

**The value of using the  
Operational Model of behaviour change  
on adult aural rehabilitation outcomes**

**by**

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<p><b>Abstract:</b> The prevalence of hearing loss in adults is well documented. Hearing loss leads to poor communication, which is essential for daily living. Cogitating that we have an ageing population who are living longer with more co-morbidities, the consequences of a hearing loss can have a devastating impact on psychosocial aspects of an individual's life. This in turn can negatively affect the quality of life of individuals with hearing loss. Although hearing aids are said to improve quality of life, studies have proven that many patients who are issued with hearing aids do not comply with aural rehabilitation services (either do not use the hearing aids at all or do not use them consistently). Research documents how this is costly (both financially and psychosocially) to patients, their caregivers as well as audiologists providing the service. Motivation and self-reported hearing disability and handicap have been highlighted in the literature as reasons why patients do not comply with aural rehabilitation. With current NHS reforms imposing cost-effective care with more patient choice and patient collaboration, aural rehabilitation services should evolve to include aspects of patient motivation and self-reported hearing disability and handicap by renouncing old medical models of rehabilitation and utilising models such as the Operational Model of behaviour change (OM). This model is said to be cost effective and patient-centred. The main aim of this study was to determine the value of using the OM of behaviour change on adult aural rehabilitation outcomes. The sub-aims outlined were designed to compare aural rehabilitation outcomes between two groups of subjects: one group that did not receive the OM of behaviour change and one that received the OM of behaviour change. This study was a quantitative, experimental study that utilised a pre-test post-test design. A total of 141 adult subjects with sensorineural hearing loss, who have never worn hearing aids, were recruited to this study and 68 of these were deemed suitable to participate as per the inclusion and exclusion criteria. Only 43 subjects completed the study and attended their final follow up appointment. Data from 24 subjects in the control group and 19 subjects in the experimental group were analysed and reported. The HHIE-S, HHIA-S, GHABP, IOI-HA and hearing aid data logging statistics were utilised as outcome measures for this study. Pre-test results displayed no significant difference between groups prior to implementation of the OM. Post-test results showed no significant difference for hearing aid use, reported benefit, hearing aid satisfaction and self-reported hearing difficulties. Conversely, the subjects in the experimental group scored significantly less residual disability for the GHABP than those in the control group. It could be inferred that subjects in the experimental group who received the OM, were more engaged and more supported during their rehabilitation process and as such had less difficulty with hearing aids. With regard to hearing aid benefit, results did have some positive effect, but this was not statistically significant. Secondary analysis of the results revealed corroborations with other studies with regard to the value of hearing aids and improvement in quality of life and reduction of self-reported hearing disability and handicap. On the basis of this study's results, further research is required to determine the value of the OM in similar audiology settings. Adaptation of service delivery models such as the OM corresponds with the drive for improving the quality of services by giving patients more control of their healthcare.</p>	

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## **LIST OF ABBREVIATIONS**

BAA -	British Academy of Audiology
BSA -	British Society of Audiology
DA -	Direct Access Services
DB -	Decisional Balance
GHABP -	Glasgow Hearing Aid Benefit Profile
HHIA -	Hearing Handicap Inventory for Adults
HHIA-S -	Screening Version of the Hearing Handicap Inventory for Adults
HHIE -	Hearing Handicap Inventory for the Elderly
HHIE-S -	Screening Version of the Hearing Handicap Inventory for the Elderly
IOI-HA -	International Outcome Inventory for Hearing Aids
MI -	Motivational Interviewing
NHS -	National Health Service
OM -	Operational Model of behaviour change
PTA -	Pure Tone Audiometry
TTM -	Transtheoretical Model

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- APPENDIX L** - Ethics approval letter from NRES Committee London – Riverside (REC Reference 12/LO/1995) dated 5<sup>th</sup> February 2013
- APPENDIX M** - Ethics approval letter from NRES Committee London – Riverside (REC Reference 12/LO/1995) dated 19<sup>th</sup> August 2014
- APPENDIX N** - Ethics approval letter from the Postgraduate Research and Ethics Committee of the Faculty of Humanities, University of Pretoria, South Africa (Reference 07098567) dated 22<sup>nd</sup> July 2013

# **1 INTRODUCTION AND BACKGROUND TO THE STUDY**

## **1.1 BACKGROUND**

Communication is central to human life and is a fundamental aspect of human function. Without communication, even in its most basic form, people will not be able to co-exist, as communication and exchange of information are essential aspects of daily living. A hearing loss can significantly impact an individual's communication with others and can lead to reduced quality of life. "Hearing loss" refers to a reduction in hearing sensitivity and implies structural or functional impairment of the auditory system (Stach, 2003).

Unlike other disabilities hearing loss is invisible, yet its impact on quality of life is evident (Tye-Murray, 2009). The consequences of hearing loss are manifested in almost all aspects of an individual's life including home, work, and social situations. The subsequent outcomes are frustration, social withdrawal, depression, and anxiety. There is also strong evidence that hearing loss is associated with cognitive decline and dementia as well as unemployment. Hearing loss contributes to lack of awareness of impending danger, thus placing individuals in harm's way. The older population is often labelled as confused, unresponsive, or uncooperative as a result of hearing loss. The term *hearing handicap* is used to describe these consequences and refers to the psychosocial disadvantages that result from hearing loss (Stach, 2003). These widespread ramifications undeniably indicate that hearing loss contributes to a poorer quality of life.

Current research shows that the older population is growing faster than the total population globally (Office for National Statistics, 2012). According to a report on World Population Ageing 1950 to 2050 (United Nations Department of Economic and Social Affairs/Population Division, 2009) the number of older persons has tripled over the last 50

years and the proportion of older persons to the general population is projected to almost triple again by 2050. This extended life expectancy is predicted to increase the prevalence of long-term diseases in the elderly populace. Since hearing loss is associated with other factors that reduce quality of life, the effect on health provision is compounded. Untreated hearing loss often means that more effort needs to be expended in treating the conditions that are associated with or that result from the hearing loss. More than 70% of people over the age of 70 and over 40% of people over the age of 50 are reported to have some form of hearing loss and these numbers will most likely increase as the elderly population increases (Action on Hearing Loss, 2014). Consequently there will be a greater demand for aural rehabilitation and support services that are aimed at restoring or optimising a patient's participation in activities that have been limited as a result of the hearing loss and to minimise the consequences of the hearing loss (Tye-Murray, 2009).

Rehabilitation in the general sense refers to the process of assisting patients to compensate for deficits that cannot be reversed medically (The Free Dictionary, 2015a). This can be related to individuals with presbycusis whereby aural rehabilitation can be defined as the reduction of hearing-loss-induced deficits of function through a combination of sensory management, instruction, perceptual training, and counselling (Boothroyd, 2007). Another definitions of aural rehabilitation include improving the efficacy of overall communication ability, the use of hearing aids, auditory training, speech reading, counselling and guidance (Mosby's Medical Dictionary, 2009a).

Aural rehabilitation plays an important role in assisting individuals with hearing loss to compensate for auditory deficits that cannot be treated with medical intervention. Such rehabilitation aims to improve overall communication ability by the use of hearing aids,

auditory training, counselling, and guidance (Stach, 2003). Hearing aids are said to have the potential to transform the lives of individuals with permanent hearing loss and offer an improved quality of life (Dalton et al., 2003; Stark & Hickson, 2004; Abrams, Chisolm, & McArdle, 2005; Chisolm et al., 2007), yet research has shown that people with hearing loss often do not have hearing aids (Walden, Walden, Summers & Grant, 2009; Pacala & Yueh, 2012) or in the event that they do have hearing aids, choose not to wear their devices (Smeeth et al., 2002; Action on Hearing Loss, 2014). According to the charitable organisation Action on Hearing Loss (2014), there are ten million people in the United Kingdom (UK) with some form of hearing loss, but only two million people have hearing aids. Out of the two million people with hearing aids, only 1.4 million use their hearing aids regularly. Out of the ten million people with hearing loss in the UK, at least four million people who do not have hearing aids would benefit from using them (Action on Hearing Loss, 2014). Other surveys conducted in Australia, Finland, Denmark, and the United States revealed that about 40% of hearing aids dispensed are never or rarely used (Smeeth et al., 2002; Hickson & Worrall, 2003; Lupsakko, Kautiainen & Sulkava, 2005). Evidently, technological advances of hearing aids have not led to significant improvements in aural rehabilitation outcomes as the needs of individuals with hearing loss are unmet even when technological needs have been addressed (Gregory, 2012). Kricos, Erdman, Bratt and Williams (2007, p 305) made the following statement: “*The underutilization of hearing aids by adults who potentially might benefit from them should be a major concern to audiologists.*”

From the preceding review it is clear that the prevalence of hearing loss, especially in the older population, is well documented and that it is a health condition often contributing to a poorer quality of life. Despite its well-known prevalence, hearing loss and its impact on

individual lives is not fully understood. People with hearing loss still do not seek professional help and if they do seek help, they do not follow through with auditory rehabilitation services. The few people who do follow through and acquire hearing aids do not comply with auditory rehabilitation services (i.e. do not use their hearing aids).

## **1.2 PROBLEM STATEMENT**

Aural rehabilitation and support services are of paramount importance in assisting those with hearing loss but the high rate of non-compliance with aural rehabilitation services could be costly to individuals with hearing loss, their caregivers as well as to audiologists. Audiologists therefore need to develop and utilise aural rehabilitation models that are cost effective, but at the same time focus on providing support that will enhance a patient's compliance with these services. In so doing they will contribute to a better quality of life for the increasing ageing population. This patient-centred model of aural rehabilitation will require of audiologists that they modify their traditional medical focus on pathology and impairment, and focus instead on integrating individuals' psychosocial effects of hearing loss with aural rehabilitation. The Operational Model of behaviour change (OM), which focuses on an individual's psychosocial effects of hearing loss (refer to section 2.3 and 2.4), could provide a patient-centred framework for aural rehabilitation.

The goal of aural rehabilitation should be to improve quality of life by focusing on reducing an individual's activity limitation (degree of difficulty a person experiences hearing in various situations) and participation restrictions (the extent to which someone is unable to participate in activities as a result of the hearing loss) through changes in behaviour (BSA, 2012a). Aural rehabilitation is regarded as essential for minimising the consequences of hearing loss (Tye-Murray, 2009). The OM outlines a course of action for

attaining the goal of aural rehabilitation, and provides individuals with hearing loss with the necessary support to enhance their compliance with rehabilitation services.

To date there are no published studies that investigated the OM and its potential contribution to aural rehabilitation outcomes within the National Health Service (NHS) in the United Kingdom (UK). The impact of applying this model has been investigated within other health fields, but more research needs to be conducted within the field of audiology to determine the effect of this model on patient outcomes (Tønnesen 2012).

### **1.3 RATIONALE FOR THE STUDY**

The NHS in the UK is a government run organisation funded by general taxation. Over the past few years, the UK NHS has been focusing on improving the quality of services by giving patients more choice, including lifestyle choices, decisions about treatments, and options regarding the way patients interact with doctors and health care professionals (NHS, 2011). The Department of Health's White paper, *Equity and Excellence: Liberating the NHS* (July, 2010) sets out how healthcare professionals should partake in clinical governance and introduce innovative methods that focus on continually improving the outcome of their healthcare. *"Clinical governance is a framework through which NHS organisations are accountable for continually improving the quality of their services, and safeguarding high standards of care by creating an environment in which excellence in clinical care will flourish"* (Department of Health, 2010). Audiologists are consequently responsible for developing and shaping the services they provide according to the evolving needs of the patients they serve.

Individuals with hearing loss should be given the opportunity to hear better and to understand the nature of their hearing loss. Furthermore, they should be assisted to understand, be aware of, and be confident in applying strategies to improve their listening skills. Finally they should be afforded access to on-going support services. As pointed out in the previous paragraph, audiologists are responsible for developing and shaping the services they provide according to the evolving needs of the patients they serve. It follows that audiologists in the NHS, who are accountable for clinical governance, need to develop aural rehabilitation services that take into consideration the increase in the ageing population and support patients to improve compliance with aural rehabilitation, but at the same time are patient-centred and cost effective.

Providing a quality service in accordance with patient needs is the key to the success of any rehabilitation service, and patient satisfaction is a significant criterion. NHS England (2014) set out their vision as follows: *“Everyone has greater control of their health and their well being, supported to live longer lives by high quality (safe, effective and positive patient experience) health and care services that are compassionate, inclusive (open, transparent, work with patients to get best outcomes) and constantly improving (committed to a dynamic NHS).”* Tønnesen (2012) also states that empowerment of patients is essential for improving health outcomes and that emphasis should be placed on an individual’s lifestyle, behaviour and readiness to change. Consequently, there is a national drive to make services more patient-centred.

The research question therefore arises: What impact would using the OM of behaviour change have on adult aural rehabilitation outcomes? It would be valuable to establish whether changing current practice from a medical model (emphasizing pathology and



diagnosis) to a more patient-centred approach (incorporating patient-centred psychosocial aspects), through use of the OM of behaviour change, can bring about improvement in compliance with rehabilitation and outcomes for subjects undergoing hearing aid rehabilitation. The purpose of this study was therefore to determine the value of using the OM of behaviour change on adult aural rehabilitation outcomes.

## **1.4 TERMINOLOGY**

### **1.4.1 Aural rehabilitation outcomes**

The term aural rehabilitation is defined above (refer to page 2), the term outcome is defined as an end result or consequence (The Free Dictionary, 2015b) and outcome measures refer to assessments of the end results of health service programs and interventions (Jette & Stephen, 2005). Each of these terms can be defined separately, however a working definition of the term ‘aural rehabilitation outcomes’ is not available from literature. Thus for the purpose of this study, the concept ‘aural rehabilitation outcomes’ represents three aspects: a patient’s hearing aid use (the number of hours hearing aids are used per day), a patient’s satisfaction with the hearing aids (satisfaction with hearing aids in different situations) and finally a patient’s self-reported hearing disability and handicap (the effect or impact of the hearing aids on the patients’ life) after

### **1.4.2 Hearing handicap**

Hearing handicap can be defined as a measure of the impact of hearing loss on an individual’s life and the psychosocial impact of hearing loss (Stach 2003; Mosby’s Medical Dictionary, 2009b). Although the World Health Organisation (WHO, 2001, in Stach, 2003) has discouraged the use of the term ‘handicap’, some outcome measures

utilised for this study still make use of the term hearing ‘handicap’. For the purpose of consistency, therefore, the term will still be utilised throughout this document.

### **1.4.3 Operational model of behaviour change**

The OM model (Tønnesen, 2012) is an integrative model that incorporates elements of preceding models of behaviour change namely the Transtheoretical Model of behaviour change (Prochaska, Norcross & DiClemente, 1994), Motivational Interviewing (Miller & Rollnick, 1991) and Decisional Balance (Janis & Mann, 1977). It is a process-related tool that supports patients and facilitates an effective process of change of lifestyle. The OM integrated three tools that assist audiologists to support a patient’s process of change: the Circle, the Line and the Box. The Circle is a tool to help the audiologist understand and monitor the different stages a patient will undergo during the process of change. The Line is used to enable patients to commence reflecting on the change they are about to make by ranking their self-efficacy. The Box assists patients to evaluate the pros and cons of the change as well as their ambivalent feelings towards the change.

### **1.4.4 Patients, subjects, prospective subjects, subjects not eligible for the study**

For the purpose of this study the term ‘patients’ will refer to patients with hearing loss in general (not necessarily in this study). The term ‘subjects’ will refer to individuals who were recruited to participate in this study and completed the study, ‘prospective subjects’ will refer to individuals who were recruited to participate in this study but did not complete the study (excluded from data analysis), and ‘subjects not eligible for the study’ were excluded from the study based on exclusion criteria.

## **1.5 SUMMARY**

Improving compliance with aural rehabilitation implies that more patients will utilise their hearing aids, which will reduce their hearing loss induced communication handicap and in turn improve their quality of life. Improving a patient's quality of life may also have a positive impact on the patient's significant others, as they are able to co-exist with improved communication. The consequence could be a positive effect on the hearing impaired population as a whole as the need for treatment of secondary factors associated with hearing loss is reduced.

Despite the prevalence of hearing loss, it is evident that many patients with hearing loss do not utilise their hearing aids, even though the use of hearing aids is said to improve the quality of life of individuals with hearing loss. Audiologists should understand and accept that aural rehabilitation services need to evolve to encourage patients to engage in their own process of change in order to gain the best rehabilitation outcomes. The OM was designed to assist audiologists to support patients throughout this process of change. The purpose of this study was to determine the value of using the OM of behaviour change on adult aural rehabilitation outcomes.

## **1.6 SUMMARY OF SUBSEQUENT CHAPTERS**

### **1.6.1 Chapter 2: Literature review**

The literature review explores the factors contributing to non-compliance with aural rehabilitation. Audiology within the UK National Health Service is discussed with reference to the service delivery model at the Royal Free Hospital in London, UK. Different aural rehabilitation service delivery models are explored with detailed description of the Operational Model of behaviour change.

### **1.6.2 Chapter 3: Method**

This chapter describes the aims, sub-aims hypothesis and research design of this study. Ethical aspects that were considered for this study are explained. The study population is described with reference to the inclusion and exclusion criteria. These criteria are tabulated for ease of reference. A comprehensive discussion of the sampling methods, apparatus and materials, including outcome measures is provided. Outcome measures and their reliability and validity are described. Results of the pilots study are noted and a detailed description of the procedures including data collection, data processing and data analysis is outlined. The threats to reliability and validity of the study are tabulated with a description of how the researcher addressed the threats.

### **1.6.3 Chapter 4: Results**

This chapter consists of 8 tables which depict the statistical analysis of this study. The results are initially reported in terms of the pre-test results. The post-test results are then reported with specific reference to the three sub-aims outlined in this study. Finally, secondary analysis of results in the form of correlations and comparisons is provided.

### **1.6.4 Chapter 5: Discussion**

The discussion provides a critical analysis of the results with regard to the value of the Operational Model of behaviour change. This chapter follows the format used for the results in Chapter 4, whereby pre-test results are initially described, followed by a discussion of the post-test results and finally a detailed discussion of additional considerations is afforded. Reference is made to other aural rehabilitation research as well as to other fields that utilised the OM, such as smoking cessation studies.

## **1.6.5 Chapter 6: Conclusion**

This chapter provides a summary of the findings of this study as well as a critical analysis of the clinical implications and limitations of this study with recommendations for further research.

## **2 LITERATURE REVIEW**

This chapter will survey the literature and examine the reasons why patients do not use hearing aids. Aural rehabilitation in the UK context will be discussed briefly and finally an outline of the different models of aural rehabilitation will be provided.

### **2.1 FACTORS CONTRIBUTING TO NON-COMPLIANCE WITH AURAL REHABILITATION**

Studies reveal many reasons why it sometimes takes as much as ten years for individuals to seek professional help for their hearing loss (Action on Hearing Loss, 2014). The studies described in this chapter investigated why many patients who seek help do not follow through with aural rehabilitation services and why some do not continue using hearing aids issued to them. The two main reasons apparent in the literature are motivation and self-reported hearing disability and handicap.

#### **2.1.1 Patient motivation**

Motivation can be described as a desire or want that energizes and directs goal-oriented behaviour (Kleinginna & Kleinginna, 1981a, as cited in Huitt, 2011). It includes the arousal, direction, and persistence of behaviour (Franken, 2006, as cited in Huitt, 2011). Audiologists have long known that motivation is prerequisite to the acceptance of recommendations of aural rehabilitation and is a key determinant of whether patients continue to use hearing aids (Harvey, 2003; Beck, Harvey & Schum 2007). Despite efforts by audiologists, however, numerous patients are still reluctant to continue with recommended strategies (Clark, 2010). The reason could be that patients in different stages of readiness for hearing aids have different rehabilitation needs (Carmen, 2009). On the one hand, researchers report that many patients with hearing loss seek aural rehabilitation

services as a result of instigation or pressure from significant others (Kochkin, 1998, as cited in Kricos, 2006; Mahoney & Cadge, 1996; Walden, et al., 2009). These patients have not accepted their hearing loss and it can be inferred that they are not truly self-motivated to seek help for their hearing loss (Carmen, 2009). Such patients would most likely be dissatisfied with any hearing aids. On the other hand, a number of studies have found that patients who are internally motivated to improve their hearing have more successful outcomes (Becker & Kaufman, 1988; Swan & Gatehouse, 1990; Grahn, Ekdahl & Borgqist, 2000; Miller & Rollnick, 2002; Jacobson, Newman, Sandridge & McCasline, 2002; Harvey, 2003; Wolfe, 2011).

A precondition of rehabilitation is that patients must want to engage in their rehabilitation process, i.e. they must want hearing aids and believe the aids will help them, they must understand the potential benefits and also acknowledge the costs, which are emotional, financial, and be willing to learn new techniques to use hearing aids (Becker & Kaufman, 1988; Kricos, 2006). This perspective will require involvement of patients in their own rehabilitation process, and the recognition that the responsibility of benefit from aural rehabilitation rests on their own shoulders. Studies in various other fields (e.g. dieting, smoking cessation, medication compliance) have shown that a motivated patient will engage in various techniques and remain positive during the rehabilitation process (Tønnesen, 2012). It is important, therefore, to attend carefully to each patient's internal motivation to pursue amplification, and to ensure that motivation becomes a fundamental part of aural rehabilitation (Kricos, 2006).

### **2.1.2 Self-reported hearing disability and handicap**

Another factor that plays a large role in seeking and complying with aural rehabilitation

services is self-reported disability and handicap. This refers to the subjective experience of the hearing loss and the effects thereof on a patient's daily life. Disability (refers to activity limitation, as described in Section 1.2) describes the degree of difficulty a person experiences hearing in various situations. Handicap (refers to participation restriction, as described in Section 1.2) describes the extent to which a person is unable to participate in activities as a result of the hearing loss (Gatehouse, 1999a; Dillon, 2001).

Studies have demonstrated that perceived severity of hearing loss can influence the decision to seek aural rehabilitation services and to obtain hearing aids (Duijvestijn et al., 2003; Carson, 2005; Palmer et al., 2009). Studies by Cox, Alexander and Beyer (2003); Takahashi et al. (2007); Laplante-Lévesque, Hickson and Worrall (2011), and Laplante-Lévesque, Hickson and Worrall (2012) revealed that greater self-reported hearing disability is associated with increased successful intervention outcomes. Knudsen, Oberg, Nielsen, Naylor and Kramer (2010) found that self-reported hearing difficulty is an important determinant in aural rehabilitation as it can be a good indicator of four key elements of aural rehabilitation, namely help seeking, hearing aid uptake, hearing aid use, and hearing aid satisfaction. A perceived decline in hearing ability facilitates the help seeking process (Meyer & Hickson, 2012).

### **2.1.3 Other factors that contribute to non-compliance with aural rehabilitation**

Some studies indicate that other factors such as age, gender, and degree of hearing loss also play a role in determining intervention outcomes (Bandura, 1986; 1989; Kricos, 2006; Knudsen, et al., 2010). These factors, however, did not strongly relate to seeking and uptake of aural rehabilitation services.



Research has shown that the stigma associated with hearing aids can influence how patients make decisions about aural rehabilitation (Kochkin, 2007; Meister, et al., 2008; Wallhagen, 2009). Many patients are reluctant to take the next step because of how they think their friends, family, or acquaintances may view them. A study by Kochkin (2007) found that stigma contributed to the decision of patients not to wear their hearing aids. Patients in that study expressed the opinion that hearing aids were too noticeable and they would be embarrassed to wear them in public, or that the hearing aids made them look disabled or old (Kochkin, 2007).

A literature review by Meister et al. (2008) revealed that insufficient awareness of hearing difficulties, underestimated handicap, alternative coping strategies, personality, low trust in the benefit from hearing aids, cognitive and functional restrictions, costs of hearing aids, and false expectations are among the reasons why people who possess hearing aids do not use them regularly. Other evidence points to convenience, nature of intervention, and other people's experiences as factors that influence rehabilitation decisions (Laplante-Lévesque, Hickson & Worrall, 2010b). According to Smith and West (2006), poor aural rehabilitation outcomes can also be attributed to lack of self-efficacy (the confidence one has concerning the abilities to care for and to use hearing aids successfully) and patients who lose confidence will withdraw from the rehabilitation process.

A final factor worth mentioning here is the role of UK NHS general practitioners as the funding gatekeepers (Refer to section 2.2). Based on the current NHS status these medical professionals also play a significant role in whether patients opt to seek or take up aural rehabilitation services. Laplante-Lévesque et al. (2010b) confirm that recommendations

and support from others influence the decision of individuals with hearing loss to pursue aural rehabilitation services.

## **2.2 AUDIOLOGY IN THE UK NATIONAL HEALTH SERVICE**

For the purpose of this study the history of Audiology Direct Access (DA) services in relation to the NHS will briefly be explained. Traditionally all patients on the NHS who required hearing aid assessments were referred to Ear, Nose and Throat (ENT) consultants who made onward referrals to audiology services as required. In 2000, The Modernising of Hearing Aid Services (MHAS) was implemented by the government to enable the change-over from all analogue hearing aids to digital hearing aids in every audiology department in the UK. This led to an increase in demand for audiology services on the NHS, and waiting times for audiology services grew substantially. The Audit Commission (a public corporation to protect the public purse) undertook a brief enquiry into the services for audiology and made recommendations for DA services. They stated that an audiologist should be the first point of call for patients with hearing loss. Since then, patients with hearing loss were all referred by a general practitioner directly to audiology services (Direct Access), which ensures that a funding pathway is established, and the ENT consultant is removed from the initial referral step.

This change in direction meant that audiologists needed to be highly skilled to ensure that contra-indications were identified and appropriate onward referrals were made. The Liaison Group of Technicians, Therapists and Scientists in Audiology (TTSA, 1989) had previously drawn up guidelines to help audiologists with identifying these onward referrals. The British Academy of Audiology (BAA) replaced these guidelines in 2009 (refer to Appendix A).

Audiologists need to be competent in hearing aid technology; being the first point of call for patients; however, they also need to be highly competent in counselling patients on hearing loss and associated difficulties. They need the skills to support patients with hearing loss through the entire assessment, diagnosis, and on-going rehabilitation phases. With this knowledge and these skills, audiologists can improve the quality of life of patients with hearing loss and assist them to seek and take up aural rehabilitation services by employing different service delivery models.

### **2.3 SERVICE DELIVERY MODELS**

Over the past few years, the UK NHS has been focusing on quality improvement. The main concern is to place patients at the centre of their treatments by giving them more choice regarding decisions about treatments and changing the interactions between patients and healthcare professionals (NHS Choices, 2011). The Health and Social Care Act (2012) promotes a greater voice for patients and states: *“If the fundamental purpose of the Government’s proposed changes to the NHS – putting the patient first – is to be made a reality, the system that emerges must be grounded in systematic patient involvement to the extent that shared decision making is the norm.”* Consequently, there is a national drive to make services more patient-centred. Audiologists are responsible for tailoring their services to the varying needs of patients, and for enabling patients to make informed decisions about their rehabilitation.

Tønnesen (2012) pointed out that empowerment of patients is essential for improving health outcomes and suggested that emphasis should be focused on an individual’s lifestyle, behaviour, and readiness to change. Research has shown that different forms of service delivery models have different implications with regard to rehabilitation outcomes.

According to Luterman (2000), audiology's origins are firmly rooted within the medical model. Traditional (medical) models of aural rehabilitation focus on the physiological aspects of pathology, impairment, and disease. In medical models audiologists dominate the rehabilitation process, determining both treatment and diagnosis. Patients are not held responsible for their problems or for solutions to them (Erdman et al., 1994; Erdman, 2013). Aspects of motivation and self-reported hearing disability and handicap are not taken into account. The medical model is not considered patient-centred and is not in line with the current drive for improving the quality of services whereby patients have more control of their care. As stated above, the primary challenge associated with hearing loss involves the psychosocial effects of communication breakdown. Aural rehabilitation and support services that focus on individual psychosocial effects are therefore paramount to assisting those with hearing loss (Clark, 2010).

The drive to change from a medical model to a more patient-centred approach comes from all levels, namely, patients seeking and receiving care, those providing the care as well as those regulating and funding the service. As far back as 1994, Erdman et al. argued that in order to enhance compliance with treatment plans; audiologists need to bridge the two factors of improving the quality of care and containing the cost of care. After more than a decade this statement is still holds indisputably true. Failure to adhere to rehabilitation plans (e.g. non-use of hearing aids) is costly to all parties involved. As more than 20 per cent of people who have hearing aids do not use them, the NHS loses millions of pounds each year. Furthermore, individuals who do not use hearing aids have a reduced quality of life (National Biomedical Research Unit in Hearing, 2008). A recent report in the UK estimated the cost of hearing loss at 30 billion pounds and noted that the larger portion of this cost is related to dealing with the health and social impacts of hearing loss (Archbold,

Lamb, O'Neil & Atkins, 2014). The International Longevity Centre UK (2014) calculated that in 2013, due to lower employment rates for those with hearing loss than across the rest of the population, the UK economy lost 24.8 billion pounds in potential economic output. Recent research by Tønnesen (2012) confirms the findings of Erdman et al. in 1994 that interventions programmes should suit the characteristics and needs of individual patients.

Laplante-Levesque et al. (2011) describe a model of shared decision-making in which both the patient and the audiologist participate in information exchange, deliberation, and the decision about intervention. The concept of shared decision making involves acknowledging the patient's perspectives and discussion of intervention options (Makoul & Clayman, 2006), as well as recognising that both intervention delay and decline of rehabilitation are valid options or outcomes for aural rehabilitation (Montori, Gafni & Charles, 2006; Laplante-Levesque, et al., 2012). Clark (2008) states that successful engagement within the clinical process is determined by the manner in which audiologists attend to individual patient's needs and by the ability of audiologists to provide an environment that is imbedded in understanding. Laplante-Lévesque, Hickson and Worrall (2010) argue that an encounter in which the clinician and patient establish a therapeutic alliance and the patient participates in the decision-making and goal setting, and self-manages health behaviour change, results in positive patient outcomes. Gregory (2012) confirms that the quality of client outcomes is inextricably linked to patient-centred care, which is described as the audiologist's ability to listen to the patient's perspective and to explore the patient's readiness and motivation for rehabilitation.

Audiologists are in the perfect position to provide the psychological and emotional support that patients need as they progress through the help-seeking process (English & Weist,

2005). Utilising a patient-centred approach does not take any additional time for an audiologist to implement and results in greater satisfaction and improved adherence (English, 2009, as cited in Gregory 2012; Abdel-Tawab & Roter, 2002 as cited in Gregory, 2012).

The services provided by audiologists need to evolve to become all-encompassing. This concept would require a shift to a patient-centred, problem-solving approach in audiological rehabilitation rather than audiological assessment and hearing aid prescription and fitting as the focal point (Jennings, 2005). The transition from a traditional medical model to a more patient-centred approach, which would enable patients to get actively involved and become more responsible for their own treatment regimes, requires of patients and audiologists to change their current behaviour. A practice guidance document (BSA, 2012a) describes the goal of aural rehabilitation as improving quality of life through changes in behaviour. Aural rehabilitation should therefore be based on identifying individual needs, setting specific goals, making shared, informed decisions, and supporting self-management in order to assist an individual with hearing loss to overcome difficulties in daily life. This approach is in contrast with the goal of ameliorating the sensory impairment (hearing loss), which focuses on the means instead of the end (BSA 2012c).

The models utilising a patient-centred approach that could lead to this change in behaviour are the Transtheoretical Model of behaviour change (Prochaska, Norcross & DiClemente, 1994); Motivational Interviewing (Miller & Rollnick, 1991); Decisional Balance (Janis & Mann, 1977) and the Operational Model of behaviour change (Tønnesen, 2012). Much research utilising these models has been done with regard to behaviour change in various other fields such as smoking cessation, alcoholism, nutrition, and diabetes. All of the

studies reported positive outcomes and treatment compliance (Babeu, Kricos & Lesner, 2004; Tønnesen, 2012). For the purpose of this study these models, discussed below, will be considered from the audiological perspective only.

The Transtheoretical Model (TTM) has been widely accepted as a valid model of behaviour change techniques. This model is the foundation for developing effective interventions to promote intentional health behaviour change and focuses on the decision making of the individual. The TTM describes stages of change as a cyclic or spiral process in which individuals move through five stages over a period of time as they progress toward adopting and maintaining behaviour change. These stages are: pre-contemplation, contemplation, preparation, action, and maintenance. A point of relapse can occur at any stage, but when individuals use hearing aids consistently and are unlikely to stop using them, they reach the termination phase. From an audiological perspective problem behaviour entails a patient's reluctance to seek professional hearing rehabilitation and/or to use hearing aids. The TTM is useful to audiologists in assisting patients who are in the process of making their decision about whether to seek and employ professional help about their hearing loss (Babeu et al., 2004). Considering the statistics of patients who could benefit from hearing aids compared to those who actually use them, this model could be recommended to audiologists who are not attentive to patients' attitudes toward readiness for hearing aid use. The TTM places emphasis on determining a patient's wants, desires, needs, and fears regarding hearing aids (Babeu et al., 2004).

Decision Balance (DB) is a measure of the importance of reasons and concerns relating to making a change in behaviour. By reflecting on the advantages and disadvantages a decision could be 'balanced' based on potential gains and losses for either staying in the

current situation or moving on to a situation where the change has occurred. Ambivalence toward the change will be included in the process.

Motivational Interviewing (MI) is a way of guiding patients by building on four principles: resistance, understanding, listening, and empowerment. The idea is to listen to and understand the patients' motivation for change and to help patients understand their resistance to change. In so doing the clinician can empower patients to explore how they will successfully change behaviour.

Tønnesen (2012) illustrated the cyclic process of change described in the TTM by depicting the stages in a circle, and combined this with two motivational tools from the Ida Institute (the Line and the Box) to create the Operational Model (OM), designed to be useful in clinical practice. This model includes concepts from the older models of behaviour change (TTM), as well as models of MI and DB. Tønnesen (2012, p.10) states: *"...this approach has the potential to improve the perception of care quality, can improve compliance, can reduce unnecessary care and can improve treatment outcomes."*

The concept behind the OM lies in the fact that despite external pressure (from doctors and / or family members), reluctant patients operate within their own internal timetable and only commence or proceed with aural rehabilitation when they feel the need (Clark, 2010). Audiologists therefore need to set the platform for patients to discover their own motivation to achieve rehabilitation goals by assisting them to recognise the negative impacts of untreated hearing loss and to express their own reasons to change their behaviour toward hearing aid rehabilitation (Clark, 2010). Studies show that patients who go through this shared decision-making process and self-manage behaviour change feel



more empowered and are more likely to adhere to the aural rehabilitation plan (Laplante-Lévesque, et al., 2010; Gregory 2012).

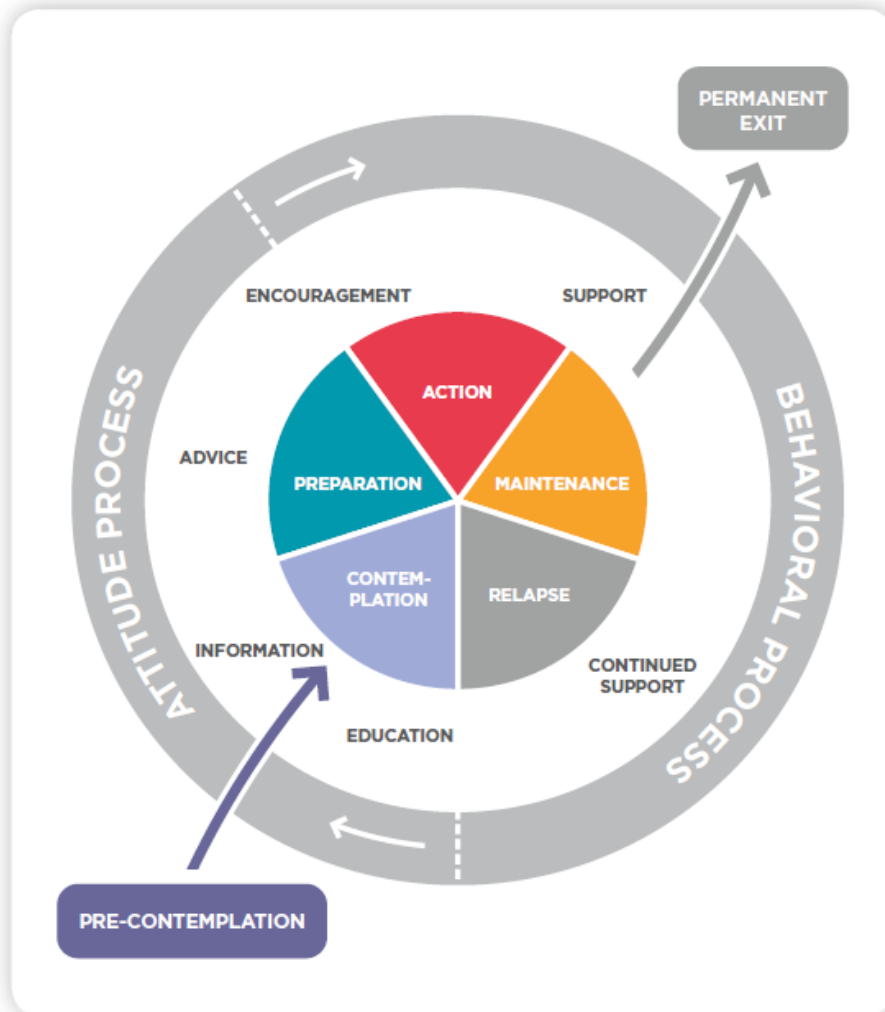
The Ida Institute, an independent, non-profit educational institute in Denmark whose mission is to foster better understanding of the human dynamics associated with hearing loss, adapted the motivational tools (Circle, Line and Box) to be effective within the field of audiology (Ida Institute, n.d.). The Ida Institute believes that by utilising these tools, audiologists are able to support and engage patients by allowing them to express their own experiences based on their personal social environment, communication needs and cultural backgrounds (Ida Institute, 2009).

#### **2.4 THE OPERATIONAL MODEL (THE CIRCLE, THE LINE AND THE BOX)**

The Circle (refer to Appendix B) is a tool that depicts the different stages of change a patient undergoes and provides guidance for audiologists to efficiently support the process of change (Tønnesen, 2012). The Line (refer to Appendix B) is used for opening dialogue and setting the scene (Tønnesen, 2012). This tool enables patients to reflect and make informed decisions based on information about the clinical consequences of unchanged behaviour (Tønnesen, 2012). The Box (refer to Appendix B) should be used in combination with the Line as it supports a patient's further reflection on their ambivalence regarding aural rehabilitation (Tønnesen, 2012). This OM (including Circle, Line, and Box) can be used in the clinical setting to fulfil the patient's need for support during the different stages of change (Tønnesen, 2012).

### 2.4.1 The Circle

The Circle (Appendix B) is not a tool to be used directly with patients, but rather a tool that illustrates to the audiologist the different stages a patient goes through when undergoing a process of change (Tønnesen, 2012). These stages relate to those described in the TTM, as illustrated in Figure 2.1.



**Figure 2.1: The Circle (Jørgensen, Hansen, Hesso, Lauritsen, Madelung & Tønnesen, 2003; Ida Institute, 2009)**

The circle is used to track present and future motivational levels of a patient with regard to the behaviour change (Ida Institute, 2009). All patients experience ambivalence and they all undergo a similar process of change, but during each stage a patient requires different support. A list of questions is presented to the patient, which will determine at which stage

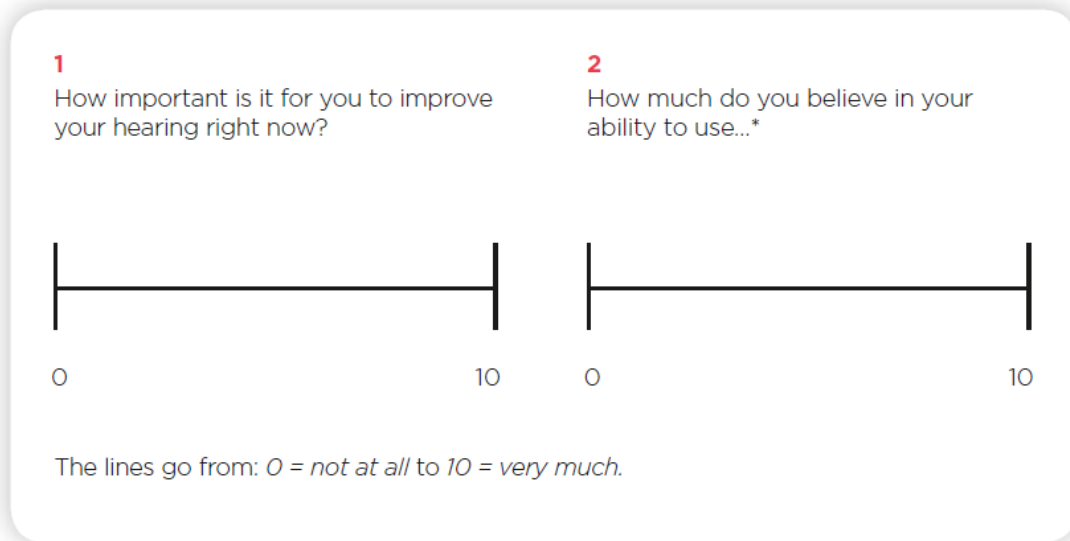
the patient currently is in this circle of change (refer to section 3.7.2.5.1). Table 2.1 was compiled utilising information from the Ida Institute's Motivational Tools with Instructions (2009) and describes the support provided to patients at the different stages of change.

**Table 2.1 Instructions for implementation of the Circle (Adapted from Ida Institute's Motivational Tools with Instructions, 2009).**

Stage	Patient	How to assist the patient in this stage
<b>Pre-contemplation</b>	Does not realise that he* has a hearing problem, becomes surprised when the problem is brought up by those around him or does not recognise any of the symptoms described.	Listen to the patient and provide clear, short and exact information.
<b>Contemplation</b>	Is ambivalent about making change, feels comfortable in the present situation, on the one hand, but is afraid of the consequences of continuing without hearing aids on the other hand.	Listen to the patient and explore his experiences with hearing and communication. Offer advice regarding possible options for improving hearing and communication. Support and acknowledge the patient's increasing awareness of ambivalence.
<b>Preparation</b>	Still expresses ambivalence but shows motivation and is ready to take action, but is not sure exactly how to proceed and seeks information to support the decision.	Support the patient in planning the use of new strategies. Listen. Give advice and ideas about what it takes to improve communication with others.
<b>Action</b>	Relieved and proud about the decision to act on the hearing problem, worries about not being able to follow through, seeks acknowledgement and appreciation.	Listen to the patient. Focus on the personal benefits of improved hearing and communication. Encourage and support the patient.
<b>Maintenance</b>	Has now become a hearing aid user and/or is using effective communication strategies, is still ambivalent and finds it hard to accept the implications of hearing loss, forgets why he wanted to change behaviour, feels either successful (leads to "Permanent Exit") or may want to give up (leads to "Relapse").	Support and encourage the patient in sustaining the change of behaviour, repeatedly.
<b>Relapse</b>	Does not want to wear the hearing aid and struggles, gives up, feels like a failure and becomes annoyed and angry, is motivated to try again.	Focus on the advantages of better hearing and communication and put focus on positive experiences even if they were of short duration. Try to make the patient agree on a new habituation scheme.
<b>Permanent exit</b>	Feels comfortable with the hearing aid and knows how to handle the hearing problem.	Provide the possibility to return for support.

\* Note: The pronoun "he" is used generically to indicate both male and female patients

## 2.4.2 The Line



**Figure 2.2: The Line (Jørgensen, et al., 2003; Ida Institute, 2009)**

The Line, as shown in Figure 2.2 (see Appendix B), is a simple visual analogue scale from zero to ten and is used for opening dialogue and setting the scene (Tønnesen, 2012). This motivational tool involves two personal questions that will help an audiologist determine if there is ambivalence between the importance of improving hearing and the patient's personal commitment to making the necessary changes (Ida Institute, 2009; Tønnesen, 2012). The first question asks about the importance of changing lifestyle immediately and the second question asks about the patient's self-confidence in their own capability to make that change (Tønnesen, 2012). This tool enables patients to reflect and decide on an informed basis and enables the clinician to understand how the patient views the importance of change and how confident they feel in making the change (Tønnesen, 2012). After readiness to embrace change is explored by use of the Line, the Box supports patients to reflect further on their decision to change behaviour.

### 2.4.3 The Box



**Figure 2.3: The Box (Jørgensen, et al., 2003; Ida Institute, 2009)**

The Box as shown in Figure 2.3 (refer to Appendix B) can be used in combination with the line as it supports a patient’s further reflection (Tønnesen, 2012). The Box is used to enable patients to be aware of their own positive and negative thoughts about hearing loss and at the same time provides the audiologist with a picture of how motivated the patient is (Ida Institute, 2009). Utilisation of this tool provides information to both the patient and the audiologist as to the perceived disadvantages of inaction and the advantages of moving forward.

Most patients who complete the Line and the Box tools will have passed the pre-contemplation stage in the Circle (Tønnesen, 2012). The OM can thus be used in the clinical setting to fulfil the patient’s need for support during the different stages of change (Tønnesen 2012).

## **2.5 SERVICE DELIVERY MODEL AT THE ROYAL FREE HOSPITAL, LONDON, UK**

The Royal Free Hospital in London is an NHS hospital. The Audiology Department at the Royal Free Hospital in London serves and provides aural rehabilitation to adult and geriatric patients with hearing loss (50 years and older).

The typical pathway for audiology patients at Royal Free Hospital Audiology Department runs over three years. The first appointment, following a referral from a general practitioner, is an initial assessment during which a full hearing assessment, diagnosis, and recommendations for amplification are made. At the second appointment, hearing aids are fitted and then a follow-up is conducted at the third appointment, to determine how the patient is progressing and adjusting to their hearing aids. Thereafter, appointments are booked based on the patient's needs, and provided there are no changes in the patient's audiological status, a patient will continue using their hearing aids for three years, after which their amplification needs are reassessed.

The Audiology Department at the Royal Free Hospital has found that many patients do not comply with aural rehabilitation recommendations. Patients report (either at follow-up appointments or at the three year reassessment appointments) that they have not used their hearing aids, a situation well documented in literature (Smeeth et al., 2002; Hickson & Worrall, 2003; Lupsakko, Kautiainen & Sulkava, 2005; Action on hearing Loss, 2012). The concept of patient motivation has never been formally evaluated in the department and patients' psychosocial needs were not traditionally integrated within the aural rehabilitation process. It could be inferred that the department was rooted in a medical model of service delivery whereby patients who reported not using their hearing aids were

simply encouraged to wear the devices, but not offered any formal support or intervention programmes.

‘Enhancing the patient experience’ is one of the Royal Free Hospitals corporate objectives and this should as far as possible be achieved by all departments. In view of the ramifications of hearing loss regarding the ageing populations’ quality of life, the Audiology Department is in the perfect position to enhance the patient experience. Audiologists should thus assess and determine the best processes required to deliver aural rehabilitation services that are in line with the NHS and patient drive for individualised, patient-centred care, such as the OM.

## **2.6 SUMMARY**

A survey of the literature revealed that the two main reasons why patients do not seek aural rehabilitation services and why they do not use hearing aids that have been issued to them are: patient motivation, and patient self-reported hearing disability and handicap. In order to take these two factors into consideration during aural rehabilitation, audiologists should review their service delivery models with a view to abandoning medical models of aural rehabilitation, and work toward providing more patient-centred care. Adaptation of service delivery models such as the OM corresponds with the UK NHS drive for improving the quality of services by “*putting the patient first*” (The Health and Social Care Act, 2012).

### **3 METHOD**

#### **3.1 INTRODUCTION**

This chapter outlines the general methodology, the design, and the aims of this study. The ethical considerations, the study population, selection criteria, and sampling methods are discussed and a description of the apparatus and materials utilised in this study are provided. Finally the procedures for data collection, data processing, and data analysis are outlined.

#### **3.2 AIMS AND SUB-AIMS**

The main aim of this study was to determine the impact of using the OM of behaviour change on adult aural rehabilitation outcomes.

The sub-aims were designed to compare aural rehabilitation outcomes between two groups of subjects: one group that did not receive the OM of behaviour change and one that received the OM of behaviour change. The sub-aims are as follows:

- To determine the impact of the OM on HA use;
- To determine the impact of the OM on satisfaction with HA use;
- To determine the impact of the OM on self-reported hearing disability and handicap.

#### **3.3 HYPOTHESES**

The null hypothesis was that the OM has no value in aural rehabilitation and will not have a positive effect on adult aural rehabilitation outcomes of subjects. The hypothesis was that the OM is valuable in aural rehabilitation and will have a positive effect on adult aural rehabilitation outcomes of subjects.



### **3.4 RESEARCH DESIGN**

This study was a quantitative, experimental study that utilised a pre-test post-test design. The goal of most experimental designs is to determine if a difference exists amongst groups with regard to a variable of interest, after implementation of a treatment (Creswell, 2009). In this study the variables were benefit, use, satisfaction and self-reported hearing disability and handicap after hearing aid use and the treatment that was implemented was the OM of behaviour change.

Quantitative research entails the collection of numerical data to explain a particular phenomenon, measuring social reality (Creswell, 2009). In this study numerical data were collated from outcome measures that were administered prior to any intervention (pre-test) as well as after the intervention (post-test) to determine if the OM had a correlation with positive post hearing aid fitting outcomes.

Experimental research seeks to determine if a specific treatment influences an outcome (Creswell, 2009). In the current research this impact was assessed by providing a specific treatment (the OM) to one group and withholding it from another, and then determining how both groups scored on outcome measures (Creswell, 2009). This study utilised a control group of subjects who received treatment according to the conventional aural rehabilitation model and an experimental group of subjects who received treatment based on the OM via the use of the Ida motivational tools in addition to conventional aural rehabilitation. Outcome measures were presented to subjects in both groups prior to any intervention (pre-tests) and after intervention (post-tests) to determine if there was a change in subjects' self-reported hearing disability and handicap over time. The pre-tests in this study formed the baseline measurement to ensure that groups were equivalent.

DePoy and Gitlin (2011) state that true experimental design refers to the classic two-group design in which subjects are randomly selected and randomly assigned to either an experimental or control group condition. All subjects recruited for this study were randomly assigned to the control and experimental groups.

### **3.5 ETHICAL CONSIDERATIONS**

Any research in which individuals are directly involved has potential risks to subjects. It is the researcher's responsibility to ensure that subjects are protected from these risks. This study considered the following ethical principles:

#### **3.5.1 Respect for autonomy**

Information sheets and consent forms provide full disclosure, and assurance of confidentiality and voluntary participation, which DePoy and Gitlin (2011) describe as the three principles on which human subject protection is based. The researcher designed an information sheet and a consent form (refer to Appendix C and D) based on the Information Sheets and Consent Forms Guidance by the NHS National Patient Safety Agency (2007) and according to suggestions by Maxwell and Satake (2006) and McBurney and White (2010). The information sheet was also amended as recommended by the Riverside Research and Ethics Committee (Appendix J).

An information sheet was presented to all prospective subjects at their first visit (refer to Appendix C) and written informed consent obtained from each subject at this first visit by means of an informed consent form (refer to Appendix D). Prospective subjects were advised that participation was entirely voluntary and that they could withdraw from the study at any time. Confidentiality of each subject was maintained throughout the study

according to the UK Data Protection Act of Parliament (1998). The researcher ensured that each subject was furnished with direct contact details if they required further information about the following: general information about research, specific information about this research, advice as to whether you should participate, who to contact if you are unhappy with the study (refer to Appendix C).

Data from this study will be stored as per university guidelines, for 15 years at the Department of Speech-Language Pathology and Audiology, University of Pretoria, South Africa.

### **3.5.2 Beneficence and non-maleficence**

Benefit to the experimental group of subjects was the introduction of a new intervention tool. Subjects in the control group were not be harmed in any way as they were subject to the department's current routine practice. In this study no subject was given an inferior treatment.

### **3.5.3 Justice**

This study excluded prospective subjects (refer to Table 3.2) who required any additional audiological and/or medical interventions according to the BAA Guidelines (2009). All subjects who participated in the study therefore received appropriate hearing aid rehabilitation, while the prospective subjects who were excluded were referred on to medical professionals (i.e. ENT consultants) for further investigations.

### **3.5.4 Procedures and protocols**

All recommended procedures and protocols as suggested by audiology governing bodies [British Society of Audiology (BSA), British Academy of Audiology (BAA) and Registration Council for Clinical Physiologists (RCCP)] as well as the departmental procedures and protocols were maintained throughout the research.

### **3.5.5 Research ethics**

In the UK each health authority has an ethics committee, which must approve all proposals for research involving human subjects. No reputable medical journals will publish the description of research that has not obtained such approval. The proposal for this study was submitted via the online Integrated Research Application System (IRAS) for ethical approval and the researcher attended a meeting with the Riverside NRES Committee, London. Their recommendation to edit part of the patient information sheet (Refer to Appendix J) was implemented and approval obtained with REC Reference number 12/LO/1995 and IRAS project ID 109076 (refer to Appendix K). Two minor amendments were subsequently made to amend the title of the study and the data analysis and approval obtained with REC Reference number 12/LO/1995 IRAS project ID 109076 (refer to Appendix L & M).

Although this study was conducted in the UK, registration for the degree M. Communication Pathology (for which the research was required) was at the University of Pretoria in South Africa. The researcher thus also applied for ethics approval from the Postgraduate Research and Ethics Committee of the Faculty of Humanities, University of Pretoria, South Africa. Approval from this committee was obtained with reference 97098567 (refer to Appendix N).

## **3.6 STUDY POPULATION**

Subjects attending DA services at the Royal Free Hospital, Audiology Department in London, UK, served as the target population. The researcher identified as possible subjects all new patients (who have never worn hearing aids) from referrals sent to the department by general practitioners to DA services.

### **3.6.1 Selection criteria**

The selection criteria for this study were determined as suggested by DePoy and Gitlin (2011) taking into consideration the purpose of the study and the literature support for establishing subject parameters.

#### ***3.6.1.1 Inclusion criteria***

A total of 68 subjects were included in this study (refer to section 3.6.2). Table 3.1 outlines the inclusion criteria and the justification for each criterion.

#### ***3.6.1.2 Exclusion criteria***

During the period of data collection a total of 73 prospective subjects were excluded from the study based on the exclusion criteria. Table 3.2 outlines the exclusion criteria and the justification for each criterion.

**Table 3.1: Inclusion criteria**

Inclusion criteria	Justification
<i>Subjects new to hearing aids</i>	Only subjects with no prior experience of hearing aids were included in this study. Studies show that greater experience with hearing aids is associated with higher satisfaction (Knudsen et al., 2010). It may not be beneficial or even necessary to utilise the OM with individuals who already use hearing aids. Hearing aid users may also obscure comparison of data with regard to compliance of suggested hearing aid usage strategies, as it may be inferred that these individuals are already compliant. Individuals who have previous experience with hearing aids may be biased in their reports of hearing aid satisfaction, use, and benefit.
<i>Gender</i>	Some studies report that women attach greater importance to social communication than men, which might influence their decision to seek help for hearing difficulties, and thus play an active part in reducing communication difficulties (Kricos, 2006). This may increase positive outcomes for seeking aural rehabilitation services and obtaining hearing aids. This study therefore included both male and female subjects.
<i>Age</i>	There is conflicting evidence in the literature about the effect of age on aural rehabilitation outcomes. A literature review by Knudsen et al. (2010) revealed that age did not influence hearing aid use or satisfaction. On the other hand, Kricos (2006) stated that individuals who are retired have fewer communication needs and this may lead to a reduced likelihood of pursuing hearing aids. Consequently, this study followed the departmental protocol for Direct Access clinics. Any adult subject above 18 years of age, who was suitable to attend the Direct Access clinic, was included in this study. From Figure 3.1 it is evident that most subjects were within the retirement age group.
<i>Type and degree of hearing loss</i>	The procedures recommended by the BSA (2012b) outline degree of hearing loss based on the pure tone average for the frequencies 250 to 8000 Hz and use descriptors related to severity: Mild hearing loss (20 to 40 dB HL) Moderate hearing loss (41 to 70 dB HL) Severe hearing loss (71 to 95 dB HL) Profound hearing loss (in excess of 95 dB HL) Subjects with sensorineural hearing loss ranging from a mild to severe were included in this study as poorer thresholds significantly increase the likelihood of seeking help and acquiring hearing aids (Knudsen et al., 2010).
<i>Language</i>	Subjects had to be proficient in English, as the all information sheets, consent forms, and standardised questionnaires to measure outcomes and finally the OM of behaviour change were presented in English. The department does employ interpreters when dealing with patients with other first languages, but it was feared that aspects of the OM might be lost during translation.

**Table 3.2: Exclusion criteria**

<b>Exclusion criteria</b>	<b>Justification</b>
<i>Subjects with previous experience with hearing aids</i>	(Refer to Table 3.1 – subjects new to hearing aids) A total of 19 prospective subjects were excluded from this study as they reported previous or current experience with hearing aids.
<i>Contra-indications for hearing assessment and/or rehabilitation</i>	These guidelines were designed for general practitioners who make referrals for adults to Direct Access audiology services. They comprise of a list of contra-indications for hearing assessment and /or rehabilitation as patients presenting with any of these contraindications may require initial or further medical assessment and /or treatment. As per BAA Guidelines (2009) prospective subjects with the contraindications were referred to ENT and not included in the study (refer to Appendix A). A total of 6 prospective subjects were excluded from this study based on contraindications as per BAA Guidelines (2009).
<i>Type and degree of hearing loss</i>	There are different types of hearing loss (conductive, mixed, and sensorineural), the names for which suggest the site of the lesion. Two types of hearing loss, conductive and mixed, are contraindications for patients attending the Direct Access clinics (refer to Appendix A). During data collection a total of ten prospective subjects presented with asymmetrical, unilateral, mixed and conductive hearing loss and were thus excluded from the study (refer to Table 3.4). It is inferred that individuals with profound hearing loss might have had some experience with hearing aids and if the profound loss was recently diagnosed or sudden in nature, this would fall under the exclusion criteria as stipulated by the BAA (2009) Guidelines (refer to Appendix A). It is well known that individuals with profound hearing loss experience limited benefits with hearing aids (Kochkin, 2007). Consequently, prospective subjects with profound hearing loss were excluded from this study. During the data collection for this study, no subjects were found to have profound hearing loss; however, nine prospective subjects were found to have normal hearing and were thus excluded from the study (refer to Table 3.4)
<i>Subjects with developmental disabilities or any reported cognitive impairment</i>	Subjects in this study were required to self-report on hearing difficulty, complete self-assessment questionnaires, and report on progress with hearing aids. Any prospective subjects who were deemed unable to provide this information (for example had Alzheimer’s Disease or dementia, etc.) were not included in this study. Four prospective subjects were excluded from this study, as they were unable to consent to participation (refer to table 3.4).
<i>Language</i>	All subjects who were not proficient in the English language were excluded from this study as all information sheets, consent forms, and standardised questionnaires as well as the OM of behaviour change were presented in English. In total five prospective subjects were excluded from the study, as they could not speak English (refer to Table 3.4).
<i>Subjects who did not attend their first assessment appointments</i>	A total of 18 prospective subjects did not attend their assessment appointments and two prospective subjects declined to participate in the study.

### 3.6.2 Sample size

The data collected from measure of satisfaction with hearing aids or the data collected from the number of hours per day that hearing aids were used, could not alone determine positive aural rehabilitation outcomes. This is because some subjects may have been satisfied with the hearing aids but only use the devices in certain situations, others may have used the hearing aids all the time but not be satisfied with the aesthetics of the device. The sample size was thus based on the presentation of a difference in the benefit (the extent to which hearing is improved) between the experimental and control groups.

The Glasgow Hearing Aid Benefit Profile (GHABP), one of the outcome measures in this study (refer to section 3.7.2.3.2), measures benefit (the extent to which hearing is improved). Previous data on the Glasgow Hearing Aid Benefit Profile (GHABP), which measures benefit, suggested that subjects (without the OM) had a mean benefit of approximately 60, with a standard deviation of approximately 14 (Gatehouse, 1999). An increase in benefit of 15 (up to a mean of 75) was deemed a clinically important increase. With a 5% significance level and 80% power it was calculated that 26 subjects per group, 52 subjects in total, was required. A dropout rate of 30% was taken into consideration, and as result a total of 68 subjects, 34 per group, was the minimum requirement for this study.

Table 3.3 displays details of the total 141 sample of prospective subjects, subjects and subjects not eligible for this study (refer to section 1.4.4). ‘Prospective subjects’ are those who attended the hearing aid assessment and hearing aid fitting appointments, but did not attend the last follow-up appointment (did not complete the study) and ‘subjects’ refer to those who attended all three appointments (completed the study).



A total of 73 subjects not eligible for this study were excluded from the study based on exclusion criteria (37 subjects not eligible for the study were excluded from the experimental group and 36 subjects not eligible for the study were excluded from the control group). Of the sample of 141, 68 subjects and prospective subjects were deemed eligible to participate as per inclusion and exclusion criteria (i.e. 34 in the control group and 34 in the experimental group) and out of the 68 a total of 43 subjects (i.e. 24 in the control group and 19 in the experimental group) completed the study.

**Table 3.3: Total sample of subjects (included) in this study and subjects not eligible for this study (excluded)**

	<b>Experimental group</b>	<b>Control group</b>	<b>Total</b>
<b>Total sample</b>	<b>71</b>	<b>70</b>	<b>141</b>
<b>Subjects not eligible for this study</b>			
Hearing within normal limits	7	2	9
Type of hearing loss - not suitable	3	7	10
Not English speaking	1	4	5
Did not attend assessment	9	9	18
Current hearing aid user	7	12	19
Could not consent	4	0	4
DA criteria (BAA, 2009)	5	1	6
Declined to participate	1	1	2
<b>Total</b>	<b>37</b>	<b>36</b>	<b>73</b>
<b>Subjects and prospective subjects included in each group</b>			
Eligible for the study	34	34	68

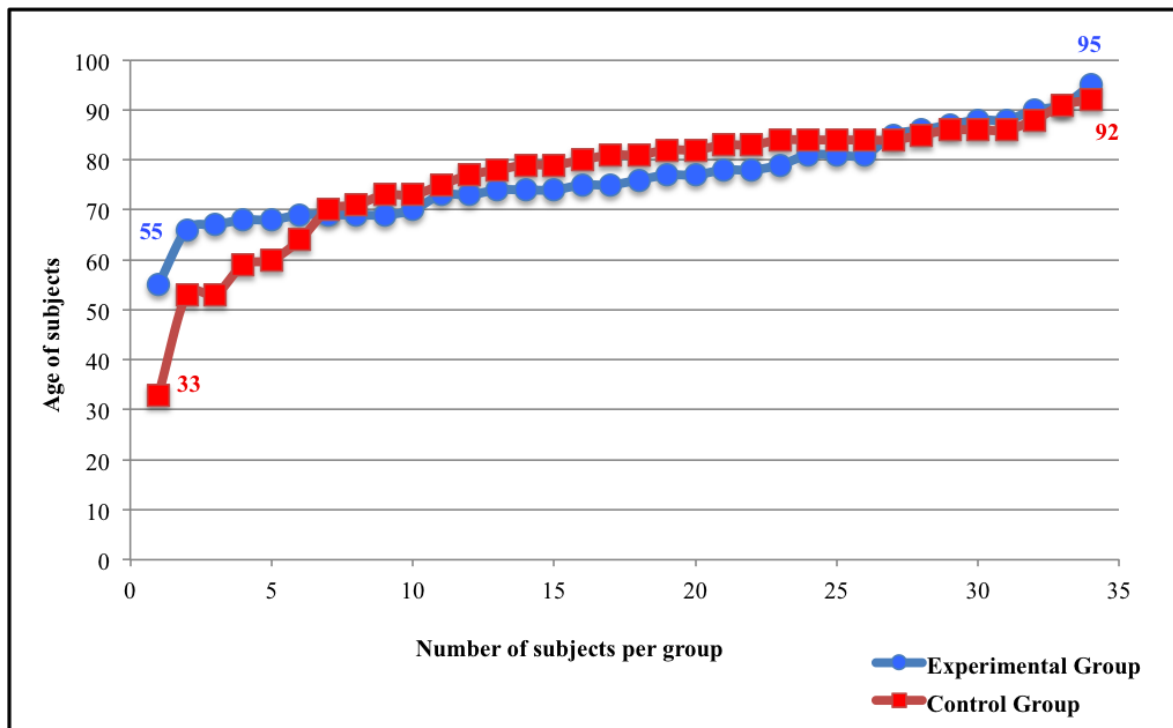
### 3.6.3 Sampling method and procedures

A stratified randomisation probability-sampling plan (Black, 2011) was used for this study. Stratified randomisation was conducted with a computer-generated table of random numbers. Stratification was performed before randomisation to keep the characteristics of the subjects and prospective subjects as similar as possible across the two study groups. In this study, parameters of the population were derived from the literature review (refer

to section 2.1.3). Stratified randomisation was conducted to keep the characteristics of age, gender, and degree of hearing loss as similar as possible across the groups.

A description of stratified prospective subjects and subjects who were included in this study is provided below with regard to age, degree of hearing loss, and gender. Figures 3.1, 3.2 and 3.3 display the even stratification of the 68 prospective subjects and subjects that were recruited into this study for age, degree of hearing loss, and gender.

**3.6.3.1 Age distribution of prospective subjects and subjects in the experimental and control groups**

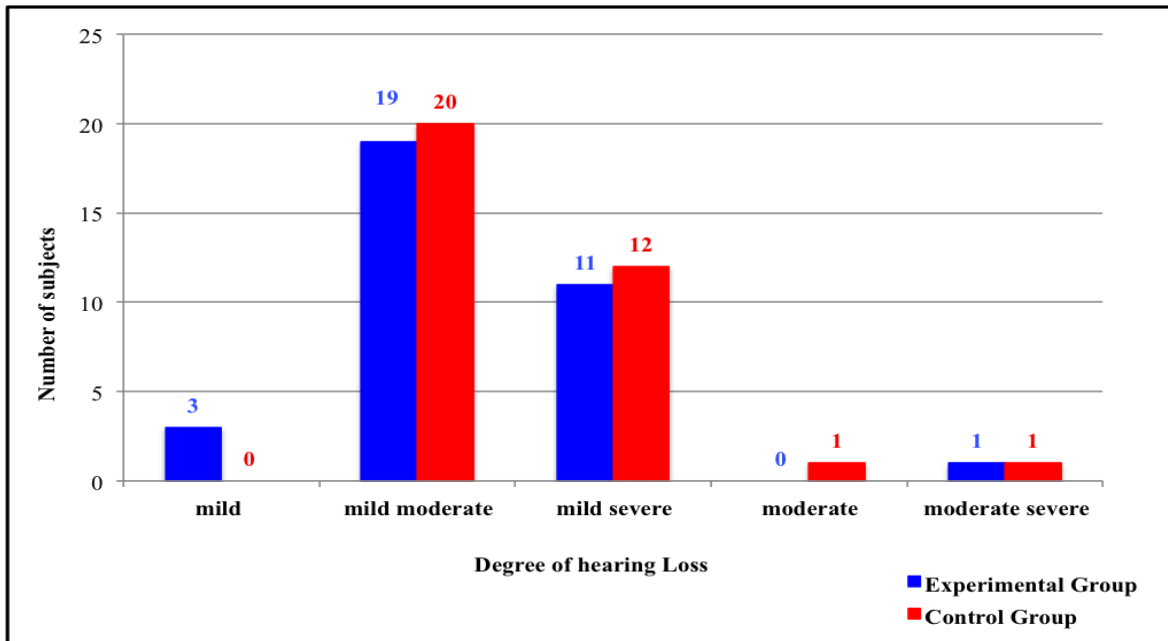


**Figure 3.1: Age distribution of prospective subjects and subjects in the experimental and control groups (n=68)**

Figure 3.1 displays the age distribution for the 34 subjects in each group. The control group age ranged from 53 years old to 92 years old and there was only one subject who was 33 years old. The experimental group age ranged from 55 years old to 95 years old.

The mean age of both the experimental and control groups was 76 years. Thus it can be inferred that the age composition of the two groups were balanced.

**3.6.3.2 Distribution of degree of hearing loss in prospective subjects and subjects in experimental and control groups**



**Figure 3.2: Distribution of degree of hearing loss for prospective subjects and subjects in experimental and control groups (n=68)**

Figure 3.2 displays the distribution of hearing loss across the groups. The audiometric descriptors as per BSA guidelines (2012b) are based on the average of pure tone hearing levels at 250, 500, 1000, 2000 and 4000Hz. The guidelines state that “*these averages to not imply any particular configuration of hearing loss and do not exclude additional terms (e.g profound high-frequency hearing loss) being used*” (BSA, 2012b, p. 22).

- **Mild hearing loss:** 20-40dB HL
- **Moderate hearing loss:** 41-70dB HL
- **Severe hearing loss:** 71-95dB HL
- **Profound hearing loss:** in excess of 95dB HL

The following categories were utilised to describe subjects' hearing loss:

- **Mild:** mild low frequency to mild high frequency hearing loss
- **Mild-moderate:** mild low frequency to moderate high frequency hearing loss
- **Mild-severe:** mild low frequency to severe high frequency hearing loss
- **Moderate:** moderate low frequency to moderate high frequency hearing loss
- **Moderate-severe:** moderate low frequency to severe high frequency hearing loss

The control and experimental group had 20 and 19 subjects respectively with mild to moderate hearing loss. The distribution across the mild to severe range was 12 subjects for the control group and 11 subjects for the experimental group. The median and mode for both groups fell within the mild-moderate hearing loss range. Based on these figures it can be inferred that the groups were balanced with regard to degree of hearing loss.

### 3.6.3.3 Gender distribution of prospective subjects and subjects in the experimental and control groups

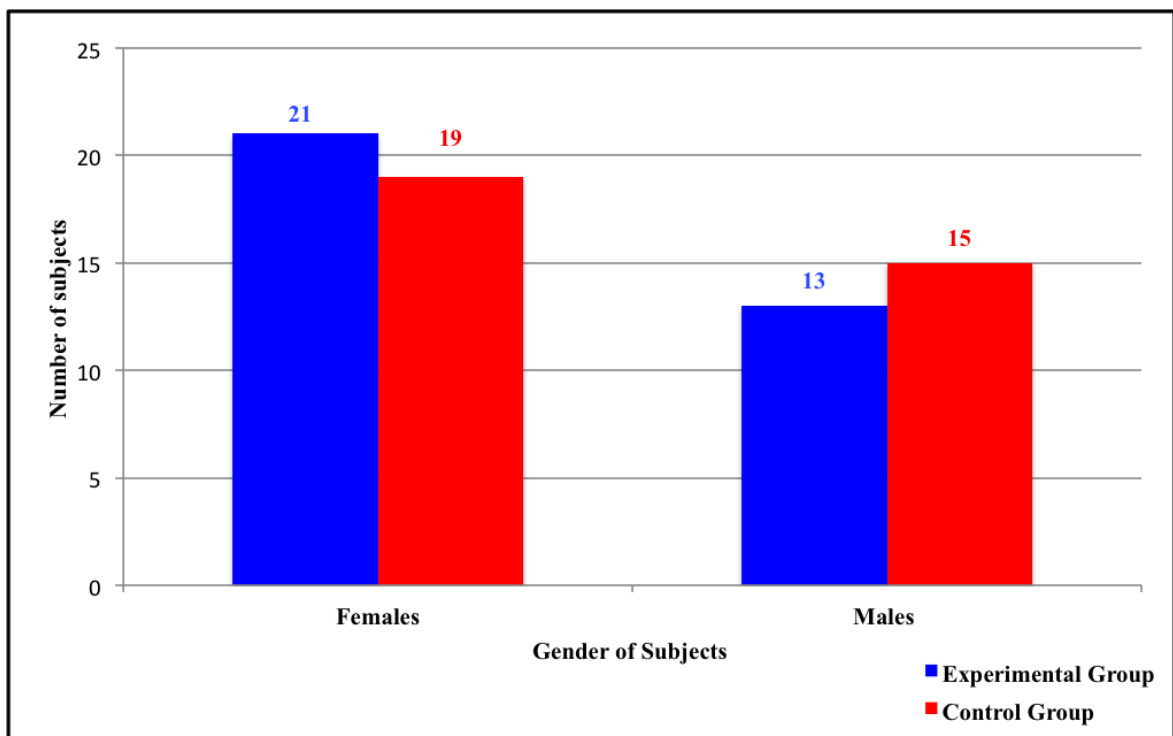


Figure 3.3: Gender distribution of prospective subjects and subjects (n=68)

According to Figure 3.3, there were 21 females in the control group and 19 females in the experimental group. The males were also quite evenly distributed with 13 in the experimental group and 15 in the control group.

#### **3.6.3.4 Subjects with missing data (prospective subjects)**

Subjects in this study were advised that the duration of their participation in this study would be approximately three months within which they would attend three appointments: a hearing assessment, a hearing aid fitting appointment, and a follow-up appointment. Table 3.4 depicts the number of subjects that attended each appointment. All subjects attended the hearing assessment and hearing aid fitting appointments. However, ten prospective subjects in the control group did not attend their follow-up appointments and thus did not complete the study, and 15 prospective subjects in the experimental group did not attend their follow-up appointment and thus did not complete the study.

**Table 3.4: Total sample of prospective subjects (excluded) and subjects (included) in this study**

	Appointment	Duration	Number of subjects that attended in the control group	Number of subjects that attended in the experimental group
First appointment	Hearing assessment	1 hour	34	34
Second appointment	Hearing aid Fitting	1 hour	34	34
Third appointment	Hearing aid follow-up	1/2 hour	10	15

A complete case analysis was conducted in this study. Subjects with missing data were omitted from the analysis. Table 3.5 displays all the subjects without data at the follow up appointment.

**Table 3.5: Prospective subjects with missing data at the follow-up appointment**

Reason for missing data	Control group	Experimental group
Cancelled follow up	3	3
Did not attend follow up	3	1
Did not use hearing aids	2	3
Declined hearing aids at assessment	2	8
<b>Total</b>	<b>10</b>	<b>15</b>

Ten prospective subjects declined hearing aids at the assessment appointment and a total of 15 prospective subjects cancelled appointments, did not attend their appointments or did not use their hearing aids. A total of 25 subjects did not complete the study, as such the drop out rate was higher than accounted for during the sample size calculation (refer to Section 3.6.2). Studies have shown that many hearing aid users abandon the rehabilitation process (i.e. not use their hearing aids), but there is limited research as to why this occurs (Gianopoulos & Stephens, 2005; Hartley et al., 2010; Hougaard & Ruf, 2011).

### 3.6.4 Description of subjects

Out of the total of 68 subjects, 43 subjects (24 in the control group and 19 in the experimental group) completed the study. Table 3.6 displays the distribution characteristics of the 24 subjects in the control group and 19 subjects in the experimental group who completed the study for age, gender and degree of hearing loss, after stratified randomisation. Despite the limited sample size, subject characteristics were relatively evenly distributed except for male gender in the experimental group, which had seven males and twelve females. Some studies report that women attach greater importance to social communication than men, which might influence their decision to seek help for hearing difficulties, and thus play an active part in reducing communication difficulties (Kricos, 2006). This may have increased positive outcomes in the experimental group. The mean age was relatively equal across groups with the control group at 74 years old and

the experimental group at 79 years old. Regarding the inclusion criterion of hearing loss, most subjects had mild-severe high frequency hearing loss (presbycusis).

**Table 3.6: Distribution of subject characteristics**

Characteristic of subjects	Control group (n=24)	Experimental group (n=19)
Age below 65years	6	0
Age above 65-75years	4	8
Above 75years	14	11
Gender male	12	7
Gender female	12	12
Mild to moderate hearing loss	9	8
Mild to severe hearing loss	14	11
Moderate to severe hearing loss	1	0
Mean age	74 years	79 years

### 3.7 APPARATUS AND MATERIALS

The apparatus and materials utilised in this study are tabulated in Table 3.7 in accordance with the three appointments subjects attended for the study, namely the hearing assessment, the hearing aid fitting, and the hearing aid follow-up. A detailed description of the materials and apparatus used in this study follows the table.

**Table 3.7: List of apparatus, materials, and outcome measures conducted at each appointment**

<b>CONTROL GROUP MATERIAL AND APPARATUS</b>			
	<b>Appointment</b>	<b>Materials and outcome measures</b>	<b>Apparatus</b>
First appointment	Hearing assessment	<b>Materials:</b> Subject information sheet & subject consent form <b>Questionnaires:</b> Medical/otological questionnaire, Pre-test HHIE-S / HHIA-S, Pre-test GHABP	Computers / Auditbase, Otoscope, Pure Tone Audiometer, Tympanometer
Second appointment - One to two weeks after hearing assessment	Hearing aid fitting	None	Computers / Auditbase, Otoscope, Aurical FreeFit®
Third appointment – Six to eight weeks after hearing aid fitting	Hearing aid follow- up	<b>Questionnaires:</b> Post-test HHIE-S / HHIA-S, Post-test GHABP, IOI-HA <b>Hearing aid data logging:</b> Average number of hours hearing aids used per day	Computers / Auditbase, Otoscope, Aurical FreeFit®
<b>EXPERIMENTAL GROUP MATERIAL AND APPARATUS</b>			
	<b>Appointment</b>	<b>Materials and outcome measures</b>	<b>Apparatus</b>
First appointment	Hearing assessment	<b>Materials:</b> Subject information sheet & subject consent form <b>Questionnaires:</b> Medical/otological questionnaire, Pre-test HHIE-S / HHIA-S, Pre-test GHABP <b>Operational Model:</b> Circle tool, Line tool, Box tool	Computers / Auditbase, Otoscope, Pure Tone Audiometer, Tympanometer
Second appointment - One to two weeks after hearing assessment	Hearing aid fitting	<b>Operational Model:</b> Circle tool, Line tool, Box tool	Computers / Auditbase, Otoscope, Aurical FreeFit®
Third appointment – Six to eight weeks after hearing aid fitting	Hearing aid follow- up	<b>Questionnaires:</b> Post-test HHIE-S / HHIA-S, Post-test GHABP, IOI-HA <b>Hearing aid data logging:</b> Average number of hours hearing aids used per day	Computers / Auditbase, Otoscope, Aurical FreeFit®



### **3.7.1 Apparatus**

#### ***3.7.1.1 Otoscope***

As per BSA (2010) recommended procedures for ear examinations, all subjects' outer ears were examined at commencement of each appointment. Welch Allyn 3.5v Fibre Optic Oscopes were utilised to examine each subject's outer ears to determine if there were any contra-indications for hearing aid fitting as per BAA Guidelines (2009).

#### ***3.7.1.2 Computers (Auditbase)***

The Audiology Department at the Royal Free Hospital utilises Sujitsu Siemens Intel Pentium computers that host the computer-based patient management system called Auditbase. This system is the department's computer-based appointment booking system. Auditbase is a software system built on a central database to which all patient demographic data, audiological history, outcome measures, and patient appointment notes are stored. This system also hosts the hearing aid fitting software required to programme digital hearing aids and verify hearing aids fittings. Auditbase was utilised in this study to store subject data, conduct an outcome measure (GHABP), and conduct the hearing aid fitting for subjects. To ensure data protection, all computers require an employee logon and password, and only audiologists with individual passwords can access Auditbase.

#### ***3.7.1.3 Pure tone audiometer***

A Grason Stadler - GSI 61 audiometer was the apparatus used by the researcher to conduct pure tone audiometry (hearing tests) on subjects. Pure tone audiometry is a behavioural test used to measure hearing sensitivity and was conducted as per BSA (2012b) recommended procedures at the following frequencies: 500 Hz, 1000 Hz, 2000

Hz, 3000 Hz, 4000 Hz, 6000 Hz and 8000 Hz, to determine the type and degree of hearing loss. The type and degree of hearing loss was a criterion that determined if subjects were included or excluded from the study (refer to Table 3.1 and Table 3.2). To ensure stability and reliability of the apparatus, all audiometers used for this study were calibrated daily prior to assessing any subjects. Stage A daily and stage B weekly calibration checks are carried out on these audiometers as per BSA (2012b) recommended procedures. Annual calibration is conducted by the manufacturer and recorded electronically by the medical electronics department at the Royal Free Hospital.

#### ***3.7.1.4 Tympanometer***

A Grason Stadler – GSI TympStar was utilised to conduct tympanometry, a quick objective test to assess subjects' middle ear function. Tympanometry was conducted as per BSA (2012c) recommended procedures in conjunction with pure tone audiometry, to determine type of subjects' hearing loss. The type and degree of hearing loss was a criterion that determined if subjects were included or excluded from the study (refer to Table 3.1 and Table 3.2). To ensure stability and reliability of the apparatus, the tympanometer used for this study was calibrated daily prior to assessing any subjects. Calibration is usually carried out on the tympanometer daily and annually as per BSA (2012c) recommended procedures.

#### ***3.7.1.5 Aurical FreeFit®***

The Aurical FreeFit® is the hearing aid programming interface and is coupled with the computer. This device together with the hearing aid software is used for programming hearing aids according to each subject's type and degree of hearing loss. The hearing aid

connects to the Aurical FreeFit® via a programming cable. The Aurical FreeFit® was also used to conduct real-ear measurements to verify the hearing aid fitting on subjects as per BSA (2007) recommended procedures. The auricals are also subject to annual calibration and daily checks.

### **3.7.2 Materials and outcome measures**

#### ***3.7.2.1 Subject information sheet and consent form***

Subject information sheets were issued to all prospective subjects at the first visit and written informed consent was obtained from each subject by means of the consent form (refer to Appendix D as well as section 3.5.1).

#### ***3.7.2.2 Medical /otological questionnaire***

A medical history/otological history questionnaire designed by the researcher (refer to Appendix E) is utilised routinely by all audiologists in the Audiology Department at the Royal Free Hospital. This questionnaire was based on the Guidelines for Referral to Audiology (BAA, 2009) and was used in this study as a criterion to determine if subjects had any contraindications that would exclude them from the study (refer to Table 3.1 and Table 3.2).

#### ***3.7.2.3 Questionnaires***

##### ***3.7.2.3.1 Hearing Handicap Inventory for the Elderly (HHIE-S – Ventry & Weinstein, 1982) and Adults (HHIA-S – Newman, Weinstein, Jacobson & Hug, 1990)***

For the purpose of this study the screening versions of the HHIE and HHIA were utilised. The full version of these questionnaires consisted of 25 items. Since this questionnaire was provided to subjects to complete by themselves in the waiting area, the

screening versions were selected as they required a simple “yes”, “sometimes” and “no” answer to only 10 items which would be easier for subjects to record themselves and also would reduce the time required to complete the questionnaire. Scoring of the HHIE-S and HHIA-S were based on three scales, whereby a score of zero was allocated to an answer “no”, a score of two was allocated to the answer “sometimes” and a score of four was allocated to the answer “yes”. These scores were then added for each of the 10 items and the total score determined the hearing handicap category into which a subject would fall (no handicap, mild-moderate handicap, and severe handicap) as displayed in Table 3.8.

**Table 3.8: Interpretation of HHIE-S and HHIA-S scores**

Total Score	Impairment	Referral for assessment
0-8	No handicap	13% probability of hearing loss (No handicap/no referral)
10-24	Mild-moderate handicap	50% probability of hearing loss (Mild-moderate handicap/refer)
25-40	Severe handicap	84% probability of hearing loss (Severe handicap/refer)

Pre-test data for the HHIE-S/HHIA-S were analysed to determine if groups were equivalent at the commencement of the study (refer to section 3.8.3.1). The post-test data of the HHIE-S and HHIA-S were utilised in this study to determine any positive impact of the OM on self-reported disability and handicap (if the use of the OM resulted in improved self-reported disability and handicap in subjects’ in the experimental group compared to those in the control group) and to determine if self-reported handicap of subjects correlated with aural rehabilitation outcomes (refer to section 3.8.3.2.3 and section 3.8.3.3.3) as suggested in some reports in the literature (Cox, Alexander & Beyer, 2003; Laplante-Lévesque, Hickson & Worrall, 2011; Laplante-Lévesque, Hickson & Worrall, 2012; Takahashi et al., 2007; Knudsen et al., 2010).

#### *3.7.2.3.1.1 Hearing Handicap Inventory for the Elderly (HHIE-S – Ventry & Weinstein, 1982)*

The purpose of the HHIE self-assessment tool (refer to Appendix F) is to assess the effects of hearing loss on the emotional and social adjustment of elderly individuals (Ventry & Weinstein, 1982). The goal of the HHIE is to measure the perceived effects of hearing loss. The HHIE hosts a combination of scales that include assessment of social and situational (patients' perceived effects of hearing loss in a variety of social situations) and psychosocial or emotional (patients' attitudes, and emotional responses toward hearing loss) consequences of hearing loss (Ventry & Weinstein, 1982). The HHIE was modified for use with adults with hearing loss who are younger than 65 years of age (Newman et al., 1991).

Ventry and Weinstein (1982) reported that results from their study indicated that the HHIE is highly reliable, is purported to have content validity and reported to have excellent internal consistency. Test-retest reliability is reported as being high, which suggests that the HHIE is a good measure of change resulting from rehabilitation (Weinstein, Spitzer, & Ventry, 1986). Johnson and Danhauer (2002) describe this as an easy measure for the elderly to complete with scores that are easy to interpret. This questionnaire was used on subjects and prospective subjects who were 65 years and older.

#### *3.7.2.3.1.2 Hearing Handicap Inventory for the Adults (HHIA-S – Newman, Weinstein, Jacobson & Hug, 1990)*

The purpose of the HHIA (refer to Appendix G) is to quantify the perceived handicap for adults younger than 65 years and to assess benefit by measuring the change in perceived handicap before and after fitting hearing aids (Johnson & Danhauer, 2002). The

HHIA is similar to the HHIE and is composed of two subscales namely emotional and social/situational (Newman, Weinstein, Jacobson & Hug, 1991). The focus of some questions in the HHIA is on the occupational effects of hearing loss.

The HHIA has a high internal reliability (Newman et al., 1990) and high test-retest reliability with a low standard error of measurement (Newman et al., 1991). This measure is easy to complete and scores can be easily interpreted (Johnson & Danhauer, 2002). Based on the inclusion criteria of 18 years and older (refer to Table 3.1), this questionnaire was used on subjects and prospective subjects who were between 18 and 64 years old.

#### *3.7.2.3.2 The Glasgow Hearing Aid Benefit Profile (GHABP) – (Gatehouse, 1999)*

Self-report measures are the only way to assess hearing aid usage and satisfaction (Dillon, 2001). The GHABP (refer to Appendix H) is a comprehensive self-report questionnaire that assesses the three dimensions of hearing aid benefit, hearing aid use, and hearing aid satisfaction (Dillon, 2001). The GHABP uses six predefined subscales which address initial disability and handicap (pre-intervention), and hearing aid use, hearing aid benefit, residual disability, and satisfaction (post-intervention) in four predefined (standardized) and four optional user-nominated (individualised) listening situations.

These subscales have been validated by using a paradigm in which sensitivity to alterations in audibility was the main factor determining the selection of predefined listening situations (Gatehouse, 1999b). Based on these normative findings, it is deemed an appropriate instrument for audiologists who want to use self-reported data to measure

improvement in audibility. The GHABP is intended for individuals who require rehabilitative counselling prior to being issued with amplification devices, and they are also able to review any problems prior to being issued with amplification devices (Johnson & Danhauer, 2002). Scores for the six different subscales of the GHABP are recorded numerically from zero to 100 with the higher score representing a better outcome except for residual disability where the lower the score, the better the outcome.

The six subscales are as follows:

- pre hearing aid fitting scores:
  - Initial disability – Degree of hearing difficulty experienced by the individual
  - Initial handicap – Effect or impact on the individual’s life
- post hearing aid fitting scores:
  - Hearing aid benefit – Extent to which the individual’s hearing is improved
  - Hearing aid use – Extent to which the individual’s hearing aid is used
  - Residual disability – Hearing difficulty experienced by the individual after the fitting of the hearing aids
  - Satisfaction – Individual’s satisfaction with the hearing aids

Pre-test data for the GHABP (initial disability and initial handicap) were analysed to determine if groups were equivalent at the commencement of the study (refer to 3.8.3.1). The post-test data of the GHABP were utilised in this study to determine the value of the OM for hearing aid use (refer to section 3.8.3.2.1), satisfaction with hearing aid use (refer to section 3.8.3.2.2) and self-reported disability and handicap (refer to 3.8.3.2.3). That is, the data revealed if the use of the OM resulted in improved hearing aid use, improved hearing aid satisfaction, and improved self-reported disability and handicap in subjects in

the experimental group compared to those in the control group. The GHABP was also utilised to evaluate the difference between pre-test and post-test data in both experimental and control groups (refer to Section 3.8.3.3.2). In addition the GHABP was utilised to determine the correlation between self-reported hearing disability and handicap and aural rehabilitation outcomes in both experimental and control groups (Refer to Section 3.8.3.3.3) and to determine the correlation between self-reported hearing aid use and actual hearing aid use recorded on data logging in both experimental and control groups (refer to Section 3.8.3.3.4).

#### *3.7.2.3.3 The International Outcome Inventory for Hearing Aids (IOI-HA – Cox, Alexander & Beyer, 2003)*

The IOI-HA (Appendix I) was developed by Cox et al. (2000) as a means to pool and compare data from various studies from different countries. The goal of the IOI-HA is to assess post hearing aid benefit, satisfaction, and quality of life changes associated with hearing aid use. The IOI-HA is a seven-item inventory with a five point rating scale, which was designed to be applied to different investigations carried out in various cultural and social environments (Cox et al., 2000). The seven subscales are:

- Hearing aid use – The number of hours that a subject uses the hearing aids per day
- Hearing aid benefit – Subject’s improvement in hearing-related activities
- Residual activity limitation – Degree of difficulty a subject experiences hearing in various situations, after hearing aid fitting
- Satisfaction – Subjects’ satisfaction with hearing aids
- Residual participation restriction – The extent to which a subject is unable to participate in activities as a result of the hearing loss, after hearing aid fitting
- Impact on others – How a subject perceives how others reacted to them using a



hearing aid

- Quality of life – Improvement in the subject’s quality of life as a result of hearing aid use

This measure is not intended by the authors to be a substitute for outcome measurement, but should rather serve as a supplement to the battery of self-reported measures of any study in hearing aid rehabilitation. It provides directly comparable data across otherwise incompatible projects (Cox et al., 2000). Cox and Alexander (2002) validated the original English version of the IOI-HA for a group of subjects in America. Stephens (2002) validated the IOI-HA for a group of English-speaking patients in Wales, and Kramer, Goverts, Dreschler, Boymans and Festen, (2002) validated the IOI-HA for a group of patients in the Netherlands.

Scoring of the IOI-HA was based on the answers to each of the seven items described above. A score of one to five was allocated to each item’s five point rating scale. These scores of the seven items were then added and the total score of seven to 35 recorded, with the higher the number the better the outcomes of the hearing aid rehabilitation.

The data of the IOI-HA were utilised in this study to determine the value of the OM for hearing aid use (refer to section 3.7.3.2.1), satisfaction with hearing aid use (refer to section 3.7.3.2.2) and self-reported disability and handicap (refer to section 3.7.3.2.3). That is, the data revealed whether the use of the OM resulted in improved hearing aid use, improved hearing aid satisfaction, and improved self-reported disability and handicap in subjects in the experimental group compared to those in the control group. Data from the IOI-HA were also utilised to determine the correlation between self-reported hearing disability and handicap and aural rehabilitation outcomes in both experimental and control

groups (refer to section 3.7.3.2.3) and to determine the correlation between self-reported hearing use and actual hearing aid use recorded on data logging in both experimental and control groups (refer to section 3.7.3.3.4).

This measure was also chosen for this study for its applicability in that effectiveness of the OM could be compared between different audiological healthcare contexts, which would hopefully enable combination of data from different studies to gain the additional power needed to assess the significance of treatment effects or effect differences (Cox & Alexander, 2002).

#### ***3.7.2.4 Hearing aid data logging statistics***

Data logging is a feature that records how a subject uses the hearing aids. Its purpose is to report the average hearing aid use, use of different programmes set on the hearing aid, and use of the volume control (Gaffney, 2008). More sophisticated data logging statistics are available, but for the purpose of this study, the average hearing aid use (i.e. number of hours use per day) was noted at a subject's follow-up appointment.

Hearing aid data logging statistics were utilised in this study to determine the value of the OM for hearing aid use (Refer to section 3.8.3.2.1), that is, if the use of the OM resulted in increased number of hours of hearing aid use in subjects in the experimental group compared to those in the control group. Data logging statistics were also used to determine the correlation between self-reported hearing use and the actual hearing aid use recorded on data logging in both experimental and control groups (refer to section 3.8.3.3.4), as some studies report that on average, patients over-report their daily amount of hearing aid use (Gaffney, 2008; Laplante-Lévesque, Nielsen, Jensen & Naylor, 2014).

### **3.7.2.5 The OM (the Circle, the Line and the Box)**

The Circle, Line and Box tools (Ida Institute, 2012) constitute the OM (refer to section 2.4), and were implemented with subjects in the experimental group only.

#### *3.7.2.5.1 The Circle,*

The Circle tool (refer to Appendix B) consisted of two parts; one that displayed the seven different stages that a subject could potentially undergo when changing behaviour and the second which consisted of five statements from which a subject chose one that best described his/her thoughts on getting hearing aids. Each stage in the circle reflected changes in a subject's behaviour and support provided to the subject by the researcher differed accordingly (Ida Institute, 2009). The statements with the appropriate stages (Ida Institute, 2009) are outlined below (refer to section 2.4.1 and Table 2.1 for a detailed description of how the patient was supported in each stage of the circle):

- I am not ready for hearing aids at this time - Pre-contemplation
- I have been thinking that I might need hearing aids - Contemplation
- I have started to seek information about hearing aids - Preparation
- I am ready to get hearing aids if they are recommended – Action
- I am comfortable with the idea of wearing hearing aids – Maintenance

#### *3.7.2.5.2 The Line*

According to the Ida Institute (2009) the Line tool (refer to Appendix B) assists in opening the dialogue with reluctant subjects and in exploring whether the subject is ready to embrace the use of recommended rehabilitation. This tool consisted of two questions, which identified whether there was ambivalence between the importance of improving hearing and the subject's personal commitment to making the necessary

changes. Subjects rated their judgement on a scale of zero to ten, on two questions (refer to section 2.4.2):

- How important is it for you to improve your hearing right now?
- If you decided to start using the necessary hearing aids, to which degree do you believe you would then be able to do so? (refer to section 3.8.1.1.4).

### 3.7.2.5.3 *The Box*

The Box tool (Appendix B) complemented the Line tool by supporting a subject's further reflection (Tønnesen, 2012). This tool also assisted the researcher to determine how motivated a subject was to continue with aural rehabilitation. The Box tool consisted of four open squares with the following statements whereby the advantages and disadvantages of not using hearing aids as well as advantages and disadvantages of using hearing aids were explored:

- Benefits of no action
- Costs/disadvantages of no action
- The potential costs/disadvantages of taking action
- The potential benefits of taking action

## 3.8 PROCEDURES

A detailed description of the data collection, data processing and data analysis of this study is stipulated in this section.

### 3.8.1 Data collection

The data collection procedure for the pilot study and main study is explained below.

### ***3.8.1.1 Pilot study***

#### *3.8.1.1.1 Aim of the pilot study*

A pilot study was conducted to increase the reliability and validity of the study, as well as to determine the applicability of the data collection protocols (McBurney, 2010). It enabled the researcher to become familiarised with utilising the OM as well as the outcome measures, in order to allow for consistent application of the OM and outcome measures throughout the study.

#### *3.8.1.1.2 Subjects in the pilot study*

Within the time frame of one month, only six out of prospective ten subjects were deemed suitable for participation in this pilot study based on the inclusion and exclusion criteria (Table 3.1 and Table 3.2). Out of the six subjects who were included in the pilot study, two subjects did not attend the follow up appointment.

#### *3.8.1.1.3 Procedure of the pilot study*

The procedure for the pilot study followed the same protocol as set out in the selection procedure for the main study (refer to Section 3.6.1), as well as for data collection (refer to Section 3.8.1.2) and data processing (refer to Section 3.8.2). The data analysis for this pilot study was not conducted as per the main study since the aim of this pilot study was to refine the procedures for subject selection and data collection. Data from this pilot study were analysed in a descriptive manner.

#### *3.8.1.1.4 Results of the pilot study*

Administration of the pilot study proved to be advantageous. Despite the fact that only four subjects completed the study (attended the follow-up), the pilot study highlighted

time constraints during the data collection process and presentation of the content of questionnaires. Administration of the OM could also be improved. Three subjects found question two for the Line tool (refer to Section 3.7.2.5.2) difficult to answer. They stated that they could not answer this as they have never had any experience with hearing aids before. The original question on line tool asked: *“How much do you believe in your ability to use a hearing aid?”* This question was then edited in accordance with Tønnesen (2012) to read: *“If you decided to start using the necessary hearing aids, to which degree do you believe you would then be able to do so?”* Changing the statement made it easier for subjects to understand the question.

### **3.8.1.2 Main study**

A total of 68 subjects who had never worn hearing aids were identified as prospective subjects. These subjects completed a medical questionnaire and those who did not display any criteria that required onward referral for medical consultation (BAA, 2009) and who met the selection criteria (refer to Table 3.1 and Table 3.2) were randomly placed in control and experimental groups. Random number generators from the software Microsoft Excel for Windows (Version 14.0. Part of Microsoft Office Professional Plus 2010: Microsoft Corp) were utilised to achieve randomisation of subjects.

During the study, subjects in both the experimental and control groups followed an adult aural rehabilitation pathway, which consisted of three appointments (the hearing assessment, a hearing aid fitting and a hearing aid follow-up). In Table 3.9 below, is a list of procedures and outcome measures conducted at each appointment. In both groups data collection was completed at the third follow-up appointment and no further data were collected beyond this visit.

**Table 3.9: List of procedures and outcome measures conducted at each appointment**

	Appointment	Duration	Outcome measures	Procedures
<b>First appointment</b>	Hearing assessment	1 hour 15 minutes	HHIE-S / HHIA-S, GHABP	Medical/otological questionnaire, Otoscopy, Pure tone audiometry, Tympanometry, Explanation of results, recommendations and further counselling as required.
<b>Second appointment - One to two weeks after hearing assessment</b>	Hearing aid fitting	1 hour	None	Subjects were fitted with behind the ear style hearing aids and fittings were verified using real ear measurements.
<b>Third appointment - Six to eight weeks after hearing aid fitting</b>	Hearing aid follow-up	1/2 hour	HHIE-S /HHIA-S, GHABP, IOI-HA, Hearing aid data logging (average number of hours used per day)	Determined progress with hearing aids and addressed any issues regarding the hearing aids. Further counselling and advice were provided as required.

### 3.8.1.2.1 Implementation of the OM

The experimental group followed the pathway outlined above, but Ida Motivational Tools (The Circle, Line and Box) were presented to subjects in this group throughout the rehabilitation process (at all three visits as individually required), in order for the researcher to implement the OM of behaviour change (refer to section 2.4).

The Circle tool was utilised to determine at which stage a subject in the experimental group was on the Circle, and enabled the researcher to appropriately support subjects during their process of change. The Line tool assisted with understanding how a subject in the experimental group viewed the importance of change and how confident the subject felt about entering the process of change (Tønnesen, 2012). If required, more individual information was gained from the Box tool. When required, the researcher utilised the Box tool with subjects in the experimental group in order to make them aware

of their own thoughts (positive and negative) about their hearing loss. Subjects who completed the Line and the Box tools were deemed to have passed the pre-contemplation stage in the Circle (Tønnesen, 2012).

#### *3.8.1.2.2 Data collection from HHIE-S /HHIA-S*

These standardised questionnaires consisted of ten closed questions that subjects completed themselves. The HHIE-S and HHIA-S outcome measures (refer to Appendix F & G) were presented to subjects to complete in the waiting area prior to the assessment (pre-test) and after some time of hearing aid use at the end of the follow-up appointment (post-test). Scores were recorded according to the scale discussed in section 3.7.2.3.1 (refer to Table 3.8), where scores between 10 and 24 placed subjects in the mild-moderate handicap category and scores between 24 and 40 placed subjects in the severe handicap category.

#### *3.8.1.2.3 Data collection from GHABP*

A computer-based version of the standardised questionnaire GHABP was conducted with subjects in both groups pre (before at the assessment appointment) and post (at the follow-up appointment) hearing aid fitting in the form of a structured face-to-face interview (refer to Appendix H for a paper version of the questionnaire). Scores for the six different subscales of the GHABP were also recorded numerically from zero to 100 with the higher score representing a better outcome except for residual disability where the lower the score, the better the outcome (refer to section 3.7.2.3.2).

#### *3.8.1.2.4 Data collection from IOI-HA*

The IOI-HA, another standardised questionnaire, was conducted in the form of a



structured interview at the follow-up appointment of each subject (refer to Appendix I). Total scores from the seven items were recorded numerically from seven to 35 with the higher scores representing better outcomes of hearing aid rehabilitation (refer to section 3.7.2.3.3).

#### *3.8.1.2.5 Data collection from hearing aid data logging statistics*

For both the control and experimental groups, each subject's hearing aid use was recorded. The average number of use in hours per day was obtained from the hearing aid manufacture's data logging software at the follow-up appointment (refer to section 3.7.2.4).

### **3.8.2 Data processing**

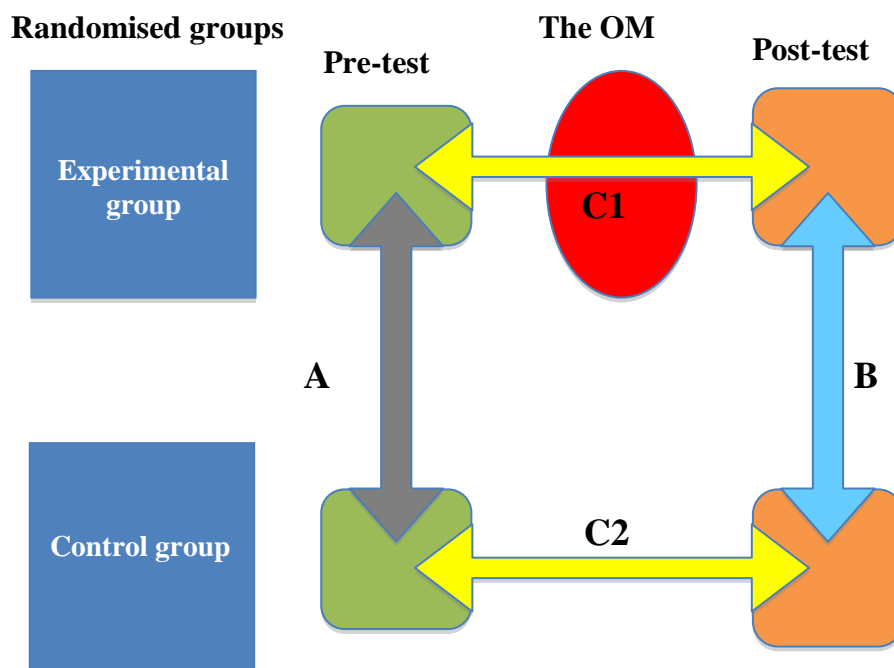
The HHIE-S, HHIA-S and IOI-HA scores were calculated from the paper questionnaires and captured on a computer-based spreadsheet on Microsoft Excel (Version 14.0. Part of Microsoft Office Professional Plus 2010: Microsoft Corp). The computer based GHABP scores from Auditbase (refer to section 3.7.1.2) and the data logging statistics from the hearing aid fitting software were captured on the same Microsoft Excel (Version 14.0. Part of Microsoft Office Professional Plus 2010: Microsoft Corp) spreadsheet. All the collated data were transferred to the statistical software of IBM SPSS Statistics for Windows (Version 20.0. Armonk, NY: IBM Corp).

### **3.8.3 Data analysis**

The intervention outcomes of the two groups were compared utilising both pre-test and post-test data. Due to the non-normal distribution of the data on pre-test and post-test outcome measures, a non-parametric statistical analysis was conducted (Pring, 2005; DePoy & Gitlin, 2011). A complete-case analysis was conducted (i.e. all missing data

were excluded from the analysis). All prospective subjects who did not complete the study were excluded from analysis.

Figure 3.4 is a schematic representation of how the data were analysed in this study. This analysis evaluated the efficiency of randomisation and also determined whether the experimental group, who underwent the OM, showed a significant difference in aural rehabilitation outcomes. Data analysis described below is noted with A, B, C1 and C2 to present the analysis on the schematic diagram.



**Figure 3.4: Schematic diagram of data analysis in this study**

### 3.8.3.1 Pre-test data analysis (A)

Randomisation was effective for subjects who attended the first assessment appointment (n=68). However, the number of subjects who completed the study in each group differed (control n=24 and experimental n=19). Thus the pre-test data for the HHIE-S/HHIA-S and GHABP (initial disability and initial handicap) were analysed to determine if groups

were equivalent. Pre-test data from the two outcome measures conducted at the first assessment visit (pre HHIE-S/HHIA-S and pre GHABP initial disability and pre GHABP initial handicap) were compared between the two groups using the Mann-Whitney U test (DePoy & Gitlin, 2011; Pring, 2005), with p-value <0.05 used as criterion of statistical significance.

### ***3.8.3.2 Post-test data analysis (B)***

Data from all the outcome measures conducted at the third follow-up appointment (post-test HHIE-S/HHIA-S; post-test GHABP scores of HA benefit, hearing aid use, satisfaction, residual disability; post-test IOI-HA scores of use, benefit and satisfaction, residual activity limitation, residual participation restriction and; post-test hearing aid data logging statistics) were compared between groups to achieve the three sub-aims of this study.

#### ***3.8.3.2.1 Sub-aim 1: To determine the impact of the OM on hearing aid use (B)***

To determine if implementation of the OM resulted in better hearing aid usage in the experimental group, post-test data on hearing aid use were compared between the control and experimental groups using the two self-reported questionnaires, GHABP hearing aid use data and the IOI-HA hearing aid use data, as well as the hearing aid manufacturer's data logging statistics on the recorded number of hours hearing aids were used. The difference between post-test data on hearing aid use of the experimental group and post-test data on hearing aid use of the control group was established using the Mann-Whitney U test (DePoy & Gitlin, 2011; Pring, 2005), with p-value <0.05 used as criterion of statistical significance.

*3.8.3.2.2 Sub-aim 2: To determine the impact of the OM on satisfaction with hearing aid use (B)*

To determine if implementation of the OM resulted in improved satisfaction in the experimental group, data were compared between the control and experimental groups using the hearing aid satisfaction data of two self-reported questionnaires (GHABP and IOI-HA). The difference between the post-test hearing aid satisfaction data of the experimental group and post-test hearing aid satisfaction of the control group was tested using the Mann-Whitney U test (DePoy & Gitlin, 2011; Pring, 2005), with p-value <0.05 used as criterion of statistical significance

*3.8.3.2.3 Sub-aim 3: To determine the impact of the OM on self-reported hearing disability and handicap (B)*

To determine if the OM had a positive effect on self-reported disability and handicap, the post-test data of self-reported outcome measures (post HHIE-S and post HHIA-S, the GHABP residual disability and the IOI-HA residual activity limitation and residual participation restriction) were analysed across the groups. The Mann-Whitney U test (DePoy & Gitlin, 2011; Pring, 2005), with p-value <0.05 was used as criterion of statistical significance.

**3.8.3.3 Secondary analysis of data**

Secondary analysis of data in this study makes reference to analysis of data that did not directly address the sub-aims of this study. It refers to further analysis of data that was conducted to address the research question of this study and to evaluate correlations of the data within and across groups, based on studies conducted on aural rehabilitation outcomes and self-reported hearing disability and handicap.

#### *3.8.3.3.1 The GHABP benefit score (B)*

Data of the benefit scores of the GHABP were analysed to address the research question in this study: What impact would using the OM of behaviour change have on adult aural rehabilitation outcomes? Previous data on the GHABP suggested that subjects (without the OM) had a mean benefit of approximately 60 (Gatehouse, 1999a). An increase in benefit of 15 in the experimental group (up to a mean of 75) was deemed a statistically significant increase (refer to section 3.6.2). The post-test data of the GHABP benefit scores were analysed to evaluate the difference in standard deviations and mean benefit scores between the experimental and control groups in this study.

#### *3.8.3.3.2 Evaluation of the difference between pre-test data and post-test data within the experimental and control groups (C1 and C2)*

Data in this study were analysed further to determine if the groups changed over time from pre-test to post-test. The two outcome measures utilised for this analysis were the pre-test and post-test data of HHIE-S and HHIA-S and the pre-test GHABP initial disability and post-test GHABP residual disability. The Wilcoxon signed-rank test (Pring, 2005) was used to assess the difference pre and post intervention for both the control and experimental groups.

#### *3.8.3.3.3 Correlation between pre-test self-reported hearing disability and handicap and post-test aural rehabilitation outcomes in both experimental and control groups (C1 and C2)*

Data were also analysed to determine if results corresponded with other studies in that subjects' pre-test self-reported hearing disability correlated with post-test aural

rehabilitation outcomes. The Spearman rank-order correlation coefficient test (Pring, 2005) was used to measure correlations within and across the groups.

#### *3.8.3.3.4 Correlation between self-reported hearing use and actual hearing aid use recorded on data logging in both experimental and control groups (B)*

Further analysis was conducted to determine if subjects' post-test self-reported hearing aid use correlated with the subjects' actual hearing aid use. The Spearman rank-order correlation coefficient test (Pring, 2005) was used to measure correlations within and across the groups.

### **3.9 RELIABILITY AND VALIDITY**

With regard to the outcome measures selected for this study, reliability refers to the consistency or precision of measurement while validity is the truth or accuracy in measurement (Johnson & Danhauer, 2002). For a measure to be valid, it must also be reliable. All the standardised outcome measures utilised in this study (HHIA-S, HHIE-S, GHABP and IOI-HA) have been validated and are deemed to have good reliability (refer to Section 3.7.2.3).

Validity refers to the extent to which a test measures what it is supposed to measure (Gosall & Gosall, 2012). All four of the outcome measures (HHIA-S, HHIE-S, GHABP, IOI-HA) provided information on initial subject opinions and post amplification effects of hearing loss. These tools were specifically chosen, as each tool provided information to realise the aim and objectives of this study, thus highlighting the validity of utilising these outcome measures for this study. Internal validity refers to the extent to which a study measures what it sets out to measure (Gosall & Gosall, 2012). External validity

indicates to what extent the results from the study can be generalised to the wider population (Gosall & Gosall, 2012). Most experimental researchers attempt to maximise external validity by a sampling procedure (DePoy & Gitlin, 2011). This study employed a probability-sampling plan known as stratified randomisation (refer to Section 3.6.3) so as to ensure that the sample adequately represented a wider population.

Reliability of this study itself depends on the use of these outcome measures. The researcher was responsible for implementing these outcome measures at both pre-test and post-test experimental phases. Although this could contribute to assessment bias it did ensure consistency of obtaining data from the outcome measures.

The health service environment is complex and does not offer the same degree of control as a laboratory setting. In applying the true experimental design in a human service environment, therefore, the researcher had to carefully examine the particular threats to internal validity and how each of these could be resolved (DePoy & Gitlin, 2011). Creswell (2009) describes internal validity threats as experimental procedures, treatments, or experiences of the subjects that threaten the researcher's ability to draw correct inferences from the data about the population, and states that external validity threats occur when researchers draw incorrect inferences from the sample data to other persons, settings, or past/future situations. Table 3.10 is adapted from Creswell (2009) and lists the possible threats to this particular study. The last column describes how the researcher addressed the threat for this study.

**Table 3.10: Threats to internal and external validity (adapted from Creswell, 2009)**

<b>THREATS TO INTERNAL VALIDITY</b>		
<b>Type of threat</b>	<b>Description of threat</b>	<b>Actions researcher took</b>
Selection	Subjects could be selected who have certain characteristics that will predispose them to have a certain outcome	Subjects in this study were randomly assigned to experimental and control groups
Diffusion of treatment	Subjects in the control and experimental groups may communicate with each other and this may influence how both groups score on outcomes	Subjects of the two groups were seen separately, individually, and allocated specific time slots for their appointments to avoid the two groups influencing each other
Compensatory / resentful demoralisation	Benefits of a study may be unequal or resented when only experimental group receives the treatment	Both groups in this study received a treatment, thus no group is disadvantaged in any way. The experimental group only received additional counselling
Instrumentation	Instrument changes between pre-test and post-test will impact the outcome measure scores	Two of the outcome measures utilised in this study were presented at both the pre-test and post-test phases
<b>THREATS TO EXTERNAL VALIDITY</b>		
<b>Type of threat</b>	<b>Description of threat</b>	<b>Actions researcher took</b>
Interaction of selection and treatment	Narrow characteristics of subjects in the study will not allow generalisation to individuals who do not have the same characteristics	The researcher has restricted claims about groups to which the results cannot be generalised. Suggestions for further research with groups of different characteristics were made
Interaction of setting and treatment	The characteristics of the NHS setting in this study may prevent results being generalised to the wider population of individuals with hearing loss who obtain hearing aids privately	The researcher has suggested additional research projects in new settings to determine if the same results occur



### **3.10 SUMMARY**

The main aim of this study was to determine the impact of using the OM of behaviour change on adult aural rehabilitation outcomes (hearing aid use, hearing aid benefit, and hearing aid satisfaction). This study had a quantitative, experimental design that utilised a pre-test post-test design on 43 subjects attending DA services at the Royal Free Hospital in London. These subjects were randomised into experimental and control groups. The experimental group received the OM and the control group did not receive the OM. Data of aural rehabilitation outcomes of each group were collected, analysed, and compared utilising questionnaires (HHIE-S, HHIA-S, GHABP, IOI-HA) and hearing aid manufacturers' data logging statistics. The pre-test data were analysed to determine if groups were equivalent and post-test data were analysed to achieve the sub-aims of the study. Secondary analysis of the data was conducted to determine if data in this study correlated with previous studies and to validate the results of this study.

## 4 RESULTS

Data were obtained from 24 subjects who completed the study in the control group and 19 subjects who completed the study in the experimental group. The 43 subjects who participated in this study attended the Audiology Department Direct Access clinics at the Royal Free Hospital in London.

Data obtained from pre-test outcome measures (HHIE-S, HHIA-S, GHABP) were utilised as a baseline to determine if the experimental and control groups were equivalent prior to further analysis of the data. Data obtained from post-test outcome measures (HHIE-S, HHIA-S, GHABP, IOI-HA and hearing aid manufacturer data logging statistics) were utilised to fulfil the sub-aims for this study, namely:

- To determine the impact of the OM on HA use
- To determine the impact of the OM on satisfaction with HA use
- To determine the impact of the OM on self-reported hearing disability and handicap

Secondary analysis of data was conducted in this study to address the research question of this study and to evaluate correlations of the data within and across groups on the following aspects:

- Hearing aid benefit data were analysed to determine the value of using the OM of behaviour change, as reflected in adult aural rehabilitation outcomes;
- The difference between pre-test data and post-test data within the experimental and control groups was evaluated;
- The correlation between pre-test self-reported hearing disability and handicap and post-test aural rehabilitation outcomes in both experimental and control groups was investigated;

- The correlation between self-reported hearing aid use and actual hearing aid use recorded on data logging in both experimental and control groups were examined.

Inferences throughout this study should be considered with caution due to limited sample size as the drop out rate was higher (36%) than that accounted for during the sample size calculation (refer to Section 3.6.2). The results of this study cannot be generalized to the entire population of patients with hearing loss in the NHS, as this study included only a small group of this population. Subjects in this study were aged 53-95 and had mild-severe hearing loss. The narrow range of characteristics of subjects in the experimental group (age, gender, and degree of hearing loss) will not allow generalisation to individuals who do not have the same characteristics.

#### 4.1 PRE-TEST RESULTS

Pre-test data for the HHIE-S/HHIA-S and GHABP (initial disability and initial handicap) were analysed to determine if groups were equivalent prior to further analysis of the data. Results in Table 4.1 display the comparison between the experimental and control group which reveals no significant difference between groups.

**Table 4.1: Initial disability and handicap in the control and experimental groups**

Post hearing aid self-reported handicap	Control group		Experimental group		p-value <sup>^</sup>
	Median	IQR*	Median	IQR*	
Pre HHIE-S/HHIA-S	22	(16.0)	17	(12.0)	0.078
GHABP Initial disability	33	(46.0)	20	(30.0)	0.058
GHABP Initial handicap	48	(44.0)	39	(54.0)	0.519

\*Interquartile Range

<sup>^</sup>p-value obtained from Mann-Whitney U test

For both the HHIE-S/HHIA-S and GHABP, none of the pre-test data comparisons across groups yielded a p-value <0.05.

## 4.2 POST-TEST RESULTS

Post-test data were compared to achieve the three sub aims of this study.

### 4.2.1 Sub-aim 1: To determine the impact of the OM on hearing aid use

To determine if implementation of the OM resulted in better hearing aid use in the experimental group, post-test data were compared between the control and experimental groups using self-reported measures (GHABP and IOI-HA) and the hearing aid manufacturer's data logging statistics. Table 4.2 displays the comparison of hearing aid use between the control and experimental groups. The p-value was obtained from the non-parametric Mann-Whitney U test (DePoy & Gitlin, 2011; Pring, 2005).

**Table 4.2: Hearing aid use in the control and experimental groups**

Hearing aid use	Control group		Experimental group		p-value <sup>^</sup>
	Median	IQR*	Median	IQR*	
<b>GHABP</b>	19	(46.0)	36	(32.0)	0.5
<b>IOI-HA</b>	3	(2.0)	4	(1.0)	0.99
<b>Hearing aid data log</b>	4	(7)	4	(4)	0.72

\*Interquartile Range

<sup>^</sup>p-value obtained from Mann-Whitey U test

Results in Table 4.2 show that on all outcome measures (GHABP, IOI-HA and the actual hearing aid data logging) there is no significant difference between the experimental and control group (i.e. p-value <0.05). Data suggests that the OM did not result in increased hearing aid use.

#### 4.2.2 Sub-aim 2: To determine the impact of the OM on satisfaction with hearing aid use

To determine if implementation of the OM resulted in improved satisfaction in the experimental group, post-test data were compared between the control and experimental groups using self-reported measures (GHABP and IOI-HA). Table 4.3 displays the comparison of subjects' satisfaction with their hearing aids between the control and experimental groups. The p-value was obtained from the non-parametric Mann-Whitney U test (DePoy & Gitlin, 2011; Pring, 2005).

**Table 4.3: Satisfaction in control and experimental groups**

Hearing aid satisfaction	Control group		Experimental group		p-value <sup>^</sup>
	Median	IQR*	Median	IQR*	
<b>GHABP</b>	30.5	(38.0)	32	(58.0)	0.5
<b>IOI-HA</b>	4	(1.0)	5	(1.0)	0.412

\*Interquartile Range

<sup>^</sup>p-value obtained from Mann-Whitey U test

Results in Table 4.3 reveal that for both outcome measures that measured satisfaction (GHABP and IOI-HA) there is no significant difference between the groups, as none of the comparisons yielded a p-value <0.05. Results suggest that the OM did not result in increased satisfaction with hearing aids.

#### 4.2.3 Sub-aim 3: To determine the impact of the OM on self-reported hearing disability and handicap

Data of post-test self-reported outcome measures (post HHIE-S and post HHIA-S, the GHABP residual disability and the IOI-HA residual activity limitation and residual participation restriction) were analysed across the groups to determine if the OM affected self-reported disability and handicap. Table 4.4 displays the comparison of post-test data

between the experimental and control groups. The p-value was obtained from the non-parametric Mann-Whitney U test (DePoy & Gitlin, 2011; Pring, 2005).

**Table 4.4: Post-test self-reported hearing disability and handicap**

Post hearing aid self-reported handicap	Control group Median	Control group IQR*	Experimental group Median	Experimental group IQR*	p-value <sup>^</sup>
Post HHIE-S/HHIA-S	5	(8.0)	4	(10.0)	0.79
<b>GHABP residual disability</b>	64	(39.0)	33	(26.0)	<0.01
<b>IOI-HA activity limitation</b>	4	(1.0)	4	(1.0)	0.354
<b>IOI-HA particip. restriction</b>	4.5	(1.0)	4	(1.0)	0.73

\*Interquartile Range

<sup>^</sup>p-value obtained from Mann-Whitney U test

As shown in Table 4.4, there is no significant difference between the two groups in self-reported handicap using the HHIE-S and HHIA-S or the IOI-HA. These data suggest that the OM did not result in better (i.e. lower level of) self-reported hearing handicap for these outcome measures.

When measuring post-test residual disability (the hearing difficulty experienced by the patient after hearing aid fitting) by means of the GHABP, however, a significant difference was obtained between the control and experimental groups. A p-value of <0.01 was obtained which indicated that subjects who received the OM of behaviour change (experimental group) reported less residual disability than those who did not (control group).

## 4.3 SECONDARY ANALYSIS OF RESULTS

### 4.3.1 The GHABP benefit score

To address the research question posed in this study post-test data of the GHABP benefit score were analysed. Table 4.5 displays the difference in standard deviations and mean benefit scores between the experimental and control groups in this study (refer to section 3.6.2).

**Table 4.5: Standard deviation and mean GHABP benefits scores**

	Number of subjects	Standard deviation	Mean
Control group	24	24.9	33.5
Experimental group	19	30.3	46.1

Results displayed in Table 4.5 show a positive difference in the mean benefit score (12.6) of the GHABP in that the experimental group did achieve higher scores (mean benefit of 46.1) than the control group (mean benefit of 33.5), but this difference is not statistically significant.

### 4.3.2 The difference between pre-test data and post-test data within the experimental and control groups

Data were analysed to determine if the groups changed over time from pre-test to post-test. The two outcome measures utilised for this analysis were the pre-test and post-test data of HHIE-S and HHIA-S and the pre-test GHABP initial disability and post-test GHABP residual disability. Results are tabulated in Table 4.6. These results show that there is a significant difference between the pre-test and the post-test measurements of HHIE-S/HHIA-S in the experimental group, and there is a significant difference between the pre-test and the post-test measurements of HHIE-S/HHIA-S in the control group (p-

value<0.01). With the HHIE-S/HHIA-S outcome measure, subjects reported positive outcomes with hearing aid fitting. Subjects in both groups found aural rehabilitation beneficial, as they reported reduced disability and handicap after some time of hearing aid use. A significant difference (a p-value of <0.01) between the pre-test GHABP initial disability and post-test GHABP residual disability was identified only in the control group. Note that the GHABP residual disability score was significantly better in the experimental group, compared to the control group (refer to Section 4.2.3 and Table 4.4).

**Table 4.6: Pre-test and post-test HHIE and GHABP**

	Median	(IQR)†	p-value*
<b>Experimental group</b>			
<b>HHIE-S/HHIA-S</b>			<0.01
Pre HHIE-S/HHIA-S	17	(12)	
Post HHIE-S/HHIA-S	4	(10)	
<b>GHABP</b>			0.435
GHABP initial disability	27	(17)	
GHABP residual disability	33	(26)	
<b>Control group</b>			
<b>HHIE-S/HHIA-S</b>			<0.01
Pre HHIE-S/HHIA-S	22	(16)	
Post HHIE-S/HHIA-S	5	(8)	
<b>GHABP</b>			<0.01
GHABP initial disability	33	(38)	
GHABP residual disability	64	(39)	

†IQR: Interquartile range

\*p-value obtained from Wilcoxon Signed Rank test

### 4.3.3 Correlation between pre-test self-reported hearing disability and handicap and post-test aural rehabilitation outcomes in both experimental and control groups

Further analysis was conducted to determine whether subjects' self-reported hearing disability and handicap improved after some time of hearing aid use, as was reported in other studies (Cox, Alexander & Beyer, 2003; Laplante-Lévesque, Hickson & Worrall,



2011; Laplante-Lévesque, Hickson & Worrall, 2012; Takahashi et al., 2007; Knudsen et al., 2010). These studies found that subjects' self-reported hearing disability correlated with aural rehabilitation outcomes. Table 4.7 displays the results from the Spearman rank-order correlation coefficient test (Pring, 2005), which was used to determine the correlations within and across groups.

**Table 4.7: Correlation between pre-test self-reported hearing disability and handicap and post-test aural rehabilitation outcomes in both experimental and control groups**

	Spearman's Rho	p-value
Pre HHIE-S/HHIA-S and GHABP Use	0.37	0.02
Pre HHIE-S/HHIA-S and GHABP Benefit	0.45	<0.01
Pre HHIE-S/HHIA-S and GHABP Satisfaction	0.41	0.01
Pre HHIE-S/HHIA-S and IOI-HA Use	0.30	0.06
Pre HHIE-S/HHIA-S and IOI-HA Benefit	0.10	0.70
Pre HHIE-S/HHIA-S and IOI-HA Satisfaction	0.32	0.04

\*Interquartile Range

^p-value obtained from Mann-Whitey U test

According to the data in Table 4.7 the Spearman's Rho calculations for GHABP use, GHABP benefit, GHABP satisfaction, and IOI-HA satisfaction show positive and significant correlations with the HHIE-S and HHIA-S ( $p < 0.05$ ). The Spearman's Rho calculations for IOI-HA use and IOI-HA satisfaction showed a positive correlation, but this was not significant as p-values were greater than 0.05.

#### **4.3.4 Correlation between self-reported hearing use and actual hearing aid use recorded on data logging in both experimental and control groups**

Data were analysed to determine if subjects' self-reported hearing aid use correlated with the subjects' actual hearing aid use as logged in the data logging statistics. Table 4.8

displays the results from the Spearman rank-order correlation coefficient test (Pring, 2005), which was used to measure the correlations within each group.

**Table 4.8: Correlations of hearing aid use within each group**

Hearing aid Use	Control Group		Experimental Group	
	Spearman's Rho	p-value	Spearman's Rho	p-value
<b>GHABP and hearing aid data log</b>	0.77	<0.01	0.81	<0.01
<b>IOI-HA and GHABP</b>	0.72	<0.01	0.77	<0.01
<b>Hearing aid data log and IOI-HA</b>	0.71	<0.01	0.72	<0.01

\*Interquartile Range

^p-value obtained from Mann-Whitey U test

Results in Table 4.8 show that across all outcome measures for both the experimental and control groups, self-reported hearing aid use and actual hearing aid data logging were positively and strongly correlated with a Spearman's Rho over 0.7 and p-value<0.01.

#### 4.4 SUMMARY

Results were obtained utilising data from the pre-test outcome measures (HHIE-S, HHIA-S, GHABP) and post-test outcome measures (HHIE-S, HHIA-S, GHABP, IOI-HA and hearing aid manufacturer data logging statistics) from 24 subjects in the control group and 19 subjects in the experimental group. These results, which are presented according to the three sub-aims of this study, show no significant difference between the control and experimental group for hearing aid use or for hearing aid satisfaction. Positive results were obtained from the experimental group, however, with regard to self-reported residual disability. Although this was not statistically significant, further analysis of data revealed a positive result in that subjects in the experimental group found hearing aids more beneficial than subjects in the control group. Finally, a positive correlation was found

between subjects' self-reported hearing aid use and actual hearing aid use as logged by the hearing aid data logging statistics.

## **5 DISCUSSION**

The hypothesis for this study was that the OM is valuable in aural rehabilitation and will have a positive effect on aural rehabilitation outcomes for subjects as they will report benefit from their hearing aids, use their hearing aids more regularly, and be more satisfied with their hearing aids. The null hypothesis was that the OM has no value in aural rehabilitation and will not have a positive effect on aural rehabilitation outcomes for subjects in that they will report no benefit from their hearing aids, will not use their hearing aids regularly, and will not be satisfied with their hearing aids.

Based on the three sub-aims that were designed for this study, data showed no significant difference between the experimental and control groups for outcome measures relating to hearing aid use, hearing aid benefit, hearing aid satisfaction, and post self-reported disability and handicap. However secondary analysis revealed some positive results.

### **5.1 PRE-TEST RESULTS**

Randomisation in this study was effective for all subjects who were included in the study at the assessment appointment (refer to section 3.6.3). However, out of the 68 subjects that were randomised, only 43 subjects (control group  $n=24$  and experimental group  $n=19$ ) completed the study. Pre-test data were thus analysed to determine if groups were equivalent prior to further analysis of the data. Results showed no significant difference between the control and experimental groups, thus groups were equivalent at pre-test.

### **5.2 POST-TEST RESULTS**

Although the following discussion of the results are presented according to the sub-aims outlined for the study; it should be noted that hearing aid benefit, hearing aid use,

satisfaction with hearing aids, and self-reported disability and handicap after hearing aid use are all interlinked. Discussion of the results under each sub-aim will detail the associations.

### **5.2.1 Sub-aim 1: To determine the impact of the OM on hearing aid use**

The OM did not have a significant effect on the number of hours a hearing aid was used by subjects in this study. However, data from the use of hearing aids cannot alone determine positive outcomes. Some subjects may have found significant benefit from the hearing aid, but only used the device in certain situations. In this study, there was a difference in the GHABP outcome measures for hearing aid benefit between the control and experimental groups (refer to Section 4.3.1) in that the OM did result in better hearing aid benefit. The difference was, however, not statistically significant.

Evidence suggests that consistent use of hearing aids over a period of 30 days will enable subjects to acclimatise to the devices, but this does vary from individual to individual (Taylor, 2007). Post-test data of this study were collected approximately six weeks after the hearing aid fitting, but subjects who did not use their hearing aids consistently during the six-week period may not have acclimatised to the devices. This could have influenced the aural rehabilitation outcomes in that maximum benefit from the hearing aids was not yet achieved. Consequently, if subjects in the experimental group (subjects who received the OM) did not find more benefit from the hearing aids than those in the control group (who did not receive the OM), then it could be inferred that they would also not be more satisfied with the devices and would not report an improved self-reported disability and handicap compared to the control group for the same outcomes.

### **5.2.2 Sub-aim 2: To determine the impact of the OM on satisfaction with hearing aid use**

The OM did not have a significant effect on the satisfaction with hearing aids among subjects in this study. Wong, Hickson and McPhearson (2009) state that one of the factors that influence satisfaction is the type of hearing aids. As the subjects in this study were not given a choice regarding the type of hearing aid with which they were issued (all subjects were issued with behind the ear style hearing aids), aesthetic aspects and stigmatisation related to hearing aids could have influenced aural rehabilitation outcomes for satisfaction, as found in other studies by Kochkin (2007), Meister et al. (2008), and Wallhagen (2009). Three subjects in the control group and one subject in the experimental group stated that they would have preferred hearing aids that were not visible. This could in turn have negatively affected the aural rehabilitation outcomes for hearing aid benefit, hearing aid use, and hearing aid satisfaction, as well as self-reported hearing disability and handicap. Previous research indicates that subjects who were fitted with smaller hearing aids (such as in-the-ear hearing aids) were more satisfied than those who were fitted with other types of hearing aids (Kochkin, 2000; Hosford-Dunn & Halpern, 2001).

### **5.2.3 Sub-aim 3: To determine the impact of the OM on self-reported hearing disability and handicap**

Many studies have shown that self-reported hearing disability and handicap is a robust predictor of aural rehabilitation outcomes (Cox et al., 2003; Takahashi et al., 2007; Knudsen, et al., 2010 & Laplante-Lévesque, et al., 2011; 2012). These studies revealed that greater pre-test self-reported hearing disability was associated with more successful intervention outcomes. Results from three outcome measures in this study (HHIE-S, HHIA-S and IOI-HA) suggest that the OM did not result in better self-reported hearing

handicap for these outcome measures. Subjects in the experimental group did not use their hearing aids more regularly than the subjects in the control group. These subjects also did not report improved satisfaction with their hearing aids compared to the control group. It can be inferred that because subjects in the experimental group did not use their hearing aids regularly, they would not report a significant improvement in self-reported hearing disability and handicap compared to the control group.

Out of all the outcome measures utilised in this study, data analysis between the experimental and control groups displayed a significant difference in only one aspect, namely the GHABP measurement of residual disability. Results of the GHABP residual disability measurement (the hearing difficulty experienced by the subject after hearing aid fitting) showed a significant difference in that subjects in the experimental group had less perceived residual disability than those in the control group. It could be inferred that subjects in the experimental group, who received the OM, were more engaged and supported during their rehabilitation process and as such had less difficulty with their hearing aids (Clark, 2010; Gregory, 2012). It could also be inferred that subjects in the experimental group, who received the OM, had more counselling and support and consequently were less ambivalent towards hearing aids than subjects in the control group who did not receive the OM (Clark, 2010; Gregory, 2012).

### **5.3 DISCUSSION OF SECONDARY ANALYSIS OF RESULTS**

The secondary analysis of data in this study is discussed in terms of the research question of this study and in terms of the evaluation of correlations of the data within and across groups. Furthermore a discussion of additional factors such as missing data, aesthetics, cost of hearing aids, cost to the economy and acclimatisation to hearing aids, is provided.

### **5.3.1 The GHABP benefit score**

Previous data that measured benefit of hearing aids, collected by Gatehouse (1999a) suggested that subjects (without the OM) had a mean benefit score of approximately 60, with a standard deviation of approximately 14 (Gatehouse, 1999a). A mean of 75 in the experimental group was deemed to be statistically significant (refer to section 3.6.2).

The sample size of this study was not statistically large enough to provide conclusive results due to subjects who did not complete the study. The total number of subjects who completed the study was below the suggested value recommended by the sample size calculation (i.e. 34 per group), thus the standard deviations were greater than estimated (24.9 in the control and 30.3 in the experimental group). The estimated increase of 15 on the mean hearing aid benefit score of the GHABP (up to 75 in the experimental group) was therefore not achieved in this study.

### **5.3.2 The difference between pre-test data and post-test data within the experimental and control groups**

The change from pre-test to post-test measurements of the HHIE-S and HHIA-S within each group showed a significant difference. Subjects in both groups did find aural rehabilitation beneficial as they reported reduced disability and handicap after some time of hearing aid use. Although there was no significant difference between the control and experimental groups in this study, results corroborated those of other studies that utilised the HHIE and found that after some time of hearing aid use, the perceived hearing disability and handicap is reduced (Taylor, 1993; Humes, Halling & Coughlin, 1996; Humes, 2001). Other studies by Hickson et al. (2008) and Chia et al. (2007) also found improvement in hearing handicap following the use of hearing aids.



A significant difference in the change from pre-test initial disability to post-test residual disability results of the GHABP was found in only the control group. This difference, however, reflects a negative outcome for the control group, as the residual disability scores (the hearing difficulty experienced by the patient after hearing aid fitting) were higher than the initial disability scores (the degree of hearing difficulty experienced by subject). Subjects in both groups still had hearing difficulty after the hearing aid fitting (in both groups the residual disability scores were higher than initial disability scores), although as discussed previously (refer to Section 4.2.3, Table 4.4, and Section 5.2.3) the residual disability score was significantly better in the experimental group compared to that of the control group. This difference indicates that subjects who received the OM of behaviour change reported less residual disability than those who did not. It is inferred that subjects who received the OM had more support and counselling and therefore had less difficulty with, and were less ambivalent towards, hearing aids than those who did not receive the OM (Clark, 2010; Gregory, 2012).

### **5.3.3 Correlation between pre-test self-reported hearing disability and handicap and post-test aural rehabilitation outcomes in both experimental and control groups**

Studies by Cox et al. (2003), Takahashi et al. (2007), Knudsen, et al. (2010), and Laplante-Lévesque et al. (2011, 2012) revealed that greater pre-test self-reported hearing disability was associated with more successful intervention outcomes. A study conducted by Mizutari et al. (2013) found that for the group of subjects studied, the HHIE was a reliable predictor for using hearing aids in that individuals with higher HHIE scores used hearing aids more regularly. Results of the current study corroborated the findings of other

research and showed a positive correlation between self-reported hearing disability and handicap on the one hand and aural rehabilitation outcomes on the other hand.

#### **5.3.4 Correlation between self-reported hearing use and actual hearing aid use recorded on data logging in both experimental and control groups**

Subjects' self-reported hearing aid use matched that of the actual hearing aid data log in both the experimental and control groups. This result did not corroborate the findings of previous research in that subjects in other studies over-reported hearing aid use (Gaffney, 2008; Laplante-Lévesque, Nielsen, Jensen & Naylor, 2014). It did, however, validate the responses from the subjects in this study with regard to hearing aid use. Subjects self-reported hearing aid use matched the recorded number hours of hearing aid use from the data logging statistics.

#### **5.3.5 Additional considerations**

##### ***5.3.5.1 Subjects with missing data***

A complete case analysis was conducted in this study whereby all subjects with incomplete data were excluded from the data analysis (refer to section 3.6.3.4). It is relevant to mention here the eight subjects in the experimental group who declined hearing aids (Table 3.6) and were excluded from the data analysis. The OM offered subjects the opportunity to consider their hearing loss and its effects as well as the benefits and barriers to aural rehabilitation, but some still choose not to pursue amplification for their hearing loss. Montori, Gafni and Charles (2006) and Laplante-Levesque et al. (2012) agree that delaying or declining intervention, in this case hearing aid fitting, is outlined in health literature as a valid option in clinical circumstances. This relates to the OM in that subjects were given a chance to make decisions about their own rehabilitation. Tønnesen (2012) stated that the

OM will eventually lead to a reduction of inappropriate use of health care services and may lead to a reduction of health care costs. This statement may be true for the eight subjects in the experimental group of this study who declined hearing aids after implementation of the OM, as they were not coerced into aural rehabilitation services when they were not motivated or ready to commence with hearing aid use. These subjects were not presented with inappropriate services and for these subjects the cost of care to the NHS was contained with regard to providing hearing aids that would not be used (refer to Section 2.3). These subjects would not be included in the statistic of the 0.6 million patients who do not use their hearing aids (Action on Hearing Loss, 2012).

These subjects' decision to decline hearing aids must, however, receive careful consideration. Untreated hearing loss could have an impact on the cost (both financial and psychosocial) of the health and social effects of hearing loss as described by Archbold, Lamb, O'Neil and Atkins (2014) and by The International Longevity Centre UK (2014).

#### ***5.3.5.2 Hearing aid aesthetics***

All subjects in this study were fitted with behind-the-ear style hearing aids. Subjects in this study were restricted in terms of choice of hearing aid based on aesthetic aspects and although this decreased the variability of results for this study, it could have had an effect on aural rehabilitation outcomes (refer to section 2.1.3). The stigma associated with hearing loss is cited among the most important barriers to hearing aid use (Kochkin, 2000; Kochkin, 2007; Meister et al., 2008; Wallhagen, 2009; Southall et al., 2010). Subjects feel embarrassed to wear hearing aids that are noticeable, as they believe it makes them look old and/or disabled. The OM may have assisted subjects in this study with regard to their ambivalence to the aural rehabilitation process, nonetheless, subjects could have either

abandoned the rehabilitation process or had poor aural rehabilitation outcomes based on the stigma associated with behind-the-ear style hearing aids.

#### ***5.3.5.3 Cost of hearing aids***

The cost of hearing aids is a factor that is reported to contribute to individuals' reluctance to pursue aural rehabilitation services (Laplante-Lévesque, et al., 2010b; Meister, et al., 2008). In this study, however, there was no apparent cost for the aural rehabilitation services, as the NHS provided hearing aids, batteries, and accessories to subjects at no additional cost. Thus the factor of cost of hearing aids should not have affected subjects' decision-making with regards to receiving aural rehabilitation in this study. However, because services and devices are provided at no additional cost, patients or carers may access NHS services to simply try out hearing aid devices for comparison to those provided by the private sector. This could have resulted in subjects not complying with rehabilitation recommendations and not attending the follow-up appointment despite undergoing the OM. Due to the characteristics of the NHS setting in this study, the value of the OM cannot be generalised to the wider population of individuals with hearing loss who obtain hearing aids privately.

#### ***5.3.5.4 Cost to the economy***

A large portion of the cost of hearing loss to the economy is related to dealing with the health and social impacts of hearing loss (Archbold, Lamb, O'Neil & Atkins, 2014). Comparably, surgical complications resulting from excessive alcohol intake costs the European union billions of pounds (Tønnesen, 2012). Studies that incorporated the OM to impact pre-operative alcohol cessation showed that 80-90% of surgical patients stopped drinking in preparation for the surgery, reducing complications. It is inferred that this has

the potential to reduce the extra costs associated with surgical complications (Oppedal, Møller & Tønnesen, 2010). This can be correlated with aural rehabilitation outcomes in that hearing impaired patients who undergo the OM and comply with aural rehabilitation programmes will have reduced psychosocial effects of hearing loss and consequently the cost of hearing loss to the economy will be reduced. Conversely, the long-term effects of the value of the OM in the NHS context should be assessed very critically, as it could take months of continual support to get patients to reach the maintenance phase (Ida Institute, 2009). This could be costly to the NHS as it would require additional resources (time and workforce/staffing) to conduct these on-going support sessions.

#### ***5.3.5.5 Acclimatisation to hearing aids***

It is well known that the time needed to acclimatise to hearing aids varies from individual to individual. Although this study collected data after the average acclimatisation period of 30 days (Taylor, 2007), subjects may have required more time to overcome the initial hurdles of hearing aid use. There are many reasons why the time required to acclimatise to hearing aids varies, including physiological discomfort, sensory overload, and manipulation (Kochkin, 2000; 2007; Lane, 2012). It is obvious that the time needed to acclimatise to hearing aids depends on individual circumstances. More time and further analysis will be required to determine the value of the OM for each subject in the experimental group. Such an analysis was beyond the scope of this study. According to the Ida Institute (2009), it is important to remember that patients can move around the Circle (refer to Appendix B) more than once, and it can take a few months before the new behaviour is well established and integrated. Data from this study were collected approximately six weeks after patients were issued with hearing aids. This may have been

a limited time for some subjects to have acclimatised to the hearing aids and/or moved along the circle of change.

Long-term studies on perioperative smoking cessation intervention programmes incorporating the OM, showed a high rate of continuous cessation after one year (Villebro et al., 2008). Although a direct comparison cannot be made with these populations (smoking cessation is an addiction and hearing loss is a disability / handicap), an association can be made with regard to the use of the OM with both populations. If a continuous smoking cessation occurred after one year; the use of OM with aural rehabilitation could imply that individuals with hearing loss, who are supported by means of the OM through the stages of change, will over time acclimatise to their hearing aids and continue to comply with recommended aural rehabilitation programmes.

Notwithstanding the results of the current investigation, the OM certainly does focus on discovery of an individual's wants, desires, needs, and fears regarding hearing aids (Babeu et al., 2004) and this will in turn lead to clearly defined and individualised aural rehabilitation programmes, which could be the key to successful and positive rehabilitation outcomes (Tønnesen, 2012; Erdman et al., 1994).

#### **5.4 SUMMARY**

The null hypothesis in this study was accepted. The OM did not have an effect on aural rehabilitation outcomes with regard to hearing aid use, hearing aid satisfaction, and self-reported disability and handicap. Secondary analysis of the results revealed minimal benefit of the OM for aural rehabilitation, however this was not statistically significant. Secondary analysis of data in this study also corroborated the findings of other studies in

that hearing aid use resulted in reduced self-reported hearing disability and handicap (Taylor, 1993; Humes, Halling & Coughlin, 1996; Humes, 2001; Chia, et al., 2007; Hickson, et al., 2008) and that greater pre-test self-reported hearing disability was associated with more successful intervention outcomes (Cox et al., 2003; Takahashi et al., 2007; Knudsen, et al., 2010 & Laplante-Lévesque, et al., 2011; 2012). A discussion of additional factors, namely subjects with missing data, hearing aid aesthetics, cost of hearing aids, and acclimatisation to hearing aids provides further considerations pertaining to this study.

## **6 CONCLUSIONS**

### **6.1 INTRODUCTION**

Communication is central to human life. If the ability to communicate is limited as a result of hearing loss, this restriction will have detrimental effects on the quality of life of the increasing elderly population. Research evidence supports the assumption that aural rehabilitation of hearing loss should enhance auditory function, thereby enhancing the ability to perceive the speech of others and allowing individuals with hearing loss to communicate by spoken language. There is an extensive amount of evidence that suggests that aural rehabilitation is beneficial to those with hearing loss (Mulrow, 1990; Stark & Hickson, 2004; Kricos, 2006; Chisolm et al., 2007; Kochkin, 2000; 2007; Barons, 2010; Laplante-Lévesque et al., 2012; Erdman, 2013), a finding that this study has corroborated. Despite advances in technology and improvements in services provided, however, many individuals with hearing loss often do not choose to use hearing aids, because of an array of complex psychological and social factors. Hence, there is a need to develop and test strategies and treatments like the OM in order to improve communication abilities and reduce long-term conditions associated with hearing loss. Aural rehabilitation models that include the OM (individualised care that supports the process of behaviour change) are said to improve hearing aid uptake and enable consistent compliance with hearing aid recommendations (Tønnesen, 2012).

### **6.2 DEDUCTIONS**

The main aim of this study was to determine the impact of using the OM for behaviour change on aural rehabilitation outcomes. The researcher set out to determine whether subjects in the experimental group would have improved aural rehabilitation compliance and improved aural rehabilitation outcomes. The experimental group in this study did not



display improved hearing aid use, hearing aid satisfaction, and self-reported hearing disability and handicap compared to the control group, which indicates that the OM had no significant value for aural rehabilitation outcomes. On the other hand, a reduced residual disability was observed with the experimental group, which could indicate that subjects who received the OM were more engaged and supported during the rehabilitation process and were less ambivalent towards, and had less difficulty with their hearing aids compared to the control group. With regard to hearing aid benefit, results did disclose some positive effect, but this was not statistically significant. Secondary analysis of the results revealed corroborations of the results of other studies with regard to the value of hearing aids, improvement in quality of life, and reduction of self-reported hearing disability and handicap. On the basis of this study's results, further research is required to determine the value of the OM in similar audiology settings.

### **6.3 CLINICAL IMPLICATIONS OF THE STUDY**

Offering recommendations concerning the technical aspects of hearing aids is an important component of adult rehabilitation in routine audiology services. It is evident from the literature, however, that the purpose of aural rehabilitation goes far beyond this. Supporting individuals with hearing loss to confront their psychological, social and emotional concerns as they relate to their hearing ability implies that audiologists should suspend the use of traditional medical models of aural rehabilitation and instead provide individualised, patient-centred care based on a supportive and counselling model. There is a current drive from all levels (patients seeking and receiving care, those providing the care, as well as those regulating and funding the service) for audiology services to become more patient-centred, whereby patients are actively involved in decisions and the option of on-going support is available. The OM is considered to be a valuable model and

incorporated with effective aural rehabilitation can fulfil the patient's need for support during the different stages of change and enhance the patient's quality of life (Tønnesen 2012).

The UK NHS provides excellent services to the population with hearing loss. However, there is always a demand on resources (time, staffing, finance) especially regarding the time spent with patients. The cost effectiveness of various interventions needs to be clearly validated, especially with a view to the limited resources in the current economic climate. Community-based, peer-delivered voluntary services that complement clinic-based audiology services can be of value to our elderly population. The use of volunteer services that are able to provide long-term, community-based support to individuals with hearing loss should be investigated and if beneficial utilised to complement aural rehabilitation provided by audiologists. The focus of voluntary, community based, peer-delivered services can be on early intervention thus potentially reducing the cost of future psychosocial effects of hearing loss.

#### **6.4 RECOMMENDATIONS FOR FURTHER RESEARCH**

The OM has been successful in improving patient outcomes in many different medical conditions and although there are some positive findings in this study, further research needs to be conducted to validate these claims within the audiology field in the UK NHS. There is a clear need for well controlled empirical studies to demonstrate the success of such approaches.

The process of seeking, finding, and then adhering to aural rehabilitation involves many cognitive and behavioural processes. Factors that influence these processes continually

change over time. It may be beneficial to conduct long-term studies that reassess individual needs of adults with hearing loss. It is recommended that these studies include analysis of subjects' responses during the OM to demonstrate individual processes of how subjects progress through the circle of change. This analysis was beyond the scope of this study.

As data were collected in a western country, it would be premature to apply this study's findings to other parts of the world where cultures and hearing services are different. The results of this study, however, can be of value for further research with the specified population group. This study could provide material for comparison to similar studies to be conducted in other audiology departments within in the NHS, as well as other studies within the different health contexts in the UK. The inclusion of the IOI-HA in this study can contribute to future comparison studies on this particular topic.

Subjects who received the OM but who did not complete this study (i.e. abandoned the rehabilitation process) should be investigated further to determine reasons why the OM was not successful. This analysis was beyond the scope of this study. Incomplete data were not taken into account in this study and therefore eight subjects of the experimental group who declined hearing aids were excluded from the data analysis. Data analysis of further studies of the OM should attempt to take subjects who decline hearing aids into consideration, as this could influence the results. It is recommended that further analysis and longitudinal studies be conducted on the costs with regard to the health and social impact of these subjects' decisions to decline aural rehabilitation.

In conclusion, any organisation providing care to individuals with hearing loss has to show that it is meeting the needs of the population it is serving. *"We have to keep up with the*

*expectations of the public. This will mean allowing people to exercise choice and be partners in decisions about their own care, shaping and directing it with high quality information and support.”* (Darzi, 2008, p. 40). There is an urge to create further awareness among audiologists regarding individuals with hearing loss’ motivation and self-reported hearing disability and handicap. Research has proven the positive effect of patient-centred care that considers an individual’s social context and addresses the individual’s significant needs; this is now a known fact; and audiologists should now put these recommendations into practice. Efforts should be concentrated on knowing how to provide individualised care in order to support individuals with hearing loss during aural rehabilitation and their process of change.

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- APPENDIX N -** Ethics approval letter from the Postgraduate Research and Ethics Committee of the Faculty of Humanities, University of Pretoria, South Africa (Reference 07098567) dated 22<sup>nd</sup> July 2013

## British Academy of Audiology Guidelines for Referral to Audiology of Adults with Hearing Difficulty (2009)

This document is intended both as a basis for service planning and to guide the practice of those who make direct referral of adults to Audiology services, primarily GPs. A simple checklist for use by Audiology departments to ensure that the guidelines have been followed is included as an appendix. This document replaces the earlier guide (TTSA, 1989) and has been approved by the Board of the British Academy of Audiology.

The guidelines comprise a set of contra-indications for adult (16+ years) *direct* referral to Audiology for hearing assessment and rehabilitative treatment either from Primary Care or via other intra-hospital Consultant pathways.

The contra-indications may be evident at the time of referral, in which case the patient should normally be referred to ENT in the first instance. Contra-indications may additionally become evident on assessment<sup>1</sup> in Audiology, in which case medical opinion should be sought regarding potential referral to ENT. This may require the patient to be seen by a medical practitioner in clinic, or may be based on discussion of relevant findings between the medical practitioner and audiologist. Referral for a medical opinion should not normally delay impression taking or hearing aid provision: the audiologist must make a professional decision based on ear examination whether it is safe to proceed with impression taking. Findings, whether positive or negative, and any advice given regarding these conditions must be recorded and the patient's GP informed. Pre-existing and investigated (medical) conditions should be taken into account if relevant.

### Contra-indications

#### *History:*

- Persistent pain affecting either ear (defined as earache lasting more than 7 days in the past 90 days before appointment);
- History of discharge other than wax from either ear within the last 90 days
- Sudden loss or sudden deterioration of hearing (sudden=within 1 week, in which case send to A&E or Urgent Care ENT clinic)
- Rapid loss or rapid deterioration of hearing (rapid=90 days or less)
- Fluctuating hearing loss, other than associated with colds
- Unilateral or asymmetrical, or pulsatile or distressing tinnitus lasting more than 5 minutes at a time
- Troublesome, tinnitus which may lead to sleep disturbance or be associated with symptoms of anxiety or depression
- Abnormal auditory perceptions (dysacusis)

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<sup>1</sup> Direct referral assessments must be conducted by suitably qualified staff, normally supervised by a qualified Audiologist registered with RCCP, or a Clinical Scientist (Audiology) registered with HPC.

- Vertigo<sup>2</sup>
- Normal peripheral hearing but with abnormal difficulty hearing in noisy backgrounds; possibly having problems with sound localization, or difficulty following complex auditory directions.

*Ear examination:*

- Complete or partial obstruction of the external auditory canal preventing proper examination of the eardrum and/or proper taking of an aural impression.
- Abnormal appearance of the outer ear and/or the eardrum (e.g., inflammation of the external auditory canal, perforated eardrum, active discharge).

*Audiometry:*

- Conductive hearing loss, defined as 25 dB or greater air-bone gap present at two or more of the following frequencies: 500, 1000, 2000 or 4000 Hz.
- Unilateral or asymmetrical sensorineural hearing loss, defined as a difference between the left and right bone conduction thresholds of 20 dB or greater at two or more of the following frequencies: 500, 1000, 2000 or 4000 Hz.
- Evidence of deterioration of hearing by comparison with an audiogram taken in the last 24 months, defined as a deterioration of 15 dB or more in air conduction threshold readings at two or more of the following frequencies: 500, 1000, 2000 or 4000 Hz.

*Other findings:*

- Any other unusual presenting features at the discretion of the audiologist.

**Notes**

Where audiologists are not qualified (according to local guidelines) to undertake wax removal, or where any findings indicate possible need for further specialist assessment (e.g. otological, medical, neurological, neuro-otological), a medical opinion (normally from ENT or Audiovestibular Medicine) is required. Example findings include: middle ear disease or indications for acoustic neuroma.

Where agreement has been reached with local medical staff, audiologists may undertake extended roles that substitute for parts of the medical opinion referred to above. They must always operate within defined local protocols. Examples include: audiologists removing ear wax; undertaking vestibular function and tinnitus assessments followed by delivery and review of appropriate rehabilitation programmes; assessment and consideration of audiological suitability for bone anchored hearing aids and cochlear

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<sup>2</sup> Vertigo is classically described hallucination of movement, but here includes dizziness, swaying or floating sensations (frequently associated with unsteadiness) that may indicate otological, neurological or medical conditions.

implants; referring directly for MRI scanning in the case of an asymmetrical sensorineural hearing loss.

**References:**

Criteria for direct referral: Guidelines of the Liaison Group of Technicians, Therapists and Scientists in Audiology (TTSA), BAAS Newsletter 1989

HAC Code of Practice, Examinations and Registration – September 2004 Edition

British Academy of Audiology: 14<sup>th</sup> September 2009

**Appendix 1 – BAA Guidelines for Referral to Audiology of Adults with Hearing Difficulty  
Direct Referral Checklist (2009)**

<b>History</b>	
Persistent pain affecting either ear (defined as earache lasting more than 7 days in the past 90 days before appointment)	Yes / No
History of discharge other than wax from either ear within the last 90 days	Yes / No
Sudden loss or sudden deterioration of hearing (sudden=within 1 week, in which case send to A&E or Urgent Care ENT clinic)	Yes / No
Rapid loss or rapid deterioration of hearing (rapid=90 days or less)	Yes / No
Fluctuating hearing loss, other than associated with colds	Yes / No
Unilateral or asymmetrical, or pulsatile or distressing tinnitus lasting more than 5 minutes at a time	Yes / No
Troublesome, tinnitus which may lead to sleep disturbance or be associated with symptoms of anxiety or depression	Yes / No
Abnormal auditory perceptions (dysacusis)	Yes / No
Vertigo including dizziness, swaying or floating sensations	Yes / No
Normal peripheral hearing but with abnormal difficulty hearing in noisy backgrounds; possibly having problems with sound localization, or difficulty following complex auditory directions.	Yes / No
<b>Ear examination</b>	
Complete or partial obstruction of the external auditory canal preventing proper examination of the eardrum and/or proper taking of an aural impression.	Yes / No
Abnormal appearance of the outer ear and/or the eardrum (e.g., inflammation of the external auditory canal, perforated eardrum; active discharge).	Yes / No
<b>Audiometry</b>	
Conductive hearing loss, defined as 25 dB or greater air-bone gap present at two or more of the following frequencies: 500, 1000, 2000 or 4000 Hz.	Yes / No
Unilateral or asymmetrical sensorineural hearing loss, defined as a difference between the left and right bone conduction thresholds of 20 dB or greater at two or more of the following frequencies: 500, 1000, 2000 or 4000 Hz.	Yes / No
Evidence of deterioration of hearing by comparison with an audiogram taken in the last 24 months, defined as a deterioration of 15 dB or more in air conduction threshold readings at two or more of the following frequencies: 500, 1000, 2000 or 4000 Hz.	Yes / No
<b>Other</b>	
Any other unusual presenting features at the discretion of the audiologist.	Yes / No
... please give details	

\*\*\* If any of the answers above is Yes, seek medical opinion \*\*\*



# MOTIVATION TOOLS THE LINE, BOX AND CIRCLE





## LET THE PATIENT DO THE WORK

Do you often feel that you waste energy persuading your hearing loss patients to change their behavior, only to achieve a questionable result? And somehow the responsibility for change inevitably becomes yours? If yes, the Ida Institute has three tools that may be helpful to you.

The “Line,” the “Box” and the “Circle” models have been used successfully by health care professionals in other therapeutic areas to coach patients into taking responsibility for their actions and making appropriate behavioral changes.

### **BACKGROUND**

The “Circle” describes the different stages and processes a patient experiences when changing behavior. It is used for tracking present and future motivational levels of the patient with regard to the behavior change. As all patients undergo similar change processes and experience ambivalence, this model provides guidance for health care professionals on ways to support the changing process in the most efficient way.<sup>1</sup>

The WHO Collaborating Centre has translated the “Circle” into clinical practice and combined it with the “Line” and the “Box.” The “Line” and the “Box” are tools that help to clarify where the patient envisions himself in the process of change and to shed light on his ambivalence.<sup>2</sup>

Since 1990, the Danish health care system has implemented these tools with surgical and chronic disease patients who required lifestyle modifications before and after medical procedures.

### **IDA'S POINT OF VIEW**

We believe that the “Line,” the “Box” and the “Circle” can be useful in the field of hearing health care to support and engage the patient and to understand and coach the patient. We have thus adapted the tools to make them workable within audiology.

When using these tools it is very important that you listen carefully to your patients and observe their reactions. This shows respect and empathy for the patient and creates a foundation for a balanced dialogue in which the patient feels accommodated and understood.

On the following pages you will find a short description of how to use the three tools.

<sup>1</sup> Rollnick, S., Mason, P. & Butler, C. (1999). *Health behavior change: A guide to practitioners*; London, Churchill Livingstone.

Miller, W. & Rollnick, S. (2002). *Motivational interviewing: Preparing people for change*, 2.ed.; New York, Guilford Press.

Prochaska, J.O., Norcross, J.C. & DiClemente, C.C. (1994). *Changing for good: A revolutionary six-stage program for overcoming bad habits and moving your life positively forward*; New York, Avon Books.

<sup>2</sup> Jørgensen, S.V., Hansen, H.V., Hessov, I.B., Lauritsen, J.B., Madelung, S. & Tønnesen, H., (2003). *Operation - Complications are preventable*; Copenhagen, International Health Promoting Hospitals & Health Services, Bispebjerg Hospital.

## THE LINE

1/2

**1**

How important is it for you to improve your hearing right now?



**2**

How much do you believe in your ability to use...\*



The lines go from: 0 = not at all to 10 = very much.

Jørgensen, S.V., Hansen, H.V., Hesso, I.B., Lauritsen, J.B., Madelung, S. & Tønnesen, H. (2003). *Operation - Complications are preventable*; Copenhagen, International Health Promoting Hospitals & Health Services, Bispebjerg Hospital.

- As the audiologist, you need to fill in the solution you suggest; e.g., hearing aids, assistive listening devices or communication strategies.

The “Line” is helpful to open a dialogue with reluctant patients and to help explore whether the patient is ready to embrace the use of recommended treatment. It consists of asking two separate questions to identify whether there is ambivalence between the importance of improving hearing and the patient’s personal commitment to making the necessary changes. The next step is to ask the patient to mark his own position along a line from 0 to 10. You can use this tool in one of the first sessions with the patient – or as often as needed.

The first question identifies the goal: How important is it for the patient to improve his hearing right now?

The second question identifies the process: How high the patient ranks his own commitment to a specific solution? If the patient gives a high ranking on both questions, he will have a high motivation to improve his hearing.

Based on the two questions above, you continue the session by elaborating on the patient’s response, empowering the patient to phrase the reasons for the change of behavior. You may find it useful to focus on the following:

If the score is low on the first question, “How important is it for you to improve your hearing right now?” the patient does not appear to take an interest in hearing. However, lifestyle questions may yet reveal that there are situations in which the patient does wish to hear. If the score is high, also try to elaborate, e.g., regarding the wish to participate in social networks or to perform a job. If the patient scores about 7, you ask “Why a 7?” in order to make the patient reflect on his own explanation and articulate his underlying thoughts.

## THE LINE

2/2

The second question, “How much do you believe in your ability to use e.g. hearing aids, assistive listening devices or communication strategies?” refers to the process of change that will lead to better communication. No matter what the score is, elaborate on the objections the patient may have regarding acting on his hearing loss. The inhibitions could concern change in lifestyle, such as emotions connected with the perception of being less attractive, lack of faith in technological devices or lack of perseverance when it comes to making things work. Try to discuss these matters with the patient and acknowledge his apprehension. At the same time, reassure him that the problems can be solved to some degree and that issues are often resolved once the patient starts to act on the hearing loss. At all costs, avoid telling the patient that his concerns are unfounded; they are real to the patient at that time.

## THE BOX 1/2

<b>1</b> BENEFITS OF NO ACTION	<b>2</b> COSTS OF NO ACTION
<b>3</b> THE POTENTIAL COSTS OF TAKING ACTION	<b>4</b> THE POTENTIAL BENEFITS OF TAKING ACTION

Jørgensen, S.V., Hansen, H.V., Hesso, I.B., Lauritsen, J.B., Madelung, S. & Tønnesen, H. (2003). *Operation - Complications are preventable*; Copenhagen, International Health Promoting Hospitals & Health Services, Bispebjerg Hospital.

The “Box” is used in combination with the “Line” primarily for two reasons: To make the patient aware of his own positive and negative thoughts about hearing loss and to give you a picture of how motivated the patient is. At the same time, pros and cons of continuing the status quo or changing the behavior become apparent to the patient.

It is important that the patient fills out the “Box” himself. Afterward, you can assist the patient by asking follow-up questions and encouraging him to elaborate.

On the following page you can see an example of how to elaborate on the response you may get from the patient.

THE BOX  
2/2

**1** BENEFITS OF NO ACTION

**No need to hear anymore than I do now!**

*Are there any situations you avoid because of your hearing difficulties?*

*Have you considered that your communication partners may be unhappy or dissatisfied because you miss out on things?*

**I do not have a hearing problem!**

*You never find that people mumble?*

*Have you experienced any situations in which it is difficult to hear?*

**2** COSTS OF NO ACTION

**I can't really think of any**

*You never feel exhausted when you are in group contexts?*

*Would your communication partners agree to that?*

**I will feel excluded from social contexts**

*In which situations do you feel excluded?*

**I might lose my job!**

*Is it only in job situations that you have hearing problems?*

**3** THE POTENTIAL COSTS OF TAKING ACTION

**Hearing aids whistle!**

*Have you experienced that?*

**Other people might not like me because hearing aids are unattractive!**

*What do you think when you see other hearing aid users?*

*Have you considered that the relationship to other people might suffer if you can't hear them or you misunderstand them?*

**4** THE POTENTIAL BENEFITS OF TAKING ACTION

**I can participate more**

**It will be less tiring for me if I don't have to pretend that I know what people are talking about**

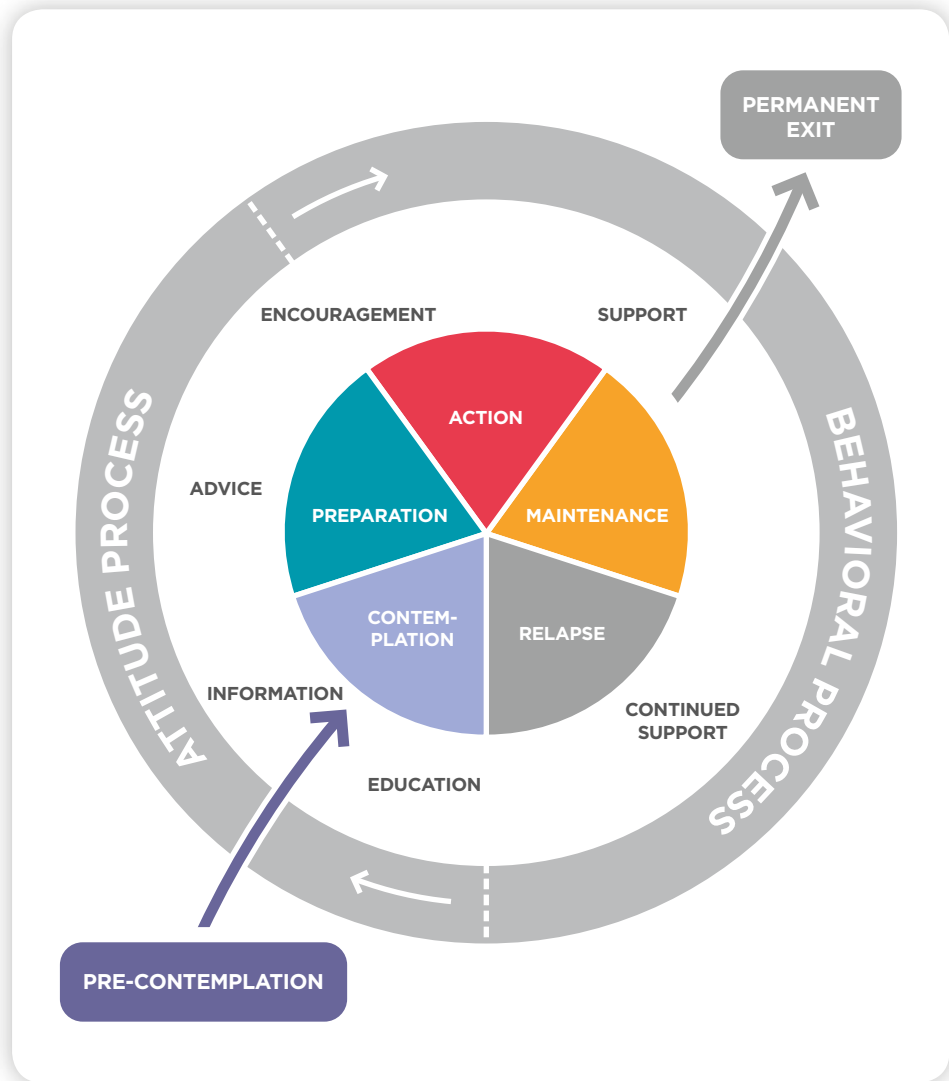
**It will help me keep my job**

**There will be less conflicts in the family**

*Acknowledge the response and ask if there are any other benefits – get as many benefits as possible on the list to keep the motivation*

Jørgensen, S.V., Hansen, H.V., Hessov, I.B., Lauritsen, J.B., Madelung, S. & Tønnesen, H. (2003). *Operation – Complications are preventable*; Copenhagen, International Health Promoting Hospitals & Health Services, Bispebjerg Hospital.

THE CIRCLE  
1/2



Jørgensen, S.V., Hansen, H.V., Hessev, I.B., Lauritsen, J.B., Madelung, S. & Tønnesen, H. (2003). *Operation - Complications are preventable*; Copenhagen, International Health Promoting Hospitals & Health Services, Bispebjerg Hospital.

The “Circle” shows the seven different stages a patient undergoes when changing behavior: Pre-contemplation, Contemplation, Preparation, Action, Maintenance, Relapse and Permanent Exit.

Different stages reflect changes in the patient’s behavior. The professional support to the patient also differs according to the patient’s specific stage. Below you will find a short description of possible patient behavior and how you can assist the patient in the process of behavioral change.

## THE CIRCLE

2/2

The first step is to determine where the patient is on the wheel of change. To identify this, we propose that you start by asking the patient the following question:<sup>1</sup> Which best describes your thinking about getting hearing aids?

Give the patient these five possible answers, which correspond to the stages of change:

1. I am not ready for hearing aids at this time. (Pre-contemplation)
2. I have been thinking that I might need hearing aids. (Contemplation)
3. I have started to seek information about hearing aids. (Preparation)
4. I am ready to get hearing aids if they are recommended. (Action)
5. I am comfortable with the idea of wearing hearing aids. (Maintenance)

We suggest that you use this question as a starting point for the dialogue; let the patient tell the story.

It is very important to remember that it is perfectly normal for a patient to move around the circle more than once before the new behavior is well established and integrated. This may take several months.

The stages in the circle interrelate with the phases of the Patient Journey, another Ida tool that you can find on our website, [www.idainstitute.com](http://www.idainstitute.com).

<sup>1</sup> Babeu, L., Kricos, P., Lesner, S. (2004). Applications of the Stages-of Change Model in audiology. *Journal of Academy of Rehabilitative Audiology*, 37.

## **PRE-CONTEMPLATION**

The patient:

- does not realize that he has a hearing problem or has realized a hearing problem but does not think it is of sufficient magnitude to seek help
- becomes surprised when the problem is brought up by those around him (Note: Do not mistake denial for lack of realizing that something is wrong.)
- does not recognize any of the symptoms you describe

### **How to assist the patient at this stage?**

Listen to the patient and provide clear, short and exact information.

## **CONTEMPLATION**

The patient:

- is ambivalent about making change (Note: Do not mistake this for lack of interest.)
- feels comfortable in the present situation, on one hand, but is afraid of the consequences of continuing without using e.g. hearing aids, on the other hand

### **How to assist the patient at this stage?**

Listen to the patient and explore his experiences with hearing and communication. Give brief advice regarding possible options for improving hearing and communication. Support and acknowledge the patient's increasing awareness of ambivalence.

## **PREPARATION**

The patient:

- continues to express ambivalence
- has reached a "tipping point" and decides to act on the hearing loss but is not sure exactly how to proceed
- seeks information to support the decision
- looks for support from the audiologist and others, but also considers the option of "going it alone"
- shows motivation and is ready to take action

### **How to assist the patient at this stage?**

Support the patient in planning the use of new strategies. Listen. Give advice and ideas about what it takes to improve communication with others. Do not present "the one and only" solution. Focus on the benefits of better hearing.



## **ACTION**

The patient:

- is relieved and proud about the decision to act on the hearing problem
- worries about not being able to follow through
- has a need to talk about the hearing difficulty with other people
- seeks acknowledgement and appreciation

### **How to assist the patient at this stage?**

Listen to the patient. Focus on the personal benefits of improved hearing and communication. Encourage and support the patient.

## **MAINTENANCE**

The patient:

- has now become a hearing aid user and/or is using effective communication strategies
- is still ambivalent
- is pleased to have taken the step to become a hearing aid user but also finds it hard to accept the implications of hearing loss
- sees hearing aids as a necessary evil
- feels sad from time to time and forgets why he wanted to change behavior
- feels either successful (leads to “Permanent Exit”) or may want to give up (leads to “Relapse”)

### **How to assist the patient at this stage?**

Support and encourage the patient in sustaining the change of behavior, repeatedly.

## **RELAPSE**

The patient:

- does not want to wear the hearing aid and struggles, gives up
- feels like a failure and becomes annoyed and angry
- feels he has a weak character
- relaxes and enjoys the freedom
- is motivated to try again

### **How to assist the patient at this stage?**

Try to focus on the advantages of better hearing and communication. Focus on the manageable steps that enabled the patient to implement new strategies previously. Put focus on positive experiences even if they were of short duration. Try to make the patient agree on a new habituation scheme. And then, once again, support as much as possible.

## **PERMANENT EXIT**

The patient:

- feels comfortable with the hearing aid and knows how to handle the hearing problem

### **How to assist the patient at this stage?**

Provide the possibility to return for support.



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## **PATIENT INFORMATION**

### **A study to determine the value of using the Operational Model of behaviour change on aural rehabilitation outcomes**

My name is Aarti Makan. I am a Senior Audiologist and have been employed at the Royal Free Hospital Audiology Department since 2003. I would like to invite you to participate in a research study that I am completing to obtain my Masters Degree in Audiology.

Before you decide I would like you to understand why the research is being done and what it would involve for you. I will go through the information sheet with you and answer any questions you have. I suggest this should take about 10 minutes. Talk to others about the study if you wish.

Part 1 tells you the purpose of this study and what will happen to you if you take part. Part 2 gives you more detailed information about the conduct of the study. Please ask me if there is anything that is not clear.

### **Part 1 of the Information Sheet**

#### **What is the purpose of the study?**

It is well known that of the patients who are issued with hearing aids, only up to 40% of patients actually use their hearing aids regularly. A lot of research has been done to determine the reasons for this, and there have been a number of factors highlighted. One main factor that this study will focus on is 'patient motivation'.

I would like to compare the effect of using an alternative therapy during an appointment process, to our current standard practice and determine if there is a link between motivation and eventual use of hearing aids.

#### **Why have I been invited?**

Patients who are referred by their GP, to the Royal Free Hospital Audiology Department for hearing assessment, are being invited to participate in this study. Patients who speak English and who have never worn hearing aids before are being selected from those who are referred by their GP for hearing assessment. There will be about 68 patients who will be invited to participate.

#### **Do I have to take part?**

Participation entirely voluntary. It is up to you to decide to join the study. We will describe the study and go through this information sheet. If you agree to take part, we will then ask you to sign a consent form. You are free to withdraw at any time, without giving a reason. This would not affect the standard of care you receive.

#### **Expenses and payments?**

As this study will form part of the usual therapy process of the department, there will not be any compensation for participating.

### What is a randomised control trial (RCT)

A randomised controlled trial (RCT) is described as the best research method to test new methods of therapy. Sometimes we don't know which way of treating patients is best. To find out, we need to compare different therapies. We put people into groups and give each group a different therapy. The results are compared to see if one is better. To try to make sure the groups are the same to start with, each patient is put into a group by chance (randomly). A computer programme will randomly select which group you will be placed in.

### What will happen to me if I take part?

If you decide to take part, you will be asked to sign a consent form before the hearing assessment. You will be given a copy of this information sheet with a copy of the consent form to keep for your records.

If you agree to take part, you will be placed at random into one of two groups

1. Receive the current therapy process
2. Receive the alternative therapy process in addition to current process.

### Duration of this study and number of visits

This entire project will last approximately 6 months. However, you will be in this study for approximately 2 - 3 months during which you will have 3 visits to the department, which is the standard care.

	APPOINTMENT	DURATION	DESCRIPTION
1st visit	Hearing assessment	1 hour	We will ask you a few questions about your hearing and medical history and then conduct a hearing test. If results indicate that you require hearing aids and you agree to have these then you will be asked to complete a questionnaire and you will attend the department for the 2nd visit about 2-3 weeks later.
2nd visit	Hearing aid Fitting	1 hour	At this appointment we will prescribe the hearing aids to you and show you how to use them. You will then be booked in for your 3rd visit 2 months later.
3rd visit	Hearing aid follow up	1/2 hour	This appointment is to see how you are getting on with your hearing aids. You will be asked to complete a questionnaire at the end of this appointment.

### What happens when the research stops?

After your 3rd visit, your participation the study will be completed, however as per standard care, you will be able to attend the department for future appointments if required.

**What are the possible disadvantages and risks of taking part?**

You should be aware that both groups will receive the current standard practice of therapy; only group two will receive the additional alternative therapy. This means that you will not be disadvantaged in any way by being placed in either group.

The current standard of practice will not change either so this means that you will have the same number of appointments and sessions if you decide to take part in this study or not.

**What are the possible benefits of taking part?**

We cannot promise the study will help you but the information we get from this study may help improve the treatment of people with hearing loss.

**What if there is a problem?**

Any complaint about the way you have been dealt with during the study will be addressed. The detailed information on this is given in Part 2.

**Will my participation be kept confidential?**

All information about you will be kept strictly confidential.

**Part 2 of the Information Sheet**

*If the information in Part 1 has interested you and you are considering participation, please read the additional information in Part 2 before making any decision.*

**What if relevant new information becomes available?**

If the study is stopped for any other reason, we will tell you and arrange your continuing care.

**What will happen if I don't want to carry on with the study?**

At any time during the study you are free to stop or withdraw from the study without permission and without giving a reason. If you decide to stop once the study has started, it will not affect the standard of your care in any way. If you decide to leave the study, the information about you that was collected before you left the study will still be used, unless you state otherwise. No new information will be collected without your permission.

**What if there is a problem?**

This study does not involve any invasive procedures. However, if you have a concern about any aspect of this study, you should ask to speak to the researcher who will do their best to answer your questions [Tel: 0207 472 6318 or email: aarti.makan@nhs.net].

If you remain unhappy and wish to complain formally, you can do this via the Royal Free Hospital Patient Advice and Liaison Service (PALS) Office. [Telephone: 020 7472 6446 / 6447].

**Will my participation be kept confidential?**

All information that is collected about you during the course of the research will be kept strictly confidential. Any information about you, which leaves the hospital, will

have your name and address removed so that you cannot be recognized. A code number will be used to identify data about you, and I will keep the list that links codes to people's identity locked separately from the data. We will keep it for 1 year and then it will be destroyed. All data use is strictly within the terms of the Data Protection Act (DPA 1998).

Data collected during the study may be sent to associated researchers to countries where the laws don't protect your privacy to the same extent as the law in the UK but the hospital will take all reasonable steps to protect your privacy.

Information that is relevant for continuity of care within the department (hearing test results, therapy plan and consultation notes) will be stored on our patient management system as part of your hospital records. Audiologists within the department are the only people who can access this system.

Any information about you that is sent out of the hospital will have a code and will not show your name or address, or any information that directly identifies you.

### **Involvement of your General Practitioner / Family Doctor**

Since you have been referred by your GP, it is current practice that your GP will be informed of the results of your hearing assessment (hearing test) and planned therapy. I will not divulge any other information to the GP other than what is standard practice.

### **What will happen to the results of the research?**

The results of this research will be reported in the form of a thesis for my Masters Degree in Audiology. I would also like to publish the results in audiology scientific journals. If you would like a summary of the findings you can tick a box on the consent form and I will send it to you when the study is complete.

### **Who is organizing and funding the research?**

This research is being organized by the Royal Free Hospital. There is no funding allocated to this study as the entire project falls within the normal standard care or process of patients who attend the Audiology Department.

### **Who has reviewed the study?**

This study was subject to review and approval by the Royal Free Hospital Research and Development Department as well as by the South African Post Graduate Ethics Committee of the University of Pretoria, South Africa.

### **Conflict of Interest**

The study design, protocol, and procedures have been developed by me, the investigator. My interests should not influence your decision to participate in this study and you should not feel pressured to join this study.

### **Further information and contact details**

If you have any further questions or require any further information:

*1. General information about research:*

Royal Free Hospital Research and Development Department  
Tel: 020 3447 2178

2. *Specific Information about this research:*  
Aarti Makan (the investigator)  
Tel: 020 7472 6318 or  
Email: [aarti.makan@nhs.net](mailto:aarti.makan@nhs.net)
  
3. *Advice as to whether you should participate:*  
Any member of the audiology team can be contacted  
Tel: 020 7472 6318  
Email: [rfh.audiology@nhs.net](mailto:rfh.audiology@nhs.net)
  
4. *Who to contact if you are unhappy with the study:*  
Patient Advice and Liaison Service (PALS) Office.  
Tel: 020 7472 6446 / 644

**Thank you for taking time to read this information sheet**

**CONSENT FORM**

**A study to determine the value of using the Operational Model of behaviour change on aural rehabilitation outcomes**

**Patient Identifier:** \_\_\_\_\_

**Name of researcher:** Miss Aarti Makan

1. I confirm that I have read and understood the information sheet dated 05/02/13 (version 3) for the above study. I have had the opportunity to ask questions and have them answered satisfactorily.
2. I understand that my participation is voluntary and that I am free to free to stop or withdraw from the study without permission and without giving a reason. I understand that this does decision will not affect any future services offered to me by the department.
3. I will need to inform the investigator if I do not want my information collected up to the point of stopping to be used in the study
4. I understand that I will be randomly placed in one of two groups. I have been informed that I will not be disadvantaged in any way by being placed in either group.
5. I understand that all my information will be kept confidential and only information that relates to my future care within the department will be accessed by audiologists working in the department.
6. I understand that I will not benefit financially if this study leads to the development of a new therapy process.
7. I understand that I should not be pressurised into taking part in this study
8. I know who to contact in the research team if I need to.
9. I agree to take part in the above named study.
10. **TICK ONLY IF YES**  
When completed, I would like a summary of the results of this study posted to me.

\_\_\_\_\_  
Print your name

\_\_\_\_\_  
Signature

\_\_\_\_\_  
Date

\_\_\_\_\_  
Name of person taking consent

\_\_\_\_\_  
Signature

\_\_\_\_\_  
Date



# AUDIOLOGY

## DIRECT REFERRAL QUESTIONNAIRE

### HEARING

1. Have you noticed a **change** in your hearing? Was this a **sudden / gradual**? (*1 week sudden A&E/ENT urgent care, less than 90 days refer*)
2. Have you noticed any **fluctuation** in your hearing (*excl colds*)?
3. Do you find it difficult to hear in **background noise**?
4. Do you have problems **localising sounds**? Or determining where/which direction sounds come from?
5. Do you feel you are **sensitive to loud sounds**? / Are you able to tolerate loud sounds? (**dysacusis**) (**hyperacusis**)? / Or do you think normal sounds are more alarming/ disturbing to you compared to others?
6. Do you have any noises in your ear (**tinnitus**)? (buzzing/ ringing/ hissing)?
  - a. One/both ears?
  - b. Length of time (more than 5min)?
  - c. Describe type (pulsatile refer imp)?
  - d. Does this affect your sleep?*(unilateral/pulsatile tinnitus/ associated HL – refer to ENT)*
7. Do you have a family **history** of hearing loss? (*Congenital HL is NB*)
8. Have you ever been exposed to **loud noises/sounds**? (*Factory work, clubbing, MP3s, DJ's, veterans, musicians, music bands managers, etc.*)
  - a. If yes, have you ever worn ear protection?

### OTOLOGICAL HISTORY

1. Have you had any **ear surgery** in either of your ears?
2. Have you had any **persistent pain** in either ear?  
*(more than 7 days in past 3months prior to appointment)*
3. Have you had any **infections / discharge** (excl wax) within last 3 months?
4. Have you ever taken any drugs that you have been informed may have affected your hearing (**ototoxic medications**)?
5. Have you had any episodes of **vertigo**? (Dizziness or feeling of spinning/ rotating/ swaying)  
*(General balance problems that cause falls and have not been assessed can be referred to falls clinic).*

## MEDICAL HISTORY

1. Do you have any **medical conditions**?

*(Hospitalisations/ operations/things that could affect hearing and/or HA rehab e.g. Strokes, Alzheimer's, Dementia, Speech disorders, Pacemakers, Diabetes, Renal, Fabry's etc)*

- a. **Kidney / renal failure**
- b. **Diabetes type II**
- c. **Stroke**
- d. **Head trauma**
- e. **Heart Conditions**
- f. **Dementia**
- g. **Alzheimer's Disease**
- h. **Parkinson's Disease**

## OTOTOXIC MEDICATIONS

1. Have you had any medication known to affect your hearing?
2. Have you had any **chemotherapy or radiotherapy**?
3. Have you had any **intravenous antibiotics**?
4. What **medication** are you taking at present?

## SOCIAL COMMUNICATION NEEDS

1. How is your **dexterity** (are you able to do up your buttons, tie shoelaces easily)
2. How is your **eyesight** (macular degeneration is a progressive disorder of the eyes where patients can become blind)
3. I am going to ask a few questions about your **social life**:
  - a. Do you live by yourself?
  - b. If by yourself any family / carer support?
  - c. Are you working / what work do you do?
  - d. What are your hobbies? (Specifically those for hearing – theatre, music etc)
4. I am going to ask a few questions about your **hearing at home**:
  - a. Are you able to easily hear your doorbell / smoke alarm?
  - b. Are you able to easily hear your alarm clock?
  - c. Are you able to easily hear your home telephone?
  - d. Are you able to easily hear your TV at a normal volume?

## PREVIOUS / CURRENT HEARING AIDS

1. Have you ever worn hearing aids
2. Were they from Private Sector or NHS (which NHS department did you get them from)?
3. How often do you wear them?
  - a. If not all the time which situations do you wear them in most
4. Do you use both hearing aids?
  - a. If one, which one do you wear the most
5. Do you find the hearing aids beneficial?
  - a. If not, what are the limitations

# HEARING HANDICAP INVENTORY FOR ELDERLY (HHIE-S)

PATIENT IDENTIFIER: \_\_\_\_\_ DATE: \_\_\_\_\_

**INSTRUCTIONS:** The purpose of this scale is to identify the problems your hearing loss may be causing you.

Please select NO, SOMETIMES, or YES for each question. Do not skip a question if you avoid a situation because of your hearing problem. If you wear hearing instruments, please answer the way you hear without hearing instruments.

Question	No	Sometimes	Yes
Does a hearing problem cause you to feel embarrassed when you meet new people?			
Does a hearing problem cause you to feel frustrated when talking to a member of your family?			
Do you have difficulty hearing when someone speaks in a whisper?			
Do you feel handicapped by a hearing problem?			
Does a hearing problem cause you difficulty when visiting friends, relatives, or neighbors?			
Does a hearing problem cause you to attend religious services less often than you would like?			
Does a hearing problem cause you to have arguments with family members?			
Does a hearing problem cause you difficulty when listening to television or radio?			
Do you feel that any difficulty with your hearing limits/hampers your personal or social life?			
Does a hearing problem cause you difficulty when in a restaurant with relatives or friends			
TOTAL	_____ x0 =	_____ x 2 =	_____ x 4 =
TOTAL SCORE			

TOTAL SCORE	IMPAIRMENT
0-8	No Handicap
10-24	Mild-Moderate Handicap
25-40	Severe Handicap

Adapted from:

Ventry, I. and Weinstein, B. E., 1982. The Hearing Handicap Inventory for the Elderly: A new tool. *Ear Hear.* 3, 128-134

# HEARING HANDICAP INVENTORY FOR ADULTS (HHIA-S)

PATIENT IDENTIFIER: \_\_\_\_\_ DATE: \_\_\_\_\_

**INSTRUCTIONS:** The purpose of this scale is to identify the problems your hearing loss may be causing you.

Please select NO, SOMETIMES, or YES for each question. Do not skip a question if you avoid a situation because of your hearing problem. If you wear hearing instruments, please answer the way you hear without hearing instruments.

Question	No	Sometimes	Yes
Does a hearing problem cause you to feel embarrassed when you meet new people?			
Does a hearing problem cause you to feel frustrated when talking to a member of your family?			
Does a hearing problem cause you difficulty hearing/understanding coworkers, clients, or customers?			
Do you feel handicapped by a hearing problem?			
Does a hearing problem cause you difficulty when visiting friends, relatives, or neighbours?			
Does a hearing problem cause you difficulty in the movies or theaters?			
Does a hearing problem cause you to have arguments with family members?			
Does a hearing problem cause you difficulty when listening to television or radio?			
Do you feel that any difficulty with your hearing limits/hampers your personal or social life?			
Does a hearing problem cause you difficulty when in a meeting or conference?			
TOTAL	_____ x0 =	_____ x 2 =	_____ x 4 =
TOTAL SCORE			

TOTAL SCORE	IMPAIRMENT
0-8	No Handicap
10-24	Mild-Moderate Handicap
25-40	Severe Handicap

Adapted from:

Newman, C.W., Weinstein, B.E., Jacobson, G.P., Hug, G.A., 1990. The Hearing Handicap Inventory for Adults: psychometric adequacy and audiometric correlates. *Ear Hear*, 11(6), pp. 430-3

**GLASGOW HEARING AID BENEFIT PROFILE**

Date of Assessment .....

Name .....

Address .....

Date of Review .....

Does this situation happen in your life? 0 ___ No      1 ___ Yes					
<b>LISTENING TO THE TELEVISION WITH OTHER FAMILY OR FRIENDS            WHEN THE VOLUME IS ADJUSTED TO SUIT OTHER PEOPLE</b>					
How much difficulty do you have in this situation?	How much does any difficulty in this situation worry, annoy or upset you?	In this situation, what proportion of the time do you wear your hearing aid?	In this situation, how much does your hearing aid help you?	In this situation, with your hearing aid, how much difficulty do you now have?	For this situation, how satisfied are you with your hearing aid?
0 ___ N/A 1 ___ No difficulty 2 ___ Only slight difficulty 3 ___ Moderate difficulty 4 ___ Great difficulty 5 ___ Cannot manage at all	0 ___ N/A 1 ___ Not at all 2 ___ Only a little 3 ___ A moderate amount 4 ___ Quite a lot 5 ___ Very much indeed	0 ___ N/A 1 ___ Never/Not at all 2 ___ About ¼ of the time 3 ___ About ½ of the time 4 ___ About ¾ of the time 5 ___ All the time	0 ___ N/A 1 ___ Hearing aid no use at all 2 ___ Hearing aid is some help 3 ___ Hearing aid is quite helpful 4 ___ Hearing aid is a great help 5 ___ Hearing is perfect with aid	0 ___ N/A 1 ___ No difficulty 2 ___ Only slight difficulty 3 ___ Moderate difficulty 4 ___ Great difficulty 5 ___ Cannot manage at all	0 ___ N/A 1 ___ Not satisfied at all 2 ___ A little satisfied 3 ___ Reasonably satisfied 4 ___ Very satisfied 5 ___ Delighted with aid
Does this situation happen in your life? 0 ___ No      1 ___ Yes					
<b>HAVING A CONVERSATION WITH ONE OTHER PERSON WHEN            THERE IS NO BACKGROUND NOISE</b>					
How much difficulty do you have in this situation?	How much does any difficulty in this situation worry, annoy or upset you?	In this situation, what proportion of the time do you wear your hearing aid?	In this situation, how much does your hearing aid help you?	In this situation, with your hearing aid, how much difficulty do you now have?	For this situation, how satisfied are you with your hearing aid?
0 ___ N/A 1 ___ No difficulty 2 ___ Only slight difficulty 3 ___ Moderate difficulty 4 ___ Great difficulty 5 ___ Cannot manage at all	0 ___ N/A 1 ___ Not at all 2 ___ Only a little 3 ___ A moderate amount 4 ___ Quite a lot 5 ___ Very much indeed	0 ___ N/A 1 ___ Never/Not at all 2 ___ About ¼ of the time 3 ___ About ½ of the time 4 ___ About ¾ of the time 5 ___ All the time	0 ___ N/A 1 ___ Hearing aid no use at all 2 ___ Hearing aid is some help 3 ___ Hearing aid is quite helpful 4 ___ Hearing aid is a great help 5 ___ Hearing is perfect with aid	0 ___ N/A 1 ___ No difficulty 2 ___ Only slight difficulty 3 ___ Moderate difficulty 4 ___ Great difficulty 5 ___ Cannot manage at all	0 ___ N/A 1 ___ Not satisfied at all 2 ___ A little satisfied 3 ___ Reasonably satisfied 4 ___ Very satisfied 5 ___ Delighted with aid
Does this situation happen in your life? 0 ___ No      1 ___ Yes					
<b>CARRYING ON A CONVERSATION IN A BUSY STREET OR SHOP</b>					
How much difficulty do you have in this situation?	How much does any difficulty in this situation worry, annoy or upset you?	In this situation, what proportion of the time do you wear your hearing aid?	In this situation, how much does your hearing aid help you?	In this situation, with your hearing aid, how much difficulty do you now have?	For this situation, how satisfied are you with your hearing aid?
0 ___ N/A 1 ___ No difficulty 2 ___ Only slight difficulty 3 ___ Moderate difficulty 4 ___ Great difficulty 5 ___ Cannot manage at all	0 ___ N/A 1 ___ Not at all 2 ___ Only a little 3 ___ A moderate amount 4 ___ Quite a lot 5 ___ Very much indeed	0 ___ N/A 1 ___ Never/Not at all 2 ___ About ¼ of the time 3 ___ About ½ of the time 4 ___ About ¾ of the time 5 ___ All the time	0 ___ N/A 1 ___ Hearing aid no use at all 2 ___ Hearing aid is some help 3 ___ Hearing aid is quite helpful 4 ___ Hearing aid is a great help 5 ___ Hearing is perfect with aid	0 ___ N/A 1 ___ No difficulty 2 ___ Only slight difficulty 3 ___ Moderate difficulty 4 ___ Great difficulty 5 ___ Cannot manage at all	0 ___ N/A 1 ___ Not satisfied at all 2 ___ A little satisfied 3 ___ Reasonably satisfied 4 ___ Very satisfied 5 ___ Delighted with aid
Does this situation happen in your life? 0 ___ No      1 ___ Yes					
<b>HAVING A CONVERSATION WITH SEVERAL PEOPLE IN A GROUP</b>					
How much difficulty do you have in this situation?	How much does any difficulty in this situation worry, annoy or upset you?	In this situation, what proportion of the time do you wear your hearing aid?	In this situation, how much does your hearing aid help you?	In this situation, with your hearing aid, how much difficulty do you now have?	For this situation, how satisfied are you with your hearing aid?
0 ___ N/A 1 ___ No difficulty 2 ___ Only slight difficulty 3 ___ Moderate difficulty 4 ___ Great difficulty 5 ___ Cannot manage at all	0 ___ N/A 1 ___ Not at all 2 ___ Only a little 3 ___ A moderate amount 4 ___ Quite a lot 5 ___ Very much indeed	0 ___ N/A 1 ___ Never/Not at all 2 ___ About ¼ of the time 3 ___ About ½ of the time 4 ___ About ¾ of the time 5 ___ All the time	0 ___ N/A 1 ___ Hearing aid no use at all 2 ___ Hearing aid is some help 3 ___ Hearing aid is quite helpful 4 ___ Hearing aid is a great help 5 ___ Hearing is perfect with aid	0 ___ N/A 1 ___ No difficulty 2 ___ Only slight difficulty 3 ___ Moderate difficulty 4 ___ Great difficulty 5 ___ Cannot manage at all	0 ___ N/A 1 ___ Not satisfied at all 2 ___ A little satisfied 3 ___ Reasonably satisfied 4 ___ Very satisfied 5 ___ Delighted with aid

We have dealt with some of the situations which in our experience can lead to difficulty with hearing. What we would now like you to do is to nominate up to four new situations in which it is important for you as an individual to be able to hear as well as possible.

How much difficulty do you have in this situation?	How much does any difficulty in this situation worry, annoy or upset you?	In this situation, what proportion of the time do you wear your hearing aid?	In this situation, how much does your hearing aid help you?	In this situation, with your hearing aid, how much difficulty do you now have?	For this situation, how satisfied are you with your hearing aid?
0 ___ N/A 1 ___ No difficulty 2 ___ Only slight difficulty 3 ___ Moderate difficulty 4 ___ Great difficulty 5 ___ Cannot manage at all	0 ___ N/A 1 ___ Not at all 2 ___ Only a little 3 ___ A moderate amount 4 ___ Quite a lot 5 ___ Very much indeed	0 ___ N/A 1 ___ Never/Not at all 2 ___ About ¼ of the time 3 ___ About ½ of the time 4 ___ About ¾ of the time 5 ___ All the time	0 ___ N/A 1 ___ Hearing aid no use at all 2 ___ Hearing aid is some help 3 ___ Hearing aid is quite helpful 4 ___ Hearing aid is a great help 5 ___ Hearing is perfect with aid	0 ___ N/A 1 ___ No difficulty 2 ___ Only slight difficulty 3 ___ Moderate difficulty 4 ___ Great difficulty 5 ___ Cannot manage at all	0 ___ N/A 1 ___ Not satisfied at all 2 ___ A little satisfied 3 ___ Reasonably satisfied 4 ___ Very satisfied 5 ___ Delighted with aid
How much difficulty do you have in this situation?	How much does any difficulty in this situation worry, annoy or upset you?	In this situation, what proportion of the time do you wear your hearing aid?	In this situation, how much does your hearing aid help you?	In this situation, with your hearing aid, how much difficulty do you now have?	For this situation, how satisfied are you with your hearing aid?
0 ___ N/A 1 ___ No difficulty 2 ___ Only slight difficulty 3 ___ Moderate difficulty 4 ___ Great difficulty 5 ___ Cannot manage at all	0 ___ N/A 1 ___ Not at all 2 ___ Only a little 3 ___ A moderate amount 4 ___ Quite a lot 5 ___ Very much indeed	0 ___ N/A 1 ___ Never/Not at all 2 ___ About ¼ of the time 3 ___ About ½ of the time 4 ___ About ¾ of the time 5 ___ All the time	0 ___ N/A 1 ___ Hearing aid no use at all 2 ___ Hearing aid is some help 3 ___ Hearing aid is quite helpful 4 ___ Hearing aid is a great help 5 ___ Hearing is perfect with aid	0 ___ N/A 1 ___ No difficulty 2 ___ Only slight difficulty 3 ___ Moderate difficulty 4 ___ Great difficulty 5 ___ Cannot manage at all	0 ___ N/A 1 ___ Not satisfied at all 2 ___ A little satisfied 3 ___ Reasonably satisfied 4 ___ Very satisfied 5 ___ Delighted with aid
How much difficulty do you have in this situation?	How much does any difficulty in this situation worry, annoy or upset you?	In this situation, what proportion of the time do you wear your hearing aid?	In this situation, how much does your hearing aid help you?	In this situation, with your hearing aid, how much difficulty do you now have?	For this situation, how satisfied are you with your hearing aid?
0 ___ N/A 1 ___ No difficulty 2 ___ Only slight difficulty 3 ___ Moderate difficulty 4 ___ Great difficulty 5 ___ Cannot manage at all	0 ___ N/A 1 ___ Not at all 2 ___ Only a little 3 ___ A moderate amount 4 ___ Quite a lot 5 ___ Very much indeed	0 ___ N/A 1 ___ Never/Not at all 2 ___ About ¼ of the time 3 ___ About ½ of the time 4 ___ About ¾ of the time 5 ___ All the time	0 ___ N/A 1 ___ Hearing aid no use at all 2 ___ Hearing aid is some help 3 ___ Hearing aid is quite helpful 4 ___ Hearing aid is a great help 5 ___ Hearing is perfect with aid	0 ___ N/A 1 ___ No difficulty 2 ___ Only slight difficulty 3 ___ Moderate difficulty 4 ___ Great difficulty 5 ___ Cannot manage at all	0 ___ N/A 1 ___ Not satisfied at all 2 ___ A little satisfied 3 ___ Reasonably satisfied 4 ___ Very satisfied 5 ___ Delighted with aid
How much difficulty do you have in this situation?	How much does any difficulty in this situation worry, annoy or upset you?	In this situation, what proportion of the time do you wear your hearing aid?	In this situation, how much does your hearing aid help you?	In this situation, with your hearing aid, how much difficulty do you now have?	For this situation, how satisfied are you with your hearing aid?
0 ___ N/A 1 ___ No difficulty 2 ___ Only slight difficulty 3 ___ Moderate difficulty 4 ___ Great difficulty 5 ___ Cannot manage at all	0 ___ N/A 1 ___ Not at all 2 ___ Only a little 3 ___ A moderate amount 4 ___ Quite a lot 5 ___ Very much indeed	0 ___ N/A 1 ___ Never/Not at all 2 ___ About ¼ of the time 3 ___ About ½ of the time 4 ___ About ¾ of the time 5 ___ All the time	0 ___ N/A 1 ___ Hearing aid no use at all 2 ___ Hearing aid is some help 3 ___ Hearing aid is quite helpful 4 ___ Hearing aid is a great help 5 ___ Hearing is perfect with aid	0 ___ N/A 1 ___ No difficulty 2 ___ Only slight difficulty 3 ___ Moderate difficulty 4 ___ Great difficulty 5 ___ Cannot manage at all	0 ___ N/A 1 ___ Not satisfied at all 2 ___ A little satisfied 3 ___ Reasonably satisfied 4 ___ Very satisfied 5 ___ Delighted with aid
How much difficulty do you have in this situation?	How much does any difficulty in this situation worry, annoy or upset you?	In this situation, what proportion of the time do you wear your hearing aid?	In this situation, how much does your hearing aid help you?	In this situation, with your hearing aid, how much difficulty do you now have?	For this situation, how satisfied are you with your hearing aid?
0 ___ N/A 1 ___ No difficulty 2 ___ Only slight difficulty 3 ___ Moderate difficulty 4 ___ Great difficulty 5 ___ Cannot manage at all	0 ___ N/A 1 ___ Not at all 2 ___ Only a little 3 ___ A moderate amount 4 ___ Quite a lot 5 ___ Very much indeed	0 ___ N/A 1 ___ Never/Not at all 2 ___ About ¼ of the time 3 ___ About ½ of the time 4 ___ About ¾ of the time 5 ___ All the time	0 ___ N/A 1 ___ Hearing aid no use at all 2 ___ Hearing aid is some help 3 ___ Hearing aid is quite helpful 4 ___ Hearing aid is a great help 5 ___ Hearing is perfect with aid	0 ___ N/A 1 ___ No difficulty 2 ___ Only slight difficulty 3 ___ Moderate difficulty 4 ___ Great difficulty 5 ___ Cannot manage at all	0 ___ N/A 1 ___ Not satisfied at all 2 ___ A little satisfied 3 ___ Reasonably satisfied 4 ___ Very satisfied 5 ___ Delighted with aid

## INTERNATIONAL OUTCOME INVENTORY FOR HEARING AIDS (IOI-HA)

1. Think about how much you used your present hearing aid(s) over the past two weeks. On an average day, how many hours did you use the hearing aid(s)?

none	less than 1 hour a day	1 to 4 hours a day	4 to 8 hours a day	more than 8 hours a day
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

2. Think about the situation where you most wanted to hear better, before you got your present hearing aid(s). Over the past two weeks, how much has the hearing aid helped in those situations?

helped not at all	helped slightly	helped moderately	helped quite a lot	helped very much
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

3. Think again about the situation where you most wanted to hear better. When you use your present hearing aid(s), how much difficulty do you STILL have in that situation?

very much difficulty	quite a lot of difficulty	moderate difficulty	Slight difficulty	no difficulty
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

4. Considering everything, do you think your present hearing aid(s) is worth the trouble?

not at all worth it	Slightly worth it	Moderately worth it	quite a lot worth it	very much worth it
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

5. Over the past two weeks, with your present hearing aid(s), how much have your hearing difficulties affected the things you can do?

affected very much	affected quite a lot	affected moderately	affected slightly	affected not at all
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

6. Over the past two weeks, with your present hearing aid(s), how much do you think other people were bothered by your hearing difficulties?

bothered very much	bothered quite a lot	bothered moderately	bothered slightly	bothered not at all
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

7. Considering everything, how much has your present hearing aid(s) changed your enjoyment of life?

worse	no change	slightly better	quite a lot better	Very much better
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

8. How much hearing difficulty do you have when you are **not** wearing a hearing aid?

severe	moderately- severe	moderate	mild	none
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Norms for the IOI-HA  
 Cox, Alexander, & Beyer, 2002

Item	Individual clients		Groups of clients	
	<i>Mild-moderate lower/upper</i>	<i>Mod-severe+ lower/upper</i>	<i>Mild-moderate mean/SD</i>	<i>Mod-severe+ mean/SD</i>
1. use	3/5	4/5	3.73/1.17	4.5/.96
2. benefit	3/4	3/4	3.39/.98	3.52/1.08
3. RAL	3/4	2/4	3.4/.95	3.19/1.05
4. satisfac.	2/4	3/5	3.2/1.21	3.84/1.17
5. RPR	3/4	3/4	3.57/1.13	3.38/1.11
6. imp-oth	3/5	2/4	3.79/1.13	3.38/1.1
7. QofLife	3/4	3/4	3.19/.93	3.68/1.02

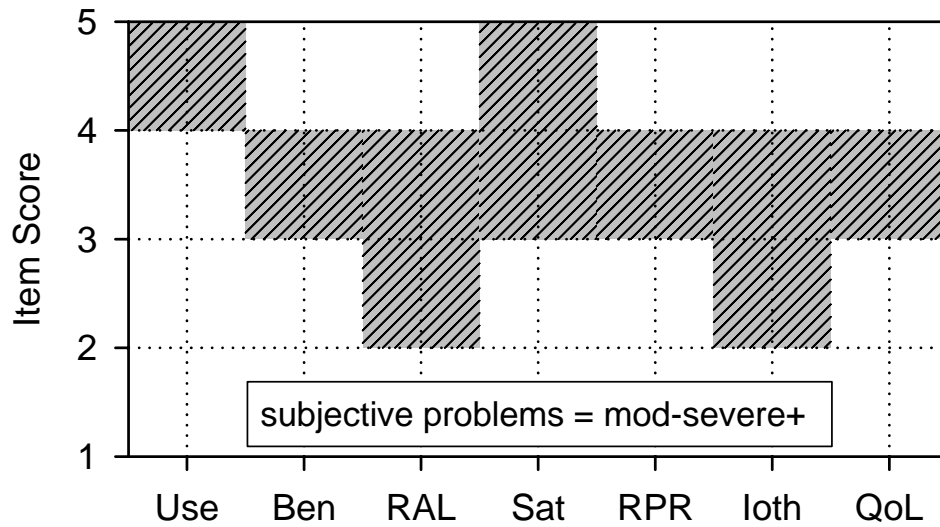
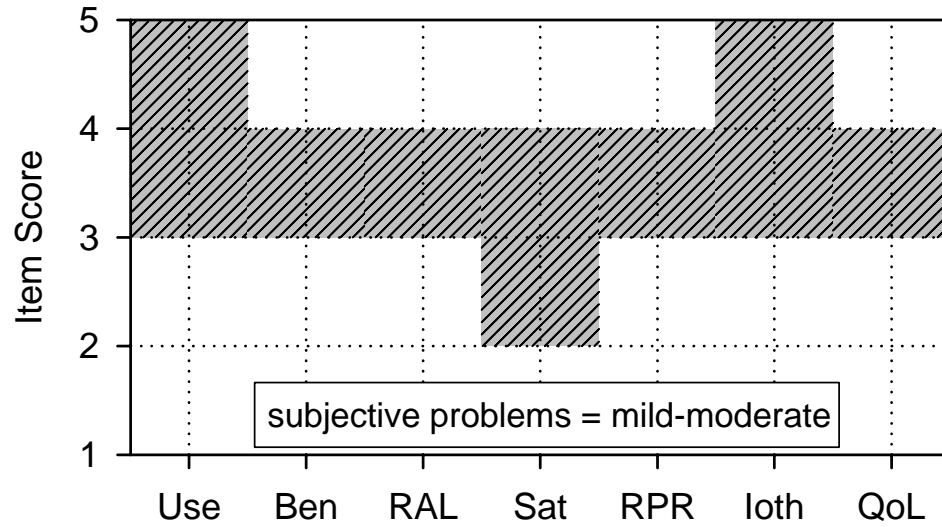
The category of norms used should depend on the patient's answer to the 8<sup>th</sup> item of the questionnaire. If they choose "none", "mild" or "moderate", use the "mild/moderate" norms. For the other 2 options, use the "mod/severe" norms.

The norms for individual clients are the middle 50% of the data. Hearing aids were: Single-channel, single-memory, ITE; All bilateral fittings; All compression (any type); standard fitting protocol; Purchased between Aug/00 & Jan/01.



# IOI-HA norm template for individual scores.

Cox, Alexander, & Beyer, 2002





## Health Research Authority

### NRES Committee London - Riverside

Bristol Research Ethics Committee Centre  
Level 3 Block B  
Whitefriars  
Lewins Mead  
Bristol  
BS1 2NT

Telephone: 0117 342 1385  
Facsimile: 0117 342 0445

18 January 2013

Miss Aarti Makan  
Senior Audiologist  
University College London NHS Foundation Trust  
Royal Free Hospital  
Audiology Department  
Pond Street, London  
NW3 2QG

Dear Miss Makan

**Study Title:** The Value of Using Motivational Tools in Hearing Aid Rehabilitation  
**REC reference:** 12/LO/1995  
**IRAS project ID:** 109076

The Research Ethics Committee reviewed the above application at the meeting held on 07 January 2013. Thank you for attending to discuss the application.

#### Documents reviewed

The documents reviewed at the meeting were:

<i>Document</i>	<i>Version</i>	<i>Date</i>
Covering Letter		29 November 2012
Investigator CV		25 November 2012
Other: Subject History questionnaire		
Other: Letter from Head of Department		30 September 2012
Other: Academic supervisors signature		29 November 2012
Other: Letter requesting PR review & PR failure sheet		29 November 2012
Participant Consent Form	2	05 November 2012

A Research Ethics Committee established by the Health Research Authority

Participant Information Sheet	2	05 November 2012
Protocol	1	26 October 2012
Questionnaire: Validated questionnaire (Motivational tools)		
Questionnaire: Validated questionnaire (HHIE-S)		
Questionnaire: Validated questionnaire (HHIA-S)		
Questionnaire: Validated questionnaire (GHABP)		
Questionnaire: Validated questionnaire (IOI-HA)		
REC application	3.4	29 November 2012

1. The Committee asked you if the motivational tool is already used in current practice.

You explained motivational tools are currently being used in other organisations and clinics for example smoking cessation clinics but the Ida Motivational Tool is used specifically for audiology. You added that she has received some training on using the Ida Motivational Tool and has used it on 3 or 4 patients already.

2. The Committee asked you to clarify what the study will involve as the PIS does not state clearly what will happen to the participant. The Committee also asked you whether there will be a follow-up programme for participants to attend.

*You explained that you will see the patients at 3 separate intervals; once to assess the participant, the second time will be to fit the hearing aid and the third time will be to invite the participant back for a follow-up programme (available for 2 years after the study has ended) to evaluate how effective the treatment has been on the participant.*

3. The Committee asked you to clarify if the participant will be aware which group they have been randomised into.

*You explained that participants will be randomly placed into 2 groups (control and experiment) and the participants will be informed which group they will be put into.*

The Committee suggested that you might wish to consider using an alternative study intervention such as a sham therapy intervention which will prevent the participant from knowing which group they have been put into and therefore reducing the results being biased.

### **Provisional opinion**

The Committee is unable to give an ethical opinion on the basis of the information and documentation received so far. Before confirming its opinion, the Committee requests that you provide the further information set out below.

Authority to consider your response and to confirm the Committee's final opinion has been delegated to the Chair.

### **Further information or clarification required**

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The Committee was unable to give a favourable opinion based on the information received so far. The Committee requested the following information before confirming its final opinion:

**1) Changes to the Participant Information Sheet (PIS);**

a) Please state clearly in the PIS what will happen to the participant, how they will be randomised and that they will not be told which group they have been selected to go into. Remove the phrase 'alternative therapy' as this may be misinterpreted by the participant as being complementary medicine.

**2) Recommendation:**

a) The Committee recommended that the researcher might wish to consider using an alternative study intervention such as a sham therapy intervention which will prevent the participant from knowing which group they have been put into and therefore reducing the risk of the results being biased.

The Committee delegated authority to confirm its final opinion on the application to the Chair.

**If you would find it helpful to discuss any of the matters raised above or seek further clarification from a member of the Committee, you are welcome to contact Tina Cavaliere.**

When submitting your response to the Committee, please send revised documentation where appropriate underlining or otherwise highlighting the changes you have made and giving revised version numbers and dates.

If the committee has asked for clarification or changes to any answers given in the application form, please do not submit a revised copy of the application form; these can be addressed in a covering letter to the REC.

The Committee will confirm the final ethical opinion within a maximum of 60 days from the date of initial receipt of the application, excluding the time taken by you to respond fully to the above points. A response should be submitted by no later than 17 February 2013.

**Membership of the Committee**

The members of the Committee who were present at the meeting are listed on the attached sheet.

There were no declarations of interest.

**Statement of compliance**

The Committee is constituted in accordance with the Governance Arrangements for Research Ethics Committees and complies fully with the Standard Operating Procedures for Research Ethics Committees in the UK.

A Research Ethics Committee established by the Health Research Authority

**12/LO/1995**

**Please quote this number on all correspondence**

Yours sincerely

*P.P. Pina Cavallo*

**Dr Sabita Uthaya**  
**Chair**

Email: [nrescommittee.london-riverside@nhs.net](mailto:nrescommittee.london-riverside@nhs.net)

*Enclosures: List of names and professions of members who were present at the meeting and those who submitted written comments.*

*Copy to: Ms Anna Jones, Joint Research Office*

## NRES Committee London - Riverside

### Attendance at Committee meeting on 07 January 2013

#### Committee Members:

<i>Name</i>	<i>Profession</i>	<i>Present</i>	<i>Notes</i>
Dr Mark Atkins	Microbiologist	Yes	
Ms Anna Bischler	Pharmacist	No	
Mr John Clifford	Lawyer	Yes	
Dr Julian Collinson	Consultant Cardiologist	Yes	
Ms Stephanie Ellis	Former Civil Servant	Yes	
Dr Matthew Hyde	Research Scientist	Yes	
Dr Margaret Jones	General Practitioner	Yes	
Miss Effie Katsarma	Consultant Plastic and Hand Surgeon	No	
Ms Alexandra Mancini	Modern Matron	Yes	
Ms Fanny Mitchell	Retired	Yes	
Dr Karen Phekoo	Researcher	Yes	
Mr Kamen Shoylev	Lawyer	No	
Ms Fiona Slomovic	Advocacy and Mediation Consultant	No	
Dr Sabita Uthaya	Consultant Neonatologist	Yes	
Dr Daniel Wood	Clinical Psychologist	Yes	

#### Also in attendance:

<i>Name</i>	<i>Position (or reason for attending)</i>
Miss Tina Cavaliere	Coordinator

#### Written comments received from:

<i>Name</i>	<i>Position</i>
Ms Anna Bischler	Pharmacist
Ms Fiona Slomovic	Advocacy and Mediation Consultant



## Health Research Authority

### NRES Committee London - Riverside

Bristol Research Ethics Committee Centre  
Level 3 Block B  
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Telephone: 0117 342 1385  
Facsimile: 0117 342 0445

31 January 2013

Miss Aarti Makan  
Senior Audiologist  
University College London NHS Foundation Trust  
Royal Free Hospital  
Audiology Department  
Pond Street, London  
NW3 2QG

Dear Miss Makan

**Study title:** The Value of Using Motivational Tools in Hearing Aid Rehabilitation  
**REC reference:** 12/LO/1995  
**IRAS project ID:** 109076

Thank you for your letter of 22<sup>nd</sup> January 2013, responding to the Committee's request for further information on the above research and submitting revised documentation.

The further information has been considered on behalf of the Committee by the Chair.

We plan to publish your research summary wording for the above study on the NRES website, together with your contact details, unless you expressly withhold permission to do so. Publication will be no earlier than three months from the date of this favourable opinion letter. Should you wish to provide a substitute contact point, require further information, or wish to withhold permission to publish, please contact the Co-ordinator Miss Tina Cavaliere, [nrescommittee.london-riverside@nhs.net](mailto:nrescommittee.london-riverside@nhs.net).

### Confirmation of ethical opinion

On behalf of the Committee, I am pleased to confirm a favourable ethical opinion for the above research on the basis described in the application form, protocol and supporting documentation as revised, subject to the conditions specified below.

### Ethical review of research sites

A Research Ethics Committee established by the Health Research Authority

## NHS sites

The favourable opinion applies to all NHS sites taking part in the study, subject to management permission being obtained from the NHS/HSC R&D office prior to the start of the study (see "Conditions of the favourable opinion" below).

## Non-NHS sites

### Conditions of the favourable opinion

The favourable opinion is subject to the following conditions being met prior to the start of the study.

Management permission or approval must be obtained from each host organisation prior to the start of the study at the site concerned.

*Management permission ("R&D approval") should be sought from all NHS organisations involved in the study in accordance with NHS research governance arrangements.*

Guidance on applying for NHS permission for research is available in the Integrated Research Application System or at <http://www.rdforum.nhs.uk>.

*Where a NHS organisation's role in the study is limited to identifying and referring potential participants to research sites ("participant identification centre"), guidance should be sought from the R&D office on the information it requires to give permission for this activity.*

*For non-NHS sites, site management permission should be obtained in accordance with the procedures of the relevant host organisation.*

*Sponsors are not required to notify the Committee of approvals from host organisations*

**It is the responsibility of the sponsor to ensure that all the conditions are complied with before the start of the study or its initiation at a particular site (as applicable).**

### Approved documents

The final list of documents reviewed and approved by the Committee is as follows:

<i>Document</i>	<i>Version</i>	<i>Date</i>
Covering Letter		29 November 2012
Covering Letter		22 January 2013
Investigator CV		25 November 2012
Other: Subject History questionnaire		
Other: Letter from Head of Department		30 September 2012
Other: Academic supervisors signature		29 November 2012
Other: Letter requesting PR review & PR failure sheet		29 November 2012
Participant Consent Form	2	05 November 2012

A Research Ethics Committee established by the Health Research Authority



Participant Information Sheet: (clean & tracked)	3	21 January 2013
Protocol	Version 2 (clean & tracked)	
Questionnaire: Validated questionnaire (Motivational tools)		
Questionnaire: Validated questionnaire (HHIE-S)		
Questionnaire: Validated questionnaire (HHIA-S)		
Questionnaire: Validated questionnaire (GHABP)		
Questionnaire: Validated questionnaire (IOI-HA)		
REC application	3.4	29 November 2012
Response to Request for Further Information		

### Statement of compliance

The Committee is constituted in accordance with the Governance Arrangements for Research Ethics Committees and complies fully with the Standard Operating Procedures for Research Ethics Committees in the UK.

### After ethical review

#### Reporting requirements

The attached document “*After ethical review – guidance for researchers*” gives detailed guidance on reporting requirements for studies with a favourable opinion, including:

- Notifying substantial amendments
- Adding new sites and investigators
- Notification of serious breaches of the protocol
- Progress and safety reports
- Notifying the end of the study

The NRES website also provides guidance on these topics, which is updated in the light of changes in reporting requirements or procedures.

#### Feedback

You are invited to give your view of the service that you have received from the National Research Ethics Service and the application procedure. If you wish to make your views known please use the feedback form available on the website.

Further information is available at National Research Ethics Service website > After Review

**12/LO/1995**

**Please quote this number on all correspondence**

We are pleased to welcome researchers and R & D staff at our NRES committee members’ training days – see details at <http://www.hra.nhs.uk/hra-training/>

With the Committee’s best wishes for the success of this project.

A Research Ethics Committee established by the Health Research Authority

Yours sincerely



**Dr Sabita Uthaya**  
**Chair**

Email: [nrescommittee.london-riverside@nhs.net](mailto:nrescommittee.london-riverside@nhs.net)

*Enclosures:* "After ethical review – guidance for researchers"

*Copy to:* Mrs Anna Jones, Joint Research Office



# Health Research Authority

## NRES Committee London - Riverside

Bristol Research Ethics Committee Centre  
Level 3 Block B  
Whitefriars  
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BS1 2NT

Tel: 0117 342 1385  
Fax: 0117 342 0445

05 February 2013

Miss Aarti Makan  
Senior Audiologist  
University College London NHS Foundation Trust  
Royal Free Hospital  
Audiology Department  
Pond Street, London  
NW3 2QG

Dear Miss Makan

**Study title:** The Value of Using Motivational Tools in Hearing Aid Rehabilitation  
**REC reference:** 12/LO/1995  
**Amendment number:** Minor Amendment 1 – Change title of study  
**Amendment date:** 1<sup>st</sup> February 2013  
**IRAS project ID:** 109076

Thank you for your email of 1<sup>st</sup> February 2013, notifying the Committee of the above amendment.

The Committee does not consider this to be a “substantial amendment” as defined in the Standard Operating Procedures for Research Ethics Committees. The amendment does not therefore require an ethical opinion from the Committee and may be implemented immediately, provided that it does not affect the approval for the research given by the R&D office for the relevant NHS care organisation.

### Documents received

The documents received were as follows:

Document	Version	Date
Notification of a Minor Amendment		
Covering Letter		

## Statement of compliance

The Committee is constituted in accordance with the Governance Arrangements for Research Ethics Committees and complies fully with the Standard Operating Procedures for Research Ethics Committees in the UK.

<b>12/LO/1995:</b>	<b>Please quote this number on all correspondence</b>
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Yours sincerely



**Miss Tina Cavaliere**  
**Committee Co-ordinator**

E-mail: [nrescommittee.london-riverside@nhs.net](mailto:nrescommittee.london-riverside@nhs.net)

Copy to: *Ms Anna Jones, Joint Research Office*



# Health Research Authority

## NRES Committee London - Riverside

Bristol Research Ethics Committee Centre  
Level 3 Block B  
Whitefriars  
Lewins Mead  
Bristol  
BS1 2NT

Tel: 0117 342 1385

19 August 2014

Miss Aarti Makan  
Senior Audiologist  
University College London NHS Foundation Trust  
Royal Free Hospital  
Audiology Department  
Pond Street, London  
NW3 2QG

Dear Miss Makan

**Study title:** The Value of Using Motivational Tools in Hearing Aid Rehabilitation  
**REC reference:** 12/LO/1995  
**Amendment number:** Minor Amendment 2  
**Amendment date:** 17 August 2014  
**IRAS project ID:** 109076

Thank you for your letter of 17 August 2014, notifying the Committee of the above amendment.

The Committee does not consider this to be a “substantial amendment” as defined in the Standard Operating Procedures for Research Ethics Committees. The amendment does not therefore require an ethical opinion from the Committee and may be implemented immediately, provided that it does not affect the approval for the research given by the R&D office for the relevant NHS care organisation.

### Documents received

The documents received were as follows:

<i>Document</i>	<i>Version</i>	<i>Date</i>
Notice of Minor Amendment [Email - Change to quantitative, experimental study utilising a pre-test post-test design ]	Minor Amendment 2	17 August 2014
Other [Summary of Changes]	May 2014	
Other [Email - Sponsor confirmation of Minor Amendment]		07 August 2014

## Statement of compliance

The Committee is constituted in accordance with the Governance Arrangements for Research Ethics Committees and complies fully with the Standard Operating Procedures for Research Ethics Committees in the UK.

<b>12/LO/1995:</b>	<b>Please quote this number on all correspondence</b>
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Yours sincerely



**Miss Maeve Groot Bluemink**  
**REC Assistant**

E-mail: [nrescommittee.london-riverside@nhs.net](mailto:nrescommittee.london-riverside@nhs.net)

Copy to: *Ms Anna Jones, Joint Research Office*



UNIVERSITEIT VAN PRETORIA  
UNIVERSITY OF PRETORIA  
YUNIBESITHI YA PRETORIA

Faculty of Humanities  
Research Ethics Committee

22 July 2013

Dear Ms Louw

**Project:** The value of using the operational model of behaviour change in hearing aid rehabilitation  
**Researcher:** A Makan  
**Supervisor:** Ms A Louw  
**Department:** Communication Pathology  
**Reference number:** 97098567

Thank you for your response to the Committee's correspondence of 1 July 2013.

I have pleasure in informing you that the Research Ethics Committee formally **approved** the above study at an *ad hoc* meeting held on 22 July 2013. Please note that this approval is based on the assumption that the research will be carried out along the lines laid out in the proposal. Should your actual research depart significantly from the proposed research, it will be necessary to apply for a new research approval and ethical clearance.

The Committee requests you to convey this approval to the researcher.

We wish you success with the project.

Sincerely

**Prof. Sakhela Buhlungu**  
**Chair: Research Ethics Committee**  
**Faculty of Humanities**  
**UNIVERSITY OF PRETORIA**  
**e-mail: sakhela.buhlungu@up.ac.za**

Research Ethics Committee Members: Dr L Blokland; Prof S Buhlungu (Chair); Prof M-H Coetzee; Dr JEH Grobler; Prof KL Harris; Ms H Klopper; Prof A Mlambo, Dr C Panebianco-Warrens; Prof GM Spies; Prof E Taljard ; Dr FG Wolmarans, Dr P Wood