling for age, level of hearing loss and gender.

H2: After the use of hearing aids for 6 months, the cognitive performance of first-time and long-term hearing aid users will be similar, after controlling for age, hearing loss and gender.

Both first-time hearing aid users and long-term hearing aid users are also expected to practise lip reading in order to supplement their language processing, resulting in the use of both the auditory and visual components of the brain during the initial MRI sensory integration task. However differences are expected in terms of the plasticity within the visual and auditory cortex of long-term and first-time hearing aid users.

In particular it is expected that at baseline:-

H3: Long-term hearing aid users will engage the visual networks of the brain less during the initial MRI sensory integration task than participants who have no experience with hearing aids, and

H4: Long-term hearing aid users will engage the auditory networks of the brain more during the initial MRI sensory integration task than participants who have no experience with hearing aids.

After wearing hearing aids for six months it is expected that first-time hearing aid users will experience a decreased reliance on the visual networks of the brain for language processing.

In particular, it is expected that:-

H5: After 6 months of hearing aid use, first-time and long-term hearing aid users will make similar use of the auditory and visual brain networks for the second MRI sensory integration task.

5.3 Methods

This section describes the recruitment and screening process, sample size selection, study design, hearing loss interventions, measures, and outcomes for the MRI Study.. The statistical analysis will be described in section 5.4.

5.3.1 Recruitment and Screening

Audiology health clinics with existing relationships with Swinburne University, such as Alison Hennessy Audiology, were contacted to distribute study promotional material to their clients who had previously undergone hearing assessments at the audiology clinic, been diagnosed as having mild or moderate sensorineural hearing loss, and had been wearing their hearing aids for at least one (1) year. The clinic also distributed promotional materials to clients who had recently been recommended to acquire hearing aids but had not yet made the decision to purchase the aids. All clients who expressed interest in the study through the audiology clinic were invited to attend an information session at Swinburne University of Technology.

Participants who lived within the Swinburne community were also contacted by telephone and email by the researcher to explain the study. These were individuals who had expressed interest in assisting with research projects run by the Centre for Human Psychopharmacology at Swinburne University of Technology. Participants who expressed interest in this study were invited to attend the information session at Swinburne University.

At the information session, researchers explained the purpose and significance of the study. At the same time, participants completed a screening questionnaire to identify participants who were willing to undergo hearing assessments, undergo two (2) one hour MRI scans, and satisfy the inclusion criteria. Prior to completing the screening questionnaire, participants provided oral consent. Selected participants were provided a Participant Information and Consent package for review. This included further detailed information on the study procedure and a consent form. Participants who were willing to take part in the study were scheduled for hearing assessment at Alison Hennessy Audiology clinic in Mitcham. At the hearing appointments, participants submitted their written consent before their hearing assessments, and those who met the inclusion criteria were scheduled to undergo their first MRI scan at a mutually convenient time at Swinburne University of Technology. Study assessments are described in section 6.2.4.

5.3.1.1 Inclusion Criteria:

- 1) 55 to 90 years
- 2) A good working knowledge of English
- Mild or moderate sensorineural hearing loss at PTA thresholds at 0.5 8 kHz in both ears
- 4) Willing to undergo two (2) one hour MRI scans over a period of 6 months
- 5) Willing to wear hearing aids for six (6) months
- 6) Must have worn hearing aids for at least one (1) year (only for people with hearing aid experience)
- 7) Written consent to participate in the study
- 8) Right handed

5.3.1.2 Exclusion criteria:

- 1) Any significant visual impairment that would prevent reading
- Suspected cognitive impairment (defined as a score less than or equal to 24 on the MMSE)
- 3) Severe or profound hearing loss

5.3.2 Sample Size Selection for MRI Study

No previous studies exist to determine what effect sizes were expected for this study. Instead of performing a power analysis, an MRI budget was used to determine what sample sizes should be considered for this pilot. Based on hearing test results a total of 28 participants who have either mild or moderate sensorineural hearing loss with average PTA between 26dB and 70dB were recruited to take part in the study. In order to accommodate the higher drop-out rate expected for first-time hearing aid users, 19 of these people were first-time hearing aid users and 9 were long-term hearing aid users. Recruitment for this pilot however is still ongoing.

This is a pilot study which will provide initial estimates for the relevant means, standard deviations and effect sizes required to design a large scale study. The depth and rigour of the MRI task (a combination of auditory and visual stimuli) may, despite the small sample size, provide sufficient sensitivity to allow discrimination between the groups.

As the selection criteria for participants in each group differed, for this pilot study, group randomization was not possible. However, the groups were matched as much as possible in terms of the degree of hearing loss.

- 1. *Group A:* Long-term hearing aid users with at least one (1) year hearing aid use experience.
- 2. *Group B:* First-time hearing aid users who will be loaned two hearing aids or who choose to purchase two hearing aids for the study period.

5.3.3 Consenting Procedure

Selected participants reviewed the consent form. They were given the opportunity to ask any questions regarding study participation. After reviewing the consent form, individuals who provided written consent underwent examinations to collect baseline information. A flowchart of the overall data collection plan is shown in Figure 5.1.

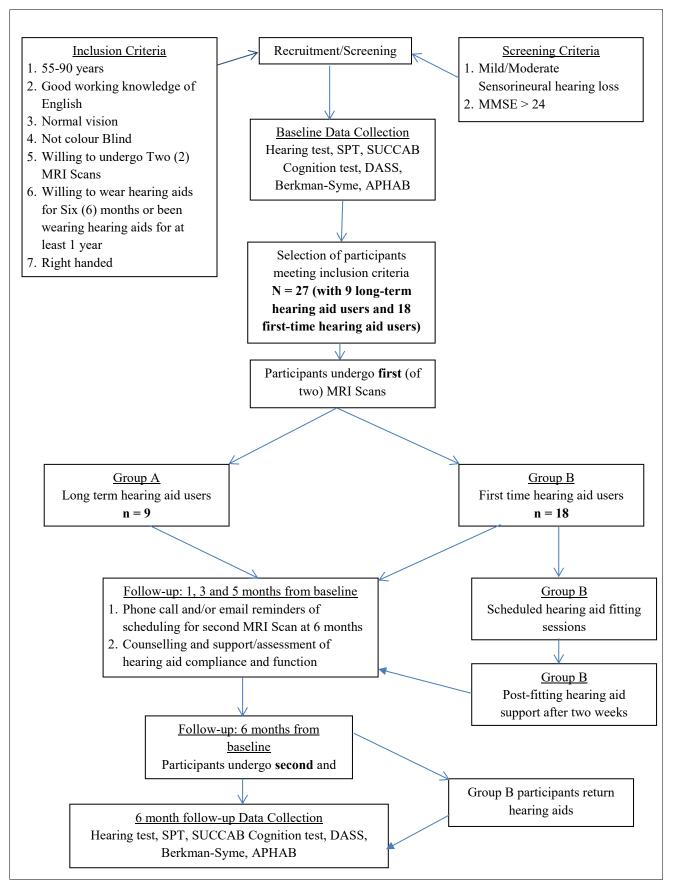


Figure 5.1 Basic data collection plan for experimental design

5.3.4 Assessments for Study

The assessments selected for this study are the following: hearing assessment, demographic questionnaire, hearing problem questionnaire, cognitive performance, mood and social interaction assessments, and MRI tests. All participants enrolled in the study will complete these assessments at baseline and again at 6 months. These assessments are the same as those used for the Crossover Study except that a neuroimaging component (i.e. MRI testing) is included, and the Geriatric Depression Scale (GDS) is replaced by the more sensitive scale known as the Depression, Anxiety and Stress Scale (DASS).

The GDS was not used in this study because it is specific to older adults (65 years and older), but the MRI Study recruited participants below 65 years (i.e. 50 - 90 years) and so the DASS was a preferred option. In addition, the DASS was used in order to measure other emotional symptoms which can affect a person's mood. These include as anxiety and stress.

- Hearing Assessments:
 - Otoscopy and tympanometry: Following otoscopy, all participants will undergo tympanometry and acoustic reflex testing to assess the status of the middle ear [360, 361].
 - Pure tone audiometry in each ear: To understand the degree of hearing impairment, and classify participants according to the type of hearing loss, hearing ability will be measured at threshold frequencies 0.5, 1, 2, 3, 4, 6 kHz in both ears. The choice of frequency to be tested corresponds to the amplification range of most modern hearing aids, and is consistent with capturing sensitivity at frequencies affected by sensorineural hearing loss and noise induced damage. Only participants with either mild or moderate sensorineural hearing loss will be included in the study [360, 361].
- Demographics: Information on a variety of demographic variables will be collected in order to describe the characteristics of the study participants.
- The Abbreviated Profile of Hearing Aid Benefit (APHAB) inventory: The APHAB will be completed by participants to assess hearing aid benefit [331] Page 129 of 309

and the four subscales of the APHAB, namely, EC, BN, RV and AV will be assessed as explained for Study 1.

- Cognitive Assessments:
 - The Mini-mental state examination questionnaire (MMSE): The MMSE will be used as a screening measure to assess cognition and was administered to test for cognitive functioning. The MMSE is a valid and reliable way of globally assessing a limited range of cognitive functions [362]. This examination tested five areas of cognitive function namely: orientation, registration, attention and calculation, recall, and language. Participants who exhibited a confusion state while completing the MMSE questionnaire were advised that they cannot be included in the trial and were advised to see their GP.

The Swinburne University Computerized Assessment Battery (SUCCAB): In addition to the MMSE, the SUCCAB will be used to assess cognitive performance. Cognitive testing allowed assessment of cognitive changes for all participants over a period of 6 months. The battery tests contextual memory, immediate recognition, simple reaction time, choice reaction time, congruent Stroop, incongruent Stroop, spatial working memory and delayed recognition memory. Reliability and validity testing of this battery has demonstrated that the SUCCAB is sensitive to ageing, and has been shown to be particularly effective for measuring short-term changes in cognition for the elderly [111]. The SUCCAB correlates strongly with memory subsets in the Wechsler Adult Intelligence Scales [318].

 Depression, Anxiety and Stress Scale (DASS): The DASS is a self-rating mood scale for measuring three related negative emotional states of depression, anxiety and stress. To assess changes in mood in this study, the DASS21 will be used [363].

- Social Interaction Measure: The Berkman-Syme Social Network Index [329] will be used to assess participants' social interaction and connections with families and friends.
- MRI Tests: To assess brain activity, all participants who have provided written consent will undergo a one (1) hour MRI test at Swinburne University. After the scanning session, a radiologist will examine the brain scans. Any abnormality found in the brain that is thought to be clinically significant and needing to be investigated further will result in a report being forwarded to the participant's nominated health practitioner for follow-up with the individual participant.

The reasons for the design of the MRI scanning session, in particular the sensory integration tasks, are explained in detail in the protocol paper for Study 2 found in Appendix B.

5.3.5 Magnetic Resonance Imaging (MRI) Session

The MRI scanning session will take approximately 1 hour, during which time 4 different types of scan data will be acquired while participants lie supine in the scanner while wearing headphones with audio input. This include a resting state scan acquisition (~10 mins), First Experimental Scan for the sensory integration task (~7 mins), a diffusion-weighted image (~10 mins), Second Experimental Scan for the sensory integration task (~7 mins), a high resolution T1 weighted image using a magnetization prepared gradient echo (MPRAGE) sequence (~8 mins). This task and the resting state data are periodically termed 'functional imaging/data' below. Total scanning time will be 42 mins.

In the sensory integration tasks participants will view a series of human faces (using only one male and one female actor) in word blocks lasting 16 seconds (one word per second). The words were derived from the MRC Psycholinguistic database [364]. The experiment consists of four such blocks under each of four(4) conditions termed matched (MAT), mismatched (MIS), no sound (NOS) and control (CON), interspersed with 10 second rest periods (FIX), providing a total time of 104 (4*16+4*10) seconds for each experiment, with an extra 10 second rest period at the end of each four sequence scan. During MAT, the faces mouth simple single syllable, high frequency words (visual stimuli) such as 'cat', or 'house', and the corresponding audio input (auditory stimuli) is played through the headphones. During MIS, the

stimuli are the same but the mouthed words and auditory stimuli are semantically unrelated (e.g., 'cat' is mouthed, but 'house' is heard). During NOS, the visual stimuli are presented but not the auditory stimuli. During CON, the faces are presented, but there are no words, instead the mouths simply open and close without auditory stimuli. Four of the above sequences will be presented over each of two scanning/presentation runs, each lasting 426 secs. There will be a gap of several minutes between the two scanning runs to give participants a break. Within each scan, the above four conditions will be presented in random order as indicated by the (seq) numbers in Table 5.1. Participants will be asked to press a button whenever a face appears.

Table 5.1 Experimental scans for MRI Study

								Time (secs)								
Rec	Scan	Word List	Sound Rec for MIS	Easy Image	Actors 1M, 1F	R	MAT (seq)	R	MIS (seq)	R	NOS (seq)	R	CON (seq)	R	Total Rest (R)	Total
1	1	1	5	No	Male	10	16(1)	10	16(2)	10	16(3)	10	16(4)		40	104
2	1	2	6	No	Female	10	16(2)	10	16(4)	10	16(1)	10	16(3)		40	104
3	1	3	7	Yes	Male	10	16(3)	10	16(1)	10	16(4)	10	16(2)		40	104
4	1	4	8	Yes	Female	10	16(4)	10	16(3)	10	16(2)	10	16(1)	10	50	114
Total															170	426
5	2	2	1	No	Female	10	16(1)	10	16(2)	10	16(3)	10	16(4)		40	104
6	2	1	2	No	Male	10	16(2)	10	16(4)	10	16(1)	10	16(3)		40	104
7	2	4	3	Yes	Female	10	16(3)	10	16(1)	10	16(4)	10	16(2)		40	104
8	2	3	4	Yes	Male	10	16(4)	10	16(3)	10	16(2)	10	16(1)	10	50	114
Total							128		128		128		128		170	426

Notes: CON: mouth opening and closing with no sound;

MAT: matched visual and sound;

MIS: mismatched sound with same visual;

NOS: no sound with same visual;

seq: sequence of presentation in video;

R: 10 second rest period;

Rec: Recording.

5.3.6 Fitting of Hearing Aids for Group B Participants

Participants in Group B will be loaned a pair of hearing aids known as the Unitron Flex Trial MoxiFit hearing aids. The hearing aids will be fitted according to the manufacturer's protocol, and explanation of the hearing aid usage, insertion of the aids and batteries along with a step-by-step guide on how to use the hearing aid will be given. Alternatively, participants can purchase their own hearing aids which will also be fitted according to the manufacturer's protocol.

5.4 Planned Procedures for Follow-up Periods after Baseline Data Collection

Post fitting support will be provided after 2 weeks to make sure that participants are progressing with their hearing aids. Checks will also be conducted at 6 weeks, 12 weeks and 18 weeks after the initial fitting of hearing aids for Group B participants.

During the six (6) month wait period between MRI scans, phone call and email reminders about the second MRI appointment will be provided for all participants at one, three and five months respectively. At the same time, counselling and other compliance-improving policies [315-317] will be provided to ensure that participants are wearing their hearing aids. An automatic internet-based data logging function installed in the hearing aids will be used to monitor and assess hours of hearing aid use by both participant groups.

Participants will return to Alison Hennessy Audiology for further hearing assessments and complete the hearing aid benefit questionnaire (APHAB) after 6 months. All participants who received loaned hearing aids will return them. After hearing assessments, participants will return to Swinburne University for a second MRI scan, and will repeat the cognition, mood and social interaction assessments at this time.

5.5 Statistical Analysis for MRI Study

The following are the planned statistical analyses for the MRI Study:

- 1. Baseline Analysis
- 2. Baseline MRI Analysis
- 3. Follow-up Analysis

5.5.1 Baseline Comparisons

Baseline comparison of the two groups (i.e. long-term and first-time hearing aid

users) will be performed in terms of hearing loss, speech perception, hearing satisfaction, mood, social interaction, and cognition. To determine the magnitude of the difference between the two groups, descriptive statistics of each group will be reported. Also, to determine the significance of any differences between the two participant groups in terms of demographic factors and baseline values, appropriate crosstab tests and independent sample t-tests will be used. Analysis of covariance (ANCOVA) will then be conducted in order to determine the significance of the baseline group differences when age, gender and level of hearing loss are controlled.

In order to satisfy the assumption of normality for the independent samples ttests and ANCOVA analyses, square root transformations will be applied for the baseline measures where necessary.

5.5.2 MRI Analysis

Brain structure/function changes that can be linked to changes in cognition, mood and social interaction over the six month period, for both long-term and first-time hearing aid users, will be analysed using SPM12 (Wellcome Department of Neurology).

- Preprocessing and statistical analysis of functional and diffusion data:
 - During stimulus presentation for the sensory integration task and resting state, BOLD sensitive T2* weighted images will be acquired. Preprocessing and statistical analysis of the image data acquired will be performed using SPM12 and associated toolboxes. This will include slice-timing correction, motion correction, co-registration of realigned functional images to structural (T1-weighted) scans, warping ('normalisation') of structural and functional scans into standardised stereotactic space, and spatial smoothing of functional images.
 - The sensory integration task data will be modelled by constructing separate regressors that depict the onset and duration of MAT, MIS, NOS and CON blocks, convolved with the canonical HRF supplied with SPM12. Covariates of no interest (e.g., image realignment parameters) will model noise components.
 - The resting state data will be analysed using the 'CONN' connectivity toolbox to test for changes in functional connectivity between brain areas. The following contrasts will be computed for the sensory

integration tasks: MAT > CON, MIS > MAT, NOS > CON. These contrast images will be entered into group level Time (baseline vs sixmonth follow-up) x Group (New hearing aid users vs Long term hearing aid users) ANOVA models.

Finally, diffusion-weighted MR white-matter tractography will be performed using 'MRTrix' (<u>https://www.florey.edu.au/imaging-software</u>) to assess white matter tract changes. Pre-processing steps will include, constructing a brain mask, estimating diffusion tensor components and performing constrained spherical deconvolution. Subsequently, whole-brain and seed-based fibre tracking will be performed.

5.5.3 Follow-up Analysis

The final statistical analysis will involve a comparison of the two groups involving change scores for speech perception, hearing satisfaction, mood, social interaction, brain function and cognition measures over the 6 month period using independent samples t-test or equivalent non-parametric tests. In addition, paired t-tests (or related non-parametric tests) will be conducted separately for each group in order to determine whether significant changes have occurred over the 6 month period of the trial.

5.6 Summary and Conclusion

For this thesis, only results of the baseline analysis will be reported, together with the experimental MRI results for a single participant at baseline. The analyses and results for this will be discussed in Chapter 6. Further MRI scans and follow-up work are still underway and will therefore not be reported as part of this thesis.

6 Baseline Results for MRI Study

The overall aim of study 2 was to investigate the effects of first-time and longterm hearing aid usage on brain activity, cognitive and psychosocial function in older adults with mild or moderate symmetric sensorineural hearing loss. As previously mentioned, the complete analysis of MRI and follow up data will be conducted in the future.

In this chapter therefore, only the baseline results for participants who have worn hearing aids for more than a year *(long-term hearing aid users)* and participants who have never worn hearing aids *(first-time hearing aid users)* will be compared in order to better understand the effects of long-term hearing aid usage. In addition, the baseline MRI results will be presented only for a single participant.

The aim of this baseline analysis is to determine whether long term hearing aid usage relates to cognition, mood, speech perception, hearing problems as measured by the APHAB and social interaction, after controlling for level of hearing loss, age and gender.

The above aim will be addressed by testing the following hypotheses:

H1a: Long-term hearing aid users will have better cognition, speech perception and social interaction at baseline than first-time hearing aid users when the level of hearing loss, age and gender are controlled.

H1b: Long-term hearing aid users will have less depression, anxiety and stress than first-time hearing aid users when the level of hearing loss, age and gender are controlled.

H1c: Long-term hearing aid users will have fewer hearing problems as measured by the APHAB (ease of communication, reverberation of sound and the effects of background noise) but worse averseness to sound than first-time hearing aid users at baseline when the level of hearing loss, age and gender are controlled.

The baseline MRI results for a single participant are presented in order to show that changes in brain activity can be observed in the auditory cortex when participants respond to various auditory and visual stimuli. This justifies the use of such experiments in the broader study which is designed to detect changes in brain function and structure in response to hearing aid use.

6.1 Results

6.1.1 Participant Demographics

Initially 40 adults expressed interest in the study, however, only 27 of these adults were eligible to participate in the study. Out of the 27 eligible participants, there were 9 adults (33.3%) who were long-term hearing aid users and 18 (66.67%) adults who were to be first-time hearing aid users. The proportion of males was higher in this eligible sample of adults, with 20 (74.1%) males and 7 (25.9%) females. All participants were cognitively healthy with an average MMSE of 28.67 (out of 30). Recruitment of these participants involved advertisements in audiology health clinics, through Swinburne University's CHP database and word of mouth. A participant recruitment agency was also used. Participants attended an information session at Swinburne University where they were advised as to what their participation would encompass. They were then screened according to the study's inclusion and exclusion criteria (See Sections 5.3.1.1 and 5.3.1.2). All participants provided written informed consent and the hearing assessments were performed by a qualified audiologist.

6.1.2 Baseline Assessments

The first test, audiometric air conductivity, was used to assess hearing thresholds in each ear at frequencies 0.5, 1, 2, 4, 6, 8 Hz. A bone conduction test was also performed for each ear at threshold frequencies 0.5, 1, 2, and 4 Hz. The audiometric air conduction results were summarized as the pure-tone average (PTA) of the first four frequencies 0.5, 1, 2 and 4 Hz, calculated for the better-hearing ear. The mean PTA for all 27 participants was 38.50 dB HL (SD: 13.31; range: 25 – 69). Out of the 27 participants, 15 (55.7%) were reported as having mild SNHL (25dB HL to 33dB HL) and 12 (44.4%) participants were reported as having moderate SNHL (43dB HL to 69dB HL).

The speech perception test (SPT) was used in addition to the standard audiogram as a measure of likely hearing aid benefit. All 27 participants completed the SPT at baseline without hearing aids and their Phoneme scores (total score of vowels and consonants correctly heard) were obtained for the two participant groups. The average Phoneme score obtained from the SPT was 91.8 with a standard deviation of 7.5. Other outcome measures for Study 2 included cognition performance as measured by the SUCCAB, mood as measured using the depression, anxiety and stress scale (DASS), social interaction and perceived hearing problems as measured by the APHAB. Baseline characteristics for all these measures are discussed in the next section. None of the participants were wearing hearing aids when these baseline measures were collected.

6.1.3 Baseline Comparison of Groups

Descriptive data for long-term hearing aid users and first-time hearing aid users is presented in Table 6.1. Square root transformations were applied to the baseline measures where necessary and independent samples t-tests were conducted in order to compare the two groups.

Characteristics	Long-Term	First-Time	Total	p-value
	HA Users	HA Users	N = 27	-
	n = 9	n = 18		
Gender, n (%)				
Male	6 (66.7)	14 (77.8)	20 (74.1)	0.653
Female	3 (33.3)	4 (22.2)	7 (25.9)	
Age, mean (SD)	75.4 (6.6)	70.2 (9.3)	72.0 (8.7)	0.145
MMSE, mean (SD)	28.2(1.6)	28.9 (1.0)	28.7 (1.2)	0.193
Hearing Loss, mean (SD)	45.3 (14.4)	34.8 (11.6)	38.3 (13.3)	0.050#
SQRT (Speech Perception Test),	87.1 (10.8)	94.1 (3.6)	91.8 (7.5)	0.018#
mean (SD)				
SUCCAB Performance Cognition	Measures (seco	onds), mean (S	D)	
Simple Reaction Time	348.3 (61.3)	351.9 (37.6)	350.7 (45.6)	0.853
Complex Reaction Time	194.7 (40.6)	195.3 (30.8)	195.1 (33.6)	0.967
Immediate Recognition Memory	59.3 (18.3)	68.1 (24.3)	65.2 (22.5)	0.347
Delayed Recognition Memory	59.3 (15.8)	72.0 (15.3)	67.8 (16.3)	0.057
Stroop Congruent	116.9 (28.3)	122.8 (16.9)	120.8 (21.0)	0.500
Stroop Incongruent	79.3 (32.5)	98.5 (22.2)	92.1 (27.1)	0.083
Spatial Working Memory	50.2 (21.2)	67.3 (24.0)	61.6 (24.1)	0.083
Contextual Recognition Memory	53.4 (31.3)	75.7 (21.5)	68.2 (26.8)	0.039#
Hearing Problems, mean (SD)				
SQRT(Ease Communication (EC))	47.0 (31.4)	26.5 (19.3)	33.4 (25.4)	0.072
Effects Reverberation (RV)	49.6 (22.1)	36.7 (21.1)	41.0 (21.9)	0.152
Effects Background Noise (BN)	55.4.4 (24.7)	41.9 (19.9)	46.4 (22.1)	0.137
SQRT (Aversiveness (AV))	23.4 (30.0)	19.2 (21.5)	20.6 (24.1)	0.842
Depression, Anxiety and Stress Sc	ale (DASS), me	an (SD)		
Depression	2.0 (1.8)	1.4 (1.8)	1.6 (1.8)	0.450
Anxiety	4.4 (3.9)	3.6 (2.9)	3.9 (3.2)	0.539
Stress	2.7 (3.0)	2.1 (2.5)	2.3 (2.6)	0.612
Social Interaction, mean (SD)	34.7 (10.7)	38.9 (7.7)	37.5 (8.8)	0.249

Table 6.1 Group comparison in terms of demographics and baseline assessment data

Notes: * p < 0.05 values are marked with (#); HA: Hearing aid; MMSE: Mini-mental state examination (value out of 30).

Table 6.1 suggests no significant differences between the two groups at baseline for most of the outcome measures with the exception of three variables: level of hearing loss, speech perception and contextual recognition memory. The results suggested that at baseline, first-time hearing aid users performed significantly better than long-term hearing aid users for the three variables. To further explore the baseline group differences, an ANCOVA analysis was performed, controlling for the following covariates, age, gender and level of hearing loss.

6.2 ANCOVA Analyses

A general linear model analyses was used to explore group differences in relation to cognition, mood, speech perception, social interaction and hearing problems as measured by the APHAB, while controlling for age, gender, and level of hearing loss. Results of the ANCOVA are displayed in Table 6.2 for each of the outcome measures. This table also shows the marginal means for all the outcome variables, when age, gender and level of hearing loss were controlled.

Table 6.2 ANCOVA results for group effects after controlling for level of hearing loss, age and gender

Outcome Measure	F	Р	Partial	Margina	l Means
	Value	value	Eta	(Standar	d Error)
			squared	Long-term	First-time
				HA Users	HA users
SQRT (Speech Perception Test)	2.702	0.114	0.109	9.4 (0.1)	9.7 (0.1)
SUCCAB Performance Cognition	on Meas	ures (sec	onds)		
Simple Reaction Time	0.057	0.814	0.003	352.7 (16.4)	357.5 (12.5)
Complex Reaction Time	0.147	0.705	0.007	198.6 (12.5)	192.7 (9.6)
Immediate Recognition Memory	1.230	0.279	0.053	60.8 (8.6)	72.5 (6.6)
Delayed Recognition Memory	4.157	0.054	0.159	58.7 (5.3)	71.8 (4.0)
Stroop Congruent	0.011	0.917	0.001	121.0 (7.4)	120.0 (5.7)
Stroop Incongruent	0.319	0.578	0.014	89.7 (7.6)	95.0 (5.8)
Spatial Working Memory	1.106	0.304	0.048	52.6 (7.4)	62.2 (5.7)
Contextual Recognition Memory	2.212	0.151	0.091	55.9 (8.6)	71.6 (6.5)
Hearing Problems (APHAB)					
SQRT (EC))	0.994	0.330	0.043	6.0 (0.6)	5.3 (0.5)
RV	0.340	0.566	0.015	44.4 (6.3)	39.8 (4.8)
BN	0.739	0.399	0.032	52.6 (7.5)	44.7 (5.7)
SQRT (AV)	0.054	0.818	0.002	3.9 (1.1)	3.6 (0.8)
Depression, Anxiety and Stress	Scale (D	ASS)			
Depression	0.277	0.604	0.012	1.8 (0.7)	1.7 (0.5)
Anxiety	0.370	0.549	0.017	4.9 (1.3)	4.0 (1.0)
Stress	0.223	0.641	0.010	2.9 (1.0)	2.3 (0.8)
Social Interaction	0.554	0.465	0.025	36.3 (3.3)	39.3 (2.7)
Notes: AV: Aversiveness of	sound;	BN: E	Background	d Noise; EC:	Ease of

Communication; HA: Hearing aids; RV: Reverberation of sound; SQRT: Square root transformation.

Results from Table 6.2 suggest that there were no significant differences between the groups for any of the baseline measures after controlling for age, gender and hearing loss. This suggests that the significant differences that were seen in Table 6.1 were all related to differences in the degree of hearing loss, gender and/or age. Firsttime hearing aid users had significantly better hearing levels than long-term hearing aid users and they tended to be younger, so it is perhaps not surprising that they exhibited significantly better mean scores on the SPT and the Contextual Working Memory test when the level of hearing loss and age were not controlled, in Table 6.1.

ANCOVA analysis results for the covariates age, gender and hearing loss are displayed in Table 6.3 together with the results of Levene's test which was used to determine whether the two groups had similar variances for the outcome measures. Only in the case of the SPT was there a significant difference in variance for the two groups. As shown in Table 6.1 the variance for the SPT results was much higher for long-term than first-time hearing aid users.

Outcome Measure		F Values			e's Test
	Age	Gender	Hearing	F Value	P Value
	_		Loss		
SQRT (Speech Perception Test)	0.009	1.097	4.899	4.775	0.010#
SUCCAB Performance Cognition	1 Measure	s (second	s)		
Simple Reaction Time	1.558	0.855	0.639	1.227	0.322
Complex Reaction Time	3.105	0.012	0.104	0.808	0.503
Immediate Recognition Memory	0.121	1.349	0.002	0.150	0.929
Delayed Recognition Memory	4.316#	0.034	3.364	0.644	0.595
Stroop Congruent	4.775#	0.034	0.023	1.719	0.191
Stroop Incongruent	9.822#	0.185	1.965	1.024	0.400
Spatial Working Memory	10.955#	1.034	0.638	0.132	0.940
Contextual Recognition Memory	7.044#	0.415	0.422	2.086	0.130
Hearing Problems (APHAB)					
SQRT (EC)	2.437	1.314	0.442	1.192	0.335
RV	1.837	0.025	13.110#	1.329	0.289
BN	0.668	0.116	3.916	0.384	0.766
SQRT (AV)	0.208	0.026	0.061	0.012	0.540
Depression, Anxiety and Stress S	cale (DAS	S)			
Depression	0.993	0.277	0.090	0.344	0.794
Anxiety	0.044	0.836	0.090	1.005	0.408
Stress	0.064	0.285	0.004	0.277	0.876
Social Interaction	0.284	0.519	0.271	1.016	0.404

Table 6.3 ANCOVA results for age, gender and level of hearing loss

Notes: p < 0.05 values are marked with (#);Hearing Loss = Pure-tone average of Better Hearing Ear; APHAB: Abbreviated Profile of Hearing Aid Benefit; AV: Aversiveness

of sound; BN: Background Noise; EC: Ease of Communication; HA: Hearing aids; RV: Reverberation of sound; SQRT: Square root transformation.

The ANCOVA results from Table 6.3 suggest a significant negative relationship between age and five cognitive outcome measures namely Delayed Recognition Memory, Stroop Congruent, Stroop Incongruent, Spatial Working Memory and Contextual Recognition Memory, suggesting lower cognition scores for older people. There was also a significant negative relationship between hearing loss and RV.

6.3 Preliminary Results of Baseline MRI Analysis

Although the full MRI and 6 month follow-up study are outside the scope of this thesis, this section will present initial baseline results for a single participant who is a long-term hearing aid user. This is to determine whether the MRI experiment has the ability to detect changes in the brain in response to various stimuli.

In this single MRI scan, only the auditory cortex was considered, and this is indicated by the yellow region shown in Figure 6.1.



Figure 6.1 Auditory cortex considered in pilot MRI scan for one SNHL participant (aged 77 years)

Notes: Left image is the right side of the brain and right image is the left side of the brain; SNHL: Sensorineural hearing loss.

In the MRI analysis, the following contrasts were estimated for every voxel: MAT > MIS, MAT > NOS, MAT > CON, MAT > FIX and NOS>CON (where MAT is matched visual and sound, MIS is mismatched sound with same visual, NOS is no sound with same visual, CON is mouth opening and closing with no sound and FIX is rest period), and the significant (peak) contrast differences are displayed in Table 6.4, identifying the locations in the auditory cortex where significant differences in brain response were observed for each of the chosen stimuli pairs. For the sake of simplicity, not all possible contrasts were studied. Instead, only what were thought to be the most interesting contrasts were considered. Higher t-values are indicative of larger voxel activation differences between any pair of conditions. A comparison between the left side of the brain and the right side of the brain was also facilitated by the results shown in Table 6.4.

	Left Side of Brain				Right Side of Brain				
Comparison	X(mm)	Y(mm)	Z(mm)	t- value	X(mm)	Y(mm)	Z(mm)	t- value	
	-48	-28	18	3.90	44	-20	14	3.65	
MAT>MIS	-60	-12	12	3.74	58	-28	16	2.89	
	-34	-30	12	2.71	60	-16	14	2.39	
	-48	-14	4	2.60					
	-50	-16	4	5.47	52	-26	12	5.66	
MAT>NOS	-56	-20	8	5.36	62	-16	10	5.08	
	-48	-24	12	4.50	52	-12	0	3.64	
	-54	-22	12	6.49	54	-24	12	5.99	
MAT>CON	-60	-12	12	6.45	62	-16	12	5.64	
	-48	-14	4	5.14	52	-18	2	3.43	
	-50	-24	14	5.5	52	-24	12	5.12	
MAT>FIX	-48	-14	4	5.31	44	-20	14	4.30	
	-58	-12	10	5.01	60	-16	14	4.02	
	-60	-12	12	4.84	48	-20	14	3.77	
	-48	-28	16	4.47	60	-16	14	3.57	
NOS>CON	-54	-22	14	4.38	58	-8	8	3.52	
NUS-CON	-48	-14	4	2.87					
	-38	-24	16	2.40					
	-36	-22	10	2.36					

Table 6.4. t-values for peak experimental contrasts in SNHL participant

Notes: CON: mouth opening and closing with no sound; FIX: rest period; MAT: matched visual and sound; MIS: mismatched sound with same visual; NOS: no sound with same visual, SNHL: Sensorineural hearing loss, X: left side of the brain; Y: back of the brain; Z: bottom of the brain.

Table 6.4 gives the co-ordinates of the most significantly different voxels (pixels) for each pair of contrasts considered, with negative "x" indicating the left side of the brain, negative "y" indicating the back of the brain and negative "z" indicating

the bottom of the brain. As shown in Table 6.4, significant differences were detected depending on whether there was no sound (NOS) and whether sound and lip movements were matched (MAT) or mismatched (MIS). There were also significant differences between the matched (MAT) and the control (CON = opening mouth with no sound) and the rest period (FIX) showing an empty screen with a cross (+). Finally there is a comparison of the control (CON) and no sound (NOS), perhaps suggesting that lip reading can be detected in the auditory cortex due to significant differences between CON and NOS for at least two voxels (X=-36 and X=-38). Also, a similarly positioned voxel (X = -34) for the MAT>MIS comparison perhaps suggests some lip reading for this comparison as well. Interestingly, it is only on the left-hand side of the brain that these possible lip reading responses are observed.

Using a threshold of 0.01 for contrast differences further evidence of brain activity in response to the different stimuli are displayed in the brain images shown in Figure 6.2. These figures also show important differences between the left and right sides of the brain. Further analysis is of course required to find out if there are differences in brain activity between the two participant groups, and MRI scans for many more participants with SNHL will need to be studied in order to better understand these results.

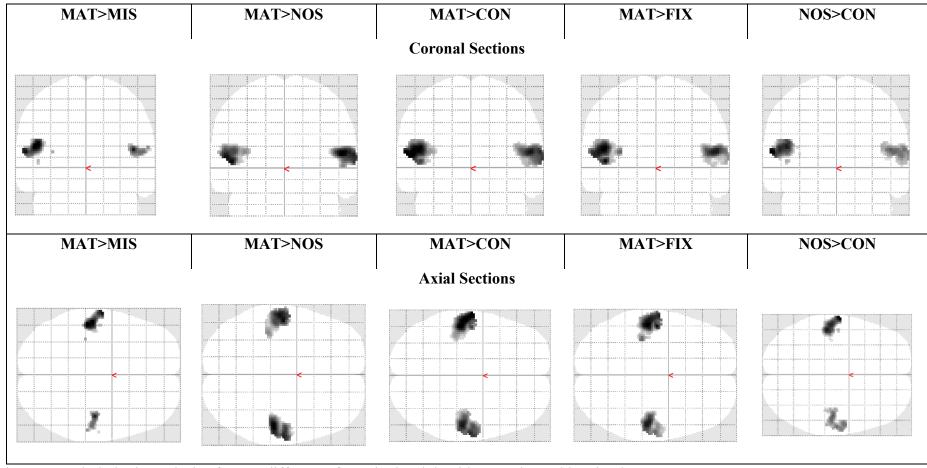


Figure 6.2 Whole-brain analysis of group difference for a single adult with sensorineural hearing loss.

Notes: MAT=matched visual and sound, MIS=mismatched sound with same visual, NOS=no sound with same visual, CON = mouth opening and closing with no sound, FIX = rest period

6.4 Discussion – Summary of MRI Study Findings

6.4.1 Baseline Comparisons

The baseline results showed that first-time hearing aid users performed better than the long-term hearing aid users for speech perception, level of hearing loss and one cognitive task, contextual working memory. However, after controlling for age, gender and level of hearing loss, no significant difference was found between the two groups at baseline. This result is contrary to expectation, providing no support for all three of the baseline hypotheses for the MRI Study.. This suggests that the hearing aid intervention did not improve cognition, mood, depression or social interaction for the long-term hearing aid users relative to first-time hearing aid users.

A significant negative relationship between age and cognition was found and this was an expected result. Naturally, as people age, mental processing becomes slower and learning more difficult. Research suggests that age-related declines in measures of cognitive functioning are large, beginning in early adulthood, and evident in several different types of cognition. In particular, negative age trends are evident in cognitive measures such as the measures of speed, reasoning, and memory [365].

Three known core deficits have been proposed to explain the pattern of agerelated cognitive decline. These are changes in sensory perception, changes in inhibitory ability, and changes in speed of processing [366, 367]. The sensory deficit hypothesis proposes that the cognitive changes associated with aging may be attributed to deficits in vision and hearing (i.e. sensation) [368]. Support for the hypothesis that sensory deficits may underlie cognitive changes has come from the notion that older adults' cognitive performance correlates strongly with their sensory abilities. For instance, research has shown that deterioration in hearing often results in older adults' slowed performance on tasks requiring auditory processing, and this could explain older adults' poorer memory for auditory information. Furthermore, there is evidence to suggest that inhibitory deficits can occur on a range of cognitive tasks that require the ability to selectively attend to information in the environment, or to inhibit a strong association or response. These inhibitory deficits impair performance not only on tasks that directly assess inhibitory ability, but also on assessments of working memory capacity [369]. Older adults may therefore find difficulty in distinguishing relevant from irrelevant information. In addition to these deficits, decline in processing speed underlie the agerelated changes in cognitive function, and longitudinal studies have shown a strong relation between changes in speed of processing and changes in performance on a large number of cognitive tasks [134].

There was also a significant relationship between level of hearing loss and hearing problems (i.e. the effects of reverberation, such as listening to sounds across a large room). This is consistent with a study which suggested that the percentage of hearing problems, as measured by the profile of hearing aid performance, increased with hearing loss [347]. In this study, the authors were able to show that a person with a mild hearing loss will benefit just as much as a person with a more severe hearing loss in reverberant or noisy situations. The results of Study 1 also showed that perceived hearing aid benefit related to the amount of gain from amplification and increases in the audibility of sound. Modern digital hearing aids can be set to amplify sound differentially across a broad frequency and input amplitude range, with the goals of maximizing audibility, intelligibility, satisfaction, listener comfort and sound quality, and this may lead to compromises in real-life situations [370, 371]. This makes it important to assess how people report the percentage of problems for different listening situations in day-to-day life, with and without their hearing aids.

Overall, the lack of a significant difference at baseline between long-term hearing aid users and first-time hearing aid users may be due to the relatively low levels of hearing loss for the first-time hearing aid users, and/or the small sample sizes. It could also be that, since the spatial arrangement of where sounds of different frequency are processed in the auditory system undergo changes following a hearing loss, the acclimatisation processes may take more than a few months, especially affecting the first time hearing aid users [372]. Another issue was the fact that in this study details on hearing aid use by long-term hearing aid users (e.g. number of hours long-term hearing aid users used their aids per day, or the number of years of experience with hearing aids) was not recorded and could not therefore be taken into account in the analysis. For long-term hearing aid users who did not use their hearing aids consistently, the hypothesised changes in cognitive function could not be expected.

In the Crossover Study, the baseline results suggested a strong negative relationship between hearing loss and speech perception. The results also showed a significant positive relationship between speech perception and most cognition performance measures. This was confirmed by the MRI Study results as shown in Table 6.1 in that the first-time hearing aid users had lower hearing loss, better SPT and better contextual working memory on average than long-term hearing aid users. Also in the Crossover Study, there was no significant improvement in cognition or social interaction observed over a 3 month period of hearing aid usage.

The Crossover Study did show a significant improvement in depressive symptoms over the course of the study (6 months). This may have been due to the effects of auditory training rather than the 3 month period of hearing aid usage. The Crossover Study however used the GDS to measure depressive symptoms instead of the DASS, and in the MRI Study, no significant improvements in other emotional symptoms such as anxiety and stress (in addition to depression) were found. This could imply that the DASS may not be more sensitive measure than the GDS although it was a suitable measure for the MRI study, as initially proposed. Also, since only baseline results were reported in the MRI study, complete hearing loss intervention and evaluation studies is needed to confirm the sensitivity of these two measures.

There are however mixed results on research investigating the impact of hearing loss on depression. For instance, previous research which used the 12 items and scoring algorithm from the Diagnostic and Statistical Manual major depressive episodes scale has suggested that hearing loss interventions do not have an impact on depression, especially for participants with a mild hearing loss [268], and this in line with the Study 2 baseline results. Also, a cross sectional study by Dawes et al. [172] found no association between depression and the use of hearing aids and this study used a depressive screening tool [373] to assess depressive symptoms. A recent study by Acar and colleagues [21] which used the GDS to measure depressive symptoms showed that hearing aids improved significantly, the psychological state and mental functions of adults with SNHL. A decreased risk for depression can therefore still be proposed as a result of auditory training effects and hearing aid use. Preliminary Findings of Functional Magnetic Resonance Imaging (fMRI)

As shown in Table 6.4, some areas of the auditory cortex did show a significance difference in their response to the different stimuli presented. In particular, significant differences were observed for all the computed contrasts considered: MAT > MIS, MAT > NOS, MAT > CON, MAT > FIX and NOS>CON.

A striking result was obtained for the comparison of NOS>CON, which was conducted in order to determine if lip reading can be detected in the auditory cortex. The results confirmed significant differences between CON and NOS for several voxels, particularly on the left-hand side of the brain. Previous research suggests that for effective communication, hearing impaired individuals rely more heavily on visual cues such as facial expression and lip reading than their normal hearing counterparts [374]. It may be posited that adults with a mild-moderate sensorineural hearing loss, after hearing loss intervention, may allocate their visual resources more efficiently than even those with normal hearing but this will need further investigation. Ultimately, the follow-up analysis for the MRI Study will seek to investigate whether cross-modal neuroplasticity has functional consequences, such as altered organization and perception in hearing impaired adults.

A limitation for Study 2 was the small sample size resulting in a study which is underpowered.

Secondly, for long-term hearing aid users, there was no data of the exact years of hearing aid experience, and daily hours of hearing aid usage (as was the case for the Crossover Study). This may have biased the baseline results obtained for the MRI Study.

Thirdly, the study could not report on all MRI baseline data analysis as initially planned, except for one SNHL participant. This was due to major technical, financial and personal difficulties experienced during baseline recruitment. Given this limitation, the MRI Study should not be interpreted as would be the case for a fully powered trial [350]. However, the MRI data reported for the first SNHL participant has shown very exciting results, as significant differences were detected for all the experimental conditions. This result suggests that the pilot novel MRI experiment planned for any future hearing loss intervention studies will be feasible.

Lastly, the lack of a significant difference in baseline cognition levels between long term and first-time hearing aid users when age, gender and level of hearing loss were controlled may be due to the fact that the SUCCAB may not be sensitive enough to detect small changes in cognition. This might have also have been the reason for the lack of a significant hearing aid effect on cognition in the case of the Crossover Study.

6.5 Summary and Conclusion

Baseline results of the MRI Study provided no support for H1a, H1b and H1c. This implies that there were no significant differences between long-term and first-time hearing aid users in terms of cognition, mood and social interaction when hearing loss, age and gender were controlled for. It was evident in this study that age significantly affected a person's cognition. Research exists to suggest hearing loss is independently associated with acceleration in cognitive decline among older adults [59], but the question of whether hearing aid use results in a reduction in rates of cognitive decline, measured longitudinally, remains unknown and needs further investigation.

A prospective study is required to further investigate the impact of hearing loss intervention on brain activity. Our initial MRI analysis for a single participant suggests that the neuroimaging experiment for the MRI Study may have the ability to detect differences in brain activity for different auditory stimuli. This provides the motivation for the MRI Study.

7 Discussion and Conclusion

The primary objective of the Crossover Study was to conduct a randomized crossover trial to investigate the efficacy of the simultaneous use of hearing aids and auditory training for improving cognition, social interaction and depressive symptoms, while also considering the cognitive functions associated with speech perception. The objective and subjective benefit of hearing aids in SNHL was also assessed with an explicit focus on auditory training as necessary to augment the benefit from hearing aids for improved health outcomes. Significant findings of this study suggested strong correlation between hearing loss and the executive function cognitive measure, Incongruent Stroop task, and that hearing intervention may reduce depressive symptoms. This provided the motivation to further investigate the effects of a chronic hearing aid use intervention on the neurocognitive and psychosocial functioning in individuals with SNHL (MRI Study).

This chapter will begin with a general discussion of the key findings from both the Crossover and MRI Study, will critically review the results and limitations of these studies, and then examine what the present findings contribute to our understanding, in the context of existing research. Finally, reflections on the neurocognitive effects of hearing aids on adults with SNHL will be discussed and this will provide some suggested directions for future hearing research and intervention studies.

7.1 Summary of Key Findings of Crossover Study

7.1.1 Hypothesis 1: In adults with SNHL, hearing aids in combination with face-to-face auditory training will be more effective for improving cognition than face-to-face auditory training on its own.

The Crossover Study examined the efficacy of the simultaneous use of hearing aids and auditory training for improving cognition. There was no significant improvement in cognition over a six month period as a result of auditory training and/or hearing aid use when we controlled for age, significant group differences at baseline, attrition probabilities and baseline outcome measures. Hence Hypothesis 1 was not supported in the Crossover Study. This result was unexpected, especially due to the negative baseline correlation observed for hearing loss and Incongruent Stroop when age was controlled. In this study a cross-over analysis was used in order to determine whether hearing aids had any effect for improving cognition in comparison with auditory training on its own. In the analysis, each participant served as his or her own control, avoiding the confounding effects of person variables such as age and sex. Moreover, these designs required lower sample sizes in order to meet the same criteria in terms of type I and type II errors.

The neuropsychology battery used for this study assessed eight cognitive domains namely; Simple and Choice Reaction Times, Immediate and Delayed Recognition, Congruent and Incongruent Stroop colour-words, Spatial Working Memory and Contextual Memory. Out of these, no significant improvements in cognition were observed and there was a significant decline in delayed recognition memory when hearing aids were used, which may be questionable due to the significant carry-over effect detected (only) in the case of delayed recognition memory. One interpretation of this result is that the neuropsychological test battery may not have been sufficiently sensitive to detect significant improvements in cognition. Another interpretation could be that hearing treatment may take longer than 6 months to impact cognition.

Studies examining the effects of hearing loss interventions on cognitive function in adults with SNHL remain inconclusive. For instance, a randomized control trial found that cognitive function measured on the Short Portable Mental Status Questionnaire (SPMSQ) improved after four months of hearing aid use in a group of older adults (mean age above 70 years, n = 13) [161]. In another study which used the MMSE as a measure of cognitive function [21], there was significant improvement in cognitive function in a group of adults after three months of hearing aid use. It may be that because cognitive function tests in both studies were administered verbally prior to hearing aid fitting, the reduced baseline cognitive function could have been confounded by the hearing disability. Lin [220] also found that the use of hearing aids was positively associated with cognitive function. Young Choi et al. [180] demonstrated significant changes in the total scores measured on the visual verbal learning test (VVLT) after six months of hearing aid use, compared to a control group of nonusers.

However, there are also other studies that were unable to demonstrate improved cognitive function after six to 12 months of hearing aid use. For example, Tesch - Romer [375] was not able to find significant changes in executive function and memory after six months of hearing aid use by those with a mild to moderate hearing loss. They attributed the lack of changes to subjects not being randomly assigned and

six months of hearing aid use being too short to cause a significant change. In another study, Van Hooren et al. [159] evaluated cognitive function in terms of processing speed, reasoning, memory, knowledge, and verbal fluency after 12 months of hearing aid use. No improvement was observed, compared to a control group of non-hearing aid users. Due to the small sample sizes, the findings in these studies should be interpreted with some caution.

Clearly the results of this investigation show that the study was under-powered as only relatively large effect sizes could be detected in the analysis. However, it is important to note that this is a feasibility trial, meant to primarily test our study protocol and gather information needed to plan a trial large enough to detect a clinically meaningful effect [376, 377]. Also, the neuropsychology battery (i.e. SUCCAB) used for both studies focused on visual based tasks as opposed to verbal tasks and this may also be a limitation in this study.

Given this limitation, the magnitude of the effects reported here should not be interpreted as would be the case for a fully powered trial [350]. It is however interesting to note the significant correlation between Incongruent Stroop cognitive performance and hearing loss at baseline, even when age was controlled. This may imply that tests of executive cognitive ability could be an important addition to rehabilitative assessment and tasks assessing selective attention. This finding may also suggest that management of hearing loss can improve the life conditions of adults perhaps reducing the burden associated with dementia. This is consistent with existing studies suggesting the importance of considering how cognitive function may impact the selection of hearing aid parameters [378] and the success of intervention [175].

7.1.2 Hypothesis 2: In adults with SNHL, hearing aids in combination with face-to-face auditory training will be more effective for improving depression and social interaction than face-to-face auditory training on its own.

The Crossover Study also examined the efficacy of the simultaneous use of hearing aids and auditory training for improving depressive symptoms and the results demonstrated that auditory interventions can improve depressive symptoms. There was however no significant improvement in social interaction hence partial support for Hypothesis 2. In particular, it was found that after receiving auditory training for 3 months, and then wearing hearing aids while continuing with auditory training for an additional 3 months, the *Delayed HA* participants experienced a significant reduction in depression levels over the second 3 month period.

Having depression reduces quality of life, exacerbates cognitive and functional impairment, is associated with increased mortality [284] and can also result in problems such as morbidity and care problems. Epidemiological studies have shown that mood disorders cause worsening of pre-existing pathological conditions such as psychiatric abnormalities with the prevalence rates ranging from 1 to 16 percent [379, 380]. Therefore, improving the life conditions of adults with SNHL using auditory training with/without hearing aids may help such individuals return to an ordinary lifestyle. Previous studies have suggested that hearing aids not only reduce hearing handicap, but also reduce concomitant social isolation and depression [55] but evidence for this is limited [381].

A randomised controlled study reported an improvement in social engagement and a small reduction in symptoms of depression in a select group of new hearing aid users [161]. In this study however, there was no significant improvement in social interaction. This finding is consistent with previous research [172] with a subsample of the United Kingdom Biobank data set (n = 164,770) of United Kingdom adults, which failed to find a positive association between hearing aid use and social isolation.

Adults with SNHL suffer significantly both emotionally and socially [382]. According to research, depression and loneliness are known to be associated with poorer quality of life, wellbeing and general functioning capacity [383]. A longitudinal study by Pronk and colleagues (2013) investigated the link between baseline hearing status, depression and loneliness. A significant association was found between hearing loss and loneliness [384]. Research suggests that men are particularly affected by hearing loss and this impacts their relationship with family and friends. Men also tend to experience greater loneliness as they are often closely attached to their partner, whereas females rely on close friends as well. The problem of loneliness is therefore exacerbated when men have hearing loss [385].

A large study with 2461 participants and mean age of 65 years by Strawbridge and colleagues [268] showed that individuals who reported moderate or worse hearing loss were twice as likely to suffer from depression as those who did not report any hearing loss. The results also showed a decline in overall health, while moderate hearing loss was associated with a decline in mental health. The authors concluded that hearing loss decreases crucial social engagement and positive mental health. They also concluded that clinicians have an essential role in educating patients on the damaging effects of noise exposure.

In the Crossover Study, improvements in depressive symptoms as a result of hearing loss intervention were observed over the course of the study. For the MRI Study, no significant difference in depression was found for long-term hearing aid users and first-time hearing aid users, suggesting that the combined effect of auditory and hearing aids might have resulted in the improvements seen in the Crossover Study. Choi and colleagues [386] conducted a prospective study to track depression symptoms on 63 hearing aid and 50 cochlear implant users who were aged 50 years or older. The hearing aid participants were either new hearing aid users or previous hearing aid users who had used their hearing aids for less than an hour. Cochlear implant users received their implants for the first time and reported verbal communication as their primary form of communication. All participants received routine clinical care, during which the participants and their audiologists determined the appropriate hearing technology (hearing aid or cochlear implant). Participants' cognitive function was assessed using the 15-item Geriatric Depression Scale (GDS) before intervention (baseline), and at six and 12 months after intervention.

Results suggested a different treatment outcome pattern between cochlear implant and hearing aid participants. Statistical analyses also indicated that only the GDS scores at six months (not at 12 months) were significantly improved from the baseline for hearing aid users, whereas scores at both six and 12 months postintervention were significantly improved from the baseline for cochlear implant users. It is however unclear in this research whether participants received auditory training as part of their clinical services.

Other researchers conducted a prospective study to examine the effects of amplification and auditory training [387]. In this study, 125 participants were divided into six groups namely: new bilateral hearing aid users with one month of auditory training (unaided thresholds: moderate – severe); bilateral hearing aid users with auditory training (unaided thresholds: moderate – severe); unilateral hearing aid users

with auditory training; non-hearing aid users with no auditory training (unaided thresholds: mild – moderate); cochlear implant users with auditory training; and normal hearing participants with no auditory training. In this study, the Geriatric Depression Scale to assess depression and mental function. Results suggested that auditory training and active learning could promote long-term positive effects for mental functions.

7.1.3 Other Supplementary Research Questions

In addition to these two hypotheses which are solely based on the primary aims in Section 3.2, the Crossover Study investigated other research questions. A summary of the key findings are discussed in the subsequent sections.

7.1.3.1 What cognitive measures are associated with hearing loss and speech perception at baseline?

The Crossover Study examined the association between cognitive measures, hearing loss and speech perception. First, the baseline findings for the Crossover Study suggested an association between most of the cognitive domains and speech perception, as there were several cognitive domains associated with SPT results. This is consistent with existing research suggesting that a number of cognitive functions are related to general speech understanding, including speed of information processing and lexical access, phonological processing skills, and working memory capacity [83, 121-123, 388]. These functions are important because they are related to the accessing of information from semantic long-term memory.

For instance, a high speed of lexical access allows efficient retrieval of information from the lexicon. Also, phonological processing skills are crucial in speech perception because they reflect the ability to detect, discriminate, and attend to speech sounds, and to maintain sounds in working memory. Several empirical studies have successfully established the link between cognitive abilities and speech recognition performance in hearing aid users [123, 201, 351]. Also, Lunner [123] found that scores for the reading span test and a rhyme judgment test, in which phonological processing speed was measured, correlated with the signal to noise ratios required to achieve 40% speech recognition using a Swedish version of the Hagerman test [389].

A review of studies on speech recognition and cognitive abilities concluded that hearing loss was the primary predictor of speech recognition performance, while individual cognitive ability emerged as the secondary factor [232]. Humes [390] also drew a similar conclusion suggesting that in addition to audibility, cognition emerged as a predictor of speech recognition performance in older adults with hearing impairment. Besser and colleagues [391] reviewed more than twenty recent studies examining the relationship between working memory measured using the reading span test and speech recognition performance in noise. A positive association between working memory capacity and speech recognition performance in both speech babble and steady-state noise was found across studies. Taken together, these three reviews indicate that working memory seems a promising predictor of speech recognition performance.

Second, a striking finding in the Crossover Study was the fact that hearing loss was associated with reduced performance in the executive function cognitive measure (i.e. Stroop incongruent task) at baseline. For this study, a computerized version of the Stroop task was used as a measure of executive function and selective attention - the coordination and regulation of cognitive performance [112]. According to research, the Incongruent Stroop task aims to cause "interference" by eliciting an automatic response that must be inhibited and there can be up to three control tasks and an "interference" task. These include reading colour words (i.e. red, green, blue, yellow) printed in black ink; naming the colour of a series of coloured bars; reading colour words printed in incongruous colours; and naming the colour of the ink of these words, ignoring what the word reads (interference task) [325].

Authors have suggested that in aging, a loss of inhibitory control means there is a greater intrusion of irrelevant information into working memory, thereby impairing performance. This effect may be exacerbated by hearing loss. Inhibition is the ability to inhibit behavioural responses that are dominant or automatic, when the need arises [114]. Impairment in these functions can be observed in patients with frontal lobe damage, who exhibit "dysexecutive syndrome" and whose skills in planning, organization, reasoning and/or decision making may be disrupted [115]. An age-related decline in performance on executive tasks has also been observed. For example, across an age range of 20-81 years, age-related cognitive decline was observed in updating and inhibition, and (non-significantly) in shifting [116].

Other processes that contribute to decline in executive function include decreased neurotransmitter function, decrease in horizontal dendrites or impaired regional efficiency of neural networks in various cortical regions [150, 325]. Brain studies confirm the evidence from cognitive trials of a deficiency in executive function with aging and consider executive behaviours as "frontal lobe functions". Neuropsychological evidence indicates that damage to frontal lobes can result in impaired ability to control and regulate behaviour [392]. The involvement of prefrontal cortex in executive control is well established. Other parts of the frontal lobes as well as other brain regions such as subcortical structures are known also to be relevant [113].

Within the brain, specific regions are thought to be associated with different modalities of executive function. For instance, the anterior cingulate cortex (ACC) is associated with error processing and conflict monitoring whereas the dorsolateral prefrontal cortex is involved with set maintenance [393]. According to Pardo and colleagues [394], the ACC was associated with Incongruent Stroop performance in a positron emission tomography (PET) study which looked at regional cerebral blood flow. Also in an event related potential (ERP) study of Incongruent Stroop performance, the ACC was activated with a later activation of the left temporo-parietal cortex [395]. A functional MRI investigation of older people have also demonstrated increased activity in the ACC in Stroop Incongruent blocks compared with younger participants [396]. It may be that the auditory cortex is also associated with executive functioning in the case of hearing loss, but further study is needed in order to verify this.

There are still a few unanswered questions such as whether the age-related decline observed in the Incongruent Stroop task is due to general slowing or to an inhibition effect that is additional to this, such as hearing loss. For instance, in a meta-analysis of twenty Stroop studies, it was determined that the decline in interference effect was due to general cognitive slowing [397]. Another study which compared young and old adults, and patients with Alzheimer's disease, observed that Stroop interference increased in old age and with Alzheimer's disease, with greater deterioration in Alzheimer's patients [398]. There are other points to consider when assessing incongruent Stroop task performance: the interference effect can be reduced with practice in young and old adults [399] age effects on Stroop are associated with age-related changes in colour perception [400]; poorer Stroop performance is found in those with less education [401]; and finally, the decline in Stroop performance is greater in men than in women [402]. Further, although age-related decline has been observed in other executive function tests such as the Wisconsin Card Sorting Test and the Tower of

London test [117], there is lack of clarity as to what, exactly, executive function tasks measure and future neuroimaging studies are needed to clarify this research question and to determine the role that hearing loss plays in terms of decline in executive function.

7.1.3.2 Is the relationship between speech perception and depression mediated by particular hearing problems?

Structural equation model of standardised path coefficients for the relationship between hearing loss and depressive symptoms suggested that there was a significant relationship between speech perception and depression. This relationship was mediated by hearing problems, in particular ease of communication and the effects of background noise. This implies that participants with speech problems experienced greater hearing problems, and this was associated with higher levels of depressive symptoms.

7.1.3.3 How does hearing aid use affect speech perception?

Baseline findings suggested that hearing loss in the better ear affected speech perception negatively. SPTs were performed immediately after hearing aid fitting and again at the end of 3 months of auditory training and hearing aid usage. The results showed no significant change for Immediate HA and Delayed HA participants. However, when SPT results were compared before (without hearing aids) and after 3 months of auditory training and hearing aids) and after 3 months of auditory training and hearing aid usage (with hearing aids), there was significant improvement for Immediate HA and nearly a significant improvement for Delayed HA. This suggests an improvement in unaided speech perception.

7.1.3.4 How does hearing aid use affect hearing satisfaction?

The Crossover Study assessed hearing aid benefit using the APHAB, demonstrating that hearing aids increased the audibility of sounds for adults with mild/moderate SNHL for both participant groups. The results showed a significant reduction in all problems of the APHAB measure for Immediate HA participants except in the case of AV which increased. However, for the Delayed HA participants, there was a significant reduction only for the RV scale when hearing aids were worn, and a significant increase in AV as expected.

Although hearing aids work satisfactorily in quiet conditions, listening in noise remains problematic and cognitively taxing. One may think that the benefit of amplification will encourage participation in social events but this may not always be the case. One of the potential problems of hearing aid fitting is caused by hyperacusis, or increased sensitivity to loud sounds [347]. Although amplification is necessary to make soft sounds audible, one may argue that people with hyperacusis may not be able to tolerate the louder sounds that are amplified, albeit by a smaller amount. It may also be that hearing aids do discourage participation in social events by amplifying aversive background noise that is typical at social venues such as clubs, cafes and restaurants.

Existing research has suggested that speech perception performance should not be the only way to measure hearing aid benefit [128, 129, 403-405]. At present, other ways to measure the outcome of hearing aid fitting include real ear measurement or functional gain measurement, speech audiometry, and self-report instruments. But a good outcome using these clinical tests may not necessarily correspond to a satisfactory outcome in daily life [406].

Individual differences in cognitive capacity are shown to be linked to differences in unaided and aided speech recognition performance in noise, success with hearing aid signal processing, and hearing aid benefit [123, 378, 407-412]. According to studies, a well-fitted hearing aid with appropriate amplification and signal processing enhances audibility and may make listening less onerous if the demand on top-down processing is reduced. While aided speech recognition performance has been commonly used to quantify hearing aid outcome, other measures, such as changes in listening effort, have been used in the literature to show the cognitive benefits of hearing aid amplification [129, 408, 409, 413]. Gatehouse and Gordon [408] evaluated the benefit of 15 hearing aids using word and sentence identification tests. Both accuracy (percentage correct) and response time (to identify target words) measures were used. In test conditions where no benefit of aided performance over unaided performance was shown using the accuracy measure, faster response time was obtained in the aided condition.

However, in test conditions where an amplification benefit as based on the accuracy measure was shown, a benefit based on the reaction time measure was also shown and was substantially greater in relative terms than that based on the accuracy measure. The authors concluded that the response time measure was sensitive and effective in demonstrating benefit, which could hardly be shown in the traditional accuracy measure. They argued that hearing loss demanded extra perceptual effort to decode a given speech signal and, consequently, a prolonged response time.

7.1.3.5 How do auditory training and hearing aids affect speech tracking over time?

In the Crossover Study, there was no evidence to suggest that it was easier to learn speech tracking when participants use hearing aids than when they did not. There were however similarities for both Immediate HA and Delayed HA during the first 3 months of the auditory training program. This could imply that, in the first 3 months, all study participants were learning how to do auditory training rather than learning to improve their understanding of speech. Alternatively, it could be that it was learning by the researcher/trainer about how to correct mistakes in the most efficient way during auditory training, which resulted in improved tracking rates for both groups. This result will require further investigation. Summary of

7.2 Key Findings of MRI Study

This section will evaluate the results and limitations of the MRI Study, and provide some suggestions for future directions.

7.2.1 H1a: Long-term hearing aid users will have better cognition, speech perception and social interaction at baseline than first-time hearing aid users when the level of hearing loss, age and gender are controlled

The MRI Study compared the cognition, SPT and social interaction of first-time and long-term hearing aid users. The proposed hypothesis was that long-term hearing aid users will have better cognition, SPT and social interaction at baseline than firsttime hearing aid users. No significant differences were found when age, gender and hearing loss were controlled hence no support for H1a.

7.2.2 H1b: Long-term hearing aid users will have less depression, anxiety and stress than first-time hearing aid users when the level of hearing loss, age and gender are controlled

The MRI Study further compared depression, anxiety and stress of first-time and long-term hearing aid users. The proposed hypothesis was that long-term hearing aid users will have less depressive symptoms, anxiety and stress at baseline than first-time hearing aid users when levels of hearing loss, age and gender were controlled. No significant differences were found at baseline hence no support for H1b. 7.2.3 H1c: Long-term hearing aid users will have fewer hearing problems as measured by the APHAB (ease of communication, reverberation of sound and the effects of background noise) but worse aversiveness of sound than first-time hearing aid users at baseline when the level of hearing loss, age and gender are controlled

The MRI Study compared the APHAB measures of first-time and long-term hearing aid users. The proposed hypothesis was that long-term hearing aid users will have fewer communication problems but worse aversiveness to sound than first-time hearing aid users. After controlling for age, gender and level of hearing loss, no significant difference was found between the two groups at baseline. This result is contrary to expectation, providing no support for H1c.

Overall, the small sample size and the relatively low level of hearing loss exhibited by the first-time hearing aid users suggested that the MRI study was underpowered. The breadth of this pilot trial was severely constrained by limited funding and technical challenges hence the study could not report on all MRI baseline data and this is a major limitation of the study. It is however important to note that the initial analysis of the MRI results reported for the first SNHL participant showed very exciting results, as significant differences were detected for all the experimental conditions. This result suggests that the pilot novel MRI experiment planned for future studies is feasible and larger studies investigating the effects of hearing aid use on changes in brain function and structure will be needed to address this limitation.

7.3 The Neurocognitive Effects of Hearing Aids on Adults with Hearing Loss

Most rehabilitation programs for adults with hearing loss involve the use of amplification. The purpose of hearing aid amplification is to improve a person's access to sound and depending on the degree and configuration of the individual's hearing loss, the hearing aid is tasked with increasing sound levels at different frequency regions to ensure that incoming speech frequencies are reaching the ear at sufficient levels to compensate for the individual's hearing loss [179]. However, there is little evidence about how the brain processes amplified sound or how this contributes to perception and the successful use of hearing aid amplification.

The auditory cortex is the first cortical waystation for acoustic information processing in the brain [249]. Functional MRI studies examining brain activity, while

hearing impaired adult listened to sentences that varied in their grammatical complexity, have suggested that listeners with poorer hearing showed a smaller degree of change in their neural activity in brain regions, including the auditory cortex, for the more complex sentences relative to the less complex sentences [242]. The authors of this research concluded that presence of a significant interaction between hearing ability and linguistic difficulty in the functional MRI data may suggest that listeners' hearing ability does not only impact their sensory processing of auditory information, but also impacts higher level linguistic processes.

In the MRI Study, preliminary results from the MRI experiment were able to detect significant differences in the auditory cortex in terms of how the brain responded to the different stimuli presented. Given the relationship between hearing ability and the differences in brain activity seen in the auditory cortex, one is bound to ask whether improving hearing ability through the use of hearing aids might help in preserving either cortical health and/or cognitive ability. Although the relationship between hearing loss and cognitive ability is probably at least partly rooted in the brain, it is only recently that cognitive neuroscientists have begun to explicitly examine the neurobiological bases for these effects.

As mentioned earlier on in this thesis, there are hypothesized theories to explain the relationship between hearing loss and cognitive impairment and decline. There is the "cascade hypothesis" which relates to sensory deprivation. This hypothesis suggests that cognition declines after prolonged sensory deprivation, either due to hearing loss or neural atrophy. The "cascade hypothesis" again suggests that hearing loss over an extended period of time affects cognitive functioning as a result of sensory underload [414]. In theory therefore, cognitive function should be improved by the use of hearing aids as sensory input is restored [414]. A study by Lin and colleagues suggested that hearing loss was independently linked to accelerated volume decline in the temporal auditory region [48]. The authors proposed that the degraded hearing signals resulted in a loss of volume in the auditory processing centre in the brain.

Another hypothesis also known as "cognitive overload" suggested that hearing impairment required additional brain resources to understand sound input [152], leaving fewer resources for demanding cognitive processes like executive function and memory due to this reallocation. Also, McCoy and colleagues [126] investigated cognitive overload by testing the recollection of words in normal hearing and mild to moderate hearing loss older participants. Participants who had a hearing loss recalled significantly fewer overall words, even though it was established that they correctly identified all words. The authors concluded that hearing loss participants required more effort to successfully perceive sound, and that this extra effort reduced the processing resources available to store speech signals in memory.

The last hypothesis known as "Common Cause hypothesis" suggested that cognitive and sensory decline were both age related and therefore shared a 'common cause', which could be explained by degeneration of the central nervous system with age. In a prospective study by Tun and colleagues [415], adults with a mean age of 70 years were randomly selected from a Gerontological and Geriatric Population Study in Gothenburg and the Prospective Population Study of Women. According to the authors none of these adults presented with dementia and all underwent hearing screening and computerised tomography scans of the brain. The authors found that general cortical atrophy was related to high frequency hearing loss in the hearing system and concluded that both the cognitive and sensory systems were affected by ageing as declines in both systems are seen. The final hypothesis suggested that poor functioning in tests of cognition was not due to poor cognitive ability but rather the impairment of information received by the brain. In a study by Valentijn and colleagues, participants were mentally able to complete the cognitive task but couldn't hear the instruction clearly and therefore made mistakes which reduced their testing scores [224]. This suggests that the "Common Cause" hypothesis relates to the method of cognitive testing itself rather than a physical age-related mechanism.

Both the Crossover and MRI Study results suggested that hearing loss intervention did not improve cognition for first-time and long-term hearing aid users, and it is proposed that the SUCCAB neurocognitive battery used in both instances was not sensitive enough to detect significant changes.

With respect to the effect of hearing aids on cognitive function, the results of studies conducted to date have been mixed [159, 161] and large-scale, long-term, prospective longitudinal studies may be required to clarify the potential benefit of hearing aids for maintaining cognitive function. There is recent interest in determining if measures of brain activity might be of use to clinicians, during hearing aid selection

and fitting, as well as to the engineers who are designing the instruments [179]. The question to be addressed according to Tremblay and colleagues is whether it is possible to use brain measures to determine a person's neural detection of amplified sound, and whether brain measures provide information about how the brain is making use of this amplified sound.

In summary, it is possible to use brain measures to determine a person's neural detection of amplified sound, and brain measures could provide information about the use of this amplified signal sound. The use of brain measures to quantify and model neural mechanism associated with the perception of amplified sound can be complex and sometimes counter-intuitive [179]. A striking finding from a recent large-scale population study has revealed a strong statistical connection between the degree of hearing loss and all-cause dementia [5]. Future research is needed to study the effects of hearing aid use intervention on neurocognitive and psychosocial functioning in individuals with SNHL. Hopefully, the novel speech processing task for the MRI experiment included in Study 2 will be able to better clarify the relationships between altered brain structure/function in adults with SNHL.

Finally the MRI Study compared the cognition, SPT, social interaction, mood and hearing problems of first-time and long-term hearing aid users. No significant differences were found when age, gender and hearing loss were controlled. The small sample size and the relatively low level of hearing loss exhibited by the first-time hearing aid users suggest that this study was under-powered. However, experimental MRI results for a single participant show promise for this approach in a larger study investigating the effects of hearing aid use on changes in brain function and structure.

7.4 Future Research - Recognizing Hearing Loss as a Risk Factor for Dementia

Recognition of hearing loss as a risk factor for dementia is relatively new, and results of cohort studies [9, 163, 220, 221, 416-419] have suggested that even mild levels of hearing loss increase the long-term risk of cognitive decline and dementia in individuals who are cognitively intact but hearing impaired at baseline. Existing research has suggested that depression is a risk factor for dementia [420].

The Crossover Study findings suggested that hearing aid use significantly reduced depressive symptoms. This is consistent with previous studies suggesting that Page **166** of **309**

hearing aids reduced depression [21, 169]. Studies have shown that depression is associated with hearing impairment [348]; it is both a risk factor and a prodromal of Alzheimer's disease and is a common occurrence in all types of dementias as well as in MCI [349]. The growing prevalence of dementia and devastating impact on affected individuals has made its prevention and treatment a public health priority.

According to World Alzheimer's 2009 report, dementia is a syndrome due to disease of the brain, usually chronic, and is characterised by a progressive, global deterioration in intellect including memory, learning, orientation, language, comprehension and judgement. Although dementia mainly affects older adults, between 2% and 10% of all cases start before the age of 65 years. Furthermore this prevalence will double with every five year increment in age. By 2050, more than 100 million people or nearly 1 in 85 persons will be affected worldwide. Interventions that could significantly delay the onset of the disease or slow its progression are being actively pursued; however, no disease modifying treatment is currently available. While partially effective treatments are available for most core symptoms of dementia, these treatments can improve a particular symptom but do not alter the progressive course of the disease [421].

With the ageing population and rising prevalence of dementia, there is widespread interest in markers of early signs of dementia and tests to identify which patients with mild cognitive impairment (MCI) will progress to dementia. MCI can be clinically defined as a condition in elderly individuals that is characterized by cognitive complaints typically related to memory, normal general cognitive abilities, impaired memory (relative to age-appropriate performance) on psychometric testing, and minimal or no impairment of activities of daily living [422]. The introduction of a national dementia strategy has led to greater emphasis on timely diagnosis and early intervention. New investigations have used cerebrospinal fluid (CSF) sampling to exclude inflammatory, infective, and malignancy related causes of dementia [423, 424]. A recent Cochrane review published in the year 2014, has determined the accuracy of these markers for detecting those patients with MCI who would convert to Alzheimer's disease dementia or other forms of dementia over time [425]. Whether these markers are

effective at predicting those MCI patients who will develop dementia, and, more importantly, whether they are practical is not yet known, putting their widespread use in doubt at present.

Sensory measures (such as vision and hearing), have generally been noted as a good predictor of higher levels of cognitive functioning especially in older age [95]. In the absence of any disease modifying treatment for dementia, various researchers have noted the important role sensorineural systems play in the diagnosis, and the treatment and management of several neurological disorders. In epidemiological studies, sensory deficits such as hearing loss, olfactory and visual disturbances have been linked with cognitive decline and the onset of dementia. This association between sensory impairment and the diagnosis of dementia although recognized for a long time has not been the focus of concerted research due to small numbers of underpowered and heterogeneous studies [60].

Currently, more than 90% of patients with Alzheimer's Dementia have some kind of hearing loss, and for patients with MCI, the relationship between hearing and cognition has not been fully assessed [426]. Since MCI is an intermediate state between normal cognitive ageing and dementia, early diagnosis of hearing impairment in such patients may offer an early opportunity to address this disease. Also, the high costs of healthcare for conditions such as dementia could also represent significant downstream costs potentially flowing from untreated hearing loss.

7.5 Summary and Conclusion

This research has confirmed that there is a strong negative relationship between hearing loss and speech perception. It has also suggested that for first-time hearing aid users, auditory training reduces depressive symptoms and communication problems. This finding suggests that early auditory rehabilitation is important in older adults as this may lead to extended benefits beyond hearing ability, including reduced depression [427-429].

Existing research suggests that auditory rehabilitation could counteract negative neuroplasticity processes [263, 264, 267]. In this study, hearing loss was found to be associated with reduced performance in executive function. Impairment in executive functions can be observed in patients with frontal lobe damage, who exhibit "dysexecutive syndrome" and whose skills in planning, organization, reasoning and/or Page **168** of **309**

decision making may be disrupted [115]. Therefore, the hearing system could be an important window for investigations into neurodegenerative disorders for older adults.

The finding that age is associated with cognition was also confirmed in this study [415, 430]. Recommendations are being made for further research to look into speech comprehension in complex conditions and meaningful-connection spoken language as this could potentially affect changes in perceptual, cognitive, and socioemotional processes [415]. In the present study, hearing aid use and auditory training over a 6 month period did not improve cognition or social interaction for both first-time and long-term hearing aid users, and this was an unexpected result. Other cognitive assessment batteries, such as the Montreal Cognitive Assessment (MoCA) have been able to demonstrate that auditory training for people with cochlear implants or hearing aids enables positive improvements in terms of social isolation, depression and cognitive performance.

The MoCA is a cognitive function screening test of various cognitive domains and research has shown it to have 90% sensitivity and 87% specificity for detecting mild cognitive impairment (MCI) [431]. Other research [164] did not give evidence that hearing aid benefit is critically associated with cognitive function in experienced hearing aid users. It may be that the SUCCAB test battery used for both Study 1 and Study 2 was not sufficiently sensitive to detect significant changes in cognition function or did not test the right modalities with regards to hearing loss, but this may be mere speculation. However, the question of whether hearing aid use results in a reduction in rates of cognitive decline measured longitudinally still remains unanswered [172].

Preliminary results from an MRI experiment suggested significant differences in the auditory cortex in terms of how the brain responds to different auditory and visual stimuli presented. This provides the motivation to design a randomized hearing loss intervention and a longer neuroimaging study with cognitive outcomes measured at baseline as well as after at least 6 months hearing aid use. A full scale prospective study has therefore been designed to learn if there is any direct causal relationship between hearing aid use and better executive function cognition, and to address important questions regarding the relationship between hearing loss and dementia. The paper describing this design is titled "The neural, cognitive and psychosocial effects of hearing aid use in older adults with post-lingual sensorineural hearing loss: A protocol for a prospective cohort study", and has been published in the *Journal of Medical Internet and Research, Research Protocols.* This paper appears in the Appendix.

This larger study will establish whether hearing aid interventions can arrest declines in cognition or slow down the onset of dementia in a randomized controlled study, with cognitive outcomes measured at baseline and after at least 6 months of hearing aid use. In addition to the SUCCAB measures, more sensitive brain function and brain structure measures will be acquired using MRI scanning.

8 References

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9 Appendices

9.1 Appendix A: Study 1 Research Protocol Paper

Investigating the Impact of Hearing Aid Use and Auditory Training on Cognition, Depressive Symptoms, and Social Interaction in Adults with Hearing Loss: the Study Protocol of a Crossover Trial

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Abstract

Background: Sensorineural hearing loss is the most common sensory deficit among older adults. Some of the psychosocial consequences of this condition include difficulty in understanding speech, depression and social isolation. Studies have shown that older adults with hearing loss show some age-related cognitive decline. Hearing aids have been proven as successful interventions to alleviate sensorineural hearing loss. In addition to hearing aid use, the positive effects of auditory training - formal listening activities designed to optimize speech perception, are now being documented among adults with hearing loss who use hearing aids, especially new hearing aid users. Auditory training has also been shown to produce prolonged cognitive performance improvements. However, there is still little evidence to support the benefits of simultaneous hearing aid use and individualized face-to-face auditory training on cognitive performance in adults with hearing loss.

Objective: This study will investigate whether using hearing aids for the first time will improve the impact of individualized face-to-face auditory training on cognition, depression and social interaction for adults with sensorineural hearing loss. The rationale for this study is based on the hypothesis that, in adults with sensorineural hearing loss, using hearing aids for the first time, in combination with individualized face-to-face auditory training will be more effective for improving cognition, depressive symptoms and social interaction than auditory training on its own.

Methods: This is a crossover trial targeting forty (40) men and women between 50 and 90 years with either mild or moderate symmetric sensorineural hearing loss. Consented, willing participants will be recruited from either an independent living accommodation or via a community database to undergo a six month intensive face-to-face auditory training program (active control). Participants will be assigned in random order to receive hearing aid (intervention) for either the first three or last three months of the six month auditory training program. Each participant will be tested at baseline, three and six months using a neuropsychological battery of computer based cognitive assessments, together with a depression symptom instrument and a social interaction measure. The primary outcome will be cognitive performance in regard to spatial working memory. Secondary outcome measures include other cognition performance measures, depressive symptoms, social interaction and hearing satisfaction.

Results: This investigation is funded by the Australian Research Council and Blamey and Saunders Hearing Pty Ltd under the Industry Transformation Training Centre Scheme (ARC Project No. IC140100023), and it attained ethics approval on July 22, 2016 (Swinburne's Human Research Ethics Committee protocol number SHR Project 2016/159).

Conclusions: Results from the study will inform strategies for aural rehabilitation, hearing aid delivery and future hearing loss intervention trials.

Trial Registration: This trial is retrospectively registered at ClinicalTrials.gov, on April 13, 2017, identifier: NCT03112850.

Keywords: sensorineural hearing loss; hearing aids; auditory training; crossover design.

Introduction

Background and Rationale

Hearing loss is a common experience for older adults and is one of the leading causes of non-fatal disease burden for Australians aged 65 years and older (Mathers et al., 2001, Kiely et al., 2012). Sensorineural hearing loss or presbycusis is the most prevalent hearing related chronic condition affecting this population, however, it is often under-detected and under-treated. This type of hearing loss cannot be medically or surgically treated (Lin, 2012, Cacciatore et al., 1999, Chien and Lin, 2012, Acar et al., 2011). The number of adults who suffer from sensorineural hearing loss worldwide is likely to increase rapidly as the population ages (Lin, 2011).

Recent studies have reported that hearing loss among older adults is strongly and independently associated with accelerated cognitive decline (Wahl et al., 2013, Lin et al., 2013, Lin et al., 2011b, Lin et al., 2011a, Kilimann et al., 2015, Lin and Albert, 2014). Epidemiologic and longitudinal studies have demonstrated that older people aged between 70 and 79 with hearing impairment who live in the community have a 24% increased risk of a decline in cognitive function, and may experience a 30% to 40% higher rate of cognitive decline over a 6 year period than those without hearing loss (Lin et al., 2013, Valentijn et al., 2005, Tay et al., 2006). The proposed theories to explain the above association relate to the effects of hearing loss on cognitive load and cognition reserve, and the effects of hearing impairment on brain structure and shared pathologic aetiology, social isolation and depressive symptoms (Lin and Albert, 2014). Social isolation and communication impairments caused by hearing loss are known to lead to loneliness and depression in older adults (Strawbridge et al., 2000, Weinstein and Ventry, 1982), often resulting in a negative perception of one's own health and a decline in daily activities, with associated declines in cognitive performance.

In aural rehabilitation, hearing aid use and auditory training strategies contribute to improving auditory abilities. The basic function of hearing aids is acoustic amplification of sound signals with the aim of restoring the audibility of sounds, thus helping to improve speech perception (Van Hooren et al., 2005). Studies have examined the effects of hearing aid use by older adults on a broad range of cognitive functions, such as information processing speed, memory, and verbal fluency. Preliminary research

evidence has suggested that hearing aids may improve the cognitive abilities, social, emotional, psychological, and physical well-being of people (Amieva et al., 2015, Mulrow et al., 1990, Meister et al., 2015, Van Hooren et al., 2005). Some studies reporting the cognitive and psychological benefits of using hearing aids in elderly people have shown that the effects of hearing aid use are most distinctive in the early periods of use (Acar et al., 2011). Despite the high prevalence of hearing loss in older adults, and the consequences for health outcomes, people are generally slow to acquire hearing aids (Forum on Aging, 2014). Less than 25% of people who would benefit from hearing aids actually own them (Blamey et al., 2015). Existing research in this area, attempting to describe the effects of hearing aids on cognition, often assessed global mental status rather than cognitive performance and often examined only a single measure of hearing (Acar et al., 2011, Amieva et al., 2015, Deal et al., 2015), thus limiting the insights gained. These studies also lack data on the duration of hearing impairment, and loosely define hearing aid use as the self-reported use of a hearing aid in either or both ears, thus making it unclear how hearing loss may affect performance on measures of cognition.

Auditory training is the use of instruction, drill, or practice, designed to increase the amount of information that hearing contributes to a person's total perception (Blamey and Alcantara, 1994). For example, a person with a hearing-impairment who is fitted with a new hearing aid may benefit from instruction and practice in recognizing sounds through the aid. Research has shown that new hearing aid users show greater benefit from auditory training than experienced hearing aid users (Olson et al., 2013). Auditory training also shares processes in common with cognitive training for improving working memory, attention and communication. Studies have shown that auditory training can produce prolonged cognitive performance improvements (Sweetow and Sabes, 2006, Ferguson et al., 2014) and improve speech understanding (Stecker et al., 2006, Burk and Humes, 2008) Other studies have shown that the benefits of training for people with hearing loss in terms of improved speech understanding are best achieved if an integrated auditory-cognitive training approach is adopted (Ferguson and Henshaw, 2015).

Although the concept of auditory training is not new, its popularity has declined in recent years and only a small proportion of audiologists (fewer than 10%) offer auditory

training to patients with hearing impairment (Sweetow and Henderson Sabes, 2010). Also, limited auditory training effort has been directed towards adults with impaired hearing, and the focus of auditory training has historically been directed towards young children with profound or severe to profound hearing loss (Sweetow and Palmer, 2005, Humes et al., 2009).

Studies have investigated the effects of auditory training with laptops and computers, such as with the Listening and Communication Enhancement (LACE) software, on generalization to speech perception, self-report of communication difficulties and cognition (Sweetow and Sabes, 2006, Ferguson et al., 2014, Sweetow and Palmer, 2005). The results of these studies have often demonstrated the efficacy of auditory training, despite the computerized method of auditory training perhaps resulting in lower compliance with training protocols (Sweetow and Henderson Sabes, 2010). In addition, Saunders et al 2016 (Saunders et al., 2016) found that LACE training did not result in improved outcomes over a standard-care hearing aid intervention on its own. Furthermore, according to research studies (Henshaw and Ferguson, 2013, Boothroyd, 2010), there are still a large number of outstanding questions on the benefits of auditory training, such as which aspects of auditory training protocols contribute to learning, how auditory training generalizes to benefits in everyday communication, how individual characteristics interact with training outcomes to identify candidacy for auditory training, and the identification of outcome measures that are appropriate and sufficiently sensitive.

Research has shown that hearing aid devices alone do not always adequately compensate for sensory losses despite significant technological advances in digital technology (Olson, 2015). Therefore, the focus of intervention will consider face-to-face auditory training in conjunction with a hearing aid device while the comparator (control) group will consider individualized face-to-face auditory training on its own.

Study Objective

Extending upon preliminary findings (Ferguson et al., 2014, Sweetow and Sabes, 2006, Henshaw and Ferguson, 2013), the objective of the current study is to investigate whether wearing hearing aids will improve the impact of individualized face-to-face

auditory training on cognition, depression and social interaction for adults with sensorineural hearing loss in a crossover intervention trial.

Study Hypotheses

The study is based on the following hypotheses

In adults with sensorineural hearing loss, hearing aids in combination with face-to-face auditory training will be more efficient for improving cognition than face-to-face auditory training on its own.

In adults with sensorineural hearing loss, hearing aids in combination with face-to-face auditory training will be more efficient for improving depression and social interaction than face-to-face auditory training on its own.

Methods

Trial Design

This study has a randomised crossover trial design. All participants will undergo an individualised face-to-face auditory training program for a period of 6 months, and will be randomly allocated to one of the following groups.

Participants who will be fitted with hearing aids only for the first 3 months of the auditory training program – Group A

Participants who will be fitted with hearing aids only for the last 3 months of the auditory training program – *Group B*

Participants will be tested at baseline, and at three and six months in terms of cognition, depressive symptoms, social interaction, and hearing satisfaction.

A crossover design is chosen in order to allow each participant to serve as their own control (Wellek and Blettner, 2012). Group A participants will have the option to withdraw from the study after 3 months if they decide to purchase hearing aids immediately. Similarly, Group B participants will also have the option of withdrawing from the study at any time. Since all participants will receive auditory training for the entire duration of the study to address their hearing loss, participants will benefit from the study even when the hearing aid intervention is not in place.

Study Setting

This study is set in Melbourne, Australia. The study will recruit men and women who are living independently - both in supported independent living accommodation and living independently in the community.

Eligibility Criteria

To be eligible to participate in the study, participants must satisfy the following criteria:

Be aged between 50 to 90 years

Have a good working knowledge of English

Have mild (26 to 40dB) or moderate (41 to 70 dB) symmetric sensorineural hearing loss with a pure-tone average (PTA) of threshold of 0.5 - 4 kHz in both ears

Never worn hearing aids previously

Willing to wear hearing aids for three months

Willing to undergo weekly auditory training for a period of six months.

Willing to provide written consent to participate in the study

Exclusion Criteria

Participants will be unable to participant in the study if they have any significant visual impairment that would prevent reading or performing computer based tasks requiring colour recognition. Additionally, study participants with severe or profound hearing loss will not be eligible to take part in the study. Finally, participants with suspected cognitive impairment (defined as a score less or equal to 24 on the MMSE) will be excluded.

Intervention

Fitting of hearing aids for Group A and Group B Participants

Participants will be loaned and fitted with two Blamey Saunders hearing aids known as the LOF (LOF is the current trade name used by the manufacturer for the model of hearing aid in this study. The name LOF, was derived from its original name, Liberty Open-Fit). The hearing aids will be fitted for participants according to the Blamey and Saunders protocol, and using the prescription procedures from the National Acoustics Laboratory's NAL-NL2 protocol for fitting hearing aids as a guide (Keidser et al., 2011). Explanation of the hearing aid usage, insertion of the aids and batteries along with a step-by-step guide on how to use the hearing aid will also be provided. To increase hearing aid compliance, support will be provided post fitting (after 1 month) to make sure that each participant is progressing with his/her hearing aid. Counselling and other compliance-improving policies (Brooks, 1979, Brooks, 1985, Brooks, 1989) will be provided when participants receive their new hearing aids and at their post fitting appointment. An automatic internet-based data logging function installed in the hearing aids will be used to assess hours of hearing aid use.

Auditory Training

Historically, auditory training has been provided in a face-to-face setting that centred on a range of auditory skills included detection, discrimination, identification, and comprehension. Training often incorporated both drill-like activities described as analytic therapy activities, and paragraph comprehension activities which were synthetic in nature. For both activities, the auditory skills that were trained used various stimuli such as syllabus, words, phrases, sentences, and continuous discourse (Olson, 2015).

All participants enrolled into the study will undergo weekly individualized face-to-face auditory training for a period of 6 months. Over the 6 month period, each participant will participate in two 12-week individualised speech tracking programs. Participants living in supported independent living accommodation will attend their auditory training sessions at their place of residence, once per week for the 6 month period. Similarly, for participants living independently in the community, they will attend their auditory training sessions once per week at Swinburne University of Technology. Each auditory training session will last for approximately 15 minutes.

The type of counselling intervention which will be provided to participants is called Continuous Discourse Speech Tracking (De Filippo and Scott, 1978). A key aspect of this approach is that the training will involve interaction (a vital component of real-life communication) between the researcher and the participants. In this process, the researcher will articulate a sentence or phrase in a novel/short story, and the task of the participant will be to repeat back verbatim the sentence or phrase. If the repetition is correct, the researcher will articulate the next phrase or sentence. If the repetition is incorrect, the researcher will repeat the phrase or sentence, or a portion of it, or may use other repair strategies, until the sentence or phrase is correctly repeated in its entirety. The procedure will be timed for 15 minutes and scored in number of words per minute (wpm) transmitted. Tracking rate will be calculated as the number of words correctly repeated divided by the time elapsed.

This program is adopted for this sample population because training materials could be tailored to the personal interests of participants. The materials chosen for the speech tracking program will consist of short stories which will be long enough to last for a full 12 week program. A new story will be started at the beginning of each 12 week program.

Outcome Measures

The primary outcome measure will be changes in cognitive performance as measured by the spatial working memory component of the Swinburne University Computerized Assessment Battery (SUCCAB). Reliability and validity assessment has demonstrated that the SUCCAB, especially the spatial working memory component of this battery, is sensitive to ageing and intervention, and correlates strongly with memory subsets in the WAIS-IV (Pipingas et al., 2010, Harris et al., 2012, Macpherson et al., 2012).

Secondary measures include the other SUCCAB cognition measures, social interaction measured using the Berken-Syme scale and depressive symptoms measured using the Geriatric Depression Scale (GDS). Hearing satisfaction (with or without hearing aids) will be measured using the Abbreviated Profile of Hearing Aid Benefit (APHAB) Inventory.

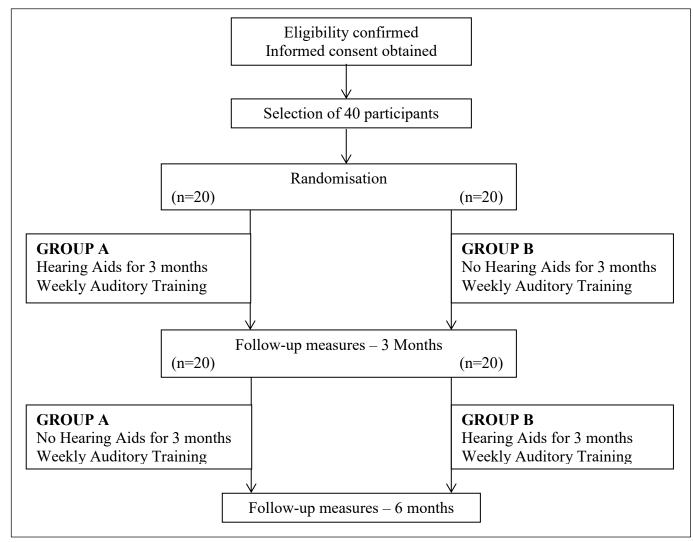
All outcomes will be measured at baseline, after 3 months and after 6 months (Table 1).

Table 1. SPIRIT diagram outlining schedule of enrolment, interventions and assessments for study.

Time points		Pre-screening	Baseline	Study	Study
rime points		telephone call	assessment T ₀	assessment T_1	assessment T ₂
			< 24 days	3 month	6 month
			following	follow-up	follow-up
			screening	ionow up	ionow up
Enrolment	Explain study	Х			
	Screen eligibility	X			
	criteria				
Outcome	SUCCAB testing		X	X	Х
measures					
	GDS		Х	X	X
	Berken-Syme		Х	Х	Х
	АРНАВ		Х	Х	Х
	Randomisation after		Х		
	completion of all				
	baseline assessment				
Interventions	Auditory training		<u>♦</u>		•
	Hearing Aid for Group				
	A participants		♦		
	Hearing Aid for Group				
	B participants			•	•

Participant Timeline

Participant pre-screening and assessment will take place at information sessions which will be held at several independent living aged care facilities located in Melbourne and at Swinburne University of Technology. Independent living aged care facilities with existing relationships with Swinburne University of Technology will be chosen. Participants attending information sessions at Swinburne University will be individuals in the community who have expressed interest in assisting with research projects run by the University, and therefore have provided their contact information to be stored in Swinburne's Centre for Human Psychopharmacology (CHP) database. After providing informed consent, eligible participants will be randomized into two equal groups (A and B) for the study described in Figure 1.



Sample Size

Allowing for 2.5% significance, 80% power and a moderate effect size (f=0.25), G-Power 3.1.9.2 indicated that a repeated measures mixed effects design with two repeated measures required a total sample size of 34 participants, split evenly between the two groups. This allows for the comparison of changes from baseline to 3 and 6 months for the two groups. Except for participants from Swinburne's CHP database who will need to travel to attend their auditory training sessions at Swinburne University, all other participants will attend their appointments at their facilities. As a result, only a 10% allowance was made for attrition resulting in an overall sample size of 40.

Recruitment

Aged care facility managers will be contacted by telephone to explain the study. If an aged care facility shows interest in the study, researchers will visit the facility to provide the facility manager with more detailed written and oral information. If the facility manager consents for their facility to participate in the study, the study will be advertised at the facility and promotional materials will be distributed to all the residents inviting them to an information session. Participants from the CHP database will be contacted by the researchers either by telephone or email to explain the study, and participants who express interest will be invited to attend an information session.

At the information session, researchers will explain the purpose and significance of the study. At the same time, a pre-selection screening will be conducted to identify participants who are willing to wear hearing aids and undergo auditory training to address their hearing loss. Selected participants will be sent a Participant Information and Consent Form package that includes detailed information on the study procedure, a consent form and a return pre-paid envelope. Once written consent is received, participants will be invited to complete baseline measures before enrolment into the study. Recruitment will commence in December 2016.

Assignment of Interventions

Allocation: Groups will be matched in terms of the degree of hearing loss (mild or moderate) with one member from each matched pair randomly assigned to *Group A* and

the other member of each matched pair assigned to *Group B*. Allocation will be performed using a system of envelopes prepared and opened by the researcher at the time of recruitment.

Blinding: Given the nature of the intervention, this study will not be blinded as both investigators and participants will know who is wearing hearing aids in each 3 month period.

Measures

Screening

All enrolled participants will not be cognitively impaired and will be screened for adequate cognitive functioning using the Mini Mental State Examination (MMSE). Participants scoring 24 or lower on the MMSE will not be eligible for participation.

Swinburne University Computerised Cognitive Assessment Battery (SUCCAB)

The SUCCAB is a validated computer based cognitive battery consisting of eight measures that were developed, based on cognitive and neuroimaging literature, to focus on cognitive domains that were most likely to decline with increasing age (Pipingas et al., 2010). Studies utilizing this battery have shown cognitive changes sensitive to interventions in 5-16 weeks (Macpherson et al., 2012, Pipingas et al., 2008). The SUCCAB battery uses a simple 5 button interface and has been validated in other studies involving the elderly (Simpson et al., 2012, Stough et al., 2012). The eight measures of cognitive tests assessed by the SUCCAB consist of Simple and Choice Reaction Times, Immediate and Delayed Recognition, Congruent and Incongruent Stroop colour-words, Spatial Working Memory and Contextual Memory.

A performance score for each task will be calculated as the ratio of accuracy and reaction time. This approach takes into account variations in accuracy and response time due to speed versus accuracy trade-offs in performance.

Hearing Assessments

Participants will undergo the following hearing assessments:

Otoscopy and tympanometry: Following otoscopy, all participants will undergo tympanometry and acoustic reflex testing to assess the status of the middle ear.

Pure tone audiometry in each ear: To understand the degree of hearing impairment, and classify participants according to the type of hearing loss, hearing ability will be measured at threshold frequencies 0.5, 1, 2, 3, 4 kHz in both ears. The choice of frequency to be tested corresponds to the amplification range of most modern hearing aids, and is consistent with capturing sensitivity at frequencies affected by sensorineural hearing loss and noise induced damage. Only participants with either mild or moderate symmetric sensorineural hearing loss will be included in the study.

Blamey Saunders Speech Perception Test (SPT): An online SPT will be used in addition to the standard audiogram for the purpose of measuring hearing loss. The SPT is a monosyllabic word test used to characterise the form and degree of hearing loss (Blamey et al., 2015). There will be five (5) SPT evaluations altogether: The SPT will be performed without hearing aids at baseline, after 3 months and then at 6 months for all participants included in the trial. It will also be performed with hearing aids immediately after participants are fitted with hearing aids for the first time and at the end of 3 months of auditory training while wearing a hearing aid.

Paper-based Questionnaire

Participants will complete a paper-based questionnaire which will be structured in the following sections:

Demographics: Information on a variety of demographic variables will be collected in order to describe the characteristics of the study sample.

The Geriatric Depression Scale (GDS): The GDS is a self-rating screening scale for measuring levels of depressive symptoms in elderly population (Yesavage et al., 1983). The short version of the GDS will be used. (Burke et al., 1991). The GDS has been found to be a reliable and valid measure of depressive symptoms (Yesavage and Sheikh, 1986), and to be highly correlated with other measures of such symptoms. The GDS was designed for older adults. Items are scored dichotomously (respondents answer "Yes" or "Not" to five items). Items assess non-somatic aspects of depression, thus allowing for discrimination between respondents with depressive symptom and those with medical problems. A cut-off GDS score of 7 will be used with a score greater than 7 indicating the presence of depression. Participants will answer the GDS at baseline, after 3 months and then at 6 months.

Social Interaction Measure: The Berkman-Syme Social Network Index (Berkman and Syme, 1979) will be used to assess participants' social interaction and connections with families and friends. Participants will answer the Berkman-Syme Social Network Index at baseline, after 3 months and then at 6 months.

The Abbreviated Profile of Hearing Aid Benefit (APHAB): The APHAB (Cox and Alexander, 1995) is a self-assessment inventory which will be answered by each participant in order to assess hearing satisfaction (with or without hearing aids). Participants will answer the APHAB at baseline, after 3 months and after 6 months. Four scales of the APHAB will be assessed namely:

Ease of communication

Effects of background noise

Effects of reverberation, such as listening to sounds across a large room

Aversiveness, which will look at uncomfortable loudness of background sounds such as traffic and alarm bells.

Statistical Analysis

Baseline comparison of the two groups in terms of demographics, cognition, depression, social interaction, hearing loss and hearing satisfaction using appropriate chi-square tests, t-tests and non-parametric Mann-Whitney tests.

Comparison of the two groups in terms of changes in cognition, depression, social interaction from baseline to 3 months and 6 months, using a per protocol approach for the crossover analysis (Wellek and Blettner, 2012) and an intention-to-treat multi-level models analysis (Gupta, 2011). These methods will be used to estimate any carry-over effects (van Velzen et al., 2008).

Analysis of speech perception test results with and without hearing aids as a measure of the efficacy of hearing aids and auditory training with and without hearing aids using multi-level models and again allowing for carry-over effects.

Analysis of the speech tracking rates from the two 12-week programs of speech tracking using a learning model as described by Blamey and Alcantara (Blamey and Alcantara, 1994). This analysis will yield learning and forgetting rates with and without hearing Page **222** of **309**

aids. These learning and forgetting rates are valid measures of cognitive processes that are likely to be affected by the use of hearing aids. This data will also be analysed using multi-level models again allowing for carry-over effects.

Analysis of the aided and unaided scores from the Abbreviated Profile of Hearing Aid Benefit (APHAB) will be used to assess how benefit of hearing aids differed between groups, and over degree of hearing impairment (mild/moderate hearing loss).

Results

This study protocol was reviewed and approved by Swinburne's Human Research Ethics Committee (SUHREC) on 22 July 2016 protocol number SHR Project 2016/159. The trial is registered in ClinicalTrials.gov with identifier NCT03112850. This investigation is funded by the Australian Research Council and Blamey and Saunders Hearing Pty Ltd under the Industry Transformation Training Centre Scheme (ARC Project No. IC140100023).

The integrity of the trial, including data collection and monitoring, trial progress, adverse events and compliance with SUHREC reporting procedures will be overseen by the chief (DM) and associate investigators. No serious adverse events are anticipated. The study coordinator (JN) is responsible for communicating protocol changes to relevant stakeholders, including ClinicalTrials.gov registry.

Recruitment will commence in December 2016. Researchers will obtain written consent from all participants prior to participating in this trial.

Discussion

Chronic hearing loss can impact negatively on several domains of ageing such as social engagement, activity, vitality, physical mobility and cognitive health. Interventions that can significantly delay the onset of sensorineural hearing loss or slow its progression are being actively pursued; however, no disease modifying treatment is currently available. Understanding the best strategies for aural rehabilitation in older people in whom hearing could compensate for other physical or sensorial limitations may help mitigate cognitive decline.

A limitation of the study is that, it will recruit community dwelling adults who are not cognitively impaired; hence they may not show improvement in cognitive functioning Page 223 of 309

due to their high baseline scores. However, by focusing on community dwelling adults, this research will be able to examine the efficacy of programs aimed at minimising cognitive decline and reducing the rate of transfer to low and high care accommodation.

For the study intervention, auditory training is being used as comparator rather than hearing aids, which is popularly known as the main clinical management approach for addressing hearing loss. Although this may be a limitation, the concept of auditory training is not new for addressing hearing loss, as its inception can be traced back to the birth of audiology decades ago, when aural rehabilitation programs were first created for people who had suffered hearing loss (Bamford, 1981). Today, auditory training is a common intervention that is effective and is still used in routine practice for paediatric clients who receive rehabilitation services (Moore et al., 2009), and with clients who receive cochlear implants (Fu and Galvin III, 2011, Zhang et al., 2012). It is hoped that with individualized face-to-face auditory training as the comparator for this study, participants will be actively involved in the rehabilitation process leading to increased compliance in terms of hearing aid usage. Auditory training plus hearing aids will also allow us to know if hearing aids provide any added benefit to face-to-face auditory training.

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Authors' Contributions

JN conceived the study. DM, JN and PB designed the study. All authors were involved in drafting the protocol. All authors read and approved the final protocol.

Conflicts of Interest

Authors 1, 2, 4, and 5 declare that they have no competing interests. Author 3 (Peter Blamey) is co-owner of Blamey & Saunders Hearing Pty Ltd, the company that sells the

hearing aids used in this study. Blamey & Saunders is a profit for purpose company with an interest in improving benefits and outcomes for hearing aid users.

Abbreviations

SUCCAB: Swinburne University Computerised Cognitive Assessment Battery

SPT: Speech Perception Test

APHAB: Abbreviated Profile of Hearing Aid Benefit

MMSE: Mini-mental State Examination

PTA: Pure-tone average

GDS: Geriatric Depression Scale

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9.2 Appendix B: Study 2 Research Protocol Paper

Title: The neural, cognitive and psychosocial effects of hearing aid use in older adults with post-lingual sensorineural hearing loss: A protocol for a prospective cohort study

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Keywords: sensorineural hearing loss; hearing aids; cognition; psychosocial function; speech processing; fMRI

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Abstract

Background: Older adults with post-lingual sensorineural hearing loss (SNHL) have a poor prognosis that not only includes impaired auditory function, but also rapid cognitive decline, especially speech related cognition, in addition to psychosocial dysfunction and an increased risk of dementia. Consistent with this prognosis, individuals with SNHL exhibit global atrophic brain alteration, as well as altered neural function and regional brain organisation within the cortical substrates that underlie auditory and speech processing. Recent evidence suggests that use of hearing aids may ameliorate this prognosis.

Objective: To study the effects of a hearing aid use intervention on neurocognitive and psychosocial functioning in individuals with SNHL aged >=55 years.

Methods: All aspects of the study will be conducted at Swinburne University of Technology (Hawthorn, Australia). We will recruit two groups (n = 30 per group) of individuals with mild to moderate SNHL from both the community and audiology health clinics (Alison Hennessy Audiology, Chelsea Hearing Pty Ltd). These groups will include individuals who have: 1. Worn a hearing aid for at least 12 months, or; 2. Never worn a hearing aid. All participants will be asked to complete, at two time points (t) including baseline (t = 0) and at follow-up (t = 6 months), tests of hearing, psychosocial and cognitive function, and to attend a magnetic resonance imaging (MRI) session. The MRI session will include both structural and functional MRI (sMRI/fMRI) scans, the latter involving performance of a novel speech processing task.

Results: This investigation is funded by the Barbara Dicker Brain Sciences (BDBSF) Foundation Grants, the Australian Research Council, Alison Hennessy Audiology and Chelsea Hearing Pty Ltd under the Industry Transformation Training Centre Scheme (ARC Project No. IC140100023). Ethics approval was obtained on November 18, 2017 (Swinburne University Human Research Ethics Committee protocol number SHR Project 2017/266).

Recruitment began in December 2017 and will be completed by December 2020.

Conclusion: This is the first study to assess the effect hearing aid use has on neural, cognitive, and psychosocial factors in individuals with SNHL who have never used

hearing aids. Further, this study is expected to clarify the relationships between altered brain structure/function, psychosocial factors and cognition in response to hearing aid use.

Trial Registration: This trial is prospectively registered with the Australian New Zealand Clinical Trials Registry (ANZCTR) on December 11, 2017, ACTRN: ACTRN12617001616369.

Keywords: sensorineural hearing loss; hearing aids; cognition; psychosocial function; speech processing; fMRI

Introduction

Aging is associated with the onset of post-lingual sensorineural hearing loss (SNHL), which refers to hearing loss (or deafness) arising from pathology of either the inner ear organs or the vestibulocochlear nerve after language acquisition. SNHL accounts for $\sim 90\%$ of hearing loss cases in adults and is insidious, progressing from normal (pure tone average, PTA = 0.25 dB, to mild (PTA = 26.40 dB), to moderate (PTA=41.70 dB) to severe (PTA = 71-90 dB) and ending with profound (PTA >91 dB) or total hearing loss. But more alarming are the sequelae of SNHL that may include rapid cognitive decline (Lin et al., 2013), impaired psychosocial functioning (Strawbridge et al., 2000), increased risk of falling (Lin and Ferrucci, 2012) and increased risk of incident dementia (Lin et al., 2011b, Livingston et al., 2017). Recent work, including a metaanalysis of 33 studies (Taljaard et al., 2016), reported that SNHL is independently related to both cognitive impairment (Lin et al., 2011a) and the risk of incident dementia (Lin et al., 2011b), and perhaps most critically, that the degree of hearing loss predicts both the degree of cognitive impairment (Lin et al., 2013) and risk of dementia (Lin et al., 2011b). Furthermore, recent work suggests that 9% of dementia risk over the life-course could be eliminated by avoiding the effects of hearing loss (Livingston et al., 2017).

The scale of these problems is brought into sharp focus in the light of SNHL being the most prevalent chronic condition affecting older adults in developed countries (16-20%) (Davis, 1995, Cruickshanks et al., 1998, Wilson et al., 1999), and the second leading cause of years lost to disability globally (Mathers et al., 2000). And sadly, SNHL often goes undiagnosed and un- or under-treated (Lin, 2012, Cacciatore et al., 1999), and the sequelae of SNHL, incident dementia in particular, impose a significant burden not only on the individual and their families and friends, but also upon national health budgets (Honeycutt et al., 2003, Mohr et al., 2000). A recent nationwide study in Australia found that all forms of hearing loss affected 14.5% of Australians (3.6 million people), especially those over 50 years, with direct costs to the Australian economy of almost \$15.9 billion (Economics, 2017). And further, the number of Australians affected is expected to grow to 18.9% of the population by 2060, hence slowing or stopping the progression of SNHL is a public health imperative.

Here we detail a prospective cohort study utilising magnetic resonance imaging (MRI) in combination with clinical, neuropsychological, and hearing tests to investigate the neurocognitive and psychosocial effects of wearing of hearing aids in older adults with SNHL (Trial Registration: the Australian New Zealand Clinical Trials Registry, trial number ACTRN12617001616369).

Study Objective

This study seeks to understand if use of hearing aids can alter neurocognitive function and effect beneficial plastic brain changes in individuals with SNHL. In particular, the study aims to determine whether early intervention can normalise the function of the speech processing brain network. To this end, we will use neuropsychological, clinical and psychophysical tests in combination with function and structural MRI (fMRI/sMRI). FMRI acquisitions will include scanning during performance of a speech processing task (see below for details) to probe the function of the speech processing network, in addition to resting state fMRI to probe brain network function more generally, while structural MRI will enable assessment of both the volume and integrity of grey and white matter.

Study Hypotheses

In comparison to the long-term hearing aid users, after wearing hearing aid for six months the non-HA group will exhibit:

Improved cognition

Reduced depression

Improved social interaction

Altered activation of the auditory cortices and attendant networks

Altered connectivity between auditory and attendant networks

In addition the study will:

Explore any baseline relationships between cognition, psychosocial functions, and neural function in non-HA participants and HA participants.

Explore any relationships between improved cognition, psychosocial functions, and neural function in non-HA participants after the hearing aid intervention (see Figure 1).

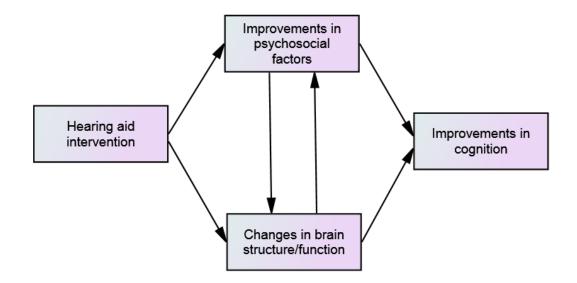


Figure 1: Hypothesised relationships associated with first time hearing aid usage

Methods

Study Design

The study is a retrospective cohort design evaluating the effect of hearing aid use on cognition, psychosocial factors (e.g., depression, social interaction), and neural function. This will involve recruitment of two participant groups of similar size consisting of people with mild to moderate SNHL. Group randomisation is not possible in this study; however, the groups will be matched as much as possible in terms of the degree of hearing loss.

Group A: SNHL patients who have used hearing aids for at least the previous 12 months who plan to continue using their hearing aids for the next 6 months.

Group B: SNHL patients who have never used hearing aids before and who will be willing to wear hearing aids for the next 6 months.

All participants will be asked to complete, at two time points (t) including baseline (t = 0) and at follow-up (t = 6 months), tests of hearing, psychosocial and cognitive function, and attend a magnetic resonance imaging (MRI) session.

Eligibility criteria

Participants must be 55 to 90 years of age, speak English as first language, exhibit mild or moderate sensorineural hearing loss with a pure-tone average (PTA) of thresholds at 0.5 - 4 kHz in both ears, be willing to undergo 2 one hour MRI scanning sessions over a period of 6 months, and be willing to wear hearing aids for six months, or must have been wearing hearing aids for at least one year. Further, participants must give written, informed consent.

Participants will be excluded if they exhibit: left handedness; significant visual impairment that would prevent reading; cognitive impairment (defined as a score less than or equal to 23 on the MMSE); severe or profound hearing loss; MRI contraindications. A flowchart of the overall data collection plan is shown in Figure 2.

Recruitment and Screening

Audiology health clinics with existing relationships with Swinburne University such as Alison Hennessy Audiology and Chelsea Hearing Pty Ltd, will be contacted to distribute study promotional material to their clients who have previously undergone hearing assessments at the audiology clinic, been diagnosed as having mild or moderate sensorineural hearing loss, and have been wearing their hearing aids for at least one year. The clinic will also distribute promotional materials to clients who have recently been recommended to acquire hearing aids but have not yet made the decision to purchase the aids. All clients who express interest in the study through the audiology clinic will be invited to attend an information session at Swinburne University of Technology.

Participants who live within the Swinburne community will also be contacted by telephone and email by the researchers to explain the study. Participants who express interest will be invited to attend the information session at Swinburne University.

At the information session, the researchers will explain the purpose and significance of the study. At the same time, participants will complete a screening questionnaire to identify participants who will be willing to undergo hearing assessments, undergo two (2) one hour MRI scans, and will satisfy the inclusion criteria. Prior to completing the screening questionnaire, participants must provide oral consent. Selected participants will be provided a Participant Information and Consent package for review. This will include further detailed information on the study procedure and a consent form. Participants who are willing to take part in the study will be scheduled for hearing assessment at the Audiology clinics. At the hearing appointments, participants will submit their written consent before their hearing assessments, and those who meet the inclusion criteria will be scheduled to undergo their first MRI scan at a mutually convenient time at Swinburne University of Technology.

Study Power Analysis

A G-power analysis assuming a moderate to large effect size (d=0.7), 80% power, 5% significance and 10% attrition rate suggests that a sample of thirty per group is sufficient for this study.

Intervention

Fitting of hearing aids for Group B participants

Group B participants will be fitted with two demonstration hearing aids known as Unitron Tempus Moxi Fit Receiver-in-the-ear hearing aids. The hearing aids will be fitted by the participating audiology clinics according to the best-practice fitting guidelines including real ear (probe tube) measures to verify the amplification and match to appropriate prescribed amplification (typically using the NAL-NL2 prescription developed by the National Acoustics Laboratory (Keidser et al., 2012)), with further adjustment and fine-tuning based on the users' subjective preferences. The study audiologists will provide oral explanation on how to use hearing aids and a stepby-step guide on hearing aid use will be provided to participants as take home materials. Post fitting support will be provided after 2 weeks to make sure that each participant is progressing with their hearing aids.

Follow-up Periods after Baseline Data Collection

During the six month wait period between MRI scans, phone call and email reminders for the second testing session will be sent to all participants at one, three and five months respectively. At the same time, counselling and other compliance-improving policies (Brooks, 1979, Brooks, 1985, Brooks, 1989) will be provided to ensure that participants are wearing their hearing aids. In addition, follow-up checks will be conducted by the audiology clinics every six weeks with first-time hearing aid users, during which hearing aid usage data will be down-loaded and the hearing aids will be re-started. An automatic internet-based data logging function installed in the hearing aids is used to collect hearing aid usage data which will be used to monitor and assess hours of hearing aid use by these participants. In addition, all participants will be encouraged to set their own goals for hearing aid use, and will be asked to assess how well these goals have been met on a regular basis.

After six month follow-up period

All participants will return to audiology clinics for further hearing assessments. Group B participants who received loaned hearing aids will return them. Hearing aid supplier information will be made available to them if they are ready to purchase hearing aids. After hearing assessments, participants will return to Swinburne University to complete the 6 month follow-up assessments.

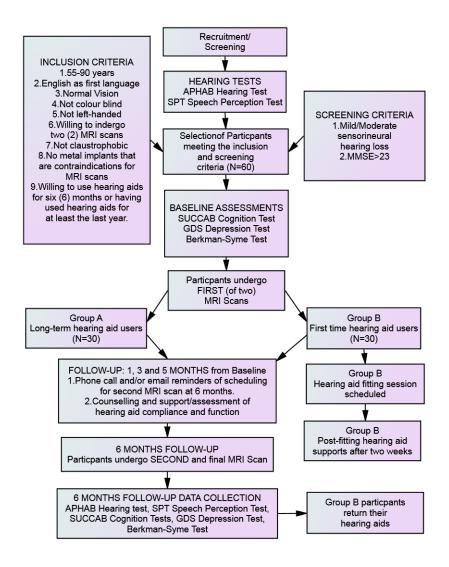


Figure 2: Data collection plan for experimental trial

Contingency Plan

Participants who decide to withdraw because of some discomfort experienced with hearing aids or decide not to undergo a second MRI testing, will be retained in the study for the purpose of baseline MRI analyses only. Intention-to-treat analyses will be used for the other analyses not involving MRI data.

Additional Costs and Reimbursements

There are no costs associated with participating in this research project other than transport costs. Participants will be reimbursed \$60 to cover these costs after the completion of the 6 month testing protocol.

Outcomes

Assessments for Study

The assessments selected for this study are categorized as: hearing assessments, demographic questionnaire, hearing aid benefit questionnaire, cognitive performance, mood and social interaction assessments, and MRI scanning. All participants enrolled in the study will complete these assessments at baseline and again at 6 months.

Hearing Assessments:

Otoscopy and tympanometry: Following otoscopy, all participants will undergo tympanometry and acoustic reflex testing to assess the status of the middle ear (Jerger and Jerger, 1980, Valente et al., 2006).

Pure tone audiometry in each ear: To understand the degree of hearing impairment, and classify participants according to the type of hearing loss, hearing ability will be measured at threshold frequencies of .25, .5, 1, 1.5, 2, 3, 6 and 8 kHz (air conduction) and 0.5, 1, 2, 4 kHz (bone conduction) in both ears. The choice of frequency to be tested corresponds to the amplification range of most modern hearing aids, and is consistent with capturing sensitivity at frequencies affected by sensorineural hearing loss and noise induced damage. Only participants with either mild or moderate sensorineural hearing loss will be included in the study (Valente et al., 2006, Jerger and Jerger, 1980).

Demographics: Information on a variety of demographic variables will be collected in order to describe the characteristics of the study participants.

The Abbreviated Profile of Hearing Aid Benefit (APHAB) inventory: The Abbreviated Profile of Hearing Aid Benefit (APHAB) inventory (Cox and Alexander, 1995) which is a 10 minute self-assessment inventory will be carried out to assess hearing aid benefit. Four scales of the APHAB will be assessed namely:

- ease of communication in favourable environments (EC)
- ease of communication with background noise (BN)
- ease of communication with acoustic reverberation (RV) such as listening to sounds in a large room.

• aversiveness (AV) which measures negative reactions to environmental sounds such as traffic and alarm bells.

Cognitive Assessments:

The Mini-Mental State Examination (MMSE) Questionnaire: The MMSE will be used to assess cognition and will be administered to test for cognitive functioning. The MMSE is a valid and reliable way of globally assessing a limited range of cognitive functions (Folstein et al., 1975). This examination will test five areas of cognitive function namely: orientation, registration, attention and calculation, recall, and language. Participants who exhibit a confusion state while completing the MMSE questionnaire will be advised that they cannot be included in the trial and will be advised to see their GP.

The Swinburne University Computerized Assessment Battery (SUCCAB): In addition to the MMSE, the SUCCAB will be used to assess cognitive performance. This cognitive test battery will allow assessment of changes in cognitive performance for all participants over a period of 6 months. The battery will test contextual memory, immediate recognition, simple reaction time, choice reaction time, congruent stroop, incongruent stroop, spatial working memory and delayed recognition memory. Reliability and validity testing of this battery has demonstrated that the SUCCAB is sensitive to ageing, and has been shown to be particularly effective for measuring short-term changes in cognition for the elderly (Pipingas et al., 2010). The SUCCAB correlates strongly with memory subsets in the Wechsler Adult Intelligence Scales (De Filippo and Scott, 1978).

Psychosocial Assessments:

Depression, Anxiety and Stress Scale (DASS): The DASS is a self-rating mood scale for measuring three related negative emotional states of depression, anxiety and stress. To assess changes in mood in this study, the DASS21 will be used (Lovibond and Lovibond, 1995).

The Berkman-Syme Social Network Index (Berkman and Syme, 1979) will be used to assess participants' social interaction and connections with families and friends.

6. MRI Assessments

Speech processing task

During fMRI scanning, participants will view a series of human faces (one male and one female actor) that mouth words in blocks (or 'epochs') lasting 16 seconds (1 word per 2 seconds) each. Each block will be one of four conditions termed *matched* (MAT), *mismatched* (MIS), *no sound* (NOS) and *control* (CON), preceded and followed by 10 second rest periods where a fixation cross ('+') will be displayed. In each of 2 scanning runs, four repetitions of each block type (16 total blocks per run) will be presented in a pseudorandom order, each utilising different word stimuli. Stimulus presentation time for each of the two scanning runs will be 426 secs (7 mins 6 secs); an additional twenty seconds of imaging data will be acquired following the end of the stimulus presentation to allow the hemodynamic response to return to baseline.

During MAT, the faces will mouth single syllable, high frequency words (visual stimuli) such as 'cat', or 'house', and the corresponding audio input (auditory stimuli) will be played through the headphones. During MIS, the stimuli will be the same but the mouthed words and auditory stimuli will be semantically unrelated (e.g., 'cat' is mouthed, but 'house' is heard). During NOS, the visual stimuli will be presented but not the auditory stimuli. During CON, the faces will be presented, but will not mouth the words, instead they will simply open and close the mouth without auditory stimuli. Participants will be asked to press a button whenever a face appears to ensure participant attendance to the task.

MRI scan acquisition

The MRI scanning session will include acquisition of 4 different types of scan data while participants lie supine in the scanner wearing MRI compatible OptoActive[™] headphones (OptoAcoustics). Participants will have either normal or corrected to normal vision using MRI compatible goggles. These acquisitions will include 2 fMRI scanning runs while participants perform the speech processing task, a high-resolution T1-weighted structural image (~8 mins), diffusion-weighted images (~10 mins), and a resting state fMRI scanning acquisition (~10 mins); total scanning time will be 42 mins.

The following details the different scan protocols including scan parameters, preprocessing and data analysis:

Scan acquisition for the speech processing task will utilise a T2* sensitive echo-planar imaging (EPI) sequence (TR = 2000 ms, TE = 30 ms, flip-angle = 90°, Field-of-view = 192 mm, 46 interleaved slices, 3 mm³ isotropic voxels). Pre-processing and statistical analysis will be performed using SPM12 and associated toolboxes. Pre-processing will include slice-timing correction, motion correction, co-registration of realigned functional images to structural (T1-weighted) scans, warping ('normalisation') of structural and functional scans into standardised stereotactic space, and spatial smoothing of functional images. The data will be modelled by constructing separate regressors that depict the onset and duration of MAT, MIS, NOS and CON blocks, convolved with the canonical HRF supplied with SPM12. Covariates of no interest (e.g., image realignment and other noise parameters) will model noise components.

Resting state scanning will utilise T2*-weighted images will be acquired continuously using an interleaved multiband sequence (multiband acceleration factor = 6, bandwidth = 1860 Hz/Px, TR = 870 ms, TE = 30 ms, echo spacing = 0.69 ms, flip-angle = 55° , field-of-view = 192 mm, voxel resolution = 2x2x2 mm, slice-thickness = 2 mm, number of slices = 66). Multiband acquisition sequences will be derived from the Human Connectome Project (Feinberg et al., 2010). Analysis of this data will be performed using the 'CONN' connectivity toolbox (Whitfield-Gabrieli and Nieto-Castanon, 2012) to test the changes in functional connectivity between brain areas we find to be critical in the sensory integration task as a function of wearing the hearing aids, in addition to broader network connectivity. Images will be realigned, normalised to MNI space, spatially smoothed with a 5 mm kernel, and temporally band-pass filtered (0.008-0.200 Hz). T1-weighted images will be segmented into grey and white matter as well as cerebrospinal fluid (CSF). Physiological noise and motion parameters will be regressed from the functional images using ACompCor (Behzadi et al., 2007). Temporal confounds regressed from the time series will include head motion parameters and their temporal derivatives, in addition to ACompCor derived noise components.

The T1-weighted image will be acquired using a magnetization-prepared gradient echo (MPRAGE) sequence (TR = 1900 ms, TE = 2.52 ms, flip angle = 9°, Field-of-view = 256 x 256 mm, 176 slices, 1 mm³ voxels). Diffusion weighted images will be acquired using an isotropic diffusion tensor imaging sequence for FA estimations (number of directions = 60, b-value = 3000s/m2, slice-thickness = 2.5 mm, TR = 8400 ms, TE =

117 ms, flip-angle = 90°). T1 weighted images will be used in the co-registration of functional data, and also to perform analysis of regional brain volumes using voxel based morphometry (VBM) using DARTEL procedures. For VBM, images will be manually reoriented and segmented (Ashburner, 2007), then a template will be created from the reoriented images using the non-linear deformations that best align the segmented images that will subsequently be warped into stereotactic space and spatially smoothed.

Finally, we will perform diffusion-weighted MR white-matter tractography using 'MRTrix' (<u>https://www.florey.edu.au/imaging-software</u>) to assess white matter tract changes as a function of wearing the hearing aids. Pre-processing steps will include, constructing a brain mask, estimating diffusion tensor components and performing constrained spherical deconvolution. Subsequently, we will perform whole-brain and seed-based fibre tracking.

Auditory stimuli input considerations

As the speech processing task will involve hearing word stimuli, auditory input for each participant will be tailored to fit a normalised audiogram, i.e., the gain will be enhanced at impaired frequencies. This will be performed by fitting a spline function to pre-recorded audiograms (across 1-8 kHz) that will be used to modulate auditory stimuli for left and right ears separately. Additionally, headphone output will be modified such it is consistent across individuals.

Primary statistical analyses

Repeated Measures Mixed Model Group (non-HA vs HA) x Time (Time 1 vs Time 2) analysis (henceforth RMMM) will be used for all analyses. Missing data is accommodated in this analysis, however in the case of whole-brain fMRI analyses, only completed protocol participants can be included. In the intention-to-treat RMMM analyses auto-regressive (AR) dependence will be assumed.

Cognitive data

The SUCCAB performance measure for spatial working memory will be used as the primary SUCCAB measure. This measure has been found to particularly effective for Page 244 of 309

measuring short-term changes in cognition for the elderly (Pipingas et al., 2010) and is calculated by dividing response accuracy by reaction time to for a spatial working memory task. Using this and the other SUCCAB performance measures, baseline values for the two groups will be compared using an ANCOVA analysis, controlling for age, gender and education level. Changes in these values over time will be compared for the two groups of respondents using an intention-to-treat RMMM, controlling for age, gender and education level and any variables that differ significantly between the groups at baseline.

2. Mood and Social Interaction Data

Mood will be assessed using the DASS scale and social interaction will be measured using the Berkman-Syme Social Network Index. Baseline measures for the two groups will be compared using an ANOVA analysis. Changes in these measures over time will be compared for the two groups of respondents using an intention-to-treat RMMM, controlling for age, gender and education level and any variables that differ significantly between the groups at baseline.

3. Neuroimaging data

Inferences from functional and structural neuroimaging analyses will be assessed using random field theory to correct for multiple comparison at the cluster level.

Speech processing task data: functional alteration

(i) To assess the effect of first time hearing aid use on speech sound processing, we will compute the contrast of MAT > NOS (NOS controls for viseme processing) for each participant, and enter the contrasts into a RMMM; (ii) Further, we will assess changes in functional connectivity in key areas determined from this analysis using the generalised psychophysiological analytic approach (McLaren et al., 2012). (iii) Finally, we will use key areas of difference as seeds in functional connectivity analysis of the resting state data.

(i) To assess the effect of hearing aid use on viseme processing, we will compute the contrast of NOS > CON (CON controls for basic face motion processing) for each participant, and enter the contrasts into a RMMM. (ii) Further, we will assess changes in functional connectivity in key areas determined from this analysis using the generalised

psychophysiological analytic approach (McLaren et al., 2012). (iii) Finally, we will use key areas of difference as seeds in functional connectivity analysis of the resting state data.

Structural T1 data: structural alteration

To assess plastic alteration in response to first time hearing aid use, these spatially smooth grey matter images will be entered into a RMMM.

Exploratory analyses

Cognitive data

Correlations between the SUCCAB performance measures and neuroimaging data will be investigated at baseline and at 6 months for each of the groups using Analysis of Covariance (ANCOVA) analyses and intention-to-treat Hierarchical Linear Model analyses.

Psychosocial data

Correlations between the DASS and the Berkman-Syme Social Network Index with the SUCCAB performance measures and the neuroimaging data will be investigated at baseline and at 6 months for each of the groups using Analysis of Covariance (ANCOVA) analyses and intention-to-treat Hierarchical Linear Model analyses. Structural Equation Modelling will also be used in order to explore the role of the mood and social interaction data as process variables for the effects of hearing aid use on cognition and neural function, testing the hypothesised model shown in Figure 1.

Neuroimaging data

We will explore changes in phoneme and viseme processing separately, and their integration, as a function of hearing aid use by modelling combinations of MAT, MIS, NOS and CON, in addition to any changes in functional connectivity using the generalised psychophysiological analytic approach (McLaren et al., 2012). We will also explore altered whole brain connectivity and inter-network coupling using the resting state data. Finally, we will assess white matter alteration using the VBM approach described above for grey matter. We also plan to explore changes in white matter integrity using diffusion tensor analyses and diffusion tractography.

Results

The speech processing task was programmed and tested during September-December 2017. Training of research staff on research protocols (cognitive, hearing and MRI session testing) was conducted intermittently between February 2016 and February 2020. Baseline testing sessions will commence in February 2018 and will be completed by June 2020, and the follow-up sessions and will be completed by December 2020.

Baseline session data analyses will be completed by October 2019, and final longitudinal data analyses will be completed by July 2020.

Discussion

Summary

Sensorineural hearing loss (SNHL) is strongly associated with cognitive decline, social and mental health problems, and incident dementia. It is well established that SNHL leads to brain atrophy and neuro-plasticity that may be detrimental to auditory rehabilitation; some evidence indicates that use of hearing aids may slow or improve this pathology. In the current retrospective cohort study, we utilise cognition and psychosocial testing in combination with structural and function neuroimaging to assess the impact of hearing aid use on neurocognitive function and brain structure in those with SNHL. To our knowledge, this is the first study to directly assess structural and functional brain changes arising from the use of hearing aids in older adults with SNHL. Currently, there is a paucity of neuroimaging studies in the SNHL field generally, which is surprising given what is known about neural plasticity in SNHL. A chief motivation for this work is to address this shortcoming, yielding critical data for SNHL research, and ideally, may prompt greater use of hearing aids in those with SNHL.

Limitations

The current study has some limitations that must be addressed. There are numerous aspects of speech processing in general, and its impairment in SNHL; here we have chosen to examine the processing of one aspect alone, namely monosyllablic word processing. This approach was taken to make the task easy to perform for participants, and to ease data interpretation. Hence our analyses will not reveal all aspects of speech processing dysfunction in SNHL such as sentence comprehension (Peelle et al., 2011). Additionally, studies examining cognitive impairment in SNHL have not utilised consistent neuropsychological testing protocols, hence the component processes probed across studies may not be consistent, inhibiting the generalisation of findings across studies. However, here we use a standardised battery that has been found to be particularly sensitive with older adults (Pipingas et al., 2010).

Conclusions

SNHL is a major and growing health problem for older adults that touches on most aspects of their lives, especially their cognitive function, mental health and well-being. Use of hearing aids enhances the lives of these individuals through not only enhanced hearing, but also improved social interaction, mood and cognitive functioning. Such day-to-day functional enhancement in individuals with SNHL suggests that beneficial plastic changes occur in their brains as a consequence of hearing aid use, yet use of hearing aids among this population is low.

Acknowledgements

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Authors' Contributions

All authors contributed to the study design and manuscript preparation.

Conflicts of Interest

None

Abbreviations

SNHL: sensorineural hearing loss

fMRI: functional magnetic resonance imaging

sMRI: structural magnetic resonance imaging

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9.3 Appendix C: Results Paper for Study 1 and Results Paper Supplementary Data

Title: The cognitive and psychosocial effects of auditory training and hearing aids in adults with hearing loss

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Abstract

Background: Hearing loss is associated with deterioration in speech perception. However, the effects of hearing loss on cognition, social interaction and depression are less well documented.

Objective: Our study assessed the efficacy of the simultaneous use of hearing aids and auditory training for improving cognition and psychosocial function in adults with hearing loss, and the relationships between hearing loss, speech perception and cognition.

Method: A 40-person (aged 50 - 90 years) pilot study in Melbourne, Australia, was conducted. Participants with hearing impairment answered the geriatric depression scale-short form, questions about social activity participation, completed a wide range of cognitive tasks and a speech perception test prior to, at 3 months, and at 6 months. Participants underwent auditory training for the 6 month period and used hearing aids for 3 months.

Results: Correlations and structural equation modelling suggested that several cognitive domains were associated with speech perception at baseline but only the Incongruent Stroop cognition measure was associated with hearing loss. Hearing aid use reduced problems with communication, but there were no significant improvements in speech perception, social interaction or cognition. The effect of hearing aids and auditory training for improving depressive symptoms was significant with a moderate to large effect size (Cohen's d = 0.87).

Conclusions: The small sample size and a relatively high rate of attrition meant that this study was under-powered. However, baseline results suggested relationships between hearing loss, speech perception and cognition and the hearing intervention provided evidence of reduced depressive symptoms.

Keywords: cognition, depression, hearing aids, hearing loss, speech perception

Introduction

Hearing loss is a highly prevalent chronic disability among older adults. Two-thirds of adults aged 70 years or older have clinically meaningful hearing loss (Lin, 2011). Agerelated hearing loss is associated with permanent damage at the cellular level of the auditory system. This is neither correctable by surgical nor pharmacologic interventions.

Recent studies have demonstrated an association between age-related hearing loss and difficulties in understanding speech (Meister et al., 2013) cognitive decline and incident dementia (Lin et al., 2011). The mechanisms by which hearing loss may impact cognition are thought to be associated with increased cognitive load, changes in brain structure, decreased social engagement and depression (Lin and Albert, 2014). Research suggests hearing loss increases cognitive load on brain activity by diverting cognitive resources to process the degraded auditory signal, at the expense of other cognitive processes such as working memory (Campbell and Sharma, 2013). Studies have shown that among adults with hearing impairments, greater number of depressive symptoms are associated with cognitive and concentration disorders which may be improved by hearing aids (Acar et al., 2011). Better understanding of the etiology behind the connection between hearing loss and cognitive decline could help lead to interventions that preserve cognitive function in hearing loss patients, hence the need for studies such as this.

The current gold standard in addressing hearing loss is amplification by hearing aids, which involves restoring the audibility of sounds in order to improve speech perception (Ferguson et al., 2016). Despite known consequences of hearing loss and significant advances in hearing aid technology, only 14% of US adults over the age of 50 years who might benefit from hearing aids actually use them (Chien and Lin, 2012). Lack of access, stigmatization, difficulty in managing hearing aids, and/or an underestimation of hearing aid benefit may contribute to low adoption rates for hearing aids (Meyer and Hickson, 2012). Also, hearing aids alone often do not overcome all adverse listening environments and first-time hearing aid users require substantial counselling and auditory training in order to ensure that they make the best use of their hearing aids (Olson, 2015). In addition, few studies have provided methodologically rigorous

evidence of the effect of hearing aids on improving health outcomes such as cognition in older adults (Valentijn et al., 2005).

Auditory training is the use of instruction, drill, or practice, designed to increase the amount of information that hearing contributes to a person's total perception (Blamey and Alcantara, 1994). Although studies have shown that auditory training results in improvements in the understanding of speech-in-noise, it is not commonly recommended to adults with hearing loss. These studies have shown that auditory training improves communication outcomes for first-time hearing aid users by optimizing acclimatization to the new auditory cues provided by hearing aids in adverse listening conditions (Sweetow and Palmer, 2005, Humes et al., 2009). However, despite this evidence, auditory training is rarely provided in conjunction with hearing aid fitting, possibly due to the lack of reimbursement for providers, and no previous studies have investigated the effect of hearing aids in conjunction with auditory training on health outcomes such as cognition. The aim of this study was to examine the efficacy of the simultaneous use of hearing aids and individualized face-to face auditory training for improving cognition, social interaction and depressive symptoms for first-time hearing aid users. Exploratory analyses also investigated the mediating role of a webbased speech perception test.

Methods

Study design

This study was a randomized crossover pilot study of 40 men and women with mild-tomoderate sensorineural hearing loss (SNHL). Participants were recruited from eight (8) independent living retirement facilities and surrounding communities across Melbourne, Australia. The complete study protocol is described elsewhere (Nkyekyer et al., 2018) (see Appendix 1 for study eligibility criteria in the Supplementary data). Enrolled participants completed an individualised in-person auditory training program for a period of 6 months, and were randomly allocated into two groups of equal size (n = 20 per group) as follows:

Participants fit with hearing aids only for the first 3 months of the auditory training program were assigned to *Group A*.

Participants fit with hearing aids only for the last 3 months of the auditory training program were assigned to *Group B*.

Participants were tested at baseline, and at 3 and 6 months in terms of cognition, depressive symptoms, social interaction, and hearing satisfaction (see Appendix 2 for details on hearing intervention in the Supplementary data).

Measures

In this study, hearing loss in the better ear was measured using the pure-tone audiometry test average threshold frequencies of 0.5, 1, 2 and 4 hearing kHz. A web-based speech perception test (SPT) (Blamey et al., 2015) was used in addition to the standard audiogram to measure hearing loss. Cognitive performance was assessed using the Swinburne University Computerized Cognitive Assessment Battery (SUCCAB) (Pipingas et al., 2010). The SUCCAB assessed eight cognitive domains namely; Simple and Choice Reaction Times, Immediate and Delayed Recognition, Congruent and Incongruent Stroop colour-words, Spatial Working Memory and Contextual Recognition Memory. A performance score for each task was calculated as the ratio of accuracy to reaction time. Depressive symptoms were measured using the Geriatric Depression Scale (GDS) (Yesavage and Sheikh, 1986). The Berkman-Syme questionnaire (Berkman and Syme, 1979) was administered to measure participant's social relationships with families and friends. Problems with hearing (with or without hearing aids) was measured using the Abbreviated Profile of Hearing Aid Benefit (APHAB) Inventory (Cox and Alexander, 1995) which consisted of four scales; Ease of communication (EC), Effects of background noise (BN), Effects of reverberation (RV), such as listening to sounds across a large room and Aversiveness of sounds (AV), which considered uncomfortable loudness of background sounds such as traffic and alarm bells. Speech tracking rates were generated from the auditory training program by calculating the number of words correctly repeated per minute of training. Tracking rates were obtained only for participants who completed the study and learning curves were derived for each participant group for each of the two 3 month periods (see Appendix 3 for more information about the study measures in the Supplementary data).

Data analyses

The two participant groups were compared in terms of demographic factors and baseline values using chi-squared and independent samples t-tests, with tests for correlation between the outcome measures and age at baseline. Square root transformations were applied where necessary. Second, structural equation modelling was used to examine the relationships between hearing loss, speech perception and cognition. Fitting the structural model using maximum likelihood estimation, goodness of fit was evaluated using a chi-squared goodness of fit statistic. Thirdly, separately for each group, we reported the objective and perceived benefit of hearing aids for the 3 months period of hearing aid usage, using paired t-tests to evaluate the significance of any improvement in terms of hearing satisfaction and SPT. Fourthly, we compared speech tracking learning curves for Groups A and B separately for the first three and last three months, in order to monitor the effects of the auditory training over time, with and without hearing aids. Finally, a mixed model analysis was performed for our crossover design to determine whether hearing aids had any significant effect on cognition and psychosocial function over and above auditory training, and to establish the significance of any period or carry-over effects.

Results

Participants

From December 2016 to March 2017, 84 individuals were screened for eligibility. Of these, 54 (64.3%) participants were recruited from retirement independent living villages while 30 (35.7%) participants were from surrounding communities. After screening, forty four participants were found to be ineligible. Out of the 40 participants who were randomly allocated, 21 (52.5%) had mild symmetric SNHL (between 21 - 40 dB) and 19 (47.5%) had moderate symmetric SNHL (between 41 - 70 dB). No significant differences were found between the two groups in terms of demographics or baseline outcome measures (see Appendix 4 Table 1 in the Supplementary data).

Baseline Relationships

Table 1 shows the relationship between all the cognitive and psychosocial measures, the APHAB measures (without hearing aids) with age, hearing loss and speech perception (without hearing aids), demonstrating several significant correlations with SPT results at baseline. In particular, there was as expected a strong negative correlation between SPT

and hearing loss, and significant negative correlations of moderate size between age and cognition. Also as expected, there were significant but weaker negative correlations between SPT and the APHAB hearing problems. Contrary to expectation, there was only one significant correlation between hearing loss and cognition (Incongruent Stroop – the only measure relating to executive function), and one significant correlation between hearing loss and problems identified with hearing (Ease of Communication). No significant correlations were observed for social interaction or depression.

Table 1: Pearson	correlations fo	r baseline	results	without	hearing aids

Outcome Measures	Age (years)	Hearing Loss (PTA)	Speech Perception Test (SPT)
Age (years)	1.000	0.278	-0.443**
Hearing Loss (PTA)	0.278	1.000	-0.695**
Speech Perception Test (SPT)	-0.443**	-0.695**	1.000
Cognition: Simple Reaction Time	-0.369*	-0.301	0.338*
Cognition: Complex Reaction Time	-0.390*	114	0.223
Cognition: Immediate Recognition Memory	-0.555**	-0.145	0.300
Cognition: Delayed Recognition Memory	-0.500**	-0.040	0.279
Cognition: Stroop Congruent	-0.400*	219	0.492**
Cognition: Stroop Incongruent	-0.079	-0.323*	0.265
Cognition: Spatial Working Memory	-0.325*	-0.153	0.393*
Cognition: Contextual Recognition Memory	-0.522**	-0.083	0.405**
APHAB: SQRT Ease of	0.129	0.404**	-0.578**

Communication (EC)			
APHAB: Reverberation (RV)	0.122	0.297	-0.332*
APHAB: Background Noise (BN)	-0.121	0.226	-0.317*
APHAB: SQRT Aversiveness (AV)	0.081	-0.121	-0.170
SQRT Depression	0.014	0.057	-0.019
Social Interaction	-0.352*	-0.095	0.238

**. Correlation is significant at the 0.01 level (2-tailed).

*. Correlation is significant at the 0.05 level (2-tailed).

Figure 1 illustrates the association between hearing loss, unaided speech perception and cognition, providing a good fit for the data (Chi-Squared = 40.67, df=35, p=.235). In this model cognition is measured as a latent variable and, although it is assumed that SPT and cognition are correlated, no assumption about the direction of this relationship is made.

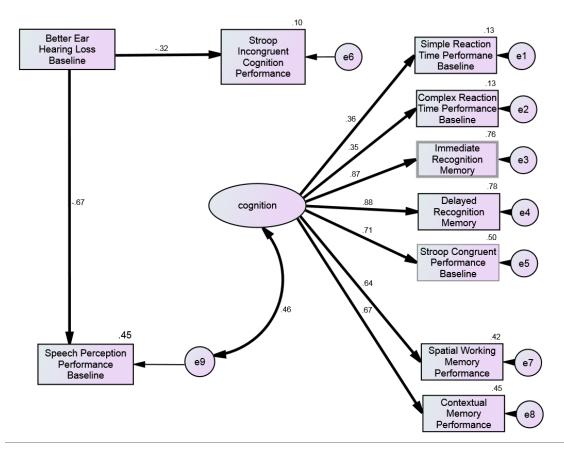


Figure 1. Structural equation model with R-Square values and standardised path coefficients with significant (p<.05) paths bolded

Effects of hearing aid use and auditory training on cognition

Assessment of outcome of hearing aids

The average daily hearing aid use for *Group A* and *Group B* as measured through objective data logged by the hearing aid for the 3 month period (when hearing aids were first fitted) was 4.6 hours and 5.25 hours respectively. However, there was a high proportion of missing data for this variable due to hard and software issues making these results unreliable.

We found significant reduction in all problems of the APHAB measure for Group A when hearing aids were worn, except in the case of AV which increased significantly. However, for Group B there was a significant reduction only for the RV scale when hearing aids were worn, and a significant increase in AV. For Group A SPT improved significantly when hearing aids were worn and this improvement was nearly significant for Group B (see Supplementary data, Appendix 5 Table 2 and Table 3 for the outcomes of hearing aid benefits).

Effectiveness of auditory training

Fitted learning curves (with and without hearing aids) from the speech tracking are displayed in Figure 2 (see Appendix 6 Table 4 for the estimated parameters from auditory training in the Supplementary data). It was expected that it would be easier to learn to do speech tracking when participants used hearing aids than when they did not, and that using hearing aids during the week would mean that forgetting was slower. However, Figure 2 shows similar Learning and Forgetting Rates for Group A and B in the first 3 months. For the second 6 months there was an initial decline for Group A when hearing aids were removed, but this decline was quickly reversed, with similar end-points achieved for Groups A and B.

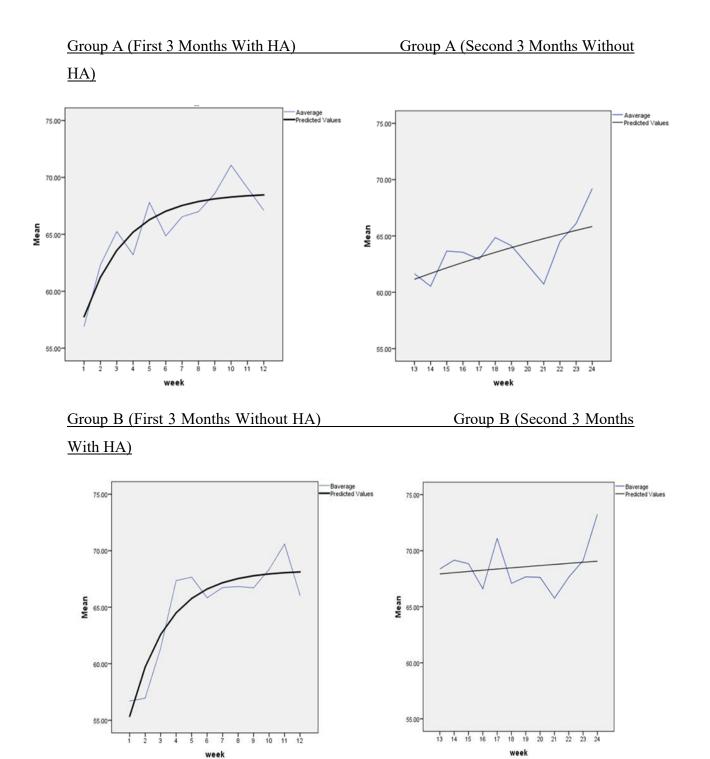


Figure 2: Experimental data and learning curves derived from speech tracking sessions for Group A and Group B

Cross-over analysis for the effects of hearing aids and auditory training

After the six month follow-up period, 9 (22.5%) out of 40 participants withdrew from the study for the following reasons: discomfort after wearing the hearing aids; health issues; personal reasons, inability to attend weekly auditory training sessions. Overall, 17 (85%) participants from Group A and 14 (70%) participants from Group B completed all measures of the study from baseline to six months.

The mixed model analysis was therefore completed only for participants who did not withdraw from the study, in order to determine whether the hearing aids had a significant effect on cognition, the APHAB measures and the psychosocial measures. In addition, we tested for significant changes between the 3 months and 6 months assessments while controlling for baseline levels. The carry-over effect was designed to detect any treatment order effect associated with the hearing aid usage. We found significant improvements in depressive symptoms from 3 to 6 months with a moderate to large effect size (Cohen's d = 0.87). In addition, we found a significant deterioration in aversiveness when hearing aids were worn. A significant carry-over effect for delayed recognition memory was also found, invalidating the results for this cognition measure (see Appendix 7 Table 5 for results of the mixed model crossover analysis in the Supplementary data).

Discussion

In this pilot study, we demonstrated the relationship between cognition and speech perception. Despite a strong relationship between hearing loss and speech perception, it was only in the case of the executive function cognitive measure did we find a significant relationship with hearing loss and cognition. This confirms the results of several empirical studies which have successfully established the link between cognitive abilities and speech recognition performance in first time hearing aid users (Lunner, 2003). Studies have also previously confirmed a relationship between auditory training and cognitive processes such as executive function (Sweetow and Palmer, 2005, Chisolm et al., 2012). The significant correlation between cognition as measured by the Incongruent Stroop test and hearing loss needs further investigation as this result may suggest that tests of visual Incongruent Stroop capability could be an important addition to aural rehabilitative assessments (Carter and Van Veen, 2007). Second, hearing aid use was associated with improved speech perception, increasing the audibility of sounds. Increases in aversiveness were also detected but this was expected (Blamey et al., 2010). We found significant improvement in depressive symptoms over the course of the study. This result is consistent with previous studies suggesting that hearing aids

reduce depression (Acar et al., 2011, Boi et al., 2012). Studies have shown that depression is associated with hearing impairment (Strawbridge et al., 2000); it is both a risk factor and a prodromal of Alzheimer's disease and is a common occurrence in all types of dementias as well as in mild cognitive impairment (Enache et al., 2011). Having depression reduces quality of life, exacerbates cognitive and functional impairment, and is associated with increased mortality (Greenwald et al., 1989). Therefore, our findings suggest that management of hearing loss could improve the life conditions of adults or may reduce the burden associated with dementia. Third, no evidence was found to suggest that it is easier to learn to do speech tracking when participants use hearing aids than when they do not. This is a surprising result requiring further investigation. Fourth, there was no significant improvement in cognition and social interaction over a six month period. One interpretation of this result is that hearing treatment may take longer than 6 months to impact cognition.

A limitation of the study was that daily hours of hearing aid usage were not reliably assessed and could not therefore be included in the analysis. This could mean that it is impossible to determine to what extent participants actually made use of the hearing aids they were given, outside of their auditory training sessions. Also, this study was underpowered given the small sample size and high attrition rate. Larger research studies, preferably taking the executive function of the brain function into account through neuroimaging are therefore needed to establish whether there does exists any causal association between hearing aid use and cognitive performance.

Conclusions

The baseline results clearly indicated better cognition performance in several domains in the case of participants with better speech perception. The effects of auditory interventions on depression over a six month period also showed significant effects in this study. Recognition of hearing loss as a risk factor for dementia is relatively new, and results of cohort studies have suggested that even mild levels of hearing loss increase the long-term risk of cognitive decline and dementia in individuals who are cognitively intact but hearing impaired at baseline (Lin et al., 2011, Livingston et al., 2017). There was however no improvements in cognition observed in this study despite the usage of auditory training in addition to hearing aids. Given the limitations of this study, including small sample size, the magnitude of the effects reported here should not be interpreted as would be the case for a fully powered trial (Leon et al., 2011).

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Conflict of interest

None declared.

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Contributors

All authors were involved in drafting the results of the study. All authors read and approved the final manuscript.

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Results Paper Supplementary data

Appendix 1: Study eligibility criteria

Study eligibility criteria specified adults aged between 50 to 90 years, bilateral symmetric sensorineural hearing loss in the mild to moderate range based on a puretone average (PTA) of 25 dB HL to 70 dB HL. Also, participants needed to be proficient in English, to have never worn hearing aids before, and to express willingness to wear hearing aids for 3 months and attend weekly auditory training for 6 months. Exclusion criteria included suspected cognitive impairment as defined by a score less or equal to 24 on the Mini-mental state examination questionnaire (MMSE), and uncorrected visual impairment and/or colour blindness as required by the Swinburne University Computerized Cognitive Assessment Battery (SUCCAB) test. This study was conducted in compliance with Swinburne's Human Research Ethics Committee (SUHREC) requirements (SHR Project 2016/159). All participants provided written informed consent prior to study protocol.

Appendix 2: Hearing interventions

Hearing aid fitting

Participants were provided with bilateral Blamey Saunders LOF (originally known as Liberty Open-Fit) hearing aids by the study audiologist. Hearing aids were adjusted and customized according to the Blamey and Saunders best-practice protocol. The study audiologist provided an oral explanation on how to use hearing aids and a step-by-step guide on hearing aid use was provided to participants as take home reading. To increase hearing aid compliance and to manage expectations as needed, counselling support was provided to participants at weekly auditory training sessions. An automatic internet-based data logging function installed in the hearing aids was used to assess hours of hearing aid use over the 3 months period of hearing aid use.

Auditory training

Study participants received weekly face-to-face auditory training sessions of Continuous Discourse Speech Tracking (De Filippo and Scott, 1978). In this process, a trained study member read a novel/short story, and the participant was instructed to repeat back verbatim each sentence or phrase. If the repetition was correct, the researcher articulated the next phrase or sentence. If the repetition was incorrect, the researcher repeated the phrase or sentence, or a portion of it, or used other repair strategies, until the sentence or phrase was correctly repeated in its entirety. Training materials was tailored to the personal interests of participants. Each training session lasted for 15 min.

Appendix 3: Measures

Blamey Saunders speech perception test (SPT)

In addition to the standard audiogram, we used a web-based SPT to measure of hearing loss and auditory training with and without hearing aids. The SPT is a monosyllabic word test that generates a display of information transmission for 50 vowels and 100 consonants in order to characterise the shape and degree of hearing loss, analogously to an audiogram (Blamey et al., 2015, Blamey and Saunders). The SPT is similar to consonant-vowel nucleus-consonant (CNC) word tests that have been used previously for various speech recognition tests (Henry et al., 1998, Peterson and Lehiste, 1962). The SPT consists of fifty consonant-vowel-consonant words designed for use in any reasonably quiet environment; presented at a "comfortable level" of 65 dB; Australian English spoken by a native Australian female speaker; one list of words (in random order) randomly chosen from thirty-two phonetically balanced lists of words; responses typed by the listener; automatic analysis and reporting of word consonant and vowel scores. The SPT score used for this study was the phoneme score – the total number of correctly identified vowels and consonants. Higher SPT scores suggest better hearing.

Participants completed the SPT without hearing aids at baseline, after 3 months and then at 6 months. The SPT was also performed with hearing aids immediately after participants were fitted with hearing aids for the first time, and at the end of 3 months of auditory training while wearing a hearing aid.

Subjective assessments of hearing

For subjective assessments of hearing (with or without hearing aids), the APHAB was used. Participants answered the APHAB at baseline, after 3 months, and after 6 months, and we used the APHAB (Cox and Alexander, 1995) to assess the following different listening situations in daily life, without hearing aids and with hearing aids when

relevant: ease of communication (EC), effects of background noise (BN), effects of reverberation (RV), such as listening to sounds across a large room, and aversiveness (AV), which measures uncomfortable loudness of background sounds such as traffic and alarm bells. We expected that participants with worse hearing to score higher on all four subscales at baseline but will improve due to hearing and auditory interventions.

Using a 7-point scale, respondents indicated how often the statement was true for them. Each point on the scale provided a descriptor and an associated percentage of time with higher scores indicating more of a problem:

А	Always	(99%)
В	Almost Always	(87%)
С	Generally	(75%)
D	Half-the-time	(50%)
Е	Occasionally	(25%)
F	Seldom	(12%)
G	Never	(1%)

Speech tracking rates from auditory training

To analyse our speech tracking rates from the auditory training, we used the following "learning and forgetting" mathematical model as described by Blamey and Alcantara (Blamey and Alcantara, 1994):

$$R(t) = \frac{1 - \exp(-f(t - T))}{L/f}$$

where

R(t) = tracking rate in words per minute at time t.

L = learning rate per week, i.e. the increase in speech tracking rate after 1 week of auditory training

f = forgetting rate per week, i.e. the reduction in speech tracking rate in between speech tracking sessions

t is time in weeks, t>0

T is a constant.

The parameters L, f and T, were estimated for each group over both 3 month periods separately. The L and f parameter estimates are valid measures of cognitive processes, learning and forgetting that may be affected by the use of hearing aids and/or auditory training.

Research in auditory training has shown that the amount of training, the amount of learning, the generalization of skills (whether auditory training will improve communication in real-life situations as well as under artificial test conditions), and the degree of retention of skills are all inter-related (Blamey and Alcantara, 1994). Therefore, a mathematical formula was helpful for tracking improvements in auditory training over time.

Cognitive Assessments - Swinburne University Computerized Cognitive Assessment Battery (SUCCAB)

The SUCCAB assessed eight cognitive domains (Simple and Complex Reaction Times, Immediate and Delayed Recognition, Congruent and Incongruent Stroop, Spatial Working Memory and Contextual Memory) (Pipingas et al., 2010). Computerised measures provided consistency in measurement across participants, and a more automated approach in analysis. A performance score for each task was calculated as the ratio of accuracy and reaction time. This approach took into account variations in accuracy and response time allowing for speed versus accuracy trade-offs in performance. Some of these tests require the identification of colours, hence the need for colour blindness as an exclusion criterion for this trial. We expected that participants with better hearing will have better cognition scores at baseline.

Psycho-social assessments (Depressive symptoms and social interaction)

The short form of the Geriatric Depression Scale (GDS) (Burke et al., 1991) was used for measuring depressive symptoms. The GDS has been found to be a reliable and valid measure of depressive symptoms (Yesavage and Sheikh, 1986), and to be highly Page **269** of **309** correlated with other measures of such symptoms. The GDS was designed for older adults. Items are scored dichotomously (respondents answer "Yes" or "Not" to five items). Items assess non-somatic aspects of depression, thus allowing for discrimination between respondents with depressive symptom and those with medical problems. Higher scores (a score above 5) is suggestive of depression.

We used the Berkman-Syme Social Network Index (Berkman and Syme, 1979) (BNI) to assess participants' social interaction and connections with families and friends. Twelve (12) types of social relationships were assessed, namely relationships with a spouse, parents, parents-in-law, children, other close family members, close neighbours, friends, workmates, schoolmates, fellow volunteers, members of groups without religious affiliation, and religious groups. We expected that people with better hearing will have higher BNI scores at baseline.

Appendix 4: Table 1: Baseline characteristics

There were no significant differences between the groups at baseline, however, moderate to large effect sizes (Cohen's d) are indicated for the Contextual Recognition Memory task (a measure of episodic memory) and aversiveness (AV)

Table 1. Baseline characteristics

Characteristics	Group A	Group B	Total	Test Statistics	p-value	Cohen's d
	n = 20	n = 20	N = 40			
Gender, n (%)						
Male	8 (40.0)	11 (55.0)	19 (47.5)	$\chi^2(1) = 0.902$	0.342	
Female	12 (60.0)	9 (45.0)	21 (52.5)			
Age, mean (SD)	75.9 (7.9)	76.5 (7.5)	76.2 (7.6)		0.807	-0.08
MMSE, mean (SD)	28.4 (0.7)	28.5 (0.9)	28.5 (0.8)		0.703	-0.12
Employment Status, n (%)						
Employed	2 (10.0)	5 (25.0)	7 (17.5)	$\chi^2(3) = 3.273$		
Retired	18 (90.0)	15 (75.0)	33 (82.5)		0.351	
Education, n (%)						
Primary/Secondary/TAFE	14 (70.0)	13 (65.0)	27 (67.5)	$\chi^2(7) = 4.254$	0.750	
University Qualification	6 (30.0)	7 (35.0)	13 (32.5)			
Hearing Status, n (%)						
Reported Hearing Trouble	18 (90.0)	17 (85.0)	35 (87.5)	$\chi^2(1) = 0.229$	0.633	

Reported Perceived Tinnitus	9 (45.0)	5 (25.0)	14 (35.0)	$\chi^2(3) = 3.788$	0.285	
Hearing Loss Better Ear, mean (SD)	37.6 (7.6)	39.5 (11.3)	38.5 (9.6)		0.537	-0.20
Speech Perception Test, mean (SD)	119.5 (18.1)	111.2 (22.0)	115.4 (20.3)		0.200	0.41
SUCCAB Performance Cognition Mea	sures, mean (SI))				<u> </u>
Simple Reaction Time	331.0 (45.4)	333.6 (47.1)	332.3 (45.7)		0.858	-0.06
Complex Reaction Time	204.9 (31.0)	203.2 (25.7)	204.1 (28.1)		0.850	0.06
Immediate Recognition Memory	67.7 (24.4)	65.2 (18.7)	66.4 (21.5)		0.723	0.12
Delayed Recognition Memory	64.8 (21.0)	58.6 (11.6)	61.7 (17.0)		0.257	0.37
Stroop Congruent	116.4 (17.5)	112.2 (19.5)	114.3 (18.4)		0.479	0.23
Stroop Incongruent	87.1 (29.1)	85.7 (20.7)	86.4 (24.0)		0.867	0.06
Spatial Working Memory	60.5 (21.9)	54.0 (16.6)	57.3 (19.5)		0297	0.33
Contextual Recognition Memory	73.3 (23.9)	59.9 (20.5)	66.6 (23.0)		0.065	0.61
Abbreviated Profile of Hearing Aid Be	nefit (APHAB)	, mean (SD)				
Ease Communication (EC)	26.0 (19.0)	26.2 (20.2)	26.1 (19.4)		0.959#	0.00
Effects Reverberation (RV)	34.2 (12.9)	34.6 (14.0)	34.4 (13.3)		0.922	-0.03
Effects Background Noise (BN)	36.4 (13.5)	34.7 (17.0)	35.5 (15.2)		0.717	-0.11

Aversiveness (AV)	35.4 (22.5)	22.5 (19.0)	29.0 (25.6)		0.058#	0.09		
Psycho-Social Measures, mean (SD)								
Depression (GDS)	1.7 (1.8)	1.5 (1.5)	1.6 (1.6)		.660#	0.01		
Social Interaction	32.5 (11.3)	32.6 (12.6)	32.5 (11.8)		.969	0.00		

Appendix 5: Outcome of perceived hearing aid benefit

SPTs were performed immediately after hearing aid fitting and again at the end of 3 months of auditory training and hearing aid usage (#). The results showed no significant change for Group A or Group B. However, when we compared speech perception test results without wearing hearing aids before and after 3 months of auditory training and hearing aid usage (@), there is a significant improvement for Group A and nearly a significant improvement for Group B.

Table 2: Outcome of perceived hearing aid benefit

Domain	Group A Mean (SD)				Group B Mean (SD)			
	N = 19			N = 14				
	Baseline	3 months	t-value	p-value	3 months	6 months	t-value	p-value
EC	27.2 (18.7)	17.0 (17.0)	2.809	0.012	18.4 (15.3)	12.8 (10.5)	1.298	0.217
RV	36.0 (14.0)	29.3 (16.1)	2.614	0.017	30.3 (13.6)	20.0 (11.7)	3.187	0.007
BN	36.6 (13.9)	24.7 (16.5)	2.926	0.009	31.3 (15.0)	26.1 (13.3)	2.062	0.060
AV	36.4 (22.7)	48.1 (23.5)	2.275	0.035	14.3 (11.8)	37.2 (29.3)	3.357	0.005
SPT#	125.1(15.7)	124.5 (17.2)	0.459	0.652	124.0 (16.7)	122.9(17.8)	0.473	0.644
SPT@	120.0(18.4)	124.5(17.2)	2.319	0.032	119.0(18.6)	122.9(17.8)	2.025	0.065

EC = Ease of Communication

RV = Effects of Reverberation

BN = Effects of Background Noise

AV = Aversiveness of Sound

SPT# = Results with hearing aids only,

SPT@ = without hearing aids before and with hearing aids after 3 months

Finally, we compared speech perception test results without hearing aids, and immediately after hearing aid fitting (see Table 3).

Table 3: Outcome of perceived hearing aid benefit with respect to SPT results when hearing
aids are first fitted and when hearing aids are removed.

Time	Group A Mean (SD)				Group B Mean (SD)			
Period				N = 14 at 3 months and 6 months				
	Without HAs	With HAs	t-value	p-value	Without HAs	With HAs	t-value	p-value
Base- line	119.5 (18.1)	124.9 (15.3)	3.03	.007				
3mths	121.5 (18.4)	124.5 (17.2)	1.32	.203	119.0 (18.6)	124.0 (16.7)	2.012	0.065
6mths					122.9 (17.8)	121.6 (21.8)	0.488	0.634

Interestingly there was significant immediate improvement when hearing aids were first fitted for Group A and nearly significant for Group B. However, when the hearing aids were finally removed, at 3 months for Group A and at 6 months for Group B, the SPT results showed no significant difference for either group with and without hearing aids. The unaided SPT scores increased during the intervening auditory training period, although not significantly (p=.543 for Group A and p=.064 for Group B) but the aided SPT scores remained fairly constant.

Appendix 6: Estimated parameters for speech tracking

Table 4: Estimated parameters (standard errors) derived from speech tracking data

Condition	Group A		Group B	
Number of sessions	First 3 Months	Second 3 Months	First 3 Month	Second 3 Month
per week	With HA	Without HA	Without HA	With HA
Constant (T)	-3.803 (5.22)	-41.78 (56.45)	-3.046 (2.92)	-136.14 (174.6)

Forgetting	rate	per	.384 (.212)	.041 (.13)	.412 (.253)	.018 (.210)
week (f)						(-2.65, 2.68)
			26 251 (14 02)	3.02 (8.29)	28.09 (16.84)	1 22 (14 25)
Learning	rate	per	26.351 (14.03)	5.02 (8.29)	20.09 (10.04)	1.33 (14.35)
week (L)						

Significant Forgetting and Learning Rates in bold.

Standard errors for these estimates were obtained using bootstrapped samples.

HA = Hearing Aids

Table 4 suggests that forgetting and learning rates were significant only for the first three months for both groups.

Appendix 7: Mixed model crossover analysis

Table 5: Mixed model crossover analysis

	Time Effect		Hearing Aid Effect		Carry-over	
Outcome					Effect HA	
Measure	Coefficient	Cohen's	Coefficient	Cohen's		
	(Std error)	d	(Std error)	d		
Hearing Loss	-1.493 (2.034)	-0.30	2.660 (2.002)	0.54	3.271 (3.747)	
Speech						
Perception Test	3.423 (3.301)	0.43	738 (3.244)	-0.09	-4.018 (6.069)	
(woHA)						
SUCCAB Performance Cognition Measures						
Simple Reaction	2.449	0.07	-9.656 (14.141)	-0.28	-13.768	
Time	(14.342)	0.07	-7.050 (14.141)	-0.20	(26.614)	
Complex	-1.599	-0.09	-7.833 (7.390)	-0.45	-4.000 (14.090)	

Reaction Time	(7.483)				
Immediate Recognition Memory	-1.675 (5.606)	-0.13	-7.469 (5.522)	-0.58	-6.958 (10.348)
Delayed Recognition Memory	6.337 (5.714)	0.47	-12.993 (5.632)*	-0.95	-22.280 (10.190)*
Stroop Congruent	1.951 (4.801)	0.17	-4.989 (4.683)	-0.44	-7.804 (8.598)
Stroop Incongruent	6.057 (8.201)	0.35	-9.109 (8.138)	-0.52	-11.565 (15.800)
Spatial Working Memory	-5.381 (4.861)	-0.44	.179 (4.739)	0.01	-1.111 (7.076)
Contextual Recognition Memory	3.411 (5.072)	0.27	.153 (4.953)	0.01	-4.869 (8.622)
Abbreviated Profile	e of Hearing Aid	l Benefit (A	PHAB) without He	aring Aids	
SQRT (Ease Communication)	.077 (.480)	0.07	.065 (.476)	0.06	.084 (.900)
Reverberation	951 (5.169)	-0.08	1.448 (5.075)	0.12	6.527 (9.243)
Background Noise	2.957 (5.272)	0.23	780 (5.199)	-0.06	-1.495 (9.807)
SQRT (Aversiveness)	472 (.558)	-0.34	1.387 (.547)*	1.01	1.432 (.987)
Psycho-Social Measures					

SQRT	469 (.230)*	-0.87	090(.226)	-0.17	.056(.403)
(Depression)					
Social Interaction	-1.489	-0.19	-1.762 (3.146)	-0.06	.506 (5.238)
	(3.261)				

*p<.05; woHA: without Hearing Aids

In addition to controlling for baseline outcome measures, we controlled for baseline scores for Contextual Working Memory and SQRT (Aversiveness) because there were large differences between the two groups on these variables at baseline. In addition, age and attrition probability were controlled for, in order to adjust for age effects and any attrition bias. In these analyses effect sizes (Cohen's d) were obtained by dividing the estimated coefficients by the residual standard deviation, as recommended by Feingold (Feingold, 2013). Confirming the results from Table 1, there was a significant increase in Aversiveness when a hearing aid was worn, with marginal mean values of 4.431 and 5.781 for the two conditions (Cohen's d = -1.01). There was a significant decline in delayed recognition memory performance when hearing aids were used (Cohen's d = 0.95). There was also a narrowly significant carry-over effect in the case of delayed recognition memory.

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9.4 Appendix D: Additional Descriptive Statistics for Demographic Questionnaire Study 1

Descriptive Statistics							
	N Statistic	Minimum Statistic	Maximum Statistic	Mean Statistic	Std. Deviation Statistic	Skewr Statistic	iess Std. Error
Depression score at	40	.00	6.00	1.6000	1.64551	1.268	.374
Baseline Depression score at 3	35	.00	6.00	1.9143	1.66930	1.149	.398
months Depression score at	31	.00	5.00	1.2258	1.52118	1.353	.421
6months Ease of Communication	40	1.00	89.00	26.0917	19.37271	1.507	.374
at Baseline Reverberation at	40	12.50	60.17	34.3917	13.26121	.096	.374
Baseline Background Noise at	40	8.67	62.67	35.5375	15.17906	.207	.374
Baseline							
Aversiveness at Baseline Ease of Communication	40 36	1.00	74.67 62.50	28.9833 19.9725	21.58317 14.36462	.591 1.299	.374
at 3 months without hearing aid							
Ease of Communication at 3 months with hearing aid	19	4.67	78.83	16.9568	17.02387	2.949	.524
Reverberation at 3 months without hearing aid	36	8.67	64.67	30.3342	13.32859	.658	.393
Reverberation at 3 months with hearing aid	21	8.67	66.67	29.2706	16.09619	.826	.501
Background Noise at 3 months without hearing aid	36	6.67	64.67	31.7086	15.40370	.135	.393
Background Noise at 3 months with hearing aid	19	8.67	66.67	24.6842	16.45872	1.234	.524
Aversiveness at 3 months without hearing aid	36	1.00	68.17	25.3239	19.15758	.871	.393
Aversiveness at 3 months with hearing aid	19	14.83	97.00	48.0695	23.48463	.227	.524
Ease of Communication at 6 months without hearing aid	31	2.80	84.83	21.3965	17.79853	1.998	.421
hearing aid Ease of Communication at 6 months with hearing aid	14	2.67	45.67	12.8443	10.50344	2.543	.597
aid Reverberation at 6 months without hearing aid	31	8.67	60.50	33.2261	15.00812	.029	.421
Reverberation at 6 months with hearing aid	14	2.83	42.00	19.9650	11.67526	.496	.597
Background Noise at 6 months without hearing	31	8.67	66.50	34.5916	15.28594	.324	.421
aid Background Noise at 6 months with hearing aid	14	6.67	54.17	26.0836	13.25633	.650	.597
Aversiveness at 6 months without hearing aid	31	1.00	85.00	28.5913	22.43235	1.007	.421
Aversiveness at 6 months	14	1.00	80.83	37.1786	29.34962	.181	.597
with hearing aid Social Engagement	40	.00	51.00	32.5250	11.81044	-1.005	.374
Score at Baseline Social Engagement	36	9.00	52.00	33.9444	9.63608	540	.393
Score at 3months Social Engagement	30	12.00	55.00	33.7667	11.37051	369	.427
Score at 6months Simple Reaction Time	40	225.38	422.39	332.3154	45.71255	215	.374
Performane Baseline Complex Reaction Time	40	146.20	274.19	204.0599	28.13452	.260	.374
Performance Baseline Immediate Recognition	40	27.29	113.97	66.4355	21.49065	.378	.374
Memory Performance Baseline Delayed Recognition	40	28.20	101.29	61.6924	17.01370	.596	.374
Memory Performance Baseline							
Stroop Congruent Performance Baseline	40	74.68	155.54	114.2730	18.40695	.027	.374
Stroop Incongruent Performance Baseline	39	.00	135.29	86.3947	25.04810	951	.378
Spatial Working Memory Performance at Baseline	40	22.74	107.19	57.2844	19.45408	.505	.374
Contextual Memory Performance at Baseline	40	19.72	123.82	66.5834	22.98966	054	.374
Simple Reaction Time Performane 3 Months	36	186.67	434.59	344.4484	50.49689	905	.393
Complex Reaction Time Performance 3 Months	36	146.24	245.58	202.5492	24.83454	175	.393
Immediate Recognition Memory Performance 3 Months	36	23.43	110.97	67.1212	17.16756	051	.393
Delayed Recognition Memory Performance 3 Months	36	20.25	104.17	64.7979	15.86709	065	.393
Stroop Congruent Performance 3 Months	36	67.53	145.66	111.1812	19.63447	.091	.393
Stroop Incongruent Performance 3 Months	36	.00	140.55	81.0823	27.74647	877	.393
Spatial Working Memory Performance at 3 Months	36	-69.71	135.53	59.1692	31.91265	-1.532	.393
Contextual Memory Performance at 3 Months	36	19.05	118.55	64.3614	24.05815	173	.393
Simple Reaction Time Performane 6 Months	31	250.92	449.84	347.1434	42.06810	.138	.421
Complex Reaction Time Performance 6 Months	31	141.18	256.09	200.6821	24.90365	.165	.421
Immediate Recognition Memory Performance 6 Months	31	28.59	118.60	63.7945	18.69655	.849	.421
Month's Delayed Recognition Memory Performance 6 Months	31	23.90	117.57	61.7062	19.84236	.648	.421
Stroop Congruent	31	66.42	157.09	111.5569	16.94499	.354	.421
Performance 6 Months Stroop Incongruent	31	40.01	151.62	87.2621	20.80677	.659	.421
Performance 6 Months Spatial Working Memory Performance at 6 Months	31	18.72	124.08	59.8334	21.82392	.814	.421
Contextual Memory	31	21.21	119.66	69.0571	21.52013	.089	.421
Performance at 6 Months Valid N (listwise)	0						

9.5 Appendix E: Completer Analysis Table

Means and Standard Deviations for Participants who Completed all Study Measures (Baseline Results without HA) – Complete Analysis Table

Outcome		GROUP A			GROUP B	
Measure	(n = 17)			(n = 14)		
	Baseline	3 Months	6 Months	Baseline	3 Months	6 Months
	Mean (SD)	Mean (SD)	Mean (SD)	Mean (SD)	Mean (SD)	Mean (SD)
PTA of Better	37.240	36.710	35.760	37.790	35.290	36.290
Hearing Ear	(7.918)	(10.463)	(8.437)	(12.491)	(9.840)	(10.321)
SPT (woHA)	119.710	120.530	121.000	116.860	119.000	121.570
	(19.218)	(18.984)	(16.993)	(19.394)	(18.585)	(21.820)
SUCCAB Perfo	rmance Cog	nition Measur	res		I	
SRT	337.357	345.001	343.424	338.426	361.421	351.660
	(42.016)	(55.092)	(52.259)	(41.054)	(32.122)	(26.128)
CRT	210.041	202.458	205.404	204.203	204.170	194.948
	(29.343)	(27.198)	(29.871)	(23.744)	(17.786)	(16.384)
IREC	69.395	67.377	65.710	68.809	69.797	61.468
	(24.198)	(19.844)	(22.507)	(17.194)	(13.137)	(13.137)
DREC	65.711	62.581	60.005	60.426	71.046	63.772
	(20.018)	(19.144)	(23.088)	(11.439)	(9.931)	(15.625)
CStrp	115.242	113.101	112.484	117.495	113.050	110.432
	(16.596)	(23.148)	(21.741)	(14.171)	(15.433)	(8.852)
IStrp	85.675	88.345	91.032	90.790	85.794	82.685
	(28.780)	(28.621)	(24.211)	(15.355)	(14.930)	(15.378)
SWM	61.078	69.168	63.170	55.545	63.542	55.782
	(21.200)	(25.057)	(26.127)	(16.820)	(18.155)	(15.056)
CWM	77.050	72.946	72.113	66.236	61.220	65.346
	(21.857)	(22.767)	(25.095)	(19.265)	(21.900)	(16.327)

Abbreviated Profile of Hearing Aid Benefit (APHAB)						
EC	26.853	21.980	23.704	22.214	18.394	18.595
	(19.249)	(15.062)	(20.081)	(15.715)	(15.269)	(14.810)
RV	34.589	31.275	35.431	35.429	30.287	30.549
	(12.881)	(13.565)	(12.424)	(14.415)	(13.554)	(17.769)
BN	37.814	33.334	35.559	35.333	31.334	33.416
	(14.188)	(17.380)	(13.621)	(17.238)	(14.987)	(17.554)
AV	38.677	36.324	33.882	21.441	14.309	22.167
	(22.924)	(20.534)	(26.229)	(16.977)	(11.769)	(15.281)
Psycho-Social Measures						
GDS	1.824	2.059	1.529	1.774	1.714	0.857
	(1.912)	(1.853)	(1.736)	(1.684)	(1.383)	(1.167)
Social	34.882	33.824	34.824	35.143	34.500	32.385
Interaction	(8.306)	(11.193)	(9.349)	(9.859)	(9.011)	(13.866)

9.6 Appendix F: Author Indication Forms



Swinburne Research

Authorship Indication Form For PhD (including associated papers) candidates

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NOTE
This Authorship Indication form is a statement detailing the percentage of the contribution of each author in each associated 'paper'. This form must be signed by each co-author and the Principal Coordinating Supervisor. This form must be added to the publication of your final thesis as an appendix. Please fill out a separate form for each associated paper to be included in your thesis.
DECLARATION
We hereby declare our contribution to the publication of the 'paper' entitled: Investigating the Impact of Hearing Aid Use and Auditory Training on Cognition, <u>Depressive symptopos</u> , and social Interaction in Adults With Hearing 'Loss: Protocol for a Grossover Inial First Author
Name: Joanna NKyekyer Signature: France France
Percentage of contribution: 90%
Brief description of contribution to the 'paper' and your central responsibilities/role on project: Submitted ethics, registe Concerved Study, Project design, Data collecton, Statist- iCal analysis, drafted and Submitted paper
second Author analysis, drafted and Submitted paper
Name: Denoy Meyer Signature: D.H. Meyer
Percentage of contribution: 4% Date: 29/08/2018
Brief description of your contribution to the 'paper': Design 2 Statistical Analysis & review of paper Third Author
Name: <u>Peter J Blamey</u> Signature: <u>Ister & B. Carry</u>
Percentage of contribution: 2% Date: 31/08/18
Brief description of your contribution to the 'paper':
Project Design. 2 raview at paper
Fourth Author
Fourth Author Name: <u>Andrew Pipingas</u> Signature:
Percentage of contribution: 2% Date: 29/06/2015
Brief description of your contribution to the 'paper': Projuct Design & raview of paper
Principal Coordinating Supervisor: Name: DEMAY MEYE Signature: DA Meyer
Date: <u>0510412018</u>
In the case of more than four authors please attach another sheet with the names, signatures and contribution of the authors.

Authorship Indication Form



Authorship Indication Form

For PhD (including associated papers) candidates

NOTE

This Authorship Indication form is a statement detailing the percentage of the contribution of each author in each associated 'paper'. This form must be signed by each co-author and the Principal Coordinating Supervisor. This form must be added to the publication of your final thesis as an appendix. Please fill out a separate form for each associated paper to be included in your thesis.

	DECLARATION	
	We hereby declare our contribution to the publication of the 'paper' entitle	· · ·
- -	Investigating the Impact of t	tearing Aid Use and.
th I	Fipst Author	\sim \sim
	Name: Sunil Bhar	_ Signature:
I	Percentage of contribution: _2_%	Date: 291 81 2018
	Brief description of contribution to the 'paper' and your central responsibi	
	Project Design & Review	of paper.
:	Second Author	
	Name:	Signature:
	Percentage of contribution:%	Date://
	Brief description of your contribution to the 'paper':	
	Third Author	
	Name:	Signature:
	Percentage of contribution:%	Date://
	Brief description of your contribution to the 'paper':	
	Fourth Author	
	Name:	Signature:
	Percentage of contribution:%	Date://
	Brief description of your contribution to the 'paper':	
	Principal Coordinating Supervisor: Name: Denny Meye	Signature: D. [] Meyer
	$D_{ate:} O^{5} IO^{4} I 2 OI 8$	
- E		

Authorship Indication Form

1 of 1



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For PhD (including associated papers) candidates

NOTE . This Authorship Indication form is a statement detailing the percentage of the contribution of each author in each associated 'paper'. This form must be signed by each co-author and the Principal Coordinating Supervisor. This form must be added to the publication of your final thesis as an appendix. Please fill out a separate form for each associated paper to be included in your thesis.

uters,
DECLARATION
We hereby declare our contribution to the publication of the 'paper' entitled: The Cognittve and Haycho- social Effects of Auditory Training and Hearing Ads in Adults with Hearing Loss
First Author
Name: Jocurna Nkyekyer signature: 19-5000.
Percentage of contribution: 90% Date: 29/08/2018
Brief description of contribution to the 'paper' and your centrel responsibilitios/role on project: COncerved study , Broyect design, date collection, Statistical analysis, obrafted and submitted paper second Author
Name: Denny Meyer
Percentege of contribution: 6% Date: 0510912018
Brief description of your contribution to the 'paper':
Design, Statistical Analysis and Review of Paper
Third Author
Namo: Andrew Lipincaissignature:
Percentage of contribution: 2% Date: 29/8/2018
Brief description of your contribution to the 'paper': Project Design and Rievièw of Paper Fourth Author
Name: Nicholas S. Reed Signature:
Percentage of contribution: 2% Date: 31.1.8 / 2015
Brief description of your contribution to the 'peper': Review of Paper
Principal Coordinating Supervisor: Name: DENNY MEYON Signature: DH. Meyon
Date: 0510912018
In the case of more than four authors please attach another sheet with the names, signatures and contribution of the authors.

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NOTE

This Authorship Indication form is a statement detailing the percentage of the contribution of each author in each associated 'paper'. This form must be signed by each co-author and the Principal Coordinating Supervisor. This form must be added to the publication of your final thesis as an appendix. Please fill out a separate form for each associated paper to be included in your thesis.

DECLARATION	
We hereby declare our contribution to the publication of the 'paper' entitle Adults With Postingual' Sen- Protocol for a Prospective	ed: Hearing Aid Use in Older sonineural Hearing Loss: Cohort Study
First Author	11.4
Name: Matthew Edward Hugher	5 Signature:
Percentage of contribution: 28_%	Date: 291092018
Brief description of contribution to the 'paper' and your central responsibility Roye's Design and Draft	
Second Author	•
Name: Joanna Nkyekyer	_Signature:
Percentage of contribution: 62 %	Date: 29/08/2018
Percentage of contribution: 62% Brief description of your contribution to the 'paper: Subvisuitie Project design, data colle Third Author Third Author	d ethics, registered as curries, chuon, statistical analysis, ublication
Name: Hamish Trops-Brown	_Signature:
Percentage of contribution:%	Date: _04/ 09/2018_
Brief description of your contribution to the 'paper': Advice & paper vicinicus Fourth Author	
Name: Susan L Rossell	Signature: http://www.sect
Percentage of contribution; $\frac{1}{2}$ %	Date: 31/08/2018
Brief description of your contribution to the 'paper':	
Principal Coordinating Supervisor: Name: <u>Denny Meyo</u> Date: <u>QSIQ912018</u>	signature: D. H. Meyor

In the case of more than four authors please attach another sheet with the names, signatures and contribution of the authors.

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NOTE

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	DECLARATION	
-	We hereby declare our contribution to the publication of the 'paper' entitled	i :
	Hearing Aid Use in Olde	r Adults With Postlingual
Fifth	First-Author	
		Signature:
	Percentage of contribution: $\frac{1}{2}$ %	Date: 29/8/18
	Brief description of contribution to the 'paper' and your central responsibilit	ties/role on project:
	Advice	
Sixi	jSecond Author	11
	Name: Sunil Bhar	Signature:
	Percentage of contribution: $\frac{1}{2}$ %	Date: 291 87 2018
	Brief description of your contribution to the 'paper':	
	Advice	
Seventh	, Third Author	X
	Name: Andrew Pipingas	_ Signature:
	Percentage of contribution: $\frac{1}{2}$ %	Date: 29/08/2018
	Brief description of your contribution to the 'paper':	
Eighth	Advice Fourth Author	
	Name: Alison Honnessy	Signature: MIAR DEANCUDY
	Percentage of contribution: 2%	_ Signature: <u>AUSPANERNER</u> BYT Date 29/8/2018
	Brief description of your contribution to the 'paper': Advice and paper viewi	
	Principal Coordinating Supervisor: Name: Denny Meyer	
	Date: 05/09/2018	7
) is the second se	the names, signatures and contribution of the authors

In the case of more than four authors please attach another sheet with the names, signatures and contribution of the authors.

Authorship Indication Form

1 of 1



Authorship Indication Form

For PhD (including associated papers) candidates

NOTE

This Authorship Indication form is a statement detailing the percentage of the contribution of each author in each associated 'paper'. This form must be signed by each co-author and the Principal Coordinating Supervisor. This form must be added to the publication of your final thesis as an appendix. Please fill out a separate form for each associated paper to be included in your thesis.

DECLARATION	
We hereby declare our contribution to the publication of the 'paper' entitle	
Hearing And Use in Older Ninth First Author	- Adults With Bottingual
Ninth First Author	
Name: Denny Meyer	signature: D. H. Meyor.
Percentage of contribution: <u>4</u> %	Date: 2610812018
Brief description of contribution to the 'paper' and your central responsibil	ities/role on project:
Design & Statistical Analysi	s e paper naview
Second Author	
Name:	_ Signature:
Percentage of contribution:%	Date://
Brief description of your contribution to the 'paper':	
Third Author	
Name:	_ Signature: ,
Percentage of contribution:%	Date://
Brief description of your contribution to the 'paper':	
Fourth Author	
Name:	_ Signature:
Percentage of contribution:%	Date://
Brief description of your contribution to the 'paper':	
Principal Coordinating Supervisor: Name: De Nuy Meyer	Signature: H! Ver 6
Date: 05/09/2018)

In the case of more than four authors please attach another sheet with the names, signatures and contribution of the authors.

Authorship Indication Form

1 of 1

9.7 Appendix G: Ethics Documentation

From: Astrid Nordmann
Sent: Friday, 22 July 2016 2:52 PM
To: Denny Meyer <<u>dmeyer@swin.edu.au</u>>
Cc: RES Ethics <<u>resethics@swin.edu.au</u>>; Joanne Tarasuik <<u>itarasuik@swin.edu.au</u>>; Andrew
Pipingas <<u>apipingas@swin.edu.au</u>>; Sunil Bhar <<u>sbhar@swin.edu.au</u>>
Subject: SHR Project 2016/159 - Ethics clearance

To: A/Prof. Denny Meyer, FHAD Dear Denny,

SHR Project 2016/159 – Investigating the impact of hearing aid use and auditory training on cognition, mood and social interaction in older adults with hearing loss

A/Prof. Denny Meyer, Ms Joanna Nkyekyer (Student), A/Prof. Andrew Pipingas, A/Prof. Sunil Bhar - FHAD

Approved duration: 22/07/2016 to 31/01/2018 [adjusted]

I refer to the ethical review of the above project protocol by Swinburne's Human Research Ethics Committee (SUHREC). Your response to the review, as emailed on 21 July 2016, accords with the Committee review.

I am pleased to advise that, as submitted to date, the project may proceed in line with standard on-going ethics clearance conditions outlined below.

- All human research activity undertaken under Swinburne auspices must conform to Swinburne and external regulatory standards, including the *National Statement on Ethical Conduct in Human Research* and with respect to secure data use, retention and disposal.

- The named Swinburne Chief Investigator/Supervisor remains responsible for any personnel appointed to or associated with the project being made aware of ethics clearance conditions, including research and consent procedures or instruments

approved. Any change in chief investigator/supervisor requires timely notification and SUHREC endorsement.

- The above project has been approved as submitted for ethical review by or on behalf of SUHREC. Amendments to approved procedures or instruments ordinarily require prior ethical appraisal/clearance. SUHREC must be notified immediately or as soon as possible thereafter of (a) any serious or unexpected adverse effects on participants and any redress measures; (b) proposed changes in protocols; and (c) unforeseen events which might affect continued ethical acceptability of the project.

- At a minimum, an annual report on the progress of the project is required as well as at the conclusion (or abandonment) of the project. Information on project monitoring and variations/additions, self-audits and progress reports can be found on the Research Ethics Internet pages.

- A duly authorised external or internal audit of the project may be undertaken at any time.

Please contact the Research Ethics Office if you have any queries about on-going ethics clearance, citing the Swinburne project number. A copy of this email should be retained as part of project record-keeping.

Best wishes for the project.

Yours sincerely

Astrid Nordmann Secretary, SUHREC



Dr Astrid Nordmann | Research Ethics Coordinator Swinburne Research | Swinburne University of Technology Ph +61 3 9214 3845 | <u>anordmann@swin.edu.au</u> Level 1, Swinburne Place South 24 Wakefield St, Hawthorn VIC 3122, Australia www.swinburne.edu.au From: Astrid Nordmann
Sent: Wednesday, 31 August 2016 1:58 PM
To: Denny Meyer <<u>dmeyer@swin.edu.au</u>>
Cc: RES Ethics <<u>resethics@swin.edu.au</u>>; Joanne Tarasuik <<u>jtarasuik@swin.edu.au</u>>; Andrew
Pipingas <<u>apipingas@swin.edu.au</u>>; Sunil Bhar <<u>sbhar@swin.edu.au</u>>
Subject: RE: SHR Project 2016/159 - Ethics extension/modification (1)

To: A/Prof. Denny Meyer, FHAD

Dear Denny,

SHR Project 2016/159 – Investigating the impact of hearing aid use and auditory training on cognition, mood and social interaction in older adults with hearing loss

A/Prof. Denny Meyer, Ms Joanna Nkyekyer (Student), A/Prof. Andrew Pipingas, A/Prof. Sunil Bhar - FHAD Approved duration: 22/07/2016 to 31/01/2018 [adjusted] Modified: August 2016.

I refer to your request to modify the approved protocol for the above project as emailed on 22 August 2016. The request (concerning use of a different hearing aid, addition of a coinvestigator (Peter Blamey) and permission to approach other Australian Unity aged care facilities for recruitment) was put to a SUHREC delegate for consideration.

I am pleased to advise that, as modified to date, the project may continue in line with standard ethics clearance conditions previously communicated and reprinted below. Please note that information on self-auditing, progress/final reporting and modifications/additions to approved protocols can now be found on the Research Ethics Internet pages.

Please contact the Research Ethics Office if you have any queries about on-going ethics clearance, citing the project number. A copy of this email should be retained as part of project record-keeping.

As before, best wishes for the project.

Yours sincerely,

Astrid Nordmann



Dr Astrid Nordmann | Research Ethics Coordinator Swinburne Research | Swinburne University of Technology Ph +61 3 9214 3845 | <u>anordmann@swin.edu.au</u> Level 1, Swinburne Place South 24 Wakefield St, Hawthorn VIC 3122, Australia <u>www.swinburne.edu.au</u>

From: Astrid Nordmann
Sent: Monday, November 28, 2016 1:08 PM
To: Denny Meyer
Cc: RES Ethics; Andrew Pipingas; Sunil Bhar; Joanna Nkyekyer
Subject: RE: SHR Project 2016/159 - Ethics extension/modification (2)

To: A/Prof. Denny Meyer, FHAD

Dear Denny,

SHR Project 2016/159 – Investigating the impact of hearing aid use and auditory training on cognition, mood and social interaction in older adults with hearing loss

A/Prof. Denny Meyer, Ms Joanna Nkyekyer (Student), A/Prof. Andrew Pipingas, A/Prof. Sunil Bhar - FHAD

Approved duration: 22/07/2016 to 31/01/2018 [adjusted] Modified: August 2016, November 2016.

I refer to your request to modify the approved protocol for the above project as emailed on 16 November 2016. The request (concerning changes to eligibility criteria and recruitment methodcswas put to a SUHREC delegate for consideration. I am pleased to advise that, as modified to date, the project may continue in line with standard ethics clearance conditions previously communicated and reprinted below. Please note that information on self-auditing, progress/final reporting and modifications/additions to approved protocols can now be found on the Research Ethics Internet pages.

Please contact the Research Ethics Office if you have any queries about on-going ethics clearance, citing the project number. A copy of this email should be retained as part of project record-keeping.

As before, best wishes for the project.

Yours sincerely, Astrid Nordmann



Dr Astrid Nordmann | Research Ethics Coordinator Swinburne Research | Swinburne University of Technology Ph +61 3 9214 3845 | anordmann@swin.edu.au Level 1, Swinburne Place South 24 Wakefield St, Hawthorn VIC 3122, Australia www.swinburne.edu.au

From: Astrid Nordmann

Sent: Friday, 17 November 2017 1:15 PM

To: Denny Meyer <<u>dmeyer@swin.edu.au</u>>

Cc: RES Ethics <<u>resethics@swin.edu.au</u>>; Matthew Hughes

<<u>matthewhughes@swin.edu.au</u>>; Andrew Pipingas <<u>apipingas@swin.edu.au</u>>; Sunil Bhar <<u>sbhar@swin.edu.au</u>>; Joanna Nkyekyer <<u>inkyekyer@swin.edu.au</u>> Subject: SHR Project 2017/266 - Ethics clearance

To: Prof. Denny Meyer - FHAD

Dear Denny,

SHR Project 2017/266 – Using Magnetic Resonance Imaging to investigate the effects of hearing aid use on brain activity and cognitive function in older adults with sensorineural hearing loss Prof. Denny Meyer, Dr Matthew Hughes, A/Prof. Andrew Pipingas, A/Prof. Sunil Bhar, Ms Joanna Nkyekyer (Student) – FSET & FHAD Approved duration: 18-11-2017 to 18-04-2019 [adjusted]

I refer to the ethical review of the above project protocol by Swinburne's Human Research Ethics Committee (SUHREC). Your response to the review, as emailed on 16 November 2017, accords with the Committee review.

I am pleased to advise that, as submitted to date, the project may proceed in line with standard on-going ethics clearance conditions outlined below.

- The approved duration is **18 November 2017** to **18 April 2019** unless an extension request is subsequently approved.

- All human research activity undertaken under Swinburne auspices must conform to Swinburne and external regulatory standards, including the *National Statement on Ethical Conduct in Human Research* and with respect to secure data use, retention and disposal.

- The named Swinburne Chief Investigator/Supervisor remains responsible for any personnel appointed to or associated with the project being made aware of ethics

clearance conditions, including research and consent procedures or instruments approved. Any change in chief investigator/supervisor, and addition or removal of other personnel/students from the project, requires timely notification and SUHREC endorsement.

- The above project has been approved as submitted for ethical review by or on behalf of SUHREC. Amendments to approved procedures or instruments ordinarily require prior ethical appraisal/clearance. SUHREC must be notified immediately or as soon as possible thereafter of (a) any serious or unexpected adverse effects on participants and any redress measures; (b) proposed changes in protocols; and (c) unforeseen events which might affect continued ethical acceptability of the project.

- At a minimum, an annual report on the progress of the project is required as well as at the conclusion (or abandonment) of the project. Information on project monitoring and variations/additions, self-audits and progress reports can be found on the Research Ethics Internet <u>pages</u>.

- A duly authorised external or internal audit of the project may be undertaken at any time.

Please contact the Research Ethics Office if you have any queries about on-going ethics clearance, citing the Swinburne project number. A copy of this email should be retained as part of project record-keeping.

Best wishes for the project.

Yours sincerely

Astrid Nordmann Secretary, SUHREC



Ph +61 3 9214 3845] <u>anordmann@swin.edu.au</u> Level 1, Swinburne Place South 24 Wakefield St, Hawthorn VIC 3122, Australia <u>www.swinburne.edu.au</u>

From: Sally Fried On Behalf Of RES Ethics

Sent: Thursday, 5 July 2018 4:29 PM
To: Astrid Nordmann <<u>anordmann@swin.edu.au</u>>; Denny Meyer <<u>dmeyer@swin.edu.au</u>>; Cc: RES Ethics <<u>resethics@swin.edu.au</u>>; Matthew Hughes
<<u>matthewhughes@swin.edu.au</u>>; Andrew Pipingas <<u>apipingas@swin.edu.au</u>>; Sunil Bhar
<<u>sbhar@swin.edu.au</u>>; Joanna Nkyekyer <<u>inkyekyer@swin.edu.au</u>>; Kathleen De Boer
<<u>kdeboer@swin.edu.au</u>>

Subject: SHR Project 2017/266 - Ethics extension/modification (1)

To: Prof. Denny Meyer - FHAD

Dear Denny,

SHR Project 2017/266 – Using Magnetic Resonance Imaging to investigate the effects of hearing aid use on brain activity and cognitive function in older adults with sensorineural hearing loss

Prof. Denny Meyer, Dr Matthew Hughes, A/Prof. Andrew Pipingas, A/Prof. Sunil Bhar, Kathleen de Boer, Ms Joanna Nkyekyer (Student) – FSET & FHAD Approved duration: 18-11-2017 to 18-04-2019 [adjusted] Modified: July 2018

I refer to your request to modify the approved protocol for the above project as e-mailed on 30 June 2018. The request (concerning the addition of Kathleen de Boer to the project) was put to a SUHREC delegate for consideration.

I am pleased to advise that, as modified to date, the project may continue in line with standard ethics clearance conditions previously communicated and reprinted below. Please note that information on self-auditing, progress/final reporting and modifications/additions to approved protocols can now be found on the Research Ethics Internet pages.

Please contact the Research Ethics Office if you have any queries about on-going ethics clearance, citing the project number. A copy of this e-mail should be retained as part of project record-keeping.

As before, best wishes for the project.

Yours sincerely,

Sally Fried for Astrid Nordmann



From: Astrid Nordmann

Sent: Monday, September 3, 2018 10:47 AM

To: Denny Meyer

Cc: Matthew Hughes; Andrew Pipingas; Sunil Bhar; Joanna Nkyekyer; Kathleen De Boer; RES

Ethics; SUT Neuroimaging Facility; Sally Fried

Subject: RE: SHR Project 2017/266 - Ethics extension/modification (2)

To: Prof. Denny Meyer - FHAD

Dear Denny,

SHR Project 2017/266 – Using Magnetic Resonance Imaging to investigate the effects of hearing aid use on brain activity and cognitive function in older adults with sensorineural hearing loss

Prof. Denny Meyer, Dr Matthew Hughes, A/Prof. Andrew Pipingas, A/Prof. Sunil Bhar, Kathleen de Boer, Ms Joanna Nkyekyer (Student) – FSET & FHAD Approved duration: 18-11-2017 to 18-04-2019 [adjusted]; extended to 18-11-2019 [September 2018] Modified: July 2018, September 2018

I refer to your request to modify the approved protocol for the above project as e-mailed on 01 September 2018. The request (concerning changing a one hour MRI session to two 40min MRI sessions, rectifying volume issues with auditory tasks, and extension of ethics clearance to 18 November 2019) was put to a SUHREC delegate for consideration.

I am pleased to advise that, as modified to date, the project may continue in line with standard ethics clearance conditions previously communicated and reprinted below. Please note that information on self-auditing, progress/final reporting and modifications/additions to approved protocols can now be found on the Research Ethics Internet pages.

Please contact the Research Ethics Office if you have any queries about on-going ethics clearance, citing the project number. A copy of this e-mail should be retained as part of project record-keeping.

As before, best wishes for the project.

Yours sincerely, Astrid Nordmann



Dr Astrid Nordmann | Research Ethics Coordinator Swinburne Research| Swinburne University of Technology Ph +61 3 9214 3845| anordmann@swin.edu.au Level 1, Swinburne Place South 24 Wakefield St, Hawthorn VIC 3122, Australia www.swinburne.edu.au

9.8 Appendix H: Questionnaire for Crossover Study



STUDY QUESTIONNAIRE

INVESTIGATING THE IMPACT OF HEARING AID USE AND AUDITORY TRAINING ON COGNITION, MOOD AND SOCIAL INTERACTION IN OLDER ADULTS WITH HEARING LOSS - 2016

Dear Participant,

This research study is being conducted in order to learn how auditory training coupled with hearing aid use impact on the mood, social interaction and cognitive performance of an older adult with hearing loss.

This questionnaire has four (4) sections and seeks to obtain data about your demographics, mood, social interaction and cognitive function such as orientation and language. The researcher will guide you through the 4th section (i.e. cognitive function assessments) of this questionnaire.

Completing the questionnaire will take approximately twenty (20) minutes.

Your privacy is assured. None of your personal information will be divulged to a third party (i.e. any individual, organization, agency or researcher not directly involved in this research). The information gathered will only be used for research purposes and will be stored securely at Swinburne University of Technology.

Thank you for your time and for your assistance.

Yours sincerely,

D. H. Meyor

A/Prof. Denny Meyer Principal Investigator

Section A: Demographic Information

a. How old are you?



- b. What is your gender?
 - a. Male
 - b. Female
- c. Which of the following best describes your highest level of education?
 - a. Completed year 11 or less
 - b. Completed year 12
 - c. Started TAFE but not completed
 - d. Started University degree but not completed
 - e. Completed TAFE degree/diploma/certificate
 - f. Completed University Degree
 - g. Other (please specify)
- d. Which of the following best describes your employment status?
 - a. Full-time employment
 - b. Part-time employment
 - c. Casual work
 - d. Home duties
 - e. Retired
 - f. Other (please specify)
- e. Do you have hearing trouble?
 - a. I do not have hearing trouble
 - b. I have trouble following the conversation with two or more people talking at the same time or in a noisy background
 - c. I have major hearing loss
- f. Nowadays, do you ever get noises in your head or ears (tinnitus) which usually last longer than five minutes?
 - a. No
 - b. Never
 - c. Some of the time
 - d. Most or all of the time

Section B: Depression Scale

Instructions: Please read each statement and choose the best answer for how you have felt over the past week.

- 1. Are you basically satisfied with your life? YES / NO
- 2. Have you dropped many of your activities and interests? YES / NO
- 3. Do you feel that your life is empty? YES / NO
- 4. Do you often get bored? YES / NO
- 5. Are you in good spirits most of the time? YES / NO
- 6. Are you afraid that something bad is going to happen to you? YES / NO
- 7. Do you feel happy most of the time? YES / NO
- 8. Do you often feel helpless? YES / NO
- 9. Do you prefer to stay at home, rather than going out and doing new things? YES / NO
- 10. Do you feel you have more problems with memory than most? YES / NO
- 11. Do you think it is wonderful to be alive now? YES / NO
- 12. Do you feel pretty worthless the way you are now? YES / NO
- 13. Do you feel full of energy? YES / NO
- 14. Do you feel that your situation is hopeless? YES / NO
- 15. Do you think that most people are better off than you are? YES / NO

Section C: Social Engagement Scale

FAMILY: Considering the people to whom you are related either by birth or marriage. *Circle one number for each of the following questions.*

- 1. How many relatives do you see or hear from at least once a month?
 - 0 = none
 - 1 = one
 - 2 = two
 - 3 = three or four
 - 4 =five thru eight
 - 5 = nine or more
- 2. How often do you see or hear from the relative with whom you have the most contact?
 - 0 = less than monthly
 - 1 = monthly
 - 2 = a few times a month
 - 3 = weekly
 - 4 = few times a week, often
 - 5 = daily
- 3. How many relatives do you feel comfortable talking to about private matters?
 - 0 = none
 - 1 = one
 - 2 = two
 - 3 = three or four
 - 4 =five thru eight
 - 5 = nine or more
- 4. How many relatives do you feel are sufficiently close that you could call on them for help?
 - 0 = none
 - 1 = one
 - 2 = two
 - 3 = three or four
 - 4 =five thru eight
 - 5 = nine or more

- 5. When one of your relatives has an important decision to make, how often do they talk to you about it?
 - 0 = never
 - 1 = seldom
 - 2 =sometimes
 - 3 = often
 - 4 =very often
 - 5 = always
- 6. How often is one of your relatives available for you to talk to when you have an important decision to make?
 - 0 = never
 - 1 = seldom
 - 2 =sometimes
 - 3 = often
 - 4 =very often
 - 5 = always

FRIENDSHIPS: Considering all of your friends including those who live in your neighbourhood. *Circle one number for each of the following questions.*

- 7. How many of your friends do you see or hear from at least once a month?
 - 0 = none
 - 1 = one
 - 2 = two
 - 3 = three or four
 - 4 =five thru eight
 - 5 = nine or more
- 8. How often do you see or hear from the friend with whom you have the most contact?
 - 0 =less than monthly
 - 1 = monthly
 - 2 = a few times a month
 - 3 = weekly
 - 4 = few times a week, often
 - 5 = daily
- 9. How many friends do you feel comfortable talking to about private matters?
 - 0 = none
 - 1 = one
 - 2 = two
 - 3 = three or four
 - 4 =five thru eight
 - 5 = nine or more

- 10. How many friends do you feel sufficiently close to that you could call on them for help?
 - 0 = none
 - 1 = one
 - 2 = two
 - 3 = three or four
 - 4 =five thru eight
 - 5 = nine or more
- 11. When one of your friends has an important decision to make, how often do they talk to you about it?
 - 0 = never
 - 1 = seldom
 - 2 =sometimes
 - 3 = often
 - 4 = very often
 - 5 = always
- 12. How often is one of your friends available for you to talk to when you have an important decision to make?
 - 0 = never
 - 1 = seldom
 - 2 =sometimes
 - 3 = often
 - 4 =very often
 - 5 = always

Kindly see the researcher for Section 4 of the questionnaire after you have completed Sections 1, 2, & 3.

THANK YOU

Please write in your full name and mobile number. This information will only be made available to researchers working on this project behalf of the Principal Investigator.

Full Name (IN BLOCK LETTERS)	
Mobile Number	
Date	

9.9 Appendix I: The Abbreviated Profile of Hearing Aid Benefit Questionnaire

ABBREVIATED PROFILE OF HEARING AID BENEFIT																		
N	ME: Maie		Fe	male	•	т	OD	AYS	S D/	ATE	<u>-</u>	1	1	_				
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 A								With Hearing Ald								
1.	When I am in a crowded grocery store, talking with the cashier, I can follow the conversation.	A	в	с	D	E	F	G	A	в	с	D	E	F	G			
2.	I miss a lot of information when I'm listening to a lecture.	A	в	С	D	Е	F	G	A	в	С	D	Е	F	G			
3.	Unexpected sounds, like a smoke detector or alarm bell are uncomfortable.	A	в	с	D	E	F	G	A	в	с	D	Е	F	G			
4.	I have difficulty hearing a conversation when I'm with one of my family at home.	A	в	с	D	E	F	Ð	A	в	с	D	Е	F	0			
5.	I have trouble understanding the dialogue in a movie or at the theater.	A	в	с	D	E	F	G	A	в	с	D	Е	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	в	с	D	E	F	0	A	в	с	D	E	F	0			
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	в	с	D	E	F	G	A	в	с	D	E	F	G			
8.	Traffic noises are too loud.	A	в	С	D	Е	F	G	A	в	С	D	Е	F	G			
9.	When I am talking with someone across a large empty room, I understand the words.	A	в	с	D	E	F	G	A	в	с	D	Е	F	G			
10	When I am in a small office, interviewing or answering questions, I have difficulty following the conversation.	A	в	с	D	E	F	G	A	в	с	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.		в	с	D	E	F	G	A	в	с	D	E	F	G			
12	When I am having a quiet conversation with a friend, I have difficulty understanding.	A	в	с	D	Е	F	G	A	в	с	D	Е	F	G			

(Continued on back)

- A Always (99%) B Almost Always (87%) C Generally (75%) D Haif-the-time (50%) E Occasionally (25%) F Seldom (12%)

- G Never (1%)

	Without Hearing Alds			With Hearing Alds										
 The sounds of running water, such as a toilet or shower, are uncomfortably loud. 	A	B	С	D	E	F	G	A	в	с	D	Е	F	G
 When a speaker is addressing a small group, and everyone is listening quietly, I have to strain to understand. 	A	B	с	D	E	F	G	A	в	с	D	Е	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	в	С	D	Е	F	0	A	в	С	D	Е	F	G
 I can understand conversations even when several people are talking. 	A	в	С	D	E	F	O	A	в	С	D	E	F	G
17. The sounds of construction work are uncomfortably loud.	A	В	С	D	Е	F	0	A	В	С	D	E	F	G
 It's hard for me to understand what is being said at lectures or church services. 	A	в	С	D	Е	F	0	A	в	С	D	Е	F	0
19. I can communicate with others when we are in a crowd.	A	В	С	D	Е	F	0	A	в	С	D	Ε	F	G
20. The sound of a fire engine siren close by is so loud that I need to cover my ears.	A	в	С	D	Е	F	G	A	в	С	D	E	F	G
 I can follow the words of a sermon when listening to a religious service. 	A	в	С	D	E	F	G	A	в	С	D	E	F	G
22. The sound of screeching tires is uncomfortably loud.	A	В	С	D	Е	F	G	A	В	С	D	E	F	G
 I have to ask people to repeat themselves in one-on-one conversation in a quiet room. 	A	B	С	D	E	F	G	×	в	с	D	Е	F	G
 I have trouble understanding others when an air conditioner or fan is on. 	A	в	С	D	E	F	G	A	в	С	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 None	None None	None
Less than 6 weeks	Less than 1 hour per day	Mild
6 weeks to 11 months	1 to 4 hours per day	Moderate
1 to 10 years	4 to 8 hours per day	Moderately-Severe
Over 10 years	8 to 16 hours per day	Severe Severe

C University of Meanphis, 1994



9.10 Appendix J: Screening Questionnaire for Crossover Study



SWINBURNE

UNIVERSITY OF

Name:
Phone Number:
Apartment Number:

SCREENING QUESTIONNAIRE

Project Title: Investigating the Impact of Hearing aid Use and Auditory Training on Cognition, Mood and Social Interaction in Older Adults with Hearing Loss Instructions:

Please CIRCLE only **ONE** of the responses which apply.

- 1. Do you have any difficulty in hearing?
 - a. No
 - b. Yes

If yes, for how long have you had this hearing difficulty?

- 2. Do you find it very difficult to follow a conversation if there is background noise (such as TV, radio, children playing)?
 - a. No
 - b. Yes
- 3. Do you find it difficult having a conversation with several people in a group?
 - a. No
 - b. Yes
- 4. Do very loud sounds annoy you?
 - a. No
 - b. Yes
- 5. How well do you hear someone talking to you when that person is sitting on your right side in a quiet room?
 - a. With no difficulty
 - b. With slight difficulty
 - c. With moderate difficulty
 - d. With great difficulty
 - e. Cannot hear at all
- 6. How well do you hear someone talking to you when that person is sitting on your left side in a quiet room?'

- a. With no difficulty
- b. With slight difficulty
- c. With moderate difficulty
- d. With great difficulty
- e. Cannot hear at all
- 7. Are you prepared to wear a hearing aid?
 - a. Yes
 - b. No

8. Are you prepared to undergo auditory training?

- a. Yes
- b. No
- 9. Are you colour blind?
 - a. Yes
 - b. No

10. Can you see reasonably well with/without spectacles or contact lenses?

- a. Yes
- b. No