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**Feasibility of conducting a randomised controlled trial on the
effect of motivational interviewing in facilitating hearing aid use**

Hashir Aazh

Thesis submitted in accordance with the requirements for the degree of

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Department of Social and Environmental Health Research

Faculty of Public Health and Policy

LONDON SCHOOL OF HYGIENE & TROPICAL MEDICINE

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“I, Hashir Aazh, confirm that the work presented in the thesis is my own. Where information has been derived from other sources, I confirm that this has been indicated in the thesis.”

This thesis is dedicated with love to my wife, Shahrzad, and my son, Daniel.

Abstract

The aim of this study was to investigate the feasibility of conducting a randomised controlled trial (RCT) on the effect of motivational interviewing (MI) in facilitating hearing aid use.

Methods used and their results are presented in the 3 sections below:

- (1) A cross-sectional survey where a questionnaire, including the International Outcome Inventory for Hearing Aids was posted to all patients fitted with hearing aids at the Royal Surrey County Hospital, Guildford, between 2011 and 2012 (N=1874). 1023 questionnaires were completed and returned (response rate of 55%). 29% of responders did not use their hearing aids on a regular basis (i.e., used them less than 4 hours per day).
- (2) 220 patients who reported using their hearing aid(s) less than 4 hours per day in the above survey were invited to take part in a pilot single-blind RCT. 37 were enrolled and randomised to MI combined with hearing aid adjustments (n=20) or hearing aid adjustments only (n=17). The results showed that it was feasible to deliver MI for facilitating hearing aid use. Hearing aid use as measured via data logging 1 month after interventions favoured the MI group.
- (3) A qualitative enquiry embedded in the above pilot RCT was conducted. 34 out of 37 participants underwent in-depth interviews. Interviews were transcribed and thematically analysed. Five themes were identified in relation to participants' perspectives about the key components of the research programme which influenced their decision about using their hearing aids.

Conclusion: Conducting an RCT on the effect of MI in facilitating hearing aid use in people who do not use their hearing aids is feasible and that MI combined with audiology standard care may have positive effects on hearing aid use.

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3 List of Abbreviations

BTE=Behind the ear

CEMI=Client evaluation of motivational interviewing

CERQ= Cognitive Emotion Regulation Questionnaire

COSI= Client Oriented Scale of Improvement

ES=Effect size

GHABP= Glasgow Hearing Aid Benefit Profile

GP=General Practitioner

HADS= Hospital Anxiety and Depression Scale

IOI-HA=International outcome inventory- hearing aids

IOI-HA-SO= International Outcome Inventory for Hearing Aid for the Significant Other

MI= Motivational interviewing

MISC=Motivational interviewing combined with standard care

MITI= Motivational interviewing treatment integrity assessment tool

NHS=National Health Service

OR=Odds ratio

PTA=Pure tone average

RCR= Readiness to Change Ruler

RCT= Randomized controlled trial

REM=Real ear measurement

RSCH=Royal Surrey County Hospital

SC= Standard care

SD=Standard deviation

WHO-DAS II = World Health Organisation's Disability Assessment Schedule II

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5 Preface

This thesis is prepared based on the Research Paper style. In Research Paper style, the thesis or parts of it are written as discrete papers rather than a single narrative (LSHTM 2014). However, this style is different from just a collection of research papers and it requires linking materials, additional details and discussions. The main aim of the Research Paper style is to help the students to write their thesis in a format that is more consistent with the style required for research papers compared to traditional book chapter style. This way the thesis can more easily be turned into papers for submission to journals. This thesis comprises 7 chapters. The paper style chapters are chapters 3, 4, and 5. After each research paper chapter, a section is dedicated to highlight limitations of this part of the work and provide recommendations for future research.

Chapter 1 contains a broad literature review appraising the evidence-base for effectiveness of hearing aids, non-adherence to hearing aid use, and interventions that have been used in the process of aural rehabilitation in order to improve hearing aid use. In addition, the concept of behaviour change and the principles and relevance of motivational interviewing (MI) to aural rehabilitation are introduced.

Chapter 2 is devoted to methodology and provides an insight about the rationale behind the decisions made by the author throughout the PhD project.

Chapter 3 is the research paper 1 which has been published (Aazh et al. 2015).

Aazh H, Prasher D, Nanchahal K, Moore BC. (2015) Hearing-aid use and its determinants in the UK National Health Service: A cross-sectional study at the Royal Surrey County Hospital. Int J Audiol. 54(3), 152-161.

Chapter 4 is the research paper 2 which has recently been published (Aazh 2015).
Aazh H. (2015) Feasibility of conducting a randomised controlled trial on the effect of motivational interviewing on hearing-aid use. Int J Audiol. Sept 2; 1-9 [Epub ahead of print]

Chapter 5 is the research paper 3 entitled “Patients’ Experience of Motivational Interviewing for Hearing Aid Use: A Qualitative Study Embedded within a Pilot Randomised Controlled Trial”.

This paper has been submitted for publication and is under revision after initial review.

Chapter 6 is the final discussion which mainly focuses on directions for future research.

Chapter 7 is the final conclusion.

6 Chapter One

This chapter includes an introduction to physiological and psychosocial aspects of hearing impairment and fundamentals of aural rehabilitation. The evidence-base for effectiveness of hearing aids in improving quality of life of the individuals with hearing impairment as well as the non-adherence to hearing aid use and its determinants are reviewed. This provides an opening discussion for the need for interventions that can be applied in order to facilitate hearing aid use.

The concept of behaviour change and its relevance to aural rehabilitation are introduced in this chapter. The stages of change model and client-centred counselling style and their applications in audiology context are critically reviewed. The principals of motivational interviewing (MI) and its relevance to the stages of change model and client-centred counselling style are described. Evidence-base for MI in promoting behaviour change are briefly reviewed. MI has not been tested in the field of audiology, however a variety of counselling-based interventions have been considered in the process of aural rehabilitation in order to facilitate hearing aid use. Therefore, a critical review of the research evidence assessing efficacy of such interventions is presented in this chapter.

6.1 Hearing Impairment and Aural Rehabilitation

Auditory system includes the outer, middle and the inner ear. Outer ear composed of the pinna (the visible part of the ear) and the auditory canal. Pinna is important in our ability to localise the source of a sound. Ear canal transfers sound into the middle ear. Middle ear consists of the tympanic membrane (eardrum) and three small bones (ossicular chain) which connect the eardrum to the cochlea. The middle ear ensures the efficient transfer of sound from the ear canal to the cochlea and reduces the transmission of internally generated bone-conducted sounds (e.g., chewing, flow of the air and blood, muscle contractions) to the cochlea (Bárány 1938). See also Aazh et al. (2005); Huxley (1990); Aazh et al. (2002) for more details on the role of the middle ear in sound transmission. Cochlea looks like a spiral shell of a snail and is filled with incompressible fluids. Inside the cochlea there are 12000 outer hair cells and 3500 inner hair cells (Wright et al. 1987a; Wright et al. 1987b). Outer hair cells produce high hearing sensitivity and sharp frequency tuning enabling us to hear and discriminate sounds with different

intensities (corresponding to loudness perception) and frequencies (corresponding to pitch perception). Inner hair cells are responsible for transducing mechanical movements in the cochlea into neural activities and convey the information about sounds to the brain via the auditory nerve. In clinical situations, hearing thresholds are measured using an audiometer and are specified by dB HL (decibel Hearing Level) which is the hearing threshold of the individual relative to audiometric zero which is the average hearing threshold at each frequency for young healthy listeners with normal hearing (Roeser et al. 2000). Although human ear responds to frequencies between 20 and 20,000 Hz, only frequencies between 250 Hz and 8000 Hz are included in typical audiometric tests as these are generally the most audible to the human ear and cover the frequencies between 300 Hz and 3000 Hz which are critical for speech perception (Roeser et al. 2000).

There are two broad types of hearing loss. The first is conductive hearing loss which is due to a reduction in transmission of sound usually in the middle ear as the result of an eardrum perforation, disruption of ossicular chain, build up of viscous fluid in middle ear cavity, or immobilization of some of the bones (mainly stapes) in the ossicular chain (Moore 2012). The second type of hearing loss is called sensorineural hearing loss. Sensorineural hearing loss is often associated with damage to the outer hair cells (OHCs) and inner hair cells (IHCs) in the cochlea, and to the neurons making up the auditory nerve (Schuknecht & Gacek 1993). In some cases, the IHCs and/or the associated neurons may be hardly functioning at all, leading to what has been called a dead region (Moore 2004). Prevalence of dead regions in the elderly with absolute hearing thresholds of 60–85 dB HL at high frequencies is about 37% (Aazh & Moore 2007a).

Presbycusis or age-related sensorineural hearing loss is the most common type of hearing impairment and it affects 25–43% of people aged between 65 and 74 years and 40–63% of those aged over 75 years (Lopez-Torres Hidalgo et al. 2009). In fact presbycusis is one of the most prevalent conditions affecting the adult population (Dalton et al. 2003). Presbycusis is related to the loss of hair cells in the organ of Corti in the cochlea (inner ear) and the loss of auditory neurons throughout the cochlear nerve and the cochlea (Roeser et al. 2007). Presbycusis typically is characterised by a sloping, symmetrical, sensorineural, high-frequency hearing loss starting at around 2000 Hz (Luxon et al. 2003; Roeser et al. 2007). In presbycusis, a

combination of sensorineural hearing loss with central auditory dysfunction and cognitive problems seem to result in poor speech discrimination in noise (Luxon et al. 2003).

The population of people with hearing difficulties is estimated to be about 10 million in the UK (RNID 2009; Action on Hearing Loss 2011), 34 million people in the US (Kochkin, 2009) and 70% of adults aged 70 years or older in Australia (Chia et al. 2007). This is a growing concern as it is estimated that there will be about 14.5 million people with hearing impairment by 2031 in the UK, and according to the World Health Organisation hearing loss will be in the top ten disease burdens in the UK by 2030 (Action on Hearing Loss 2011). Similar statistics are reported in other developed countries. People with hearing impairment face great difficulties in their day to day life. They are less likely to be in paid work and more likely to be retired or employed part-time (Kochkin, 2009; Hogan et al, 2009). There is a higher prevalence of symptoms of anxiety and depression in hard of hearing people in comparison with people without hearing loss (Kvam et al, 2007).

Use of hearing aids improve various functions of hearing which briefly comprise: hearing thresholds (Dillon 1993), localizing source of sound (Keidser et al. 2006; Köbler & Rosenhall 2002), monitoring and controlling one's own voice (Laugesen et al. 2009) and most importantly speech perception in noise and quiet (Alcantara et al. 2003; Magnusson et al. 2001; McArdle et al. 2012). However, hearing aids do not replace normal hearing. In the other words, some of the consequences of hearing impairment cannot be compensated with the use of hearing aids (Ahlstrom et al. 2009; Faulkner et al. 1990; Moore 2004). Hearing aids send the amplified sound through the middle ear to the cochlea which will stimulate damaged and intact hair cells. Damaged IHCs which typically are at higher frequencies, in the case of presbycusis, do not transduce sound to the auditory nerve. Hence the auditory brain will get only part of the message. Damaged OHCs cause broadening of the auditory filters and consequently loss of frequency selectivity (Moore 1998). When the auditory filters are broadened, much more of the noise gets through the filter, so the detectability of signals in noisy environment is reduced (Florentine et al. 1980).

Adoption of hearing aids does not automatically improve the patient's activity limitations, participation restrictions and health related quality of life (Boothroyd

2007; Hawkins 2005). Many people have difficulties in accepting and adjusting to their hearing aids (Knudsen et al. 2010; Stark & Hickson 2004). Therefore, although fitting of hearing aids is an important component of audiologic rehabilitation (AR), further considerations seem to be necessary in order to minimise restrictions imposed on individuals by their hearing impairment. A holistic approach in planning and implementation of AR has been recommended by many authors in the audiology literature (Boothroyd 2007; Erdman et al. 1994; Gagne et al. 1995; Noble 1996; Noble & Hetu 1994; Stephens 1996). The American Speech and Hearing Association defined Audiologic Rehabilitation (AR) as “an ecological, interactive process that facilitates one’s ability to minimise or prevent the limitations and restrictions that auditory dysfunction can impose on well-being and communication, including inter-personal, psycho-social, educational, and vocational functioning” (p.2.ASHA 2001). Boothroyd (2007) summarised AR in 4 steps comprising: (1) management of the impairment through fitting of hearing aids or other listening assistive devices, (2) providing instructions and education, (3) perceptual training in order to improve speech perception and listening skills with hearing aid and (4) counselling to enhance participation and enable the individual to lead their normal life despite their residual hearing limitations. These definitions are influenced by the World Health Organisation’s (WHO) International Classification of Functioning Disability and Health (ICF; WHO 2001). The ICF model defines functioning and disability as multidimensional concepts relating to impairment, activity limitation, participation restrictions, environmental and personal factors which affect these experiences. Figure 1.1 illustrates interaction between ICF components.

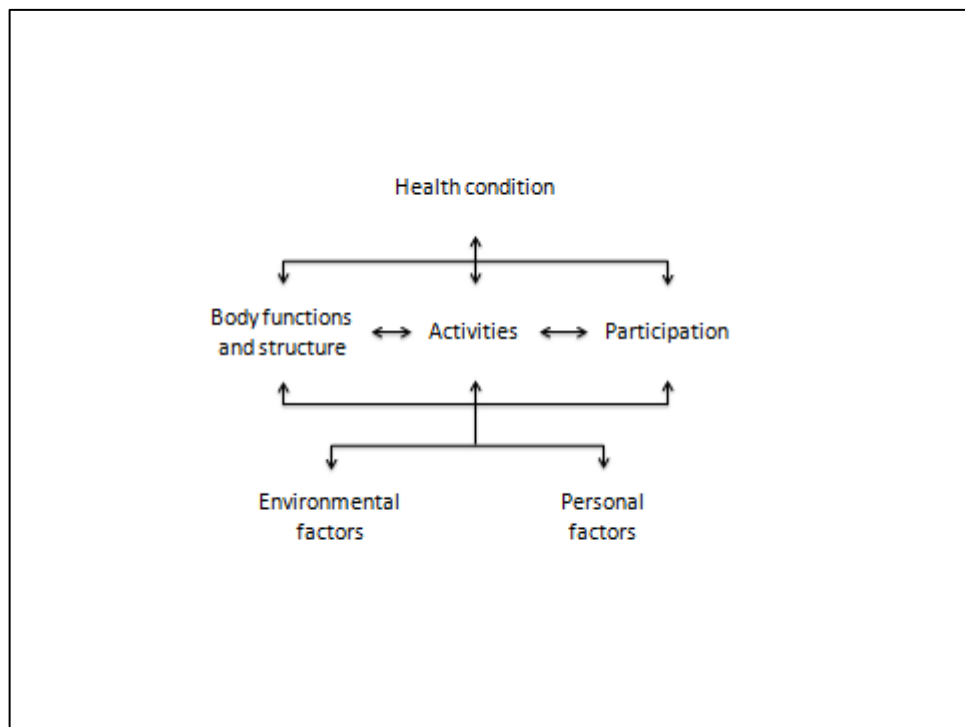


Figure 1.1: International Classification of Functioning Disability (Boothroyd 2007).

6.2 Evidence-Base for Hearing Aids

Research studies suggest that use of hearing aids increases ability to detect, discriminate and localise sound, enhance speech discrimination, and improve health related quality of life (HRQoL) of individuals with hearing impairment (McArdle et al. 2005; Chisolm et al. 2007; Hickson & Scarinci 2007). There are many studies supporting the benefit of hearing aids in improving hearing and subsequently reducing hearing related disability and handicap. Chisolm et al (2007) conducted a systematic review of the evidence assessing the effect of hearing aid use by individuals with hearing impairment on their health related quality of life (HRQoL). The outcome of their meta-analysis revealed that the mean between-subjects effect size (ES) of amplification calculated for disease-specific HRQoL measures was equal to 2.07, with 95% CIs of 0.51 and 3.63. This result suggests that hearing aids have a robust, medium-to-large effect on HRQoL when outcomes are measured using disease-specific instruments. The pooled ES for generic HRQoL measures was equal to 0.28, with 95% CIs of 0.09 and 0.48. The data-base search for this systematic review was conducted during July 2004. Since then there have been several more research studies assessing effects of hearing aids on hearing disability and quality of life, their results are consistent with this review (Cohen et al, 2004;

McArdle et al, 2005; Vuorialho et al, 2006; Vestergaard, 2006; Tsakiropoulou et al, 2007; Lotfi et al, 2009; Bertoli et al, 2009; Kochkin, 2009; Kochkin, 2011). Design of these more recent studies were mainly non-controlled trials and cross sectional studies except one RCT by McArdle et al (2005). McArdle et al (2005) conducted an RCT on 380 participants assessing the effect of amplification on disease-specific and generic HRQoL measures. The ES of hearing aid intervention on generic HRQoL outcome was 0.20 and the ES for disease-specific HRQoL outcome was 1.42.

However, there are several studies reporting that many owners of hearing aids do not use them regularly and do not achieve an improved quality of life (Stark & Hickson 2004; Vuorialho et al. 2006b; McCormack & Fortnum 2013).

6.3 Non-Regular Use of Hearing Aids and its Determinants

There is no widely agreed definition for non-regular use of hearing aids (Perez & Edmonds 2012). In this study non-regular use of hearing aids is defined as use of less than four hours per day. Approximately 30% of people who own hearing aids do not use them regularly (i.e., less than 4 hours per day) (Hickson et al. 2010; Stark & Hickson 2004; Vuorialho et al. 2006b; Takahashi et al. 2007; Brännström & Wennerstrom 2010). Non-use or infrequent use of hearing aids not only wastes resources but also has other implications: (1) non-use of hearing aids has been associated with increased risk of “loneliness” among hearing impaired individuals (Pronk et al. 2013); (2) failure to communicate adequately may adversely affect the non-user’s occupational, educational, leisure, and social activities (Hickson & Scarinci 2007); (3) partners and family of the non-user may experience activity limitation and participation restriction as a result of their partner’s communication difficulties (Scarinci et al. 2012); (4) non-users may not benefit from the learning and reorganization of the auditory cortex associated with consistent hearing-aid use (Gabriel et al. 2006; Hamilton & Munro 2010; Munro & Trotter 2006), and (5) non-users need to increase their attention, concentration and “listening effort” in order to compensate for their lack of hearing making them more susceptible to mental fatigue in demanding listening situations (Hornsby 2013).

So what is it that discourages some individuals from using their hearing aids? Many people with acquired hearing loss expect full restoration of hearing, a “cure” (Boothroyd 2007). It is plausible that the difference between this expectation and the

reality of technological limitations of hearing aids can result in non-regular use or complete abandonment of hearing aids and continued avoidance of the day-to-day situations where hearing aids could offer benefit (Boothroyd 2007). Several authors suggested that non-regular use of hearing aids can be related to the stigma of deafness and psychosocial aspects of the hearing impairment in general (Manchaiah et al. 2011; Babeu et al. 2004; Hogan 2010; Noble 1996; Claesen & Pryce 2012). Noble (1996) suggested that the ability to hear properly is taken for granted in our society, hence it is understandable why some people with hearing impairment tend to avoid being identified by others, or to self-identify, as hearing impaired or “abnormal”. Stigma of deafness and fear of marginalisation seem to be the main factors making people reluctant to accept their hearing condition or use of hearing aids (Hogan, 2010). There has been a social stigma attached to deafness across the centuries. In ancient Israel, those born deaf were not allowed to own property or conduct major business transactions. In ancient Greece, those born deaf were considered "non-persons" in the society (Edwards, 1994; Carver, 1999). Aristotle is quoted as saying that those, "born deaf become senseless and incapable of reason" (Nelson, 1998). Hearing loss still carries a social stigma. St Claire and He (2009) reported that hearing loss is associated with being a phoney, an isolate, an incompetent, and simply with growing old. Hogan (1990) interviewed a group of twenty hearing-impaired people in a lip-reading class. Hard of hearing people reported being labelled as deaf, snobbish, inattentive, stupid, idiotic, not with it, dumb, ignorant, useless, retarded, boring, arrogant, stubborn, slow, and vague (Hogan, 1990). Ability to hear well is taken for granted in our society or as a social fact (Haslam et al, 1998; Hogan, 2010). In sociological perspective, social facts are the values, cultural norms, and social structures external to the individual (Durkheim, 1971, 1982). People living with hearing loss routinely refuse to implement behavioural changes (i.e., hearing aid use) that would marginalise them (Hogan, 2010). Claesen and Pryce (2012) conducted a phenomenological study in order to explore psychosocial needs of people who seek help with hearing loss. They reported that some patients did not regard the hearing aid as an acceptable solution but agreed to get them mainly to please their communication partners. This suggests that audiologists need to consider the reasons that people seek hearing help into account when providing rehabilitative services. Those who are not ready for hearing aid might need more counselling and support. Relying on technological features of

the hearing aids is unlikely to address the psychosocial consequences of hearing loss or hearing aid use.

Knudsen et al (2010) conducted a review study assessing factors influencing hearing aid use and satisfaction. They reviewed 39 papers and identified 31 factors. After synthesising the results of these studies they concluded that self-reported hearing problems as well as patient's attitude toward hearing aid are the main predictors of hearing aid use. Jenstad and Moon (2011) conducted a systematic review of literature in order to identify the main barriers and facilitators to hearing aid uptake in older adults. They included 14 studies in their review. After integrating the findings of the individual studies they concluded that self-reported hearing loss and stigma of deafness were the main factor affecting on hearing aid uptake.

Several authors suggested that patient's readiness and motivation to use hearing aids are the main predictors of hearing aid use (Abdellaoui & Tran Ba Huy 2013; Vernon & Pratt 1977; Babeu et al. 2004; Laplante-Levesque et al. 2014a; Laplante-Levesque et al. 2013a). The result of a recent French national survey on hearing aid use suggested that patient's motivation is the key determinant of success or failure for adoption and use of hearing aids (Abdellaoui & Tran Ba Huy 2013). It has long been acknowledged that a patient's acceptance of a hearing aid cannot be predicted from audiometric data alone but depends on their motivation to accept their hearing impairment, the need for a hearing aid, and the limited benefits received from hearing aids (Erdman & Demorest 1998; Vernon & Pratt 1977). Vernon and Pratt (1977) wrote that "without motivation a patient will not accept the hearing aid (p.1414)". In the next section readiness to change and the relevance of the stages of change model to aural rehabilitation is discussed.

6.4 Adherence to Hearing Aid and Stages of Change Model

6.4.1 Behaviour Change and Hearing Aid Use

Use of hearing aids often requires patients to change their cognitions and behaviours (e.g., acknowledge a hearing disability, seek professional help, wear their hearing aids on regular basis and change their avoidance coping strategies) (Laplante-Levesque et al. 2013a). Behaviour change is a complex process determined by various psychological and environmental factors , hence simply providing people with education, advice and skilfulness may not necessarily help them to change

(Rollnick et al. 2005; Mosler 2012). Babeu et al. (2004) emphasised that prior to recommending/ prescribing hearing aids, audiologists should assess patient's readiness for hearing aids and hearing health care. They wrote "just because an individual schedules an appointment does not mean that he or she is ready for a hearing aid" (p.42). In the section below the transtheoretical model for behaviour change and its relevance to hearing aid use is discussed however a comprehensive review of behaviour change models and their applications in health and social care is beyond the scope of this thesis and for a detailed review see Darnton (2008b); Darnton (2008a).

6.4.2 Transtheoretical Model and its Application in Audiology

Stages of change model which is also known as transtheoretical model is one of the popular behaviour change theories (Prochaska & DiClemente 1986). The transtheoretical model describes that behaviour change occurs gradually and the individual moves through a series of stages in the process of changing behaviour from being unwilling or unaware to make a change (pre contemplation stage), to considering a change (contemplation stage), and to deciding and preparing to make a change (preparation and action stages) (McConaughy et al. 1983). The transtheoretical model highlights the need for health care providers to be flexible and tailor their interventions to match with patient's current level of readiness for change. For instance, during pre-contemplation stage, people may hold certain beliefs and attitudes toward change. Some examples of these comprise: (1) they may not believe that there is a need to change their behaviour, (2) they may not believe that the current behaviour negatively affect them, (3) they may rebel against the change, or (4) be resigned due to past failed efforts to change their behaviour (Prochaska & DiClemente 1992). The transtheoretical model has been given some attention in the field of audiology too (Babeu et al. 2004; DiClemente 2002; Laplante-Levesque et al. 2013a). For instance, Babeu et al. (2004) described that at the pre-contemplation stage individual may not acknowledge that they have hearing difficulties and instead they may complain that people mumble or speak too softly. At contemplation stage, the individual may wonder whether things would be different if he/she used hearing aids. At this stage they may participate in a community hearing screening or talk to friends who use hearing aids. At the preparation stage, the individual may seek information about hearing loss and

hearing aid use and arrange an appointment to see an audiologist. At the action stage, they may start using hearing aids. For more details about the processes of change relevant to hearing aid use, see Babeu et al. (2004). Babeu et al. (2004) recommended the application of the transtheoretical model in audiology. They suggested that after determining whether the patient has a hearing loss which can be helped with amplification, the audiologist should establish the patient's stage of readiness to use hearing aids by asking them: "Which best describes your thinking about getting hearing aids? (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)" (Babeu et al. 2004)(p.51). Then they move on to suggest what actions should be taken by audiologist at each stage. The method that they suggested for patients in pre-contemplation and contemplation stages was heavily reliant on informational counselling and comprised of: (1) overview of hearing loss issues, (2) statistical information, (3) provide a list of reading materials that would inform the individual about hearing loss, (4) list advantages and disadvantages of getting help for hearing loss, (5) offer hearing test, (6) discuss how communication misunderstandings impact the individual, (7) try stock hearing aids, (8) discuss ways that society at large is assisting hearing impaired individuals, (9) use role play in which patient's partner plays the part of the patient with hearing loss and vice versa to show the impact of hearing loss on the family, and (10) discuss stigmatisation of hearing aids.

Providing this amount of information to convince patients in pre-contemplation stage who are typically argumentative, hopeless or in denial usually engenders resistance to the idea of hearing aids (Zimmerman et al. 2000; Miller et al. 1993; Laplante-Levesque et al. 2013a). Some authors suggested that providing information is only effective when patient seeks information (Rogers 1959; Miller 1983). If they are not ready then an emphatic listening style is more likely to facilitate the process of change.

Several studies show that educating people about the disadvantages of smoking, unhealthy diet, and substance abuse or advising people to adhere to long-term medication regimens, physical activity, drinking sanitized water, or use of contraception may not be enough to help them to change their risky behaviours (Lai

et al. 2010; Resnicow et al. 2006; Smedslund et al. 2011; Butler et al. 1996; Lopez et al. 2013; Thevos et al. 2000). Despite the fact that clinicians believe that patients' lack of knowledge about treatment is the primary barrier to adherence, there is only a modest association between treatment-related knowledge and adherence (Gelb et al. 2008). Patients' negative attitudes toward treatment, readiness to change and lack of motivation appear to be more important determinants of non-adherence than lack of knowledge (Miller & Rollnick 2012; Miller & Rose 2009; Prochaska & DiClemente 1986).

Lately in the field of audiology, some authors acknowledged the use of client-centred counselling skills instead of informational counselling, educating, for patients at the pre-contemplation stage. For instance Laplante-Levesque et al. (2013a) wrote "Audiologists can address the typical reluctance, rebellion, resignation, or rationalisation pre-contemplators exhibit with active listening, which can raise problem awareness and encouragement to improve self-efficacy toward behaviour change." (p.448). However, informational counselling was overrepresented in their suggested approach for contemplators as Laplante-Levesque et al. (2013a) wrote "contemplators can benefit from evidence-based information highlighting the pros and cons of intervention uptake, therefore reducing ambivalence and instilling hope that change is possible." (p.448). Providing advice and informational counselling for people who are not ready for change or are ambivalent about the change, at contemplation stage, is premature and can push the patient to a position of defensiveness. It appears that patients have reservations about being told what to do by their doctors and a patient-centred approach produces better outcomes in terms of promoting health and life style behaviour change (Rollnick et al. 1992). According to the Health Belief Model if patients do not believe that their behaviour is a problem or that it will negatively affect them it is unlikely for them to accept the clinician's argument for change (Katatsky 1977; Janz & Becker 1984; Bowers 1980). Similarly, if the patient don't believe that they can control or change their unhealthy behaviour due to the previous failed efforts, according to the External Locus of Control Model (Rotter 1966), they would hesitate to make further efforts.

Milstein and Weinstein (2002) discussed application of Health Belief Model and the transtheoretical model in the audiology context and hypothesised that providing

information about the nature of hearing loss, its consequences, and the advantages of hearing aids might affect the individual's willingness to comply with the recommendation of aural rehabilitation and help them in moving forward in stage of change cycle. In order to test their hypothesis, they conducted a study assessing the outcomes of a hearing screening (hearing test) alone with no information sharing versus hearing screening plus information sharing which was delivered via watching a videotape regarding hearing loss and hearing aid. 147 people took part in their study and randomly assigned to the two treatment arms. They developed a readiness for change questionnaire based on the work of Prochaska et al. (1992). Participants were asked to select one statement out of four that best described their view of their hearing status: (1) I don't think I have a hearing problem, and therefore nothing should be done about it. (2) I think I have a hearing problem. However, I am not yet ready to take any action to solve the problem, but I might do so in the future. (3) I know I have a hearing problem, and I intend to take action to solve it soon. (4) I know I have a hearing problem, and I am here to take action to solve it now. Prior to the screening, 76% of participants were at pre-contemplation and contemplation stages based on their selection of statements 1 or 2 in readiness for change questionnaire. The same questionnaire was applied after the screening session but no significant differences between pre-and post- screening responses were found within or between the groups. Eight percent had no hearing loss but 92% (n=135) of the participants failed the hearing screening indicating presence of a hearing impairment. Those who failed the screening test were recommended to make an appointment at their local hospital to see an audiologist. To their surprise their results showed that subjects who received hearing screening only were more likely to comply with the recommendation of visiting an audiologist (28% compliant) compared to those who received hearing screening plus information sharing video (13% compliant). They concluded that providing additional information is unlikely to motivate people with hearing impairment who are at pre-contemplation and contemplation stages to seek hearing help and obtain hearing aids. In the other words trying to convince them about their hearing loss and the need for hearing aid didn't help them to accept the problem and take action. The authors concluded that simply providing information to people at pre-contemplation and contemplation stages may not necessarily improve readiness or compliance. They suggested that "motivational interviewing that utilises a client-centred style for eliciting behaviour change, in

combination with the transtheoretical stages of change model may be an approach that could be effective (p.53)” (Milstein & Weinstein 2002). However, to the author’s knowledge, there is no published study examining effect of motivational interviewing in facilitating hearing aid uptake and use.

6.4.3 Recent Studies on Stages of Change Model and Readiness to Use Hearing Aids

There have been few other studies assessing stages of change in people seeking help with regard to their hearing impairment (Laplante-Lévesque et al. 2012; Laplante-Levesque et al. 2014a; Laplante-Levesque et al. 2011). Laplante-Levesque et al. (2013a); Laplante-Lévesque et al. (2012) studied the application of stages of change model in audiology rehabilitation. Stages of change score was measured via the University of Rhode Island Change Assessment (McConaughy et al. 1983) in 153 patients seeking hearing help for the first time prior to offering any intervention. They also completed several self-report hearing disability questionnaires. The mean age of participants was 71 years (SD=7.5) and on average they reported 10 years (SD=10.9) since they first noticed the onset of their hearing impairment. The degree of hearing impairment (average of pure tone hearing thresholds at 0.5, 1, 2, and 4 kHz in the better ear in dB HL) was 32.2 dB (SD=8.56). Their analysis showed that 1.96% of participants were at pre-contemplation stage, 10.46% at contemplation, 7.84% at preparation and 79.74% at action stage of change. Severity of hearing impairment and self-report hearing disability as measured via HHQ were correlated with the stages of change score, people with greater hearing impairment and self-perceived hearing disability scored significantly lower on pre-contemplation stage ($r = -0.19, p = 0.02$ and $r = -0.48, p < 0.01$, respectively) (Laplante-Levesque et al. 2013a). Participants with lower scores on the contemplation stage were significantly less likely to pursue an intervention than those with higher contemplation scores. Pre-contemplation stage was negatively associated with hearing aid outcome (HHQ), higher pre-contemplation stage score was associated with less reduction in self-report hearing disability (HHQ) for participants who did obtain hearing aids. However, the score on action stage was not significantly associated with hearing aid outcome (Laplante-Lévesque et al. 2012). It may be that some patients who were not truly ready or in action stage could have been misclassified as in action stage hence

leading to the observed lack of a significant relationship between the score on action stage and hearing aid outcome.

In a more robust and recent study, Laplante-Levesque et al. (2014a) assessed the stages of change as measured via University of Rhode Island Change Assessment Scale (URICA) (DiClemente & Hughes 1999) in 224 adults who had failed an online hearing screening test. Their results revealed that 50% of the participants were in the preparation stage of change (between contemplation and action), 38% in the contemplation stage, 9% in the pre-contemplation stage, and only 3% at action stage. The ratio of people who were classified to be in the action stage was considerably lower than what was suggested in their previous study. They concluded that as very few people were in the action stage, simply testing their hearing and informing them about their hearing impairment and the option of hearing aid is unlikely to be enough to improve help-seeking and rehabilitation rates.

6.5 Counselling and its Interpretation in the Context of Audiology

6.5.1 Recent Focus on Possible Benefits of Counselling and Motivational Interviewing in Audiology

Possible benefits of using motivational tools and application of a client-centred counselling with a focus on patients' readiness to change and motivation for hearing help have recently become a popular topic in audiological literature (Beck et al. 2007; Hogan 2010; Erdman 2009; Montano & Spitzer 2009; Saunders & Forsline 2012; Laplante-Levesque et al. 2013a; Milstein & Weinstein 2002). Since 2007, Ida institute in Denmark has organised a series of workshops and seminars for audiologists in order to promote motivational engagement and counselling strategies. They have developed several motivational enhancement tools parts of which were informed by various motivational interviewing concepts (Janis & Mann, 1977; Prochaska & DiClemente, 1986; Rollnick et al, 2008). Hogan (2010) in New Zealand has developed a self-assessment tool in order to assess patients' readiness to accept their hearing loss and motivation to deal effectively with their hearing difficulties. Erdman (2010) argued that resources and attention are disproportionately focused on advances in hearing aid technology rather than studying how hearing impairment affects the patient's quality of life and this is largely responsible for patients' failure to adhere to treatment recommendations.

Clark (2006) developed the Audiology Counselling Growth Checklist (ACGC) in order to provide a framework for audiology supervisors and students to improve patient-clinician relationship by focusing on 5 specific areas comprising: (1) the manner in which students greet the patient and open the session, (2) audiologist's clinical demeanour and style of information delivery, (3) skilfulness to affirm the worth of their patient, (4) encouraging the patient to share their stories, and (5) the manner in which they support patients to explore potential solutions to their hearing difficulties. Beck et al (2007) argued that spending a lot of time on informational counselling in order to demonstrate a need for amplification may actually alienate patients. Several authors suggested combining audiological rehabilitation with Motivational Interviewing (Milstein & Weinstein 2002; Beck et al. 2007; Perez & Edmonds 2012; Montano & Spitzer 2009). Motivational Interviewing (MI; Miller 1996; Miller 1983) is "a collaborative conversation style for strengthening a person's own motivation and commitment to change"(Miller & Rollnick 2012, p.12). As MI is rooted in the client-centred counselling method of Carl Rogers (Rogers 1959), and the client-centred counselling has been cited many times in the audiology literature, it seems reasonable to first address the role of a general client-centred counselling method in the audiology context, then move on to describing MI and its distinctive approach in promoting conversations about change.

6.5.2 What is Client-Centred Counselling?

Client-centred counselling was developed by Carl Rogers and emphasises on respecting and trusting the patient's capacity for growth, development and creativity (Rogers 1951). According to Carl Rogers, a non-authoritarian and non-directive approach by the clinician which encompasses the core counselling conditions facilitates the change process. The core conditions of client-centred counselling comprise: (1) the therapist is congruent in the relationship (In client-centred counselling, congruence means realness in a way that the counsellor is willing to be who he is), (2) the therapist is experiencing unconditional positive regard towards the client, and (3) the therapist experiences an empathic understanding of the patient's internal frame of mind (Rogers 1951; Merry 2002). A wide range of counselling micro-skills will be used throughout the process in order to (1) help the patient in establishing priorities and developing action plans, (2) explore various options and strategies as well as understand barriers and facilitators to change, and

(3) improve confidence and helping the patient to mobilise their resources and develop an achievable timetable (Egan 2013; Egan & Thompson 1975). A summary of the micro-skills used in client-centred counselling comprise: open-ended questions, silence, focusing, empathy, paraphrasing, reflecting meaning, reflecting feelings, structuring, summarising, recognising patterns & themes, self-disclosure, immediacy, challenging, timing & pacing, goal setting, decision making, and problem solving (Egan 2013; Egan & Thompson 1975; Jenkins et al. 2000).

Recent studies suggest that the application of client-centred counselling method in the audiological context is acceptable to patients and audiologists (Grenness et al. 2014a; Grenness et al. 2014b; Laplante-Levesque et al. 2014b). Grenness et al. (2014a) conducted a qualitative research and interviewed 10 hearing impaired individuals in order to assess their perspectives and expectations from patient-centred audiologic rehabilitation. Their study revealed that providing information/education was only a small factor in what participants described as being the key to the patient-centred care. The dominant theme was the therapeutic relationship. According to patients, without this relationship all other processes and tasks are likely to be inefficient or fail (Grenness et al. 2014a). Grenness et al (2014) did not fully explore this therapeutic relationship and their description was limited to a sense of trust and loyalty between audiologist and patient. However, therapeutic relationship or alliance has a central role in the client-centred counselling approach (Merry 2002). Therapeutic relationship in client centred counselling is not simply about being nice to the patient or listening to their concerns. According to Carl Rogers therapeutic alliance can be achieved through providing the core counselling conditions which are empathy, unconditional positive regard and congruence (the therapist to remain genuine, open, and honest throughout all therapeutic interactions) (Merry 2002). Wampold (2001) conducted a meta-analysis and concluded that at least 70% of psychotherapeutic effects are due to the therapeutic alliance. Therapeutic alliance includes (1) patient's affective relationship with the therapist, (2) patient's motivation and ability to accomplish working collaboratively with the therapist, (3) the therapist's empathic response, and (4) client and therapist agreement about the goals and tasks of therapy.

6.5.3 Can Non-Psychologists Use Client-Centred Counselling in Their Day-to-Day Practice?

Although achieving skilfulness in providing client-centred counselling seems to be beyond the remit of most audiology training programmes and providing 50-60 sessions of counselling is not feasible in outpatients audiology clinics, the application of counselling skills in the process of audiological rehabilitation has been recommended by many authors (English et al. 2000; Brooks & Johnson 1981). Carl Rogers himself encouraged the use of counselling skills by non-psychologists (Cain 1993). Acquiring skilfulness in using counselling skills by non-psychologists in rehabilitation, nursing, pharmacy and general medicine contexts has been studied by many authors (Bernstein 1978; Burnard 1988; Burnard 1991; Cassidy 2009; Corney 1993; Crawley 1990; Dewing et al. 2014; Dryden 1985; Gribben 2002; Jacob 2000; Jeavons 1991; Johnston & Smith 2005; Jones 1995; Keady & Williams 1998; Kokkinn & Stupans 2011; Lee et al. 2007; Maguire & Faulkner 1988; Moorhead & Winefield 1991; Pannacciulli 2012; Santos et al. 2013; Zamierowski & Gordon 1995). Use of counselling skills in order to establish therapeutic relationship and alliance has been suggested to be important especially in interventions aiming to change behaviour (Cain 1993). Many studies suggest that counselling skills can be added to the training programmes of non-psychologist health care professionals and seems to have a positive sustainable effect on their use of communication skills (Kosowicz et al. 2007). Zolnierek and Dimatteo (2009) conducted a meta-analysis in order to assess the relationship between physician's communication and patient adherence, and the effects of communication training on adherence to treatment regimens for various medical conditions. Their meta-analysis included 106 studies assessing correlation between patient adherence and communication skills of the physician and 21 studies on relationship between training in communication skill and patients' adherence. Their results revealed that (1) patient adherence is 2.16 times higher if a physician used effective communication skills ($p < 0.001$), and (2) training physicians in communication skills results in substantial improvements in patient's adherence ($p < 0.001$), the odds of adherence are 1.62 times higher for those patients seen by a physician with communication training than when a physician received no training.

6.5.4 Client-Centred Counselling in Audiology

Several authors addressed the need for the application of client-centred counselling skills in aural rehabilitation (Dahl et al. 1998; Laplante-Levesque et al. 2006; Ventura 1978; English & Archbold 2014; English et al. 1999; English et al. 2007; McCarthy et al. 1986; Nair & Cienkowski 2010; Searchfield et al. 2010; Stone & Olswang 1989). Despite this, there seems to be a gap in audiology training programmes and audiologists often rely on providing technical information in response to patient's emotional reactions to the psychosocial aspects of living with their hearing impairment (English et al. 1999). Audiology programmes focus more on technological aspects of hearing aids and diagnostic procedures while patient-centred counselling aspects of service delivery often are not emphasised or ignored. Clark (2006) wrote "The person-centred practice of audiology has often taken a backseat to the more mechanical administration and interpretation of diagnostic measures and the electroacoustics of hearing instrumentation" (p.116). However, more recently there seems to be a shift towards patient-centeredness as evidenced by inclusion of counselling modules to most of the audiology training programmes in the UK and USA (English et al. 2007). The extent to which patient-centeredness occurs in routine audiology clinics is a question which needs to be investigated further (Grenness et al. 2014b). It is not uncommon for audiologists to feel unprepared to utilize client-centred counselling strategies. Often due to the organisational processes and requirements, audiologists have to work with a pre-set agenda and strict time schedules for each appointment and play the dominant role in decision making (English et al. 2000; Grenness et al. 2014b). This is not consistent with client-centred counselling approach.

6.5.5 Interpretation of Counselling in Audiology

It seems that there is a discrepancy between audiologists' perception of counselling and the client-centred counselling approach. In many audiology textbooks and research papers, counselling is described as explaining and providing technical information to patient (English et al. 2000). However, in the context of a client-centred approach, counselling is a process that should allow the patient, not the clinician, to talk about their concerns and emotions. The counsellor should use empathic listening skills to help the patient explore their feelings and support them

in finding their own insight and solutions to the problem (Merry 2002). Unlike the concept in audiology, counsellors commonly do not give advice as their underpinning theoretical stand emphasises that the solution to the problem lies within the patient. Their role is to trust the patient, promote self-realisation, and help them find their own solutions. For example it is the patient, not the therapist, that should come up with a solution on how they might go about using their hearing aids.

However, it is not an uncommon perception that audiologists should “counsel” by providing further education to patients about hearing loss and how hearing aid might help, and also to stress the negative consequences of not using hearing aids. In what follows several examples of the discrepancy between the audiology interpretation of counselling and the counselling definition are provided.

In a hearing aid textbook the importance of incorporating counselling in aural rehabilitation has been emphasised but the authors interpreted counselling as an educational session where the hearing aid user could easily understand the information using visual or auditory presentations and a demonstration of the information (Dillon 2001). Chisolm et al. (2004) discussed that some approaches to audiological rehabilitation focus on listening training and others attempt to support the individual with hearing impairment through discussion and education in a more counselling-oriented paradigm. According to them, counselling oriented programmes should cover two areas: (1) information and (2) personal adjustment. They wrote “The information aspect helps create an informed patient by providing education about areas such as” (Chisolm et al. 2004). They acknowledged that because adult-onset hearing impairment elicits grieving and other emotional reactions the personal adjustment aspect of the counselling programmes, are vital too. However, they failed to include application of client-centred counselling strategies to address the personal adjustment aspect instead they wrote “ Specific approaches used to enhance personal adjustment include attention to (1) problem-solving techniques, (2) coping strategies; and (3) assertiveness tactics.(Chisolm et al. 2004)” . In the other words, in order to help the individual cope with grieving and psychosocial aspect of their hearing impairment they suggested more education on behavioural coping techniques (e.g., problem solving and assertiveness). Missing the true nature of counselling has hampered the value of the counselling-oriented audiological rehabilitation (AR) programme they developed which in fact did not

include any counselling component rather focused on additional education and instructions to patients (Chisolm et al. 2004). Their programme did not have any additional benefit with regard to hearing aid use and outcome (Chisolm et al. 2004).

Vuorialho et al. (2006a) interpreted counselling as providing additional education on using and handling hearing aids. They wrote “The home counselling was in addition to the routine counselling which was included in the hearing aid fitting, and it focused on noticed deficiencies in using and handling the hearing aids. The interviewer visited each hearing aid user to counsel and instruct them on how to use their hearing aids...” (p.990).

Nair and Cienkowski (2010) wrote: “out of 35 adults with hearing impairment, who were surveyed shortly after they had an audiological examination and received counselling, none knew what an audiogram was” (p.71) and “...the patient that cannot clearly understand the counselling or the hearing aid instruction guide..”(p.74). Their interpretation of counselling was in fact providing technical information about the patient’s audiogram and their hearing status. Saunders and Forsline (2012) assessed the effect of different forms of hearing aid counselling on self-perceived hearing disability and handicap. Their interpretation of counselling was again providing information and education. They wrote “ One form of counselling focused on providing information to participants.....The other, referred to as performance perceptual counselling, focused on discussion of the participants performance perceptual discrepancy, its implications, and ideas for more closely aligning perceived and measured hearing ability [educating patient] (p.755; Saunders & Forsline 2012)”.

The notion that counselling means educating is not limited to the counselling provided for hard of hearing individuals but also extends to the services that audiologists offer for other auditory disturbances namely tinnitus. Despite the established links between tinnitus and emotional disturbances (Bartels et al. 2010; Blaesing & Kroener-Herwig 2012; Hesser & Andersson 2009; Udipi et al. 2013), the key component in tinnitus management used by audiologists is to provide education to patients and they call it counselling. Aazh et al. (2008a) wrote that “counselling [for patients suffering from tinnitus] was based on explanation of the nature of tinnitus and how to manage it. Its aims were: (1) to reassure patients that

the annoyance from tinnitus would gradually reduce with the passage of time following the natural process of habituation; (2) to inform them that reduction in annoyance and distress caused by the tinnitus would promote habituation to the tinnitus and reduction of the tinnitus itself; (3) in cases of tinnitus combined with hearing loss to explain that if they could not hear properly, this was most likely because of their hearing loss and not the tinnitus; and (4) to advise them to avoid silence by using sound enrichment” (p.2). Henry et al. (2006) wrote “TM [tinnitus masking] patients receive counselling that focuses mainly on effective use of sound for providing a sense of immediate relief from the tinnitus. Depending on the patient’s particular set of tinnitus related problems, counselling can also include (1) providing reassurance to allay fears concerning the potential health/psychological ramifications of their tinnitus; (2) basic principles for preventing exacerbation of their tinnitus; (3) hearing loss and its relation to tinnitus; and (4) reducing stress in their lives” (p.108). Jastreboff and Hazell (2004) wrote “Counselling for tinnitus retraining therapy has a special meaning. It involves the teaching of the neurophysiological model, tailoring the explanation to the precise needs of an individual patient” (p.85).

This method of counselling is sometimes called “informational counselling” (English et al. 2000).

6.5.6 Informational Counselling and Mismatch in Communication

Informational counselling is about educating people. It is not about providing counselling in the way described in the psychological literature. Although informational counselling/education is a fundamental component in aural rehabilitation, it may only be effective for patients who are seeking information. English et al. (2000) described that an accurate technical response is warranted when a patient seeks information and advice from their audiologist. For instance when the patient asks “How long will these batteries last?” or “When should I use a directional programme in my hearing aids?” or “How do I clean these?”, the audiologist should provide the appropriate information. On the other hand, if the patient is not ready to accept their hearing loss due to grieving (Tanner 1980), denial (Herbst & Humphrey 1980), sorrow and depression (Martin et al. 1987), vulnerability and confusion (Luterman 1999), hostility toward authority figures

(Clark 1990), or other factors then providing information on benefits of hearing aids is often worthless and it may even provoke resistance. Simply telling people what to do and what not to do is likely to produce negative response from people, which then may be interpreted by the practitioner as denial or resistance to change (Rollnick et al, 2005). English et al. (1999) provided an example of how a mismatch in communication can occur between the parents of a recently diagnosed hard of hearing child and their audiologist. In their scenario, parents expressed their emotional concerns that “*their family is depressed about the recent diagnosis of their daughter’s hearing loss*” but they were faced by the technical comments from their audiologist that “*children with similar type of hearing loss do relatively well in academics*”. In this scenario the audiologist provided a technical information to a nontechnical comment which resulted in the parents walking away with the impression that their audiologist did not understand or did not care about the family concerns (English et al. 1999). Providing technical information in response to people’s non-technical comments may convey to the patient that their audiologist is maintaining an uncaring professional distance instead of making a genuine and caring contact with them. Other authors called this “well-intended pep talks” (Clarke 1990) or “wearing an expert mantle” (Beazely & Moore 1995). Other examples of patient’s affective comments which do not necessarily warrant a technical response comprise “I am not wearing these hearing aids anymore; they make me look ugly and stupid” or “I can’t show up at work with hearing aids; my boss will think I am not a good worker” (English et al. 2000). Application of client-centred counselling skills can help the patients to talk about their concerns and feel that somebody understands them. This can improve patient-clinician relationship which will put the audiologist in a better position to engage with the patient and support them using their expert knowledge and skills when indicated. To achieve this, audiologists would need to gain skilfulness in the use of counselling skills and attitudes.

6.5.7 Learning Counselling Skills for Audiologists

There have been several studies investigating audiologist’s counselling skills and the effect of providing complementary counselling training courses. English et al. (1999) conducted a small study in order to assess (1) whether audiology students provide technical information to patient’s expressions of psychosocial aspects of hearing loss, and (2) whether this communication mismatch would change after

attending a counselling training course. Fourteen graduate audiology students took part in their study and enrolled in a counselling course in the fall semester of their third year in an audiology doctorate (AuD) programme. Student's ability to recognise and respond appropriately to expressions of personal adjustment concerns was assessed before and after the course via a written exam. Their results revealed that 88% of the audiologist's responses (pre-course) to expressions of psychosocial aspects of hearing loss were technical. After the course a considerable change was noted in the number of affective responses from audiologists given to affective comments from patients (English et al. 1999). However, apart from the small study sample size this study also didn't include a control group hence it is not clear whether the changes observed were linked to the counselling course provided. In another study English et al. (2000) assigned 23 MSc level audiology students to a distance learning counselling programme and 10 students to no intervention. The counselling programme aimed to facilitate reflective listening and to learn to differentiate the intent of a patient's communication and to match their response accordingly. Pre-course assessment of audiologist's counselling skills using a written exam showed that 85% of responses to affective statements were predominantly technical. For post-course exam, only 12% of responses in students enrolled in the course were technical responses and affective responses increased to 64%. No change was observed in the control group. A shortcoming of this study was their outcome measurement procedure. Their outcome measure was via a written exam which could only have assessed the students' knowledge of counselling skills not the actual skills in practice. A better way of evaluating the clinician is through an independent observation of a video or audio recording of the clinician with simulated or standardized patients and rating their counselling skills against a predefined criteria (Bowyer et al. 2010; Okuda et al. 2009; Rosenbaum et al. 2004). English et al. (2007) developed an assessment tool which could be used by an independent assessor in order to rate the videotaped audiologist's counselling skills. This was called Audiologic Counselling Evaluation (ACE) which was an adaptation of "Breaking bad news Assessment Schedule" designed by Miller et al. (1999). ACE consisted of 22 items which mostly focused on capturing client-centred counselling skills of the clinician (e.g., whether the clinician makes the patient comfortable, uses active listening, asks open questions, offers reflections, makes sure that the patient understands the key information, acknowledges the patient's feeling and concerns,

helps the patient to express their concerns freely, gives choice, conveys empathy, compassion and sense of hope, uses supportive body language, and tailors the session to the patient's need). Although this method showed good internal reliability (Cronbach's alpha = 0.91) and good inter-rater reliability ($K=0.61$) (English et al. 2007). To the author's knowledge, it hasn't been used in any published research so far. In a recent study, English and Archbold (2014) assessed the effect of a 20-hours counselling programme from the participants' perspectives (n=20 audiologists). In their study the key component of the patient-centred counselling skills was described as the ability to elicit patient's concerns and expectations and to respond to these empathically. Participating audiologists reported that they used the counselling skills learned in the programme and they believed the skills learned helped them make positive changes in patient-clinician dynamics. However, the researchers relied on qualitative analysis of the responses provided by the audiologists about the effect of the counselling programme and did not objectively measure their counselling skills with an instrument like ACE (English et al. 2007) which they had developed earlier.

There seems to be a great appetite among audiologists for combining patient-centred care with audiological activities. A survey conducted among audiologists in Australia (n=715) using a modified version of Patient-Practitioner Orientation Scale (Krupat et al. 2000), revealed that audiologists understand the value of patient-centred interactions, however the preference for patient-centeredness was stronger in older and more experienced audiologists compared to their younger and less experienced peers (Laplante-Levesque et al. 2014b). This result suggests that audiologists seem to learn the value of the client-centred approach as they become more experienced in their clinical practice not necessarily through their formal audiology trainings. This is consistent with several authors who reported that counselling skills often are not adequately addressed in graduate audiology training programs (English et al. 2000; Erler & Garstecki 2002). A recent review by Grenness et al. (2014b) revealed that although patient-centred approach is in line with the aims and scope of practice for audiological rehabilitation, it hasn't been given enough attention and there is a need for research to explore its role in audiological rehabilitation.

6.5.8 Client-Centred Counselling, Informational Counselling or Motivational Interviewing: Which is a Better Fit?

In summary, (1) the application of the client-centred counselling skills could be helpful in the process of audiological rehabilitation by strengthening the patient-clinician relationship (Clark 2006; Wampold et al. 2007), (2) audiologists often use their technical knowledge and skills in order to facilitate hearing aid use and do not routinely employ client-centred counselling skills (English 2010; English et al. 1999; English et al. 2000), (3) audiologists and patients appreciate the value of a client-centred counselling approach (Grenness et al. 2014a; Grenness et al. 2014b; Laplante-Levesque et al. 2014b), and (4) complimentary training in counselling skills can help audiologists to gain the appropriate knowledge about counselling, although there is lack of empirical evidence on the effect of such training programmes on the actual counselling skills of audiologists as measured via an independent assessor (English & Archbold 2014; English et al. 1999; English et al. 2007; English et al. 2000).

Despite the potential benefits of employing client-centred-counselling approach in audiology, there is a lack of empirical evidence on the effect of such an approach on facilitating hearing aid use. Moreover, it is not clear how client-centred counselling skills can be integrated with audiological tasks.

In a client-centred approach the clinician should listen empathically to the patient's concerns and follow their story and seek to be supportive. According to Carl Rogers this helps the patient to better realise what they are experiencing and explore their feelings which in time will facilitate process of change (Rogers 1951). In a client-centred approach, the clinician does not attempt to direct the conversation toward change and only reflect and focus on that when it is raised by the patient. The attitude in client-centred counselling is "I won't change or push you. I trust your wisdom about yourself, and I will let you work this out in your own time and at your own pace"(p.14; Rollnick et al. 2008). In audiology clinics, this style of non-directive counselling may not be practical because (1) the sessions may deviate from the topic of hearing aids and aural rehabilitation, and (2) audiologists are often under time constraints and need to perform certain specialist tasks with regard to the technical aspects of the hearing aids, providing education and instructions. Suppose

that you have a patient who doesn't use his hearing aids and complains about the quality of sound and the loudness of the background noises. He also mentions that he doesn't like people to find out that he is using hearing aids. You have adjusted his hearing aids several times but you have a clear professional opinion to what he should do (i.e., he should use his hearing aids on regular basis to get used to them). One option is to offer your straightforward advice as an audiologist. But suppose that you already have done this and you told him several times that he would need to use his hearing aids consistently. Unfortunately this didn't make any difference. He simply doesn't seem to be ready to accept that he needs to use hearing aids. A second option is to use client-centred counselling style. You don't offer any advice. Rather you try to be an understanding professional on this journey that is clearly his to make. The journey is from denying the need to use hearing aids and avoiding social situations to acceptance of his hearing loss and consistent use of his hearing aids in order to improve his quality of life. Although a brief period of this style of counselling maybe beneficial to help you to understand your patient's perceptions of his hearing impairment and how these fit into the bigger picture of his life, there wouldn't be any focus on promoting consistent use of hearing aids and the problem he hired you to solve for him "the poor quality of sound and the loudness of the background noises" may persist for many years to come. Because if he doesn't use his hearing aids consistently, he wouldn't get used to the sound of it no matter what adjustment you make. Motivational interviewing (MI) is the third approach that goes down the middle ground between the other two and combines some of the better qualities of both (Rollnick et al. 2008). In MI you take a guiding style and you listen empathically to patient's concerns. Then you maintain the focus of the session by asking questions and reflecting on patient's own ideas about his need, desire, reasons, and ability to use hearing aids on regular basis. Here or there you may also offer a bit of your specialist knowledge on hearing impairment and how people use hearing aids, recognising and honouring that ultimately it is his life and his decision to make. In the next section more details about MI is discussed.

6.6 Motivational Interviewing

6.6.1 Principles of Motivational Interviewing

Motivational Interviewing (MI; Miller 1996; Miller 1983) is “a collaborative conversation style for strengthening a person’s own motivation and commitment to change”(Miller & Rollnick 2012, p.12). MI is rooted in the client-centred counselling method of Carl Rogers (Rogers 1959) and gives great importance to understanding of patient’s internal frame of mind and exhibiting unconditional positive regard (Miller & Baca 1983; Miller & Rose 2009). However, unlike Rogerian client-centred style where the counsellor follows the patient’s lead in a truly non-directive form and perhaps over time the counsellor moves toward clearer goals for change when they are raised by the patient, MI applies a guiding style of counselling where direction of the session is influenced by both patient and therapist in a collaborative way (Miller & Rollnick 2012). In MI it is important to encourage the patient to explore and verbalise their reasons, need, desire and ability to change (e.g., use hearing aids regularly), as opposed to lecturing and giving them information and advice about benefits of change, or arguing about negative consequences of not making the change (Miller & Rollnick 2002). In MI, the clinician responds deferentially to the patient’s speech and the efforts are focused on evoking and strengthening the patient’s verbalised motivations and desires to change, which are called the “change talk”. The guiding style of MI, as opposed to the directive style of “informational counselling” on one end of the spectrum and to the “following style” of Carl Rogers’s client-centred counselling at the other end, helps the patient to voice the argument for change. The idea is that hearing oneself to argue for change promotes change but feeling of being pushed and confronted evokes further defence of the status quo. Providing lots of education and advice, when the patient is not ready or hasn’t asked for it, can be perceived as being pushed to do something that they may not be ready for. Providing education about hearing impairment and benefits of hearing aids is very common in audiology practice. This is an absolutely essential element of the audiology service for people who are ready to use hearing aids or are contemplating the idea of obtaining hearing aids. However, for those who are less ready to accept the need for hearing aids or are ambivalent, providing information may provoke resistance. Patients may feel that their side of story hasn’t been heard.

According to MI no one is completely unmotivated for change but they may be ambivalent. Ambivalence is a state of uncertainty and people can stay in that state for a long time (Rollnick et al. 2008). People have reasons and desires for change as well as for the status quo. In MI it is important to encourage the patient to explore and verbalise their own reasons, need, desire and ability to change (e.g. to using hearing aids regularly) as well as their defence for the status quo (Miller & Rose 2009). The therapist will emphatically reflect on both patient's reasons for the current behaviour and their reasons for change. However, MI is directive in a way that the therapist deliberately gives more emphasis to the change talk and helps the patient to further explore their aspirations for change and strengthen their commitment for change. This is different from the truly non-directive method of Carl Rogers on the one hand, and from lecturing and giving them information and advice about benefits of change, or arguing about negative consequences of not making the change on the other (Miller & Rollnick 2002).

6.6.2 Key Components of MI

The key elements of MI are partnership, acceptance, compassion, and evocation (Miller & Rollnick 2012). Partnership refers to collaboration and power sharing between therapist and the patient in such a way that a patient's ideas are valued and influence the direction of the session. This is in contrast to a clinician assuming the expert role and prescribing a treatment. Acceptance or unconditional positive regard which is embedded in MI is a key concept developed by Carl Rogers and involves (1) prizing the inherent worth and potential of every human being, (2) understanding another's internal perspective, (3) honouring their autonomy, right and capacity for self-direction, (4) seeking and acknowledging the person's strengths and efforts (Miller & Rollnick 2012; Rogers 1962; Rogers 1980). Compassion is to actively promote the other's welfare and give priority to other's needs. Evocation in MI refers to actively helping the patient to explore and verbalise their own reasons for change and ideas about how change should happen. This is in contrast with educating the patient about change without paying attention to what they already know or have achieved so far (Miller & Rollnick 2012).

MI involves a flexible and strategic application of some core communications and counselling skills (Miller & Rollnick 2012) including: open questions, affirmation,

reflective listening, summarizing, and finally informing and advising with patient's permission. Use of open-ended questions, as opposed to closed-ended, invites the patient to reflect before responding and gives them freedom of how to answer (e.g., *How have you been coping with your hearing difficulties?* [Open question], *Did you use your hearing aids last week?* [Closed question]). Affirmation recognises, acknowledges and supports a patient's strengths and efforts (e.g., *You are doing your best. I know it is hard to use hearing aids in noisy environments*). Reflective listening is communicating to the patient your understanding of what they meant. It can vary in depth from simple repetition or slightly rephrasing what they said to complex reflections where you add some meaning and guesses about unspoken content (e.g., Patient: *I feel that I don't need a hearing aid.* Clinician: *Your hearing is good enough.* [Simple reflection], Patient: *My hearing aid doesn't really help me in noisy environment. That's why I don't use it.* Clinician: *You feel disappointed about your hearing aid. It seems to be just an extra burden.* [Complex reflection]). Summarising is producing reflections that combine several things that the person has said (Miller & Rollnick 2012).

Although MI is an intervention which has emerged from reflecting on clinical practice by William Miller, its conceptual approach seems to be consistent with several psychological theories comprising formulation of cognitive dissonance (Festinger 1957), reformulation of self-perception theory (Bem 1967), and Roger's theory of necessary and sufficient interpersonal conditions for fostering change (Rogers 1959) (Miller & Rose 2009). In addition, MI conceptually fits well with the transtheoretical (stage of change) model proposed by (Prochaska & DiClemente 1986). The transtheoretical model postulated that the individual moves through a series of stages in the process of changing behaviour from being unwilling or unaware to make a change (pre contemplation stage), to considering a change (contemplation stage), and to deciding and preparing to make a change (preparation and action stages) (McConaughy et al. 1983). Most of the health and lifestyle behaviour change interventions (e.g., smoking cessation, cognitive behaviour therapy, family planning, encouraging regular use of hearing aids, etc.) seems to be designed for people who are ready for change (action stage), not for those who are at the earlier stages (pre-contemplation, contemplation, and preparation). In contrast, it seems that MI can be more helpful for individuals who are not ready for change (pre

contemplation and contemplation stages) but when people take definitive action to change then MI may not add any additional benefit to other interventions (Project MATCH Research Group 1997; Rohsenow et al. 2004; Stotts et al. 2001).

The contrast between application of the stages of change model in audiological practice as described by Babeu et al. (2004) and MI is the fact that MI is less reliant on providing information. In MI, the clinician elicits or evokes patient's own argument for change by asking open questions and offering reflections (Rollnick et al. 1992). Providing information at the right time, when the patient is ready, is an important part of MI too. In MI the clinician should pay attention to patient's readiness to receive information, provide information with patient's permission in a neutral way, and more importantly invite the patient's reaction to the information provided with the use of open questions (e.g., what do you make of this?) (Rollnick et al. 1992).

More details on practical aspects of MI as well as a real example of an MI session for facilitating hearing aid use is provided later in the following sections. MI is one of the most researched psychological interventions. A simple search of Pubmed on 22/12/2014 of motivational interviewing [in title] revealed 754 papers published since 1996 which means 40 papers per year. Below a brief review of the evidence base for MI is provided.

6.6.3 Evidence-Base for MI

There are over 200 RCTs on the effects of MI on a wide array of problems. Several systematic reviews and meta-analyses support efficacy of MI on adherence to long-term treatments and promoting behaviour change in management of alcohol abuse, addiction, weight loss, diabetes, physical activity, and smoking cessation (Rubak et al. 2005; Lai et al. 2010). Rubak et al. (2005) included 72 RCTs assessing effectiveness of MI on a broad range of behavioural problems in their review. 74% of the RCTs reported an effect of MI with no report of any adverse effect related to MI. 94% of the RCTs used one-to-one MI sessions with median duration of MI sessions of 60 minutes (range between 10 and 120 minutes). The likelihood of an effect rose with the number of encounters. In 55% of RCTs the health providers who delivered MI were psychologist, 30% were doctors, and 15% were nurses and other health care professionals. MI delivered by medical doctors achieved an effect in

83% of the RCTs, psychologists 79%, and other health care professionals 46% of the RCTs. They concluded that MI effectively help patients change their behaviour and outperforms traditional advice giving in approximately 80% of the RCTs (Rubak et al. 2005). Lundahl et al. (2013) conducted a systematic review and meta-analysis to investigate MI's efficacy in encouraging people to make behavioural changes to improve health outcomes. They included 48 studies in their review. The overall effect size of MI was statistically significant with an odds ratio of 1.55 (CI: 1.40-1.71) $p < .001$. Foxcroft et al. (2014) conducted a Cochrane review assessing effect of MI on alcohol abuse in young adults. 66 RCTs were included to their review. The meta analysis revealed that the effect size for the quantity of alcohol consumed at 4 month (or more) follow up was -0.14 (95% CI= -0.20 to -0.08) or a reduction from 13.7 drinks per week to 12.2 drinks per week. Effect size for frequency of alcohol consumption was -0.11 (95% CI -0.19 to -0.03) and for peak blood alcohol concentration was -0.14 (95% CI -0.23 to -0.05). No effects were found for binge drinking. The quality of RCTs assessed for the above outcomes were classified to have moderate quality according to the Cochrane criteria (Foxcroft et al. 2014). Consistent with this the results of the systematic review conducted by Appiah-Brempong et al. (2014) suggested that MI was effective in reducing alcohol consumption among college students, when compared to alternative interventions or no intervention. They also reported that practitioner's adherence to MI techniques and the individual's drinking motives seemed to be the moderating factors related to the treatment effect. Easthall et al. (2013) conducted a systematic review and meta-analysis of interventions to improve medication adherence. They included 26 RCTs in the meta-analysis. The intervention most commonly used in the included RCTs was MI (11 out of 26), other studies used a combination of techniques relevant to cognitive behaviour therapy and counselling. The pooled effect size for all 26 RCTs was 0.34 (95% CI: 0.23 to 0.46, $p < 0.001$). Subgroup analysis did not show any significant interaction related to intervention type.

In a Cochrane review on theory-based interventions for contraception 4 RCTs assessing effect of MI were included (Lopez et al. 2013; Lopez et al. 2011). They reported that 2 out 4 RCTs showed that compared to a control group with minimal information, the MI group described less 'ineffective contraception' and more 'effective contraception'. Gao et al. (2014) conducted a systematic review in order to

appraise the evidence on the effectiveness of MI compared with conventional health education in improving oral health. They included 16 RCTs to their review. 5 out of 7 RCTs concerning periodontal health, showed superior effect of MI on oral hygiene compared to conventional health education. Their results also showed that MI outperformed education in improving at least one outcome in four RCTs on preventing early childhood caries, and in one RCT on adherence to dental appointments.

O'Halloran et al. (2014) conducted a systematic review and meta-analysis in order to determine whether MI leads to increased physical activity in people with chronic health conditions. They included 11 RCTs to their review. Their result showed that MI had a significant effect in increasing physical activity levels in people with chronic health conditions relative to comparison groups, the effect size was 0.19 (95% CI 0.06 to 0.32, $p = 0.004$).

There are also some studies which show no additional benefit from MI compared with standard care or other active treatments (Carroll et al. 2006; Ball et al. 2007; Mbuagbaw et al. 2012). A Cochrane review on the effect of MI for improving outcomes in youth living with HIV showed that although the 2 RCTs included to their review reported reductions in viral load and unprotected sexual acts, no significant effect was reported on adherence to HIV medication, mortality or quality of life (Mbuagbaw et al. 2012).

MI is designed as a brief intervention, with typically 1 to 4 sessions, and it has successfully been used as a stand-alone treatment as well as in combination with other active treatments to enhance patients' outcomes and adherence (Campbell et al. 2009; Heffner et al. 2010).

Cognitive behavioural therapy (CBT; Hawton et al, 1989) is also likely to be of benefit in motivating people to change their behaviour. There are several well-controlled studies supporting the benefit of CBT in promoting behaviour change (McD Young et al, 2010) as well as treatment adherence (Safren et al, 2009). Garnefski and Kraaij (2012b) conducted an RCT in order to assess the effect of a CBT self-help programme on symptoms of depression and anxiety in people with severe to profound acquired hearing loss. Their result revealed that patients who received CBT had larger improvement in anxiety and depression scores in

comparison with participants in waiting list control group. However, they did not include any hearing aid measures hence it is impossible to know whether self-help CBT improves hearing aid use or HRQoL in hearing impaired individuals. Although CBT is effective in identifying unhelpful thoughts and feelings and promoting behaviour change, it too suffers from the issue of non-adherence (Alvarez-Jiménez et al, 2009). In fact, some investigators used MI in order to motivate patients to fully engage in CBT and reported promising results (Parsons et al, 2005; Meyer et al, 2010). Moreover, CBT can take about 10 to 12 sessions which may not be feasible in busy hearing aid clinics. However, MI is typically provided as a brief intervention, with 1 to 4 sessions (Burke et al, 2003), which seems to be more suitable as a supplementary intervention to amplification.

To the author's knowledge there is no published trial on assessment of MI in facilitating hearing aid use. However, several authors in the field of audiology studied the benefits of applying various audiologic rehabilitation programmes in facilitating hearing aid use and improving HRQoL of hearing impaired individuals. These will be discussed in the next section.

6.7 Evidence-Base for Audiologic Rehabilitation

In the last decade, several authors have studied the efficacy of various audiologic rehabilitation (AR) programmes in facilitating hearing aid use and improving HRQoL of hearing impaired individuals (Kramer et al. 2005; Hickson et al. 2007; Preminger & Yoo 2010; Lundberg et al. 2011; Thoren et al. 2011; Saunders & Forsline 2012; Abrams et al. 2002; Chisolm et al. 2004; Hawkins 2005; Barker et al. 2014).

In addition, there are 2 systematic reviews (one of them is a 2014 Cochrane review), that examined the studies that assess efficacy of various AR programmes (Barker et al. 2014; Hawkins 2005). As a part of this PhD thesis, the author originally planned to conduct a systematic review on this topic. However, as the recent Cochrane review by (Barker et al. 2014) has addressed the same topic the author decided not to proceed with the systematic review. Instead in this section some of the key RCTs assessing effect of AR programmes on hearing aid outcomes as well as the 2 systematic/Cochrane reviews are critically discussed. These critical analyses helped

to contextualise and guide the formulation of the research questions and the design of the studies involved in this PhD project.

6.7.1 Hawkins (2005)

Hawkins (2005) conducted a systematic review of the literature regarding the effectiveness of counselling and communication strategy-oriented AR programs. He focused his search on AR programmes which are implemented through group settings. Providing AR programmes in group setting is mainly due to limitations in resources as well as some beneficial factors related to group dynamics. Participation in group AR helps the individuals share their feelings, problems, and solutions with one another. Group AR can help people deal with the stigma and the loss of social identity associated with hearing loss, and is potentially an ideal forum for learning and practising communication strategies (Preminger 2007). The question of the systematic review was: “Do adult group AR interventions that focus on counselling and communication strategies provide measurable benefits over the short or long term in benefit/satisfaction with hearing aids, adjustment to hearing loss, or perceived hearing handicap?”

Their search strategy identified 22 papers. Twelve papers met the inclusion criteria. Hawkins (2005) reported that the majority of studies that he reviewed showed some reduction in the perception of hearing handicap as a result of being in an AR group. However, not all studies found that result, and the effect was not always large. Moreover, he reported that the findings of improved use of communication strategies, enhanced personal adjustment, and better use of hearing aids were not well documented or replicated in the included studies to his review. Therefore Hawkins (2005) argued that drawing a firm conclusion regarding effectiveness of AR was not possible due to the lack of well designed trials. He explained that the AR programmes probably allow the patient to deal with their hearing handicap better, but not necessarily reduce the hearing handicap or disability beyond the amplification component; hence the impact of AR plus amplification on disability and handicap measures was not significantly different from those of amplification alone.

6.7.2 Abrams et al. (2002)

Abrams et al. (2002) conducted an RCT in order to evaluate additional benefits of combining AR programme with provision of hearing aids in a veteran hospital. The idea was that AR may improve hearing aid use and satisfaction which eventually could lead to better health-related quality of life. Fifty two patients were assigned to receive hearing aid only and 53 patients were assigned to hearing aid plus AR (HA+AR). They used 36-item Short-Form Health Survey modified for veteran population (SF-36V) as their outcome measurement tool. This is a multi-item scale that measures 8 general health concepts in 2 major domains of mental and physical functioning (Ware & Sherbourne 1992).

All patients were fitted with hearing aids and provided with a routine hearing aid orientation. Participants in intervention group then returned once a week for 4 weeks for a 2-hours group meeting. The meetings covered (1) education on hearing system and communication strategies, (2) improving communication in adverse listening conditions, (3) anticipatory strategies, repair strategies, and environmental management, and (4) telephone communication and resources for hard of hearing people. Two weeks after the end of the AR group programme all participants completed SF-36V.

Their results revealed that use of hearing aids (with or without additional AR programme) resulted in significant improvements in the mental health domain of SF-36V. The improvement in the mean score of the mental domain of SF-36V for patients in HA+AR was 3.0 points while the mean change for HA only participants was 1.4 points. However, the difference between the intervention and control groups failed to reach statistical significance. Their study didn't seem to have enough statistical power to detect small or medium effect sizes (e.g., between 0.2 and 0.5 (Cohen 1988)) which are typically anticipated to be achieved for psychosocial interventions. Therefore it is possible that due to the small sample size and type II error, Abrams et al. (2002) failed to reject the null hypothesis. Another limitation of this study is that a veteran population was used which may be different from the general population, reducing the external validity of their results.

6.7.3 Chisolm et al. (2004)

Chisolm et al. (2004) conducted an RCT on 106 people with adult-onset hearing loss. Intervention group received hearing aids and AR (HA+AR) and people in the control group received hearing aid with no additional AR (HA only). Patients in both groups were fitted with hearing aid(s) as required and provided with routine hearing aid orientation information with regard to hearing aid use, troubleshooting techniques, battery ordering, and what to expect during the hearing aid adjustment period. Patients in the AR group returned once per week, for 4 weeks, for 2 hours group meetings (total 8 hours of AR intervention). AR sessions comprised providing education on 1) basic anatomy and physiology of the auditory system, 2) improving communication in adverse listening conditions, including a focus on the use of visual cues and listening strategies, 3) practice in the areas of anticipatory strategies, repair strategy usage, and environmental management, and 4) telephone communication strategies, use of assistive technology, and community resources for the hard of hearing.

Participants in the AR and control groups were assessed 2, 6 and 12 months after fitting. They used the Communication Profile for Hearing Impaired (CPHI; Demorest & Erdman 1987) as their outcome measurement tool.

Their results showed that hearing aid use improved CPHI scores 2 months after fitting and this effect was maintained over the period of one year. However there were no additional benefit from participation in the AR program as the general linear model analyses on the data showed that the main effect of group, AR+HA vs. HA only, was not significant. In this study the authors did not investigate the difference in the amount of hearing aid use between the two groups.

Although addition of the AR programme did not make any statistically significant difference in the scale scores of CPHI (i.e., Communication Importance, Communication Performance, Communication Environment, Communication Strategies and Personal Adjustments), it did improve subscale scores for Communication Strategies scale. Communication Strategies scale comprises 3 subscales: (1) maladaptive behaviours, (2) verbal strategies, and (3) non-verbal strategies. No group effect for maladaptive behaviours was observed. However, statistically significant increases were found for the two scales of verbal strategies

and non-verbal strategies from pre-intervention to 2 and 6 months post intervention intervals for the AR group only. Verbal strategies refer to use of assertive behaviours, informing others of hearing problems, and asking for cooperation. Non-verbal strategies refer to use of visual cues, positioning oneself where their good ear face the speaker, lip reading, etc (Demorest & Erdman 1986). This result means that people who received further education and practice on the use of communication strategies through the AR programme in comparison with HA only reported a higher usage of these techniques. However, enhanced use of communication strategies in the AR group didn't seem to improve communication performance or personal adjustment scales.

Although the AR programme was designed to help patients overcome their activity limitations and participation restrictions (Chisolm et al. 2004), the interventions were mainly focused on providing technical education rather than addressing emotional and psycho-social aspects of deafness and hearing aid use through counselling. The authors focused on creating "informed patients" by providing education but with respect to the emotional support they only relied on the group dynamics (e.g., patients may receive emotional support from one another who share similar feelings). They did not provide client-centred counselling or any form of psychological support. In the other words, it seems that the content of intervention in this study was not consistent with the majority of its goals. Therefore, it is not surprising that it failed to show any additional benefit to amplification on CPHI questionnaire. The instrument used for the outcome measure, CPHI, included items assessing communication performance at work, home, average conditions, adverse conditions and problem awareness. CPHI did include factors related to personal adjustment which comprised self-acceptance, acceptance of loss, anger, displacement of responsibility, exaggeration of responsibility, discouragement, stress, withdrawal, and denial. However, it is not clear how these educational sessions could have modified self adjustment items (i.e., self-acceptance, acceptance of loss, anger, displacement of responsibility, exaggeration of responsibility, discouragement, stress, withdrawal, and denial).

To sum up, this study had relevant aims for AR, applied robust research methodology, and used a relevant validated outcome measurement tool. However the application of an AR programme which heavily relied on providing additional

education to patients didn't seem to be capable of improving emotional aspects of living with hearing impairment.

6.7.4 Kramer et al. (2005)

Kramer et al. (2005) developed a home education programme which comprised 5 videotapes /DVDs and an instruction booklet. The films covered different daily life situations wherein a person with hearing impairment typically has problem hearing and communicating. In the videos education of coping strategies and instructions on communication tactics were provided. The videos include: Film 1: One-to-one conversation in a quiet room at home (13 min). Film 2: Birthday party in a noisy environment (11.5 min), Film 3: Conversation with a stranger, outside in the street (14.5 min), Film 4: Visit to a doctor in the hospital (11.5 min), Film 5: Group meeting with strangers (18 min).

Forty eight hearing impaired individuals who visited the audiology centre were randomly assigned to intervention group (hearing aid fitting plus home education program) or a control group (hearing aid fitting only). The duration of the course ranged from 5 to 12 weeks.

They used some of the items of Hearing Handicap and disability Inventory (Van den Brink et al. 1996) questionnaire in order to assess patient's emotional response (e.g., acceptance of loss, interaction with others, and lack of self-confidence). In addition, they added few items addressing use of communication strategies.

An improvement in communication strategies in the training group was observed after the treatment while no improvement was observed in the control group ($p < 0.05$). No significant group difference was found for the emotional response scale. They concluded that home education programme increased individual's awareness of the benefits of speech reading but did not have an extra effect beyond hearing aid fitting on the emotional response. They didn't compare hearing aid use and outcome between intervention group and hearing aid only control group.

6.7.5 Hickson et al. (2007)

Hickson et al. (2007) conducted an RCT on 178 people with mild to moderate hearing impairment. They assessed the effectiveness of an active communication education (ACE) programme compared with a placebo social programme in the

control group. Patients in placebo group were also taking part in ACE once they finished the social programme.

The aim of ACE was to minimise activity limitations and participation restrictions for people who do not use their hearing aids, unsuccessful aid users, and hearing aid users who require more help. The assumption was that teaching a set of communication skills will enhance patient's function in their environment and minimise activity limitation and participation restrictions. ACE was mainly educational and focused on teaching assertiveness, lip-reading, and other communication strategies.

The ACE program is a group program, which is designed for older people with hearing impairment, with and without hearing aids (Hickson et al. 2007). The programme runs for 2 hours per week over 5 weeks (total 10 hours) and involves both people with hearing impairment and their significant others. During the first session of ACE, the facilitator encourages the members to identify, discuss and prioritise their communication difficulties. Depending on the identified communication problems by the group members, a series of educational and problem solving modules are provided directed toward the specific communication settings in which individual participants identify difficulties. In addition, members are encouraged to think about what goals they would like to achieve during the ACE program. The sessions are interactive and involve detailed discussions of communication strategies and practical exercises. The teaching topics comprise: 1) communication needs analysis, 2) understanding conversation in background noise, 3) communicating around the house, 4) understanding people who do not speak clearly, 5) listening to other signals (e.g., telephone, television), 6) listening to the public address system/listening in church, 7) sound localization, 8) safety issues and maintaining independence, 9) communicating with family members, and 10) concentrating to understand.

Participants in the control group received a social programme which involved the same amount of face to face contact as the ACE programme. The following topics were covered by the facilitator: introduction to communication; communication and technology; communication changes in ageing; communication and memory

changes; and communication and reading and writing. All patients in placebo group were also took part in ACE once they finished the social programme (social +ACE).

Their results revealed that the difference in change between the ACE group and the social program control group was not significant for any of the measures. The Effect sizes for the ACE were relatively small (between 0.06 and 0.27) hence their study did not have enough statistical power to detect between group differences.

Although the difference between the ACE and social programme didn't reach statistical significance, it seemed that participants in the ACE group showed greater improvement in some of the measures (i.e., HHQ and SAC) but not in other measures (i.e., SF-36, and QDS). Hickson et al.(2007) reported that there were significant reductions in measured activity limitations (SAC) and participation restrictions (HHQ) for participants who completed the ACE program. Effect size (ES) for the ACE on the SAC was 0.36 and it was 0.23 on HHQ. SAC measures communication activity limitations and participation restrictions (e.g., "Do you experience difficulties when speaking with one other person?" and "Do you feel any difficulty with your hearing limits or hampers your personal or social life?"). HHQ measures participation restrictions and emotional distress and discomfort (e.g., How often does your hearing difficulty restrict the things you do?" and "How often do you feel tense or tired because of your hearing difficulty?"). It seems that learning communication strategies through the ACE programme helped the individuals to minimise their activity limitation (e.g., better understand speech via lip-reading) and participation restrictions (e.g., have better experience of social activities with the use of assertive skills and problem solving). However, improved communication activity and participation were not translated to improved self perceived HRQoL as there were no significant improvements in SF-36 score. SF-36 measures health related quality of life (e.g., physical functioning, role functioning, bodily pain, general health, vitality, mental health, emotional role limitation, and social functioning).

Effect on QDS was greater in social programme (ES=0.16) than ACE (ES=0.12). QDS measures participation restrictions and family relationships (e.g., "I am not an outgoing person because of my hearing loss", and "The members of my family are annoyed with my hearing loss"). This result suggests that learning communication strategies does not necessarily improve participation restrictions. This is consistent

with the ICF model which explains the impact of various personal and environmental factors on participation restrictions and quality of life (Danermark et al. 2010; Granberg et al. 2014). As there was an improvement in QDS too, it can be concluded that just taking part in a group programme of any sort could help individuals to produce small improvements in their outcomes.

Qualitative analysis of the comments provided by the participants showed that 53.9 % of them expressed that the main action that they took after the ACE programme was to use communication strategies. This is not surprising as the ACE programme was mainly focused on technical education on communication strategies; hence it improved the use of such skills.

Only 6.12 % of participants said that they obtained hearing aids or wear their current aids more consistently after the ACE programme. The post-intervention assessment revealed that just over 80% of their participants were using their hearing aids for less than 4 hours per day. This amount of hearing aid use has been interpreted as non-regular use by many authors (Bertoli et al. 2009; Kochkin 2005; Kochkin 2010; Takahashi et al. 2007).

Only 5.23 % said that ACE increased their awareness of and acceptance of hearing impairment. ACE didn't help people to further acknowledge their hearing problem, nor did it help them to overcome the stigma of using hearing aids. Individual's perception of their hearing problem and stigma of deafness are reported to be the main factors affecting on hearing aid uptake and use (Jenstad & Moon 2011; Knudsen et al. 2010). Consistent with this line of reasoning, Hickson et al. (2007) reported that patients who had greater awareness of their hearing impairment as measured via attitude to hearing impairment subscale of HARQ prior to the ACE programme showed greater change in their HHQ, QDS and SAC scores after taking part in ACE. The amount of variance explained by the HARQ varied from 12.25% for the HHQ measure to 5.2% for the QDS. It seems that barriers to hearing aid use were not addressed fully during the ACE programme because 80.1% of 171 people taking part in Hickson et al. (2007) trial used their hearing aids or listening strategies for less than 4 hours per day as measured via the IOI-AL questionnaire (Noble 2002). This suggests that interventions other than education are required in order to promote hearing aid use.

6.7.6 Preminger and Yoo (2010)

Preminger and Yoo (2010) conducted an RCT in order to determine whether the content of group AR programme affected the final outcomes. They emphasised that an AR programme should enhance the individuals' problem- and emotion-focused coping strategies (Lazarus & Folkman 1984). They stated that educational sessions on hearing aid use and communication strategies enhance patients' problem-focused coping (e.g., defining the problem and identifying and practising possible solutions), and exploring and sharing their anxieties, fears, sadness, shame, and grief related to their hearing loss and hearing aid use addresses the emotional coping strategies. Fifty-two participants were randomly assigned to one of three groups: (1) communication strategies training group (ComStrat; $n = 18$), (2) communication strategies training plus psychosocial exercises group (ComStrat + PS; $n = 17$), and (3) group in which no training was given but time was spent on informational lectures and psychosocial exercises (Info + PS; $n = 17$). On average their participants had about 10 years ($SD=11$) experience of hearing aid use and their mean score on Hearing Handicap Inventory (HHI) (Newman et al. 1990) was 60 ($SD=20$) indicating a significant hearing handicap.

All AR classes met once per week over a 6-week period. At least 60 minutes was spent each week on ComStart, 30 minutes on PS and 1 hour on Info. The content of the interventions provided are briefly described here:

- (1) ComStrat included both anticipatory strategies and repair strategies.
- (2) PS included stress reduction exercises and was designed to encourage discussions of (a) patients' problems, feelings, attitudes, and emotions associated with hearing loss; (b) other people's reactions to their hearing loss; and (c) the impact of hearing loss on personal and professional relationships.
- (3) Info comprised slide presentations on their hearing status, model of communication, hearing aid features, assistive devices, tinnitus and balance problems, and cochlear implants.

Their results revealed that all groups showed significant short-term and long-term treatment effects; the repeated measures ANOVAs showed significant time effects with no statistically significant interactions with group. However, the effect size

(ES) of interventions was greater for groups that included psychosocial exercises (ComStrat+PS & Info+PS groups vs. ComStrat). For instance, ES on total Hearing Handicap Inventory score (baseline vs. post intervention) for ComStrat group was 0.445, for ComStrat+PS was 0.787 and for Info+PS was 0.775. Similar result on communication-related subscales on WHO-DASII was achieved. ES for Getting Along With People subscale of WHO-DASII (baseline vs. post-intervention) for ComStrat group was -0.162, for ComStrat+PS was 0.250 and for Info+PS was 0.225. This study suggests that focusing on communication strategies may not be enough to enhance patient's quality of life and additional psychosocial component aiming at modifying people's emotional reaction to hearing loss should be included in AR programmes. In this study hearing aid outcomes and amount of hearing aid use in participants were not assessed therefore it is impossible to know whether any of these interventions promoted hearing aid use among the participants. Due to the small sample size, their study didn't seem to have enough statistical power hence it is possible that due to type II error, they failed to reject the null hypothesis.

6.7.7 Lundberg et al. (2011)

Lundberg et al. (2011) conducted an RCT in order to assess the effect of an educational programme delivered through telephone consultations on self perceived hearing disability, anxiety and depression as well as hearing aid outcome. The idea was to develop an interactive counselling based AR programme in order to increase patient's self-esteem and motivation to learn. They believed that AR based on counselling promotes hearing aid use and consequently reduces self-reported hearing handicap. 33 hearing aid users were randomised to the intervention group and 36 hearing aid users to the control group. Their baseline average score on HHI was 39 (SD=11) indicating a mild to moderate hearing handicap.

All patients completed the Hearing Handicap Inventory for the Elderly (HHIE; Ventry and Weinstein, 1982), the Hospital Anxiety and Depression Scale (HADS; Zigmond and Snaith, 1983), the IOI-HA and COSI (Dillon, 1997).

Participants in the intervention group received a book plus 5 tasks which were posted to their homes on weekly basis as well as 5 weekly telephone consultations with an audiologist. The individual weekly tasks were constructed by an audiologist and their aim was to facilitate learning of the book chapters. In order to suggest the

weekly tasks, the audiologist took account of the individual's specific hearing-related problems which were identified in the base line COSI questionnaire. An example individual weekly task might be "After reading chapters 5 to 8, try out different communication strategies that you can use during a meeting. For example, think about your location during the meeting". Telephone consultations lasted for about 10 to 15 minutes and provided an opportunity to discuss the tasks, book chapters and any other concerns. The book chapters covered basic information about hearing, audiogram, audiometry results, and the speech area on the audiogram, challenges that can occur with inner ear damage, hearing aids, their benefits and their limitations, and finally various communication strategies.

The control group received the same book and were given two weeks to read it. No task and telephone consultations were provided. Their results revealed that on HHIE a significant interaction effect was found between group and time for the total scores. This means that participants in both groups showed reduced self-reported hearing handicap as measured via HHIE, however, patients in intervention group showed more improvement and the difference from the control group was statistically significant ($P < 0.05$). The estimated ES in intervention group for pre and post scores on HHIE was 0.55. The analyses for the HADS identified an interaction effect between group and time for the total scale and the depression subscale. Patients in the intervention group produced better outcome in comparison with control which was statistically significant ($P < 0.05$). No improvement in IOI-HA was identified. Thus they concluded that their education program had no effect on overall hearing aid outcomes nor it promoted hearing aid usage. This result suggests that an educational programme may help hard of hearing people learn communication strategies and improve perceived hearing handicap, but it does not seem to improve hearing aid use.

The effect of this educational program (book, tasks and telephone consultations) on HHIE and HADS seem to be much more than what has been reported in other placebo controlled trials. The placebo intervention in the control group was not matched to the education programme in intervention group with respect to contact time with professional, hence receiving special attention from audiologist could have produced placebo effect.

6.7.8 Thoren et al. (2011)

Thorén et al. (2011) conducted an RCT to evaluate the effectiveness of an online education program facilitated by an audiologist for hearing aid users in comparison with the effect of participation in an online discussion forum without any professional contact. 29 people were randomised to the intervention group and 30 people to the control group. The idea was to inform and guide people with hearing impairment about communication strategies, hearing tactics, and how to handle hearing aids in order to reduce activity limitation and participation restrictions imposed by hearing loss and increase satisfaction from and usage of hearing aids. Their participants were experienced hearing aid users and their average score on HHI at baseline was 24.4 (SD=8) indicating a mild to moderate hearing handicap. Their baseline hearing aid use as measured via IOI-HA was 4 (SD=1.2) indicating 4 to 8 hours daily use of hearing aids.

Patients in the intervention group received a book, and weekly interactions with an audiologist via email. Participants were expected to spend 1.5 hours per week on reading designated chapters in the book, performing the tasks, and writing about their experiences. The chapters of the book covered (1) introduction and hearing anatomy, (2) measuring hearing loss, (3) five dimensions of hearing, (4) hearing aids, and (5) coping strategies and future goals.

The participants in the control group were referred to an online discussion forum without professional interaction with an audiologist. Each week they were assigned a new topic to discuss. The five topics were (1) Tell us about your hearing problems, how do they affect you? (2) How do your hearing problems affect your significant others? (3) Tell us about an ordinary day with your hearing loss, (4) Some people argue that society nowadays demands more from people's hearing than before, what do you think about that? (5) Describe in what way your hearing loss limits you.

They used HHIE, IOI-HA, SADL and HADS as outcome measurement questionnaires.

Their results showed a significant within-group effect for the total HHIE score ($p < 0.001$). A significant interaction effect was also detected ($p < 0.05$). The post hoc analysis showed that the intervention group decreased their scores significantly from baseline to immediately post intervention ($p < 0.001$) but not from baseline to 6

month follow up, whereas the control group decreased their scores significantly from baseline to 6 month follow up but not from baseline to immediately post intervention. The ES in intervention group for baseline to immediately post intervention on HHIE was 0.54.

Results for the total score of SADL showed a significant interaction effect over time ($p < 0.05$). The post hoc analysis did not show any significant results in the groups separately at the three occasions.

There was no significant difference on HADS total score from baseline to immediately post intervention in either group. However, the intervention group showed significant improvement on the depression subscale of HADS from baseline to immediately post intervention. Results from the IOI-HA did not show any significant results in the total score or in the items separately.

This study showed that an educational intervention can help people achieve improvement on perceived activity limitation and participation restrictions (ES=0.54). However, their interventions did not show any effect on hearing aid use or satisfaction from hearing aid as measured via IOI-HA.

6.7.9 Garnefski and Kraaij (2012a)

Garnefski and Kraaij (2012) conducted an RCT to assess the effect of a cognitive behavioural self-help programme on symptoms of depression and anxiety in people with severe to profound acquired hearing loss. The intervention had three main components: relaxation, changing maladaptive cognitions, and attainment of personal life goals. Twenty patients were assigned to CBT group and 27 patients took part in waiting list control group. Patients in CBT group received self help programme consisted of a work book, a work programme, and a CD-ROM. They were asked to work on intervention 4 days per week, 1 hour per day for a period of 4 weeks. Week 1 focused on relaxation. At week 2 and 3 participants practiced identifying irrational cognitions and creating counter conditioning. Finally at week 4, they were guided to formulate a realistic goal and to improve their self-efficacy to reach this goal.

Participants completed Hospital Anxiety and Depression Scale questionnaire before, immediately after and 2 month after the intervention. 11 patients dropped out from CBT group and 1 patient dropped out from the WL group.

Their result revealed that change in depression score from pre intervention to 2-month post intervention was -0.77 (SD=2.68) in CBT group which was significantly larger than the 0.12 points change (SD = 2.43) in WL group (P=0.05). Anxiety scores reduced by 2.40 (SD=2.63) in CBT group and by 0.70 points (SD=2.33) in WL group (P=0.011).

Limitations of this study were the small sample size and large number of drop outs from the CBT group. Garnefski and Kraaij (2012) did not include any hearing aid or quality of life measures hence it is impossible to know whether self help CBT improves hearing aid use or in fact improves health related quality of life in hearing impaired individuals. Although this was an RCT but people in control group did not receive any intervention, hence receiving special attention from audiologist could have produced placebo effect.

6.7.10 Barker et al (2014)

Recently Barker et al. (2014) conducted a Cochrane review appraising the evidence-base for AR interventions which are designed to improve hearing aid use in auditory rehabilitation. They included 32 studies in their review with a total of 2072 participants. They rated the quality of the evidence to be “low” or “very low”. All studies tested self-management interventions which were mainly designed to support people manage their hearing loss and hearing aids better through providing educational materials, practice in application listening and communication strategies. Barker et al. (2014) did not find any evidence of statistically significant effect on adherence to hearing aids or on quality of life measures. However their meta-analysis (2 studies included, 87 participants) showed a reduction in self-perceived hearing handicap as the consequence of being in an AR programme. Increased use of communication strategies was also shown in one study with 53 participants. Barker et al. (2014) concluded that there were “low” or “very low” quality evidence to support the application of any additional support offered through the AR programmes beyond the benefit received from the fitting of the hearing aids.

6.7.11 Conclusions and Research Implications

In this section the key conclusions from reviewing the literature on effect of AR programmes in facilitating hearing aid use and hearing-related quality of life are discussed. The main aim of this section is to highlight choices that need to be made in designing of a study assessing the effect of an intervention for facilitating hearing aid use. These comprise (1) content of intervention, (2) characteristics of participants, (3) outcomes, and (4) intervention for control group.

6.7.11.1 *Content of Intervention*

The outcome of the 2 systematic reviews which were published one decade apart were relatively similar (Hawkins 2005; Barker et al. 2014). They suggested that although educational interventions seem to be useful in the process of AR through enhancing use of communication strategies, there is weak evidence for their effect on hearing aid use and hearing-related quality of life (Barker et al. 2014; Hawkins 2005). Reviewing some of the key efficacy RCTs on AR showed that in majority of the studies the interventions provided were heavily reliant on providing additional education and practice. As discussed in the previous chapters use of hearing aids often requires patients to change their behaviours and cognitions (e.g., acknowledge a hearing disability, seek professional help, wear their hearing aids on a regular basis and change their avoidance coping strategies) (Laplante-Levesque et al. 2013a). Behaviour change is a complex process determined by various psychological and environmental factors, hence simply providing people with education, advice and skilfulness may not necessarily help them to change (Rollnick et al. 2005; Mosler 2012). Although educating patients and providing practical training on communication/listening strategies are important components of the AR process but they do not appear to address psychosocial aspects of deafness and hearing aid use. According to many studies the main determinant of non-regular use of hearing aids is not the lack of knowledge or skilfulness but are self-reported hearing problems, patient's attitude toward hearing aid, stigma, patient's readiness and motivation to use hearing aids (Knudsen et al. 2010; Jenstad & Moon 2011) (Abdellaoui & Tran Ba Huy 2013; Vernon & Pratt 1977; Babeu et al. 2004; Laplante-Levesque et al. 2014a; Laplante-Levesque et al. 2013a).

The application of approaches based on client-centred counselling has not been examined in the process of AR. There is a need to assess the feasibility and effect of interventions which are designed to address psychosocial aspects of hearing impairment through a more counselling-based approach as opposed to an educational intervention.

6.7.11.2 Participants

The characteristics of participants across the AR RCTs reviewed here were variable. Some studies included new patients only (Abrams et al. 2002; Chisolm et al. 2004), some studies included experienced hearing aid users (Lundberg et al. 2011; Preminger & Yoo 2010; Thoren et al. 2011; Garnefski & Kraaij 2012b), and some studies included a mix of new patients and experienced hearing aid users (Kramer et al. 2005; Hickson et al. 2007).

The extent of baseline hearing-related handicap and amount of hearing aid use at baseline were also varied across the studies. In some studies patients included had larger (worse) self-report hearing handicap at baseline giving them more scope for improvement as the consequence of taking part in the study (Preminger & Yoo 2010). However, in some studies the self-perceived hearing handicap of participants at baseline was only mild and their hearing aid use was over 4 hours per day leaving little scope for improvement during the study (Thoren et al. 2011; Hickson et al. 2007). It is possible that only a subgroup of hard of hearing individuals would need a more comprehensive AR programme beyond what is typically offered in audiology services which includes fitting of hearing aids and minimal education/instructions. According to previous studies, approximately 70% of people who own hearing aids use them regularly (Hickson et al. 2010; Stark & Hickson 2004; Vuorialho et al. 2006b; Takahashi et al. 2007; Brännström & Wennerstrom 2010), and amplification even without any additional AR leads to a large effect size for disease-specific HRQoL measures (Chisolm et al. 2007). Therefore, the inclusion criteria for potential participants to the trials aimed at promoting hearing aid use should be studied and debated further. For instance including all new patients may not be appropriate as many of them may not need such interventions. Including all new patients to a study assessing effect of additional AR could lead to reducing the overall effect size of the intervention.

6.7.11.3 *Outcome Measures*

The majority of the AR RCTs used self-report questionnaires as their outcome measurement tool. The self-report questionnaires varied across the studies. Some studies used only one questionnaire (Chisolm et al. 2004; Garnefski & Kraaij 2012b) but the majority used a wide range of questionnaires. Most of the outcome measurement tools used were validated questionnaires assessing dimensions of benefit/satisfaction from amplification, hearing related activity limitation and participation restrictions, use of communication strategies, cognitive and emotional coping, anxiety and depression symptoms. Although, hearing aid use was not the primary outcome in most of the AR RCTs, some studies assessed amount of hearing aid use as one of their outcomes (Lundberg et al. 2011; Thoren et al. 2011). In these studies, the main tool used was IOI-HA which assesses the number of hours per day that patients used their hearing aid over the past 2 weeks. IOI-HA uses pre-defined categorical options (e.g., less than hour per day).

Although the amount of time a hearing aid is used does not guarantee a successful patient outcome, it is important to know whether patients use their hearing aid or not. While the final outcome may be whether the hearing aid makes any difference to the patient's life, using their hearing aids is the first step in the causal chain. The amount of hearing aid use can also be measured objectively via built-in data logging systems. This can provide an excellent tool for future research. However, some authors debated that the data logging systems do not represent a true objective measure of use because they are only able to measure whether the hearing aid is switched on and the acoustic environments it is in, not whether it is switched on and in the patient's ear (Barker et al. 2014). However, this is simply speculation and to my knowledge there is no evidence suggesting that people do not understand the instruction to switch off their hearing aids when not using them. Switching off appliances when unused is common sense. There is no evidence suggesting that people deliberately keep the hearing aids switched on even when unused in order to mislead the researchers. People are usually concerned about the battery life hence they are likely to make sure to switch the hearing aids off when un-used. For some patients who have mild hearing loss it is possible that the hearing aid runs out of battery without the patient noticing. Therefore, while patient thinks that they are using a hearing aid the hearing aid is switched off. In such scenario a data logging

system provides a more reliable reading than a self-report questionnaire. There is a need for future research to assess the reliability of using a data logging system to measure the amount of hearing aid use.

A recent systematic review on studies measuring and reporting hearing aid usage suggested that both type of outcomes (i.e., the amount of hearing aid use as measured via data logging and self-report questionnaires) need to be included in studies to help cross validate the data (Perez & Edmonds 2012).

The review of the AR RCTs here shown that some authors included a qualitative component in their studies and asked a few open questions from the participants in order to gain more insight with regard to their experience of taking part in their studies (Hickson et al. 2007; Kramer et al. 2005). This provided an opportunity for the participants to discuss wider effects of the research participation on their life and provide additional information which were not covered in the standardised questionnaires. For instance in the study by Hickson et al (2007) participants were asked (1) what did they like about the ACE sessions? (2) How could the sessions be improved? And (3) What actions have you taken as a result of attending the ACE programme? They used a qualitative content analysis method to code participants' comments. This helped them to examine the participants' perspectives about the important components of their intervention. As we do not fully understand determinants of hearing aid use and factors related to benefit from amplification and improving hearing related quality of life, adding a qualitative component nested in future RCTs on assessing effect of AR programmes could provide valuable insight about the mechanism in which use of hearing aid, AR programme, and/or taking part in the research could lead to a change in patient's self-report hearing-related quality of life measures.

Finally some authors included questionnaires assessing comments of significant others (SO) of the hard of hearing person (Kramer et al. 2005). It seems that perspective of SOs can provide some additional insight about the process and outcome of the AR interventions because SOs also bear the burden of hearing impairment (Chmiel & Jerger 1996).

6.7.11.4 *Intervention for the Control Group*

The content of the interventions used for patients assigned to the control groups varied across AR RCTs. Some studies assigned patients to a waiting list control group with no active treatment (Garnefski & Kraaij 2012b). When no intervention is offered to people in control group, it is difficult to work out whether any outcome in the intervention/treatment group is due to the target intervention or due to the psychological effect of being treated in some way (Pocock 1983). This can lead to observation of exaggerated effect for the target intervention.

Some studies offered a minimal contact for people in the control groups by for example referring them to an online discussion forum or asking them to read a book (Lundberg et al. 2011; Thoren et al. 2011). In these studies the treatments in the control group were not matched with the treatments in the intervention group with respect to the contact with the professionals. Therefore, it is not clear whether the target intervention (i.e., AR) produced the observed outcomes or simply receiving special attention from an audiologist.

In some studies, participants in the control group received hearing aids (HA only) and participants in the intervention group received hearing aids plus AR in the form of additional education, communication training, and psychosocial support (HA+AR) (Chisolm et al. 2004; Abrams et al. 2002; Kramer et al. 2005). In such studies, the treatments in the intervention group were not matched with the treatment in the control group with respect to the duration and amount of time that participants were engaged to the treatment activities. For instance in one study patients in the control group received HA only with total contact time of approximately 2 hours but people in the intervention group received HA+AR with total contact time of approximately 10 hours (Chisolm et al. 2004). Therefore, it is not clear whether the intervention content caused the observed outcomes or if it was due to the fact that they were getting more of something.

Introducing a matching comparison intervention to participants in the control group is very important as it helps to control the possible confounding effects of social contact and general research participation effect (Parsons 1974; McCambridge et al. 2014). However, for some interventions, it may not be feasible to introduce a matching comparison intervention to participants in the control group. Developing a

comparison intervention is more of a challenge in RCTs assessing efficacy of complex psychosocial interventions because often the active ingredient of the target intervention is not clear (Medical Research Council 2008). Therefore, it may be difficult to develop a placebo intervention which is similar to the true intervention except for the active ingredient. Assigning patients to a standard care group could be an alternative but for some novel interventions there may not be any comparable standard care. However, two of the AR RCTs reviewed here offered some form of intervention to the patients in their control groups which were relatively comparable to the treatments offered in the intervention groups. Therefore, it seems that in the context of AR RCTs it is feasible to use some form of comparison treatment for people in the control group which is matched with the AR programme in the intervention group with respect to its duration and intensity as well as the total contact time with the professionals.

7 Chapter Two: The Design Journey

In this chapter the methodology applied for this project is discussed. This chapter describes the rationale for decisions made by the author throughout the project.

7.1 Emergence of the Research Questions from the Clinical Practice in the NHS

The author, during his 10 years of clinical experience in the NHS audiology, had gained an insight about the extent of the non-adherence to hearing aid use. Although, the majority of people seemed to be highly motivated and very happy with their NHS hearing aids, non-regular use of hearing aids was common. There didn't seem to be a direct relationship between the severity of hearing impairment and hearing aid use. Some people with a minor hearing loss used their hearing aids all the time during their waking hours but some with severe hearing loss hardly used their hearing aids. The amount of non-regular use of hearing aids and its determinants varied among patients. Some scenarios which were commonly observed by the author in his audiology clinics are presented below.

1- Some patients did not want to use their hearing aids at all. In fact they didn't want to get hearing aids in the first place, but only agreed to get them due to external pressures imposed on them by family members or their doctor. A common scenario was that they used their hearing aids once or twice then said that "it is uncomfortable" and abandoned them. When family members enquired why they were not using their hearing aids they typically said that they were uncomfortable hence cannot be used or they were useless and didn't help hence it seemed pointless to use them. The author found it impossible to convince such patients to use their hearing aids. Despite numerous sessions of hearing aid fine tuning and adjustments and providing education and advice on consistent hearing aid use, they often did not use their hearing aids. The consequence was that the family members kept complaining that the TV is too loud and the patient could not hear them hence they had to give up talking to the patient or the patient complained that young people mumble and do not enunciate properly.

2- Some patients did not want to use their hearing aids when they were outside their home. They didn't want other people to see them using hearing aids. They used their hearing aids only for TV at home. When they were outside, they avoided having

conversations with people if they felt that they may not be able to hear the other person. This affected their social life. If they were in employment or education, non-use of hearing aid affected their role at work place or hampered their progress in their studies. Every time that they attended the audiology clinics, their hearing aids were adjusted and calibrated and they were given further education and advice that they would need to use their hearing aids consistently. These didn't seem to influence their hearing aid use for many years. Over the years, the researcher found himself in a situation that he couldn't convince some patients that they were missing out on so many things by not using their hearing aids.

3- Some other patients often attended the audiology clinics and complained that they did not benefit from their hearing aids. At every visit the hearing aids were re adjusted but it didn't seem to make any difference and the problem persisted. When the author explored their hearing aid use pattern it often became apparent that they did not use their hearing aids long enough to get used to them. A common scenario was that the patient wished to use their hearing aids only when absolutely needed. People often said that "I do not need my hearing aid at home as nothing critical is going on but I need them in meetings and parties". So they often did not use their hearing aids most of the time, depriving their brain from getting used to the amplified sound. Amplified sound is different from normal hearing and there are always some background noises which are picked up and amplified by the hearing aids (e.g., footsteps, wind noise, paper clipping, cutlery, etc). People do not necessarily wish to hear such noises and after a while their brain usually habituates to them so they can ignore them. People with hearing impairment usually do not hear these background noises when they do not use their hearing aids. Once they begin to use their hearing aids, they start hearing the background noises which are amplified through the hearing aid. It takes time for the brain to get used to them. If they don't use their hearing aids at home situations long enough, they wouldn't get used to the amplified sound. In noisy places when they put on their hearing aids, then they will get overwhelmed by hearing all the background noises. In such encounters with patients the author used to feel that he couldn't make any progress. According to the patient the hearing aids were too loud in noisy places and they wanted them to be turned down. But doing so would have made the amplification too little to help them to hear any better. The patient didn't seem to listen to the

information and advice provided by the author with regard to the importance of regular use of hearing aid and getting used to them. It seemed that they didn't want to use their hearing aids consistently and were only signed up to a part-time use of hearing aids. They perhaps were not ready for a full commitment. They could stay in this state for many years.

4- Another scenario was for people who had hearing loss combined with tinnitus. The author is an audiologist specialised in hyperacusis and tinnitus rehabilitation. Hyperacusis is an umbrella term for several types of intolerance to sound (Aazh et al. 2014; Aazh et al. 2011b; Baguley 2003). Tinnitus is the perception of sound in the ears or the head that does not have an external source (Tyler & Conrad-Arnes 1983). Tinnitus is most commonly associated with hearing loss (Aazh et al. 2011a; Brunnberg et al. 2008). There is not a one-to-one relationship between tinnitus and hearing loss; many people with normal hearing have tinnitus, and many people with hearing loss do not experience tinnitus. Nevertheless, the relationship between tinnitus and hearing loss has widely been acknowledged (Moore et al. 2010; Aazh et al. 2011a; Searchfield et al. 2010). Patients with tinnitus combined with hearing loss are typically advised to use hearing aids (Searchfield et al. 2010; Jastreboff & Hazell 2004; Jastreboff & Jastreboff 2000; Jastreboff & Jastreboff 2003). The idea is that hearing aids may help: (1) to reduce the effort of hearing, and (2) to amplify background noises and facilitate tinnitus habituation by decreasing the strength of the tinnitus signal (Aazh et al. 2008a; Jastreboff & Jastreboff 2000). However, in his clinical experience the author often faced non-compliance to hearing aids use among his patients with hearing loss combined with tinnitus similar to those described earlier for people with hearing loss and no tinnitus.

The method typically used to promote adherence to hearing aid use among patients with tinnitus combined with hearing loss is to provide detailed and extensive education on (1) basic functions of the auditory system; (2) basics of brain function and the interactions of various systems of the brain; (3) theoretical basis of habituation based on the Jastreboff neurophysiological model; and (4) role of hearing aid as a component of sound therapy (Jastreboff & Jastreboff 2000; Aazh et al. 2008a). This method was used by the author at the time and still is widely used by many clinicians in the field of tinnitus rehabilitation. Despite this, in the author's clinics about 26% of patients with tinnitus combined with hearing loss did not use

their aids at all (Aazh et al. 2008a). The author then decided to offer patients a greater choice and leave it to them to decide which component of the therapy they would like to receive. He developed a Patient-Centred Tinnitus Management Tool (PCTMT) (Aazh et al. 2008b; Aazh et al. 2008c) in the form of an educational poster that explained the causes of tinnitus and encouraged patients to decide for themselves the way in which they want to deal with their tinnitus. So in practice, people who didn't want hearing aids as a part of their tinnitus therapy programme were not offered hearing aids. The intention was to improve the quality of care and reduce waiting time by identifying the patients' choice of treatment before deciding whether to add them to the tinnitus or hearing aid waiting lists. Then the author conducted a clinical audit to evaluate his service encompassing PCTMT (Aazh et al. 2009). A total of 55 consecutive patients who were referred to the Audiology Department at Ealing Hospital, London, from the ENT Department over a period of 6 months were asked to read the PCTMT and to decide what they wanted to do regarding their tinnitus (Aazh et al. 2009). Forty two percent of the patients (23 of 55) wished to undertake tinnitus counselling. Nine percent (5 of 55) of patients decided to try to ignore their tinnitus without help (therefore, they were given the leaflet and discharged). Twenty-six percent (14 of 55) wanted to deal with their tinnitus with the help of a sound generator (therefore, they were given a sound generator). Finally, 24% (13 of 55) decided to use hearing aids (therefore, they were added to the hearing aid waiting list). Not all patients with tinnitus combined with hearing loss chose to have hearing aids (Aazh et al. 2009). The idea behind PCTMT was that the choice of the patient should always be respected, no matter how unhelpful it seems to those who see only the small picture (Power 1999).

At the time the author felt that if people were not ready to use their hearing aids then he shouldn't try to convince them or prove his points about the need for hearing aids by providing excessive information and education. Instead he should only listen to their concerns and build a good rapport and at most provide some modest information to them in case in future they felt ready to use hearing aids then they have some directions on what to do and where to go. This seemed a reasonable approach at the time, despite the fact that as a professional the author always knew that those patients with considerable hearing loss who did not agree to use hearing aids were missing out on many things and their hearing loss was affecting their

quality of life, occupation, mental health, recreation activities, social life as well as causing frustration and annoyance for their partners. They could have benefited from hearing aids as majority of their peers did. If they only were willing to give a fair chance to hearing aids and tried them with open mind they would have noticed the difference they can make. But it was a decision that patients should make on their own whenever they feel ready for it.

A year later, during his MSc course in Rehabilitative Audiology at Bristol University, the author became more familiar with the concept of behaviour change and psychological interventions including MI which has been examined in promoting healthy behaviours (Rollnick et al. 2005). This was a break through as the author started contemplating the idea of applying MI in facilitating hearing aid use instead of giving up on people who needed hearing aids badly but perhaps were not fully ready for a life time commitment of using hearing aids. As outlined in the previous chapters, there hasn't been any study assessing the effect of MI on hearing aid use. Hence there were several challenges in designing the study which are described in the following sections.

7.2 Defining Non-Regular Use of Hearing Aids

One challenge was to define the non-regular use of hearing aids. There are no widely agreed criteria for regular hearing aid use. There is a gap in our knowledge on whether it is ok to use hearing aids only 1 hour per day, 2 hours, 4 hours, 8 hours, or 10 hours per day. Many audiologists recommend using hearing aids during all waking hours if possible (Laplante-Levesque et al. 2013b). Some studies suggest that consistent use of hearing aids is related to improvement of speech understanding and greater patient satisfaction (Uriarte et al. 2005; Roup & Noe 2009). Perez and Edmonds (2012) described that “While usage of hearing aids does not guarantee successful patient’s outcome, it is important to ensure that patients are using their hearing aids regularly and that the device makes a difference to the patient’s ability to listen and communicate effectively” (p.7). Others suggested that hearing aid usage does not necessarily relate to benefit from hearing aids (Humes et al. 2001). Although Laplante-Levesque et al. (2013b) reported that patients and audiologists expressed that the more time spent using the hearing aid the better, the optimal use did not necessarily correspond to wearing the hearing aid all or most of the time. They suggested that optimal use of hearing aids could be less than using it during all

working hours and perhaps only in specific situations based on the individual's needs (Laplante-Levesque et al. 2013b). Hickson et al. (2014) suggested that successful hearing aid use requires a minimum of one hour of daily use and at least moderate self-reported benefit from hearing aids in the situations where it is most desired to hear better. There hasn't been any study directly examining the variations in biological and psychosocial benefits of amplification based on the amount of hearing aid use. This is clearly an area which needs further research.

In survey studies, many authors used questionnaires, mostly IOI-HA, in order to assess hearing aid use (Knudsen et al. 2010; Perez & Edmonds 2012). People who reported using their hearing aid for less than 4 hours per day were often classified as non-regular users (Hickson et al. 2010; Stark & Hickson 2004) (Vuorialho et al. 2006b) (Olusanya 2004), (Kochkin 2005; Kochkin 2010; Takahashi et al. 2007; Williams et al. 2009) (Bertoli et al. 2009) (Brännström & Wennerstrom 2010) (Liu et al. 2011).

On IOI-HA, there are 5 answers to choose from in response to the question:

“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)?”

The choices are:

- (a) None
- (b) Less than 1 hour a day
- (c) 1 to 4 hours a day
- (d) 4 to 8 hours a day
- (e) More than 8 hours a day

With the criteria for non-regular use adopted here, people who chose “a”, “b”, or “c” were classified as non-regular users. Therefore the non-regular users will be a group of people who either do not use their hearing aids or typically use it for only 1 to 3 hours per day. As this is based on a self-report measure it is possible that the responder even uses their hearing aids less than what they report. Studies that compared digitally recorded usage time with self-reported use suggest that patients

tend to under-report non-regular use (Mäki-Torkko et al. 2001; Taubman et al. 1999).

One might argue that 1-3 hours per day of hearing aid use may be enough for some individuals depending on severity of their hearing loss as well as their life style. But why someone might want to use their hearing aid for only 1-3 hour per day as opposed to wearing them all the time during waking hours. One reason could be that they may only need to use their hearing aids in certain situations. Another reason could be that their hearing aids need adjustments. But why they haven't come forward and asked for them to be adjusted? It is also possible that they did see their audiologists on several occasions but no further improvements could be made due to the inherent technical limitations in the hearing aids.

However, it is possible that they are not ready to commit to full-time use of their hearing aids. May be they don't want others notice that they use hearing aids. Although previous research pointed out that self-reported hearing problems are the main predictors of hearing aid use, recent studies highlighted the importance of patient's attitude toward hearing aids and motivation as the main predictors of hearing aid use (Abdellaoui & Tran Ba Huy 2013; Jenstad & Moon 2011; Knudsen et al. 2010). The exact underlying cause for non-adherence to hearing aid use in each individual is not clear.

To be comparable to other studies, non-regular use here is defined as hearing aid use less than 4 hours per day as measured via IOI-HA. One might argue that this criterion might label some people who are happy with their hearing aids and use them as much as they need as "non-regular users". However, the intention is not to label people but is to explore whether such individuals benefit from further assistance and support.

7.3 Study Population: Who Should be Included?

The next challenge was to decide at which stage of the patients' journey application of MI for facilitating hearing aid use would be appropriate. Here I briefly describe a typical patient's journey from being referred for hearing aid evaluation to fitting and post-fitting maintenance.

Under NHS, adults with hearing impairment can be referred by their GP directly to the audiology department for hearing aid evaluation. People who do not meet the

criteria for direct referral, typically with asymmetrical hearing loss, dizziness, accompanying ear infections, severe tinnitus or other contraindications for hearing aid fitting are referred to ENT for appropriate treatment (BAA 2007). Patients who are referred by their GP for hearing aid evaluation will be offered an assessment session with a qualified audiologist. This session is usually allocated 45-60 minutes and includes taking a case history, otoscopy, pure tone audiometry based on the BSA guideline (BSA 2004), and completing Glasgow Hearing Aid Benefit Profile (GHABP) (Gatehouse 1999) questionnaire. If the patient decides to have hearing aids then an impression will be taken from their ear canal and custom made ear moulds will be ordered. People who meet the criteria for open fit hearing aids do not need ear moulds (Aazh et al. 2012b). Then a hearing aid fitting session will be arranged for them usually in 4-6 weeks time. The fitting session can last up to 60 minutes. Real-ear measurements (REM) are performed routinely according to the British Society of Audiology recommended procedure (BSA 2007) to ensure that the hearing aids are adjusted to match a prescription target reasonably well (Aazh & Moore 2007b; Aazh et al. 2012a; Seewald et al. 1999). With regard to post-fitting support, patients are advised to attend a walk-in hearing aid service clinic to deal with straightforward problems (sessions last approximately 15 minutes). If the problem is not resolved, the patient is offered a review appointment (30-60 minutes) for further adjustments or consideration of a different type of hearing aid, and may be provided with advice on other assistive listening devices and hard of hearing social support groups.

The challenge for the author was to decide on the study population. The first idea was to include all new patients with hearing impairment who are referred for hearing aid evaluation. However, as the majority of the previous studies pointed out almost 60% of people do use their hearing aids on regular basis (Vuorialho et al. 2006b; Olusanya 2004; Bertoli et al. 2009; Brännström & Wennerstrom 2010; Liu et al. 2011). Therefore, they may not need MI to use their hearing aids because they are already motivated. It is worth mentioning that back in 2012 the author had an interesting meeting with the founder of MI, Professor William Miller. The author described his research ideas on the effect of MI for hearing aid use. In response William Miller said: *I didn't need MI to use my hearing aids. In fact I am using them right now.* So majority of people may not need additional support beyond what

typically is offered in audiology clinics. The problem lies with the 40% who despite coming forward for hearing aid evaluation will end up not using their hearing aids. If we include all patients to a trial where majority of them (60%) will use their hearing aids regardless and might not need MI, then it will be very likely that even if MI will prove to be effective, it only would produce a small effect size. However, as this was the first time that MI was going to be tested for hearing aid use we simply didn't know how it might work. For instance, it was also possible that MI would have been beneficial even for those who were in fact motivated to use hearing aids and could have helped to strengthen their commitment to use hearing aids in long-term. Moreover, if MI was going to prove effective in promoting hearing aid use then offering MI within the initial hearing aid evaluation session for new patients seemed to be reasonable and could minimise the occurrence of the non-adherence at source. Therefore, there were advantages and disadvantages for considering all new patients referred for hearing aid evaluation as the study population.

In MI literature, MI is usually used to promote a behaviour change from an unhealthy behaviour (e.g., smoking, substance abuse, unsafe sex, lack of physical activity, etc.) to a healthier one (not smoking, stop substance abuse, safe sex, improved physical activity, etc.). In most of the studies there was a behaviour that needed to change. They never did MI on people who never smoked to motivate them not to smoke. Or they didn't use MI for people who never had a drinking problem to avoid this to occur. They didn't use MI to promote contraception in a random population of college students who did not have a specific pregnancy risk. In fact they assessed effect of MI in reducing alcohol-exposed pregnancy risk among college binge drinkers (Lopez et al. 2013), people who were at risk of alcohol-exposed pregnancies (Floyd et al. 2007; Petersen et al. 2007) or patients who attended female adolescent pregnancy clinics (Lopez et al. 2013). The risk for alcohol exposed pregnancy was defined as having sexual intercourse with a man in the past 90 days while using contraception ineffectively (e.g., no use, incorrect use of an effective method) and drinking at risky levels which was defined as engaging in at least one binge in the past 90 days or consuming an average of eight standard drinks per week (Ingersoll et al. 2005). So usually people first committed the unhealthy behaviour then MI came into effect in order to promote a behaviour change. In the context of audiology, because it is only a subgroup of the new

patients who will end up not using their hearing aids, offering MI to all people who have not yet committed the so called unhealthy behaviour of not using their hearing aids seemed to be an attempt to solve a problem that didn't exist for many patients.

Then there was the idea of predicting non-regular use of hearing aids by identifying people who are at risk of non-regular use at the assessment session and include them in the study. Although based on the findings of past studies we had some idea about factors related to non-regular use of hearing aids, there was no validated tool at that stage that could have helped us to reliably predict those who might end up not using their hearing aids in future. In addition, the current rate of non-adherence to the hearing aid use in the NHS was not clear.

The other option was to identify people who have not been using their hearing aids and invite them to the research. The idea was to achieve this by conducting a postal questionnaire survey on people who have been fitted with hearing aids at our centre in a one-year period in order to assess their self-report hearing aid use. This way, we could have an up-to-date data on the rate for non-adherence to hearing aids among NHS patients. In addition, we would have a pool of non-regular users identified via the survey whom can be invited to a trial assessing feasibility of MI in facilitating hearing aid use at a later stage. However, this approach also had its disadvantages. For instance one problem would be related to non-responders to the survey questionnaire. It is possible that people who do not use their hearing aids will be over represented among the non-responders to the survey. Therefore, we potentially lose a large number of candidates who might benefit from the MI. Another problem is the report bias. Studies that compared digitally recorded usage time with self-reported use suggest that patients tend to under-report non-regular use (Mäki-Torkko et al. 2001; Taubman et al. 1999). Therefore again some people who in fact do not use their hearing aids regularly and might benefit from MI may report consistent use and do not meet the inclusion criteria of the study.

The Audiology Department at Royal Surrey County Hospital (RSCH) has a catchment area of 320,000 people and receives approximately 55 referrals per week from GPs for hearing aid fitting. In the year 2011-2012 almost 2000 people were fitted with hearing aids at RSCH. We estimated that if we sent the survey questionnaires to all patients fitted in 2011-2012 we might have about 1000

responders based on the average 50% return rate observed in many of the patient surveys in European countries (Grol et al. 1999; Grol et al. 2000; Coulter & Cleary 2001). Average return rate was 55% in the surveys assessing patient's priorities with respect to primary health care services in UK, Norway, Sweden, Denmark, Germany, Netherlands, Portugal, and Israel (Grol et al. 1999). The average return rate was 56.5% in a study on patients' experiences from hospital health care in Germany, Sweden, Switzerland, and UK (Coulter & Cleary 2001).

Based on the previous studies the average rate for non-regular use is about 30% (Hickson et al. 2010; Stark & Hickson 2004; Vuorialho et al. 2006b; Olusanya 2004; Kochkin 2005; Kochkin 2010; Takahashi et al. 2007; Williams et al. 2009; Bertoli et al. 2009; Brännström & Wennerstrom 2010; Liu et al. 2011). This means that for the survey in Audiology at RSCH, 300 people out of the 1000 potential responders will probably report non-regular use of their hearing aids hence will be suitable to be invited to the study assessing the effect of MI in promoting consistent hearing aid use. The author believed that there will be at least 50 people out of 300 who will take part in his study. In fact, he felt that if the invitation letters were sent to about 200 people we will have 40 people consenting which would be enough for a pilot study. The author was confident that people would welcome the idea of the research because (1) the study was going to provide some additional support and care for patients who already visited our department and received their hearing aids from us, (2) there were no invasive procedures or time-consuming or complicated examinations involved, and (3) the majority of patients were over 75 so they may have more free time to spare for taking part in a study in their local hospital. However, there was the risk of not meeting the recruitment target due to the fact that we were inviting people who presumably did not want to use their hearing aids regularly to a study that is aimed at facilitating consistent hearing aid use. Low recruitment rate in trials is a very common problem facing researchers (Prescott et al. 1999; Ross et al. 1999). Many trials recruit fewer participants than planned (Ross et al. 1999). Therefore this was an area that we needed to explore during the feasibility study.

The first challenge was to find out how regularly people who are fitted in NHS use their hearing aids. The second question was whether MI can actually improve

hearing aid use. However, prior to designing an efficacy RCT there were several questions which needed answering hence a pilot or feasibility study was required.

7.4 Pilot Study Versus Feasibility Study

Meta-analyses of high quality RCTs with low risk of bias are considered as the highest level of evidence on which to base clinical practice (Harbour & Miller 2001). RCTs are the gold standard study design for evaluation of health care interventions (Bowling & Ebrahim 2005). As full scale RCTs are costly and time consuming, pilot studies are crucial in producing information which can inform planning and justification for RCTs (Anderson & Prentice 1999). Prior to conducting a full scale RCT to test the efficacy of a novel intervention in a new context it is necessary to demonstrate the feasibility of delivering the intervention and test the study methods with the population of interest (Bowen et al. 2009). This is consistent with Medical Research Council guidance for developing and evaluating complex interventions that recommends application of pilot or feasibility studies prior to evaluating the effect of a complex intervention (Craig et al. 2008; Craig et al. 2012). The feasibility of conducting a full scale RCT can be tested through a pilot study which doesn't have to be the scale model of the planned full trial but it should address issues related to the feasibility of the research procedures (Arnold et al. 2009; Craig et al. 2008; Craig et al. 2012).

There seems to be little agreement among researchers about what exactly constitutes a pilot study (Lancaster et al. 2004). In this section the definitions and applications of pilot studies and feasibility studies are compared and discussed in detail.

Dictionary of epidemiology defines a pilot study as "...test of the methods and procedures to be used on a larger scale if the pilot study demonstrates that the methods and procedures can work" (Porta et al. 2014). Dictionary of medical statistics describes pilot study as "...investigation designed to test the feasibility of methods and procedures for later use on a large scale or to search for possible effects and associations that may be worth following up in a subsequent larger study" (Everitt 2003). The distinction between pilot studies and feasibility studies is not widely agreed. Some authors do not distinguish them from one another (van Teijlingen & Hundley 2002; Thabane et al. 2010; Lancaster et al. 2004) but some appear to do so (Arnold et al. 2009; Arain et al. 2010).

Arnold et al. (2009) argued that despite the fact that the terms pilot work, pilot study, pilot trial and feasibility study are currently used without a clear distinction there are certain differences among them. They described that pilot work is any ground research that informs a future study. Pilot study has a specific hypothesis, objective and methodology. Pilot trial includes randomisation. And they discouraged use of the term feasibility study (Arnold et al. 2009). Arain et al. (2010) conducted a literature search in order to find out the differences between pilot and feasibility studies by comparing the content of the published studies distinguished by the keywords “pilot” and “feasibility”. They reported that of 54 studies published between 2007 and 2008, 20 were described as pilot and 34 were described as feasibility studies. They reported that the main contrasts between studies which were identified by the keyword “pilot” and those identified by the keyword “feasibility” were (1) 35% of pilot studies versus 8% of feasibility studies had a pre-study sample size estimation, (2) 55% of pilot studies versus 24% of feasibility studies used randomisation, (3) 65% of pilot studies versus 32% of feasibility studies included a control group, and (4) 80% of pilot studies versus 44% of feasibility studies suggested the need for further study. However, other research method components comprising blinding (15% of pilot studies versus 9% of feasibility studies) and hypothesis testing (in 70% of both pilot and feasibility studies) were almost evenly distributed among pilot and feasibility studies. It seems that some studies labelled as pilot or feasibility had in fact a very similar design and aims. However, the number of pilot studies with a design resembling full scale RCTs was higher than feasibility studies with such a design. This suggests that the majority of pilot studies seem to be just one step behind a full scale trial compared to the feasibility studies which may or may not be followed by a full scale RCT. There is also another explanation for this. It is possible that some of the pilot studies included to Arain et al (2010) review were in fact conducted as full scale RCTs in order to assess efficacy of an intervention but due to the inherit limitations in their design (e.g., small sample size, etc.) and the strict criteria for publication of RCT studies in peer reviewed journals (Boutron et al. 2008; Schulz et al. 2010) they were published as pilot studies instead. Despite this, it seems that feasibility studies have a wider scope in terms of their aims and designs. Bowen et al. (2009) proposed eight questions that can be addressed through conducting a feasibility study. These comprise: (1) acceptability of the intervention to its target population, (2) demand for the intervention, (3) ease

of implementation as planned, (4) practicality of the intervention in real world settings, (5) modifications needed in order to make the intervention accommodate requirements of the target population and context, (6) how to integrate the new intervention with other interventions and the organisational changes required, (7) examine potential success of an already successful intervention with a different population or in a different setting, and (8) limited efficacy testing in a convenience sample with shorter follow up periods and limited statistical power. Depending on their aims, feasibility studies may be in the form of a pilot RCT. For instance, if the aim is to examine feasibility of conducting an RCT, then the suitable design for feasibility study may in fact be RCT. So despite their differences, pilot studies and feasibility studies may overlap for some cases. In fact, Arian et al (2010) suggested that the distinction between the two terms is not clear-cut. They suggested that a feasibility study can in fact be a small RCT as they wrote: “If a feasibility study is a small randomised controlled trial, it need not have a primary outcome and the usual sort of power calculation is not normally undertaken. Instead the sample size should be adequate to estimate the critical parameters (e.g. recruitment rate) to the necessary degree of precision.”(p.5).

There are many authors who do not agree with the distinction between feasibility and pilot studies. For example, Thabane et al. (2010) suggested that a pilot study is synonymous with a feasibility study and both are intended to inform the design and planning of a large scale RCT. They wrote that “the main goal of pilot studies is to assess feasibility so as to avoid potentially disastrous consequences of embarking on a large study which could potentially “drown” the whole research effort.” (p.1). Consistent with this, van Teijlingen and Hundley (2002) wrote that “The term 'pilot studies' refers to mini versions of a full-scale study (also called 'feasibility' studies), as well as the specific pre-testing of a particular research instrument such as a questionnaire or interview schedule” (p.33).

Pilot RCTs seem to be a suitable design for studies aiming to examine the feasibility of conducting a full scale RCT. Lancaster et al. (2004) stated that pilot studies can be used in (1) determining initial data for the primary outcome measure in order to perform a sample size calculation for the full trial, (2) testing research procedures (including/excluding criteria, intervention preparation, randomisation procedure, training of clinician and admin staff, and additional supports needed for the smooth

running of the main trial), (3) testing of data collection forms, objective as well as self-report outcome measurement tools, (4) determining the recruitment and consent rates, (5) determining whether the intervention is acceptable to patients, (6) assessing reliability and feasibility of the outcome measurement tools which can be proposed for the main trial. Feeley et al. (2009) suggested that pilot study may be used in order to assess feasibility of a full trial through (1) assessing feasibility and acceptability of the intervention and research procedures, and (2) facilitating the determination of effect sizes to use in sample size calculations for the main trial. They defined feasibility as whether research procedures and the intervention can be delivered with high fidelity by the researcher(s) as planned. Acceptability is whether the intervention or research design are suitable from the perspective of participants and staff members. Fidelity of intervention is the extent to which the intervention provided is consistent with the protocol and theory.

However, the analysis of pilot studies should be mainly descriptive or focus on estimation of confidence interval and results from hypothesis testing should be treated as preliminary and interpreted with caution (Lancaster et al. 2004; Arain et al. 2010; Thabane et al. 2010).

National Institute of Health Research (NIHR) is one of the major funding bodies in the UK who also supports pilot and feasibility studies. A glossary of terms on NIHR website (NIHR 2014) describes feasibility studies as pieces of research conducted prior to a main study in order to examine whether the study can be done. According to their definition, feasibility studies are used to estimate important research design parameters comprising (1) standard deviation of the outcome measure, (2) willingness of participants to be randomised, (3) willingness of clinicians to recruit participants, (4) number of eligible patients, (5) characteristics of the proposed outcome measure, (6) follow-up rates, response rates to questionnaires, adherence/compliance rates, etc., and (7) availability of data needed and time needed to collect and analyse data (NIHR 2014). They described pilot studies as “a smaller version of the main study used to test whether the components of the main study can all work together. It is focused on the processes of the main study, for example to ensure that recruitment, randomisation, treatment, and follow-up assessments all run smoothly. It resembles the main study in many respects, including an assessment of the primary outcome”(NIHR 2014).

To sum up, it seems reasonable to adopt a feasibility study with a pilot RCT design in order to address the feasibility of conducting an RCT on effect of MI in facilitating hearing aid use. In the next section, more discussion is provided with regard to the design of the feasibility study.

7.5 Study Design

7.5.1 Introduction

Randomised controlled trials (RCTs) have been described as the gold standard method for evaluating the effect of a treatment (Chelimsky 1997). The original plan prior to start of the PhD was to conduct an RCT assessing effect of MI on hearing aid use. During the first six months of the PhD programme, the author examined more research literature and gained a more in-depth understanding concerning the decisions that need to be made with regard to the research design. These led the author to realise that there was a large amount of uncertainty about the appropriate research procedures, feasibility of conducting MI for hearing aids use, sample size, and relevance and acceptability of the research questions to patients. It seemed that given these uncertainties, designing a full scale efficacy RCT would be premature. Therefore the author decided to conduct some preliminary studies which can inform planning and justification for a full scale RCT in future. So the aim of the project deviated from conducting an efficacy trial and focused on assessing feasibility of conducting a full scale RCT instead. The next challenge was to decide on the design of the feasibility study. As outlined in previously there is little agreement among researchers about what exactly constitute as feasibility study (Lancaster et al. 2004). Below the challenges are described under 6 headings.

7.5.2 Design of the Feasibility Study

There are several study designs which can be used for the feasibility study. Some of the experimental designs comprise: RCT, cluster RCT, controlled trial, before/after comparison, randomised crossover trial, and historical controlled study (Bowling & Ebrahim 2005). The feasibility of conducting a full scale RCT can be tested through a pilot RCT which doesn't have to be the scale model of the planned full trial but it should address issues related to feasibility of the research procedures (Arnold et al. 2009; Craig et al. 2008; Craig et al. 2012). RCT design as a pilot study seemed appropriate for the purpose of determining feasibility of a full trial. In RCT participants will be randomly assigned to MI or control arm. As the result of random

allocation, groups will be balanced in everything except treatments received. If randomisation is concealed it can also prevent selection bias. Cluster RCT can be logistically easier as groups of participants will be randomised to intervention or control; however, it needs larger sample size and more complex analysis. Non randomised controlled trials have higher risk of selection bias. Before/after comparison experiment design seems suitable for a feasibility study. However, with this design it is not possible to examine neither the feasibility of the interventions for the control group nor the practical aspects of the randomisation process. Comparison interventions for the control arm and practicality of the randomisation process are among the important feasibility objectives which need addressing prior to the design of a full scale RCT. Crossover randomised trial reduces variability between groups by using paired data. In crossover design each patient receives control and intervention treatments in random order and paired comparisons will be made. However this method is unsuitable for interventions with long-term effect. For instance, it is possible that MI improves patients' motivations to use hearing aid and this effect will be carried forward to the control intervention. Historical controlled studies also maybe suitable for a feasibility study as they require minimum data collection. They compare data collected after an intervention to data collected on some other group which did not experience the intervention. However, there may be differences between the intervention arm and the historical controls other than the experimental intervention (Bowling & Ebrahim 2005). Moreover, with this design it is not possible to examine feasibility of the interventions for the control group and the practical aspects of the randomisation process. Finally it was decided to use an RCT design in order to address questions related to feasibility.

7.5.3 Self-Report Outcomes

Appendix 1 contains the self-report questionnaires used for this study. In this section the rationale behind selecting these tools and their psychometric properties are briefly discussed.

7.5.3.1 *Disease specific health related quality of life (HRQoL)*

It is recommended that in order to provide the most comprehensive evaluation of the effects of an intervention, it is useful to include both disease-specific and generic health measures to clinical trials (Abrams et al. 2005; Jackowski & Guyatt 2003). Three self report disease-specific health questionnaires are included to this pilot

study: Glasgow Hearing Aid Benefit Profile (GHABP; Gatehouse 1999), International Outcome Inventory for Hearing Aids (IOI-HA; Cox & Alexander 2002) and Client Oriented Scale of Improvement (COSI; Dillon et al. 1997). These 3 outcome measurement tools are chosen for this pilot trial over a large number of other audiological questionnaires for 3 reasons: 1) there is empirical evidence regarding their validity, reliability and sensitivity to hearing aid intervention (Cox et al. 2000; Cox & Alexander 2002; Dillon et al. 1997; Gatehouse 1999; Vestergaard 2006), 2) they have been widely used in assessing the effect of amplification and various aural rehabilitation programmes in recent audiological research making the outcome of this study more comparable to other relevant studies (Bertoli et al. 2009; Hickson et al. 2007; Kemker & Holmes 2004; Laplante-Lévesque et al. 2012; Munro & Lutman 2004; Öberg et al. 2008; Takahashi et al. 2007), and 3) these questionnaires are widely used in audiology clinical settings hence making the results of this study more meaningful and relevant to clinicians.

7.5.3.1.1 GHABP

GHABP is a validated questionnaire for English-speaking patients and uses 6 predefined subscales. The subscales assess initial disability and handicap (pre-intervention); hearing aid-use, hearing-aid benefit, residual disability, and satisfaction (post-intervention) in four predefined and four optional user-nominated listening situations (Gatehouse 1999). GHABP is designed to be used in routine clinical practice, both for individual patient management and as part of a quality-assurance programme. GHABP is translated to 10 other languages. There also is a computer version of the GHABP which is used routinely within the NHS audiology departments. Computer version will be used in this pilot trial. Part 1 of GHABP will be completed at the baseline assessment session. Part 2 of GHABP will be completed at follow up. The score on GHABP is in percentage. Higher percentage indicates is favourable outcome on use, benefit, and satisfaction. Lower percentage is favourable outcome on residual disability.

7.5.3.1.2 IOI-HA

IOI-HA is a seven-item inventory for hearing aid outcome assessment (Cox et al. 2000). IOI-HA has been validated in the original English version as well as for 21 other languages. Cox and Alexander (2002) assessed psychometric properties of the English version of IOI-HA. The Cronbach's alpha of IOI-HA was 0.78. This

suggests that the items have reasonable internal consistency, providing adequate statistical support for summing the scores to generate a total outcome score. IOI-HA will be completed at baseline and follow up session 1 month after intervention. Total score on IOI-HA range from 7 to 35. Higher score indicates more self-report benefit from amplification.

7.5.3.1.3 *COSI*

COSI is a clinical tool developed by National Acoustic Laboratories (NAL) for outcomes measurement. It allows clinicians to document their client's goals/needs and measure improvements in hearing ability. Unlike GHABP and IOI-HA that mainly have predefined questions, COSI focuses on the client's individual needs by letting them to identify listening situations that they would like to have improved with amplification. Finally COSI has been found to have good test-retest reliability and relates well to other measures of outcome such as benefit (Dillon et al. 1997). Part 1 of COSI will be completed at the baseline assessment session. Part 2 of COSI will be completed at follow up. Total score range from 1 to 5 for degree of change and the final ability. Higher scores indicate better final ability and more change.

7.5.3.2 *Generic health related quality of life (HRQoL)*

Although hearing specific instruments are more responsive to change following hearing aid intervention, they suffer from inability to compare the effect of different disorders and interventions. Relying solely on disease specific measures doesn't allow us to compare improvements in functional health status as a result of hearing aid intervention with improvements in health status arise from treatment for other chronic diseases such as arthritis, depression, etc (McArdle et al. 2005). This has implications for health care resource allocation and calculation of the cost for a service as a function of improved patient's general health status (Beck 2000). For this reason, use of generic measures that focus on the self-perceived overall health status of the individual is recommended. The 5 common generic HRQoL instruments are Euroqol 5-Dimension (EQ-5D; EuroQoL Group 1990), The Short Form 36 (SF-36; Ware & Sherbourne 1992), The Sickness Impact Profile (SIP; Bergner et al. 1981), Health Utilities Index Mark 3 (HUI3; Grootendorst et al. 2000), and World Health Organisation's Disability Assessment Schedule II (WHO-DASII; WHO 1999). Two review studies suggested that most of the generic HRQoL instruments lack sensitivity to hearing aid intervention (Abrams et al. 2005; Bess

2000). Abrams et al (2005) suggested that as WHO-DASII includes items loading on the consequence of hearing impairment, it seems to be most suitable for audiological research. Hence it is included to this pilot study.

The WHO-DAS II is organized into six domains: communication, mobility, self-care, interpersonal, life activities, and participation in society. The WHO-DAS II assesses difficulties with functioning and disability in each of these domains over the past 30 days. A nonparametric item response analysis of WHO-DASII showed that all items provide good discrimination across varying standardized levels of the trait (Luciano et al. 2010). Üstün et al (2010) reported that WHO-DASII has high internal consistency (Cronbach's alpha: 0.86), a stable factor structure, high test-retest reliability, good concurrent validity in patient classification when compared with other recognized disability measurement instruments, and good responsiveness (i.e. sensitivity to change). WHO-DASII will be administered at the baseline assessment session as well as in the follow up session. Total score range from 0 to 48. Higher scores indicate lower health related quality of life.

7.5.3.3 Significant other's opinion

It has been reported that significant others (SOs) (e.g., partner, family member, etc) of the hard of hearing person may bear the burden of hearing impairment to a greater extent than the person with the impairment (Chmiel & Jerger 1996). Effect of amplification on quality of life of SOs has also been studied (Stark & Hickson 2004). However, it is unclear whether adding MI to standard care result in any improvement from perspective of SO. Therefore, International Outcome Inventory for Hearing Aid for the Significant Other (IOI-HA-SO; Noble 2002) which assesses satisfaction, participation restriction, impact and quality of life, as experienced by the SO is included to this study. IOI-HA-SO will be completed by SO at follow up. Total score range from 7 to 35. Higher scores indicate more benefit from amplification from the perspective of the SO.

7.5.3.4 Coping measures

Given the client-centred Rogerian route of MI, although the therapist compassionately have the best interest of patient in mind they should also have non-conditional positive regard for patient and accept their final decision regardless of whether they agree to use their hearing aid or not. This means that for some patients

a successfully delivered MI may not necessarily lead to increased use of hearing aid but could help them cope better with their hearing impairment. For instance, reflective listening in MI could help the patient to talk freely about their emotions and deeper psychological concerns with regard to deafness and/or hearing aid use. Non-judgmental attitude of the therapist and empathic understanding of patient's difficulties and concerns help them to feel being understood and provides a unique opportunity for them to move on and think of their aspirations for change. While focusing on desires, needs, reasons and their abilities to improve their hearing may give them a direction for change, empathic understanding and acceptance exhibited from the therapist helps them to feel in charge and under no obligation to change. These may help patient to develop acceptance and more positive attitude in dealing with their hearing impairment. This could be a step forward to use of hearing aid which may happen in future should they feel ready for it. In order to capture potential outcome of MI which could be beyond hearing aid use, a coping questionnaires, the cognitive emotion regulation questionnaire (CERQ; Garnefski & Kraaij 2007). CERQ has nine subscales comprising: self-blame, acceptance, rumination, positive refocusing, refocus on planning, positive reappraisal, putting into perspective, catastrophizing, and other blame. Each subscale consists of 4 questions. The total score for each subscale range from 4 (almost never) to 20 (almost always). Higher scores indicate the higher chance that the individual taking a certain coping scale identified by the sub-scale.

Psychometric properties of this questionnaires have been validated and they previously have been used in assessment of coping strategies in people with hearing impairment (Garnefski & Kraaij 2012a).

7.5.3.5 Readiness for change measures

There is no validated questionnaire to assess motivation and readiness for hearing aid use. Therefore, readiness to change ruler (Zimmerman et al. 2000) which is a generic measure is included to this study. Readiness to change ruler will be administered during the baseline assessment session. Scores range from 0 (not motivated for change) to 10 (Highly motivated/already changed).

7.5.3.6 *Anxiety and depression*

Hospital anxiety and depression scale (Zigmond & Snaith 1983) will be will be administered at the baseline assessment session as well as in the follow up. Total scores range from 0 to 21. Scores above 10 indicates possible symptoms of anxiety or depression.

7.5.3.6.1 *Client Evaluation of Motivational Interviewing*

In order to assess whether MI was acceptable to patients Client Evaluation of Motivational Interviewing Scale (CEMI; Madson et al. 2013) was used. CEMI is a self-report questionnaire with 16-items which are divided into two subscales (relational and technical). Relational subscale includes items assessing whether the clinician avoid pushing the patient forward when they are unwilling to talk about an issue further, telling them what to do, arguing with patient that they need to be 100% ready to change their behaviour, and acting as an authority. Technical subscale include items focusing on whether clinician helped patient to talk about changing their behaviour, therapist acting as a partner, and helping the patient to feel hopeful about changing their behaviour. Each item assesses the degree to which a clinician exhibited specific MI-related behaviours from patient's perspective and is rated from 1 (low consistency with MI) to 4 (consistent with MI). Patients should complete CEMI after their MI session. Madson et al. (2013) reported that internal consistency of CEMI was 0.91 for the technical factor and 0.89 for the relational factor.

7.5.4 Shortfalls of RCT Design

Application of RCT design and its post-positivist philosophical underpinnings has been criticised when it comes to assessment of complex psychosocial interventions (Greene 2003). MI is a complex intervention and has several components related to the therapist's attitude, knowledge, skills, and behaviour as well as to the patient's within the session behaviours and attitudes (Apodaca & Longabaugh 2009; Gaume et al. 2009). In fact, the content and delivery of MI may changes from one to another clinician based on their personal factors and training background and from one to another patient based on their individual needs. Moreover, behaviour of using hearing aids and its outcome in terms of improving quality of life are complex phenomena which are affected by several personal and environmental factors (Abrams et al. 2002; Boothroyd 2007).

Postpositivist approach is criticised because its experimental designs such as RCT do not accommodate the open complex reality that is the social world (Brady & O'Regan 2009). In other words in the context of hearing aids use the implicit assumptions of postpositivist approach that the facts about behaviour of hearing aid use and its effect on patient's quality of life can be separated from values and perspectives of the patients is debatable. In addition, some authors questioned the external validity of RCTs because the sample is chosen from a specific group of people who are referred to a particular centre instead of a random sample from all members of a given population (Brady & O'Regan 2009). This limits the degree to which the findings of RCTs can be generalised. Another criticism of the RCT design is its focus on reductionist approach to understanding the nature of causality in the social world (Pawson & Tilley 1997). In the RCT design it is asserted that any difference in outcomes between two groups randomly assigned to treatment and control can be proved mathematically that is because of the treatment. This may be the case in laboratory study in a highly controlled environment but may be difficult to prove if the treatment is a complex intervention and a wide range of known and unknown psychosocial factors influence the outcome behaviours. Finally, RCTs commonly rely on quantitative outcomes such as scores on questionnaires which may not necessarily be suitable to address the construct of interest (Brady & O'Regan 2009).

7.5.5 Mixed Methods Design: Challenges and its Underlying Philosophy

In order to address the shortfalls of the RCT design in the assessment of complex interventions, the author decided to use a mixed method design informed by pragmatism philosophy. Despite the debate that post-positivist and interpretivist approaches cannot be combined due to the differences in their ontological and epistemological assumptions (Greene 2007), pragmatism offers an alternative view point and encourages application of a diverse range of approaches including quantitative and qualitative research methods in order to answer the research questions (Tashakkori & Teddlie 2010). Basically as a philosophical underpinning of mixed methods studies, pragmatism emphasises the use of pluralistic approaches to drive knowledge about the research questions without having any entanglement to making forced choices between methodologies (Cherryholmes 1992). Moreover, in feasibility studies mixing qualitative and quantitative methodologies will help to

refine the research question, generate hypothesis for future studies, and add depth to the finding and improve our understandings of them (Green & Thorogood 2009c; Silverman 1998). Mixed method design has widely been used in pilot and feasibility studies in order to produce more in-depth knowledge which can be used to inform the design of the future full-scale trials (Baral et al. 2014; Chesser et al. 2014; Iribarren et al. 2013; Secomb & Smith 2011; Fisher & Boudreau 2014; Leemans et al. 2014).

There are a variety of mixed methods designs. The major mixed methods designs comprise convergent design, exploratory design, explanatory design, embedded design, transformative design, and multiphase design (Creswell & Clark 2011). So the next challenge facing the author was to identify an appropriate mixed methods approach that can address the research questions. There were several factors that the author needed to take into account in choosing an appropriate mixed methods design for the study. These comprise (1) the level of interaction between qualitative and quantitative methods, (2) the relative priority of the quantitative and qualitative strands, (3) the timing of the methods, and (4) where and how to mix qualitative and quantitative strands (Creswell & Clark 2011).

The author wanted to conduct a postal questionnaire survey which is a quantitative method in order to assess the current extent of non-regular use among their patients at RSCH but more importantly to identify a group of non-regular users who can then be invited to take part in the feasibility study. In order to test feasibility of the research procedures and delivery of MI in the context of audiology the author wanted to conduct a pilot study with RCT design. With the pilot RCT it was possible to answer the feasibility questions with regard to the recruitment and retention rates, fidelity of intervention to MI theory and protocol, preliminary assessment of the intervention effect, suitability of the outcome measures, practicality of randomisation, intervention protocol, and uptake of follow up sessions. However some other feasibility-related questions including acceptability and relevance of the research questions to patients and perspective of participants about the key components of the research programme could be explored better using an in-depth interview, which is a qualitative method, instead of using questionnaires. In the other words, there were different questions that needed to be answered and each type of question required different types of data. Therefore it was reasonable to add a

qualitative strand within a quantitative design of the pilot RCT in order to enhance the overall design of the feasibility study. This is consistent with the embedded mixed method design (Creswell & Clark 2011).

With regard to the timing of the methods, because main aim of the qualitative component was to assess participants' views about the trial components it seemed reasonable to expect that the qualitative study should occur after the survey study and the pilot RCT. This makes the study a sequential embedded design (Creswell & Clark 2011). This way the qualitative stand would be a supplemental stand occurring after the primary quantitative stand.

The embedded design is a mixed methods approach where the qualitative component helps the researcher to contextualise the quantitative findings and explore participant's responses to quantitative variables (Creswell 2009; Wagner et al. 2012; Pluye et al. 2009). There are many challenges associated with embedded design. For instance the researcher needs to have expertise in both qualitative and quantitative methods in addition to expertise in mixed methods research. In addition, within the 3 years time frame for the PhD programme, the researcher will not be able to gain an in-depth knowledge and skills in all 3 methods (qualitative, quantitative and mixed methods). Although the thesis will cover a boarder range of outcomes it will inevitably have shallower depth compared to scenarios where only one method is used. Despite these, there is an increased recognition of embedding qualitative stands within experimental design of RCTs in order to gain more insights about the participants' perspectives with regard to the research procedures as well as the processes and intervening factors related to the observed quantitative outcomes (Lewin et al. 2009; Oakley et al. 2006; Bower et al. 2006).

7.5.6 Interpretivist Approach

The next challenge was to decide on the methods which need to be used within the qualitative component. There are various qualitative approaches, for instance ethnographic approaches, interpretivist approaches, biographical, conversation analysis, discourse analysis, and psychoanalytic approaches (Mason 2002). The distinct factor about the interpretivist approaches is that they consider people, their interpretations, meanings, and perceptions as the primary data sources. The interpretivist approach does support studies like this that the aim is to explore

participants' perspectives about acceptability of the research programme and their accounts of what influenced their hearing aids use. The important factor about the interpretivist approach is that it seeks people's perceptions, the "insider view", rather than imposing an "outsider view" on them (Blaikie 2000) (e.g., asking open questions versus questions with fixed multiple choice responses). This was appealing to the author because he wanted to provide an opportunity for participants to openly discuss their feelings and understandings about various components of the research programme without the inherent limitations of standardised questions or any entanglement to what has been described in theory about how MI might work. In addition, as the aim of the current project is to explore participant's individual and collective understandings it seems that engaging with ideas of interpretivist approach to be suitable. Having said that, qualitative research method is emergent and the researcher should be flexible in applying methods and modifying research procedures (Mason 2002; Creswell 2009).

Another role of qualitative methods in a feasibility study is to appraise and refine the research question and its underpinning assumptions (Green & Thorogood 2009c; Mason 2002). The research questions in this project are based on the assumption that consistent use of hearing aids is inevitably a good outcome. However, this may not mean the same from the perspective of patients. There is a body of sociological literature which suggests that patients evaluate medical advice and instructions in the wider context of their life and their views do not necessarily match the views of medical professionals (Adams et al. 1997). Qualitative research has shown that in some cases apparent irrational behaviour (e.g., non-adherence to medical advice) becomes understandable when viewed from the patients' perspective (Green & Thorogood 2009b). Interpretivist approach helps to explore how people cope with their health conditions, what the rationality of their behaviour is (Green & Thorogood 2009b).

7.5.7 In-Depth Interviews

As mentioned earlier the data sources in interpretivist approach are the people, their interpretations, meanings, and perceptions. There are several methods that can be used in order to generate such data. The key methods comprise interviews, group interviews, ethnography, as well as using documentary sources (Green & Thorogood 2009c). In many RCTs with embedded mixed methods design, it is common that the

researchers conduct interviews with the participants either on a one-to-one basis or in the form of a group interview at the end of the trial in order to explore their experiences throughout the research (Shinde et al. 2013; Leamy et al. 2014; Schoultz et al. 2013). Given the author's extensive experience in providing therapy, counselling and interviewing people on a one-to-one basis he was more comfortable with conducting interviews with participants individually as opposed to a group interview. Some authors classified interviews into 3 main categories: semi-structured, in-depth, and narrative interview (Green & Thorogood 2009a). A semi structured interview seemed to be the appropriate method for this study because the researcher could set the agenda in terms of the topics to be covered but the interviewee's responses will generate the information about those topics. The author could use his counselling skills (e.g., active listening, reflecting, empathy, non-judgmental, open questions, probing, confronting, etc.) in order to build a good rapport with patients and to make them feel comfortable so they can openly talk about their ideas and concerns. This way, the author will also be able to probe the responses people give in order to gain more detailed accounts of their experiences. The plan was for the researcher to use reflexivity throughout the interview process in order to improve the content and style of his interviews based on his reflections on the previous interviews and make an attempt to further explore trends emerging from previous interviews (Dowling 2006; Watt 2007). Analytic memos and annotations were made throughout the interviews about the practical aspects of conducting the interviews as well as about the emerging ideas relevant to the analysis of the data.

7.5.8 Thematic Analysis

The next challenge was to decide how to analyse the qualitative data. There are several different styles of analysis. Four common approaches comprise: thematic content analysis, grounded theory, framework analysis, and narrative analysis (Green & Thorogood 2009c). Thematic analysis is the most basic type of qualitative analysis which has widely been used in mixed methods studies in health and social care (Ayres et al. 2014; Finch et al. 2014; Lins et al. 2014; Morris et al. 2014; Murray et al. 2014; Bailie et al. 2012; Paramasivan et al. 2011). The author had no previous experience in qualitative research therefore it seemed reasonable to choose the simpler method of analysis that can still address the research questions on (1) acceptability of the research and (2) participants' accounts with regard to what

components of the research influenced their hearing aids use. In addition, compared to the other methods thematic analysis is less time consuming hence fits well in the limited timeframe of the PhD programme. There are several articles which outline the theory and application of thematic analysis in a way that is accessible to students and people who are less familiar with qualitative research which can help the author to obtain the practical knowledge required for this task (Braun & Clarke 2006; Braun & Clarke 2014).

7.5.9 Integrating the Qualitative and Quantitative Data

The next challenge was to decide on how to integrate the qualitative and quantitative data. Although there is no widely agreed protocol on the nature and shape of the analytical process for combining results of qualitative and quantitative studies (Farmer et al. 2006), there are several key techniques comprising: triangulation, following a thread, and mixed methods matrix (O'Cathain et al. 2010). The triangulation protocol involves separate data collection and analysis for the quantitative (Survey, and RCT) and qualitative (semi-structured interviews) phases in order to produce 2 sets of findings. Then the findings will be combined at interpretation stage of a study in order to gain a more complete picture. This technique seemed to be appropriate for this feasibility study, as the quantitative components are planned to be conducted before the qualitative analysis. Triangulation helps the researcher to look for convergence, complementarity, or discrepancy between results of quantitative and qualitative strands which may lead to a better understanding of the research questions (Farmer et al. 2006). Detailed description for triangulation protocol is given by Farmer et al. (2006) which was helpful for the author who does not have previous experience in mixed methods design. Triangulation is mainly used to enhance validity of the research through convergence of information from different sources (Dootson 1995; Carter et al. 2014). For instance triangulation may include comparing themes emerging from a qualitative method and results of the quantitative methods in order to develop a comprehensive understanding of phenomena. It seems that in the triangulation protocol, different methods are used to answer the same or similar research questions. This way, if different methodological approaches produce convergence findings about the same question, it may lead to enhanced validity of the results or if they produce contradictory findings about the same question then exploring the

apparent inter-methods dissonance may lead to better understanding of the research question too (Erzberger & Prein 1997).

However, for this feasibility study which has an embedded sequential design, the research questions for the quantitative component (e.g., rate for recruitment and retention, fidelity of intervention to MI theory and protocol, preliminary assessment of the intervention effect, suitability of the outcome measures, practicality of randomisation, intervention protocol, and uptake of follow up sessions) are different from the questions that needed to be addressed via the qualitative component (e.g., acceptability and relevance of the research questions to patients and perspective of participants about the key components of the research programme) hence triangulation protocol did not seem to be a suitable technique initially. On the other hand, the overarching question of whether conducting a full scale RCT on the effect of MI in facilitating hearing aid use is feasible, could in fact be further explored by triangulating the results from the pilot RCT and the embedded qualitative interviews. Therefore, triangulation technique may be used in order to explore convergence, complementarity, and dissonance between some of the results of the pilot RCT and qualitative enquiry.

As mentioned earlier, another option for mixed methods is following a thread (Moran-Ellis et al. 2006). Following a thread takes place at the analysis stage and the initial analysis of the first phase helps to identify key themes and questions which need to be explored at the second stage (Moran-Ellis et al. 2006). Given the sequential nature of the current feasibility study where the qualitative study was planned to be conducted after the quantitative phase, initially it seemed that following a thread was a relevant approach. However, a more detailed assessment of this approach revealed that it may not be suitable for this study because in following a thread approach there is a need for conducting analysis of the data of the pilot RCT in order to guide the qualitative interviews. This was not possible because, in order to reduce any unnecessary visits for patients, the plan was to conduct qualitative interviews at the same visit where the final quantitative outcomes were going to be collected.

Another option for combining qualitative and quantitative methods was the mixed methods matrix which seemed very relevant to this study. Mixed methods matrix is

used when both qualitative and quantitative data are available on the same cases (Creswell & Clark 2011). For example in this feasibility study, qualitative interviews will be carried out on majority of patients taking part in the pilot RCT who will also have completed a wide range of self-report questionnaires. All data collected on a single patient can be studied together. For example, it is possible to compare patient's responses to questionnaires, their objectively recorded amount of hearing aid use, and the themes emerging from their interview transcript. The data can be displayed on a matrix where the rows represent the patients for which there is both quantitative and qualitative data and the columns display different data collected on each case (O'Cathain et al. 2010). This will allow the researcher to look for discrepancies among the data for each case and compare those with entire data set (Wendler 2001).

7.6 Intervention Development

MI is a psychological intervention which is not normally taught in audiology courses. The author did not have any previous training or experience with regard to conducting MI. Therefore, the first challenge faced by the author was to learn MI and develop skilfulness in delivering it with high fidelity in clinical practice.

MI is an intervention which is designed to help people change. It has been used in many different clinical contexts ranging from substance abuse, to promoting healthy lifestyle, and adherence to medication. However, it was the first time that MI was going to be examined in audiology outpatient clinics. Therefore, the exact way that MI could be combined with audiological sessions was not clear.

7.6.1 Who Should Deliver MI?

The first question was whether the author should learn MI himself and integrate that to the usual audiology sessions or to employ few people who have already been trained in MI. There are many people outside the field of audiology who have had MI training. They may have a wide range of educational and professional backgrounds comprising behavioural psychology, cognitive psychology, psychiatry, counsellors, dieticians, medics, social workers, researchers, and people with no health or medical background. It was possible to employ someone with adequate MI training in order to provide MI for hearing aid users in the research. The MI counsellor probably would have needed to have some additional training in order to

become familiar with aural rehabilitation and the problems faced by hard of hearing individuals.

At first this idea was appealing because if MI, delivered in this manner, proves to be effective in facilitating hearing aid use then the audiology departments could employ non-audiologist MI-counsellors, in order to address motivational and psychosocial aspects of hearing aid use before or after fitting of hearing aids by qualified audiologists. Although this seemed to be an interesting idea which could encourage a more multi-disciplinary approach within the audiology teams and potentially strengthen the process of aural rehabilitation, it had its drawbacks.

Firstly, it is not clear whether an intervention which is MI plus standard care (SC) and is delivered by 2 different people (i.e., MI counsellor and audiologist) would work in outpatient audiology clinics. For example if patients with hearing impairment would be offered to see a counsellor instead of their audiologist, it might cause some confusion as they may complain that they just want their hearing aids to be adjusted so why they would need to see a counsellor.

Secondly, it is not clear whether the option of offering MI delivered by an MI counsellor in addition to the usual/standard audiology care (MI plus SC) would be better than integrating MI with the skill set of audiologists (MI combined with SC). If integrating MI with usual audiology sessions (MI combined with SC) delivered by an audiologist proves to be feasible, then there may not be a need to employ additional staff to deliver MI separately from the audiology sessions. In MI combined with SC, within the same session the audiologist could spend some time in providing counselling in MI style then carry on audiological tasks as required. This way, audiologists become better equipped to offer technological solutions as well as addressing the psychosocial aspects of using such technologies.

Thirdly, learning MI provides an opportunity for audiologists to extend their scope of practice and integrate counselling and MI skills into their day to day activities. The author's vision was that learning MI would be a valuable tool for audiologist which can enhance their skills in providing a more comprehensive holistic approach in the process of aural rehabilitation. It wasn't an appealing idea for the author that an MI counsellor listens to the patient's concerns, builds a good rapport, helps them with decision making, and enhances patient's motivation then send them off to the

audiologist who would just continue to do whatever they were doing in the past (e.g., technical adjustments of hearing aids, informational counselling, etc.). In fact in the eyes of the author, listening to the patient's concerns, building a good rapport, helping them with decision making, enhancing their motivation and generally addressing psychological aspects of hearing aid use are the most important parts of the aural rehabilitation without which the audiologists' role is not beyond a technician job. Current audiologist's approach, although lacking the counselling component, seems to work well for patients who are ready to use hearing aids but there is a gap in the services provided for those who are not fully ready to use their hearing aids. Learning MI could help the audiologists to bridge the gap.

Fourthly, the author had a great personal aspiration to learn MI. He liked to use the 3 years of PhD period as an opportunity to master MI skills as well as conducting the research. He wanted to have a first-hand feel of how this intervention might be delivered for hearing aid users and what the reaction from patients would be. There was not enough time though for the author to gain skilfulness in MI, and then teach this to other audiologists who then may be involved in the pilot/feasibility study. Should integrating MI with audiology tasks prove to be feasible, then other audiologists can be trained and get involved to the future trials.

7.6.2 How can MI be Integrated to the Usual Audiology Care?

The plan was for the author to gain appropriate knowledge and skilfulness to deliver MI. Then he could use MI in his routine clinics in an opportunistic manner in order to figure out how to combine MI counselling style with the audiological tasks in routine audiology practice. In a typical audiology session with patients who present with difficulties with their hearing aids, a hearing aid review session, audiologists usually conduct the activities listed below based on the needs of the patient:

- 1- Discuss patient's problems with regard to their hearing aid use.
- 2- Check comfort and suitability of hearing aid and ear moulds/open tubes.
- 3- Problem solving, practice using hearing aid functions, changing batteries, hearing aid maintenance, as well as insertion and removal of the hearing aid.

4- Real Ear Measurements (REM) (if needed, REM had already been undertaken for all patients at the time of the initial fitting as a part of the routine practice).

5- Adjusting the gain-frequency response of the hearing aid(s), feedback manager, acclimatisation setting, compression, directional microphones, loop system and additional programmes as well as automatic applications (when needed).

6- Provide brief education and explanations with regard to (a) patient's hearing status (description of audiogram), (b) why they need a hearing aid, (c) how a hearing aid operates and its limitations, (d) communication strategies/assistive listening devices.

7- Advise patient that they need to use their hearing aids consistently.

The authors' plan was to keep all the audiological tasks (1 to 5 in the list above) but provide information and advice (6 & 7 in the list above) in MI style. This way within the same session he could spend some time in counselling in MI style then carry on audiological tasks needed.

7.6.3 How to Learn MI?

The decision was that the author should learn and gain skilfulness to deliver MI prior to onset of the study. This was a very big responsibility as the author kept thinking of "What if I cannot learn MI?" in addition, it was important to make sure that MI can be delivered with high fidelity consistently from one session to another. Because if during the trial the intervention evolves over time, due to the author gaining more experience, then it will be hard to establish what effects are produced by any given form of the intervention. Some authors even suggested a minimum of 2 years of running an intervention is necessary before it can be tested in an RCT (Rossi et al. 2004; Ghate 2001).

There is no specific amount of training that guarantee competency in MI (Miller & Rollnick 2012). However, research studies suggest that attending an MI workshop plus practice feedback and coaching increases post training proficiency (Bennett et al. 2007; Miller et al. 2004).

A training programme in order to achieve skilfulness in MI was developed and implemented by the author. The training involved attending a 2-day MI workshop.

Following the workshop, the author had 30 hours of practicing MI skills in audiology clinics for patients who didn't use their hearing aids on a regular basis (these patients were not part of the pilot RCT). All of the sessions were audio recorded for training purposes so the author could review them and reflect on the skills used as well as areas for improvements.

These were followed by 10 hours of supervision/coaching with 4 MI experts where recordings of the sessions were analysed and coded using Motivational Interviewing Treatment Integrity 3.1.1 (MITI 3.1.1; Moyers et al. 2010) and feedback and additional training were provided to improve MI skills as necessary. The MI experts who supported the author were registered as MI trainers on the official website of the motivational interviewing network of trainers. The process of supervision comprised the steps as described below:

- 1- The author provided the recording of a practice MI session to the MI trainer. The practice sessions were conducted at the audiology clinics at RSCH for patients who didn't use their hearing aids on a regular basis (these patients were not part of the pilot RCT).

- 2- The MI trainer listened to the recording and coded it using the MITI 3.1.1.

- 3- The MI trainer sends his/her feedback form to the author. Two examples of the feedback forms are shown in Table 2.1 & 2.2. Table 2.1 is an example of the feedback provided to the author at the earlier stages of training while Table 2.2 shows the feedback provided to the author at a later stage in the training/supervision process.

- 4- The MI trainer arranged 1-hour meetings with the author (mainly over phone) in order to discuss his/her feedback and provide further coaching/guidance.

- 5- The author reflected on the feedback and information provided to him. He listened back to the recording and planned for the next practice session.

- 6- The author conducted the next practice MI session at audiology, RSCH, and sent its recording to the MI trainer(s).

- 7- The same cycle continued until the author produced a minimum of 5 consecutive MI sessions which were coded by the MI trainers as competent in accordance with

the criteria described in MITI 3.1.1. This was achieved after 10 hours of MI supervision.

The training process also involved 100 hours of self-directed learning (i.e., reading MI literature and reflective practice).

TABLE 2.1: This is an example of a feedback form used by an MI trainer during the early stages of the supervision process.

MITI Feedback: Hashir Aazh			
Overall impression			
Your approach was warm and you were clearly engaged and listening. You established a good rapport with this client and demonstrated clear effort in attempting to understand her situation. I've made some more comments and notes on your use of skills below.			
Re: the MITI – it's good news! From your scores on this tape you are just about at MI proficiency on MI spirit, and on MI proficiency for your reflection to question ratio, % complex questions and % MI adherent statements. Your closed to open question ratio needs some work and I've made some comments below on the impact this had on your session. Of course this is a “snapshot” of 20mins of one clinical encounter but it does demonstrate that your skills are there, just in need of some polishing. And all in a second language ... – am very impressed!			
MITI3.1.1 summary scores			
	Proficiency	Competency	Your score
Global clinician ratings	Ave 3.5	Ave 4	3.3*
▪ Evocation			3
▪ Collaboration			4
▪ Autonomy support			3
▪ Direction			4
▪ Empathy			4
Reflection to question ratio [R:Q]	1	2	4.3
% open questions	50%	70%	25%
% complex reflections	40%	50%	54%
% MI adherent	90%	100%	100%
<i>* Note: this is an average of the first 3 global scores only (i.e does not include direction & empathy)</i>			
Notes			
On the whole my observations overlap fairly well with your reflections on the session – and MITI did a good job of picking up the areas of skilfulness we can work on.			
<ul style="list-style-type: none"> ▪ You made a great affirmations – “one of those things you can't buy” - and also an excellent complex reflection - “you feel old” – short, clear, and exactly the essence of what she is grappling with. 			

- You used mostly reflections in this session – evidenced in your very high question to reflection ratio. While the reflective listening statements demonstrated a real commitment to understanding this client’s experience, it also had the effect of her talking a lot (!) and taking charge of where the conversation was going. This is fine but also meant that some opportunities for you to actively steer the conversation in one or other direction was lost. Try including a few more open questions – this will also allow you to shift into a more evoking style of communication with her.
- Where you did use questions these were mostly closed – e.g. “can you tell me ...”; “is this something that you think you can do?”; “does that make sense to you?” – how would you phrase these to make them open questions? If you have time, you could listen back through your tape and try and spot the closed questions then pause the tape and ask yourself how the conversation may have sounded different if you had asked an open question at that point.
- We could also work on shifting reflections from simple to complex, and this would have allowed you to go further in the session with this client.
- A few questions for you to ponder - where (if anywhere) was this client expressing ambivalence? What (if any) were your observations about change talk in this clinical encounter? How explicit was the focus of your conversation?

Best wishes

xxxx

TABLE 2.2: This is an example of a feedback provided to the author during the later stages of the supervision process.

MITI Feedback: Hashir Aazh			
Tape number 16 . Minutes coded: 10.13-31.13			
Overall impression			
An excellent session Hashir, I can see that you have taken the feedback given to you on board, and acted upon it. On starting this session at 10 minutes I was keen to see where you were at, at that point. You were indeed focusing on the here and now and on change rather than on the history. It is very good to see that this tape is at competency, that takes some doing.			
MITI3.1.1 summary scores			
	Proficiency	Competency	Your score
Global clinician ratings	Ave 3.5	Ave 4	4.3
▪ Evocation			4

▪ Collaboration			4
▪ Autonomy support			5
▪ Direction			5
▪ Empathy			4
Reflection to question ratio [R:Q]	1	2	2.6
% open questions	50%	70%	100
% complex reflections	40%	50%	40
% MI adherent	90%	100%	100

** Note: this is an average of the first 3 global scores only (i.e does not include direction & empathy)*

Notes

Very nice use of hypothetical questions including using them as part of 0-10 questions “if you did decide to, how important is it for you on a scale of 0-10.....” .

I really liked the use of “what would it be like if you could hear properly?” – lovely envisioning question

Very nice use of E-P-E, lovely asking of permission “I’ve got some info to share with your permission”

You focused a lot on supporting his autonomy and used a lot of affirmation, in fact you had 10 MI adherent behaviour counts! (and no MINA) so although your complex reflections are not as high, your use of MIA trumps that, and that pushes up your globals;

“You are determined”

“You are a persistent person”

“That’s honest and open minded”

I felt your use of affirmations seemed very genuine and thoughtful and helped your patient see their own strengths.

You used much less “I think” talk and hardly any “ok” facilitative utterances.

There was one piece of change talk that could have been explored and missed when the patient said “Maybe I could get used to it”.

Thanks for sending this through.

Best wishes

Xxxx

7.7 MI Protocol: A Real Example (uncut)

No specific intervention manual for MI will be used in this project. MI is a person-centred counselling style; hence it should be delivered in harmony with the patient’s

feelings and experiences. An intervention manual that sets out certain activities or topics to be covered is likely to force the interviewer into premature focusing or planning for change while the patient may not be ready (Miller & Rollnick, 2012). Miller and Rollnick emphasised that “MI is foremost a clinical style, and not one amenable to formulaic presentation”(2012, p.385).

The plan was for patients in the intervention group to receive MI combined with hearing aid review with the author. The sessions will be allocated 60 minutes during which the author provides MI combined with the activities related to hearing aid review as described earlier. Typically, the first half of the session will be allocated to MI in order to explore and enhance patient’s motivation to use their hearing aids. Instructions and education will be provided within the MI component when indicated. The second half will be allocated to review and adjustment of the hearing aid settings. The blend of MI with hearing aid adjustment tasks is expected to be flexible and based on the needs of each patient. MI will be provided based on the principles described by Miller and Rollnick (2012). Key elements of MI should be present throughout the intervention sessions. These key elements are partnership, acceptance, compassion, and evocation (Miller & Rollnick 2012). Typically the MI combined with SC sessions should involve: (1) engaging and building a good rapport with the patient through emphatic application of a range of client-centred counselling skills, (2) exploring and emphatically reflecting on both sides of the patient’s ambivalence (e.g., motives to use hearing aid as well as motives for not using hearing aids), (3) emphasising their autonomy by communicating to them that the final decision on whether or not to use their hearing aids is theirs, (4) arriving at a shared sense of direction where the patient and the therapist are working collaboratively for the benefit of the patient, (5) actively evoking and emphatically reflecting on patient’s desire, ability, reasons, and need for using their hearing aids, (6) helping the patient to verbalise their intentions and plans with regard to use of their hearing aids, (7) enhancing their commitment by empathically reflecting on their plan(s) and helping them to explore possible obstacles in achieving their plans and how they might go about solving them, and (8) enhancing their confidence in their ability to make this change by encouraging them to explore their strengths in character and draw upon their life experiences where they successfully had managed difficult situations.

Although no specific intervention manual for MI will be used in this project, the author formed a unique style of delivering MI during the training period. This style of MI was consistent with the MI theory however was focused on hearing aid use as the target behaviour. A combination of the MI trainers' comments on the authors' practice recordings and the reflective practice of the author himself resulted in developing this style of MI which then was used consistently throughout the pilot RCT.

In order to demonstrate this unique MI style, a transcript of one of the actual MI sessions is provided here. The overall outline of sessions was consistent with the main MI processes which comprise: engaging, focusing, evoking and planning (Miller & Rollnick 2012; Miller & Rollnick 2002). It involved a flexible and strategic application of some core communications and counselling skills (Miller & Rollnick 2012). These include: open questions, affirming, reflective listening, summarizing, and finally informing and advising.

Below is the transcript of one of the MI sessions for hearing aid use which was conducted by the author during the pilot RCT. The processes of MI as well as the techniques used by the author are also described.

CLINICIAN (AUTHOR): OK, so you have been here once for a hearing test and then they fitted the hearing aids for you.

PATIENT: Yes.

CLINICIAN: So how was your general experience of coming here? [Open Question]

PATIENT: Oh, it was good, yes, I think, and certainly the last time I came it had improved it, because before that I think the volume was too great just on the normal setting and so it was becoming quite tinny, but following the last visit, I'm not sure when it was, some months ago, that was, it was an improvement, yes, I think the volume was turned down and it was adjusted, and that helped, yeah.

The author typically opened the sessions by asking the patient about their general experience of attending audiology department. This is a part of the engaging process in MI. Engaging is the first step of MI process within which the clinician should build a collaborative working relationship with the patient. During the engaging

process the clinician should help the patient to feel like an active participant in the session (Miller & Rollnick 2013). To achieve this, the clinician should use a wide range of reflective listening skills which will be described later in the text. This is different from having just a friendly conversation or a chat with someone. Although off-topic chat can feel comfortable and have an icebreaking function, it does not convey the important message to the patient that the clinician understands and recognises their concerns (Miller & Rollnick 2013). In fact some studies in the field of substance abuse treatments showed that higher levels of informal chat between the clinician and patient during therapy sessions predicted lower levels of patient's motivation to change (Bamatter et al. 2010; Martino et al. 2009). They concluded that training and supervision of counsellors in MI should suppress the tendency of counsellors to talk informally in the sessions (Bamatter et al. 2010).

Application of the core communication and counselling skills (Miller & Rollnick 2012) including: open questions, affirmation, and reflective listening are important to build a good relationship with patient. Use of open-ended questions, as opposed to closed-ended, invites the patient to reflect before responding and gives them freedom of how to answer. Affirmation recognises, acknowledges and supports the patient's strengths and efforts. Reflective listening is communicating to the patient your understanding of what they meant. It can vary in depth from simple repetition or slightly rephrasing what they said to complex reflections where you add some meaning and guesses about the unspoken content.

CLINICIAN: So at the beginning you were not happy with the hearing aid?

[Simple Reflection]

PATIENT: Well no, because everything seemed to be amplified.

CLINICIAN: Too much. [Simple Reflection]

PATIENT: Too much, yes, yeah.

CLINICIAN: But then you didn't give up, you came back. [Complex Reflection]

PATIENT: Oh yeah, yes, yeah I've been back maybe, I've been here three, maybe three or four times I think.

Here the author provides some reflections. Some of them were mere repetitions of what the patient said. These are called Simple Reflections and they add little or

nothing to what the person said (Miller & Rollnick 2013). After couple of Simple Reflections, the author offered a Complex Reflection “you didn’t give up”. Complex Reflection adds some meaning to what the patient said and makes a guess about the unspoken content or what might the patient say next (Miller & Rollnick 2013). Complex Reflections help to take the conversation forward. Good reflections convey to patients that their concerns were heard. It is common that during the conversations with medical professionals or even in normal day-to-day conversations people try to repeat themselves when they feel that they are not being heard. In that sense, providing accurate reflections can save time.

CLINICIAN: So how was your experience when you came back, when you came and did a bit. [Open Question]

PATIENT: Generally it was an improvement each time, yeah generally, yes.

CLINICIAN: And then you were happy with the way that they dealt with the problem. [Simple Reflection]

PATIENT: I wouldn’t say I was happy, because I still have difficulty, but I suppose there's only so much that can be done to compensate for hearing loss, yeah.

CLINICIAN: OK, so you feel that there is still room for improvement? [Complex Reflection]

PATIENT: Absolutely, yes, yeah, and I will tell you I have been to a private clinic also. I haven’t done anything, so I'm keeping that in abeyance, but we’ll see how this goes.

CLINICIAN: OK.

PATIENT: Yeah, yeah, yeah.

CLINICIAN: Tell me a bit more about how do you use your hearing aids, like on a typical day? [Open Question]

PATIENT: On a typical day I usually put them in first thing in the morning and they’re in I suppose 50, 60% of the time, but when it comes maybe to the evening, if I’m listening to television, I don’t listen all that much, it’s just maybe if there's sport on or if there's the news, then I take the hearing aids off and I use headphones, which are connected through WiFi to the television.

Here the author provided few Simple and Complex Reflections then moved on to ask an Open Question “Tell me a bit more about how do you use your hearing aids, like on typical day?”. The aim of this question is to provide an opportunity for the patient to reflect on his hearing aid use behaviour and try to identify any areas for improvement. In respond to the Open Question, the patient described his hearing aid use and indicated a use of around 50% of the time. In addition, he provided some clues about the situations that his hearing aid did not help him much.

The other option for the author was to ask a series of Closed Questions in order to pin point where the problem lay. Often audiologists ask a lot of Closed Questions in order to identify the problems with the hearing aids or the behaviour of hearing aid use. For example: How many hours per day do you use your hearing aids? Do you use them outside? How often do you change batteries?

Asking too many Closed Questions, doesn't help to take the conversation forward and reduces the collaborative nature of the session. Although Closed Questions are important in gathering specific information, they hamper the collaborative relationship and assert the expert role (Miller et al. 2008). As shown in the interview segment above, it was the patient, not the audiologist, who was exploring and talking about his hearing aid use behaviour as opposed to the audiologist taking the lead and asking questions while the patient takes the passive role and just answering them. The aim of these sessions was to promote consistent use of hearing aids, hence it was vital to strengthen the collaborative relationship through providing an opportunity for the patients themselves to reflect on their behaviour and explore areas for improvement. Even asking a series of back-to-back Open Questions can turn the session to a question and answer style and reduces the partnership between patient and clinician. In fact the rhythm in MI is to ask Open Questions then reflect to what the person says. It is recommended to offer two reflections per question (Moyers et al. 2010). Of course some Closed Questions need to be asked but the recommendation is to offer more Open Questions (70% Open Questions) and a Reflection to Questions ratio of 2 (Moyers et al. 2010).

CLINICIAN: And that seems to be helping. [Simple Reflection]

PATIENT: Oh yeah, that helps greatly because I can adjust the volume independently.

CLINICIAN: Without interfering with other people. [Complex Reflection]

PATIENT: That's right, yeah.

CLINICIAN: That's clever. [Affirmation]

PATIENT: Yeah.

CLINICIAN: So one area that you felt that you are not completely satisfied with the hearing aid is [Simple Reflection]

PATIENT: Yeah, the most difficult thing is if I'm in with a group of people, say at a meeting, or if it's a social event, then I have difficulty picking up one to one conversation when there's a lot of background noise. That's probably the most frustrating thing I have.

CLINICIAN: And so, and how the hearing aid would react to that? [Open Question]

PATIENT: Well it seems to amplify things, but unfortunately of course it amplifies the background noise as well and so picking up clearly what someone is saying becomes increasingly difficult.

CLINICIAN: OK, so in noisy situations you did try the hearing aids. [Simple Reflection]

PATIENT: Oh yeah, I do try it, yes I usually use it, I usually use it.

CLINICIAN: OK.

PATIENT: But then I find it frustrating because quite often I'm not picking up what the person beside me is saying.

CLINICIAN: And those are some of the situations that are most important to you? [Complex Reflection]

PATIENT: Well that's important, yes, I mean you can't keep nodding and not understanding what someone is saying really, sooner or later you nod in the wrong place. *Laughter*

CLINICIAN: So you feel a bit disappointed about hearing aids. [Complex Reflection]

PATIENT: Oh yeah, well it's, it's, yeah it's a bit frustrating really, yes, yeah, yeah.

Here the author offered few simple and complex reflections in respond to the patient's description of his hearing aid use behaviour. The author also provided an affirmation "That's clever". As MI relies upon patient's own strength, recourses and

motivations for change, it is important to consciously look out for patient's strength, good steps and intentions and acknowledge them (Miller & Rollnick 2002). Affirmation is to accentuate the positive (Miller & Rollnick 2013). This is opposite to highlight people's weaknesses and faults or to make them feel bad enough so they change (Polacsek et al. 2001). More detailed role of affirmations will be discussed later in this section.

After receiving the affirmation, then the patient moved on to further reflect on his hearing aid use and explores areas that he has difficulties "Yeah, the most difficult thing is if I'm in with a group of people...". The author offered some Simple and Complex Reflections in order to help the conversation move forward and as soon as the patient articulated his emotional reaction to the difficulties with hearing aids "I find it frustrating because quite often I'm not picking up what the person beside me...", the author offered a Complex Reflection on patient's expressed emotions "So you feel a bit disappointed about hearing aids". Complex Reflection on patient's emotions is very important because it conveys to patient that the clinician understands how they feel. Actively seeking to understand patients' internal frame of mind and to see the world through their eyes is called accurate empathy (Rogers 1965). Accurate empathy is one of the key aspects of MI and the client-centred counselling method of Carl Rogers. Accurate empathy means to understand and feel other's perspectives so deeply as if they are your own without losing the "as if" quality (Rogers 1965). This is different from sympathy and is completely opposite imposing your own views with the assumption that patient's views are inaccurate or misguided (Rollnick & Miller 1995).

After providing this empathic Complex Reflection on patient's emotions, the author felt that the patient might be ready for more probing questions in order to explore his understanding of his hearing impairment. The author also had some plans to offer some information to patient with regard to his hearing impairment. But first he needed to ensure that providing information will be in a collaborative manner. Collaboration is one of the principals of MI (Moyers et al. 2010).

CLINICIAN: And I was wondering how much you know about your hearing test results? [Seeking Collaboration]

PATIENT: Well I know that my right ear has lost hearing ability more than my left and I think there's a general loss at the lower frequencies, you know, so I can pick out, still pick out female voices better than male voices, generally.

CLINICIAN: So the lower frequency, there is the loss? [Simple Reflection]

PATIENT: I believe that's the case. It's the right antenna those curves, that's the lower frequency is that right?

CLINICIAN: That's the lower frequency [Giving Information]

PATIENT: Oh, then it's the higher frequency that's dropped off, I got it round the wrong way, yes, OK.

CLINICIAN: That's right, yes, but you are right in terms of your hearing is rather a bit different in different frequencies. [Giving Information]

PATIENT: Yeah, yeah, yeah.

CLINICIAN: You said that you use the hearing aid for about 50% of the time. [Simple Reflection]

PATIENT: Probably on average that's, yeah.

CLINICIAN: So tell me a bit more details, like on a typical day you said first thing in the morning you put them in. [Open Question]

PATIENT: Yeah, I put them in, yeah, and then if I'm working on the computer, if I'm on my own, then I don't always bother about them. If I take a phone call I usually take them off because I can hear better without them on with the phone call. If I'm driving, sometimes I leave them on if my wife's with me then I leave them on so I can hear what she's saying but I find that with driving, the hearing aids amplify tyre noise and traffic noise, and sometimes that makes things worse so I have more difficulty hearing when I'm driving, so I don't always use them then.

In the above segment, the author invited collaboration from the patient by asking how much he already knew about his hearing condition. Then the author displayed the patient's audiogram on his computer monitor and patient started explaining the graph. Here and then the author gently gave some information. The plan was to lead the conversation toward a point that the patient would ask questions about his audiogram, so the author could give him some important clues with regard to his hearing loss. However, at this point the author changed his mind about providing

information. He felt that he did not yet have enough information about patient's current behaviour of hearing aid use. The patient hasn't yet had the opportunity to explore and fully reflect on his hearing aid use either.

The author felt that providing information at this stage could lead to early disengagement. In MI this is known as avoiding a premature focus trap (Rollnick et al. 2008). Premature focus trap is when you try to solve the problem before you have established a good working alliance with the patient. You may identify the patient's problem but the patient may have more pressing concerns or do not share the importance placed by you on the problem (Miller & Rollnick 2013). To avoid this, the author takes the conversation forward and encourages the patient to talk by offering a Simple Reflection "You said that you use the hearing aid for about 50% of the time" followed up by an Open Question inviting patient to talk more about his hearing aid use this time with a more focus on non-regular use.

As shown in the transcript above the patient identified several situations that he didn't use his hearing aids. Although he is using his hearing aids where he feels is needed, he doesn't use it often enough to get used to them. It is possible that part of his problem in noisy places that he mentioned earlier in the interview is related to the fact that he hasn't been using his hearing aids consistently enough, so still hasn't got used to hearing the background noises. So the question here was whether the patient is happy with his current situation? He of course could hear in many places even without his hearing aids. So was his problem in noisy places significant enough to encourage him to use his hearing aids more consistently? This was an area needed to be explored so the author planned to facilitate that. In MI, it is important that the motivation and argument for change should come from the patient not the clinician. So the plan was to help the patient to explore his intrinsic motivations to hear better as opposed to the author suggesting them to him.

CLINICIAN: So you want to use them, and when you use them you are to some extent happy with them, but they are not brilliant [Complex Reflection]

PATIENT: Yeah.

CLINICIAN: And you like to use them more but there are some practical problems in the way that makes you frustrated? [Simple Reflection]

PATIENT: That's right, yes. Driving, if there's background noise, if there's a group of people with other conversations going on, or if it's a party, then I mean I use them, but I find them less effective then, for me, so quite, sometimes I use them early on when it's a social event, but then you know when people are starting, the noise level goes up and I think it becomes more and more frustrating for me to carry out conversations in.

CLINICIAN: OK and that makes you feel isolated. [Complex Reflection]

PATIENT: In a sense yes, yes, absolutely, in fact a bit stupid at times, so I tend not to get involved in conversations and discussions as much as I used to in the past, so, as a result of that.

CLINICIAN: You can't really fully engage. [Complex Reflection]

PATIENT: That's right, exactly, yes that's, yeah.

CLINICIAN: And that somehow doesn't let you to fully enjoy the experience? [Complex Reflection]

PATIENT: Exactly, yes, yes, that's right, yeah, yeah, that's right

Here the author offered few Simple and Complex Reflections on patient's hearing aid use. He particularly offered reflections acknowledging patients desire to hear well and his past efforts in using hearing aids in meetings and parties. Then the patient talks more about situations that are important to him and he says "it becomes more and more frustrating for me to carry out conversations in". The author here focused on patient's emotional reaction to his hearing related problems by offering a Complex Reflection "that makes you feel isolated". Please note that "feeling of isolation" is a new concept that the patient hasn't verbalised. Patient said "the situation is frustrating" but the author offered a new meaning of "isolation". That's why this was a Complex Reflection as opposed to a Simple Reflection which is a mere repetition of what the patient says. Complex Reflections are a guess about an unspoken content; hence they carry a certain amount of risk as you may get it wrong. But whether you are right or wrong Complex Reflections will help the conversation to move forward as the patient either will agree with what you say or disagree and correct you. However, if the reflection is accurate then it will be more helpful as it conveys to patient that the clinician understands how they feel, the basic principal of empathy as described by Carl Rogers (Rogers 1965).

In the segment above the Complex Reflection offered was in fact accurate as it led to patient talking more about how exactly he feels “...in fact a bit stupid at times, so I tend not to get involved in conversations...”. Then the author offered couple of more Complex Reflections to draw a clearer picture of how the patient feels when he can’t hear well in noisy places. Doing this the author demonstrates accurate empathy which means he can see the problem from the eye’s of the patient. At this point in the interview, it seemed that both the author and the patient have gained a shared understanding about the problem. The next task is to establish a shared sense of direction with regard to the solutions ahead. This is consistent with the concept of collaboration in MI where the clinician works collaboratively with the patient toward the goals of the interview without relying on dominance, expertise or authority to achieve progress (Moyers et al. 2010).

CLINICIAN: If you could hear better in those situations, how would it be like? [Open Question]

PATIENT: Well if I could hear better that would be a great improvement, yes, yeah, sure I’d be much happier with the situation and better able to engage and discuss and, yeah, be more involved, that would be the result, yes.

CLINICIAN: Because you are an active person. [Complex Reflection]

PATIENT: Well still, yeah, try to be.

CLINICIAN: And the hearing, it’s like a blockage to whatever things. [Complex Reflection]

PATIENT: It’s an impediment, yes, it’s an impediment to being fully involved in what’s going on, especially socially, yeah.

CLINICIAN: In noisy environments, on one hand if you use them they amplify the background noises. On the other hand if you don’t use them you still cannot hear as good. [Complex Reflection]

PATIENT: Yeah, yes, it’s well, yeah.

CLINICIAN: It’s not helping with that. [Simple Reflection]

PATIENT: No.

One of the principals of MI is evoking the “change talk”. Change talk is defined as any self-expressed language that is an argument for change (Miller & Rollnick 2013). The idea is that when people hear themselves talking about change, it is more

likely that they change. Saying that “I will use my hearing aids” to the audiologist, tends to strengthen individual’s commitment to do so. In MI, it is assumed that talking about one’s own motivations to change can facilitate change hence MI practitioners pay special attention to evoking and exploring change talk. There are several studies in the field of substance abuse suggesting that different forms of patient’s change talk seem to be important predictors of the change in behaviour (Apodaca & Longabaugh 2009; Strang & McCambridge 2004; Gaume et al. 2009). Later on in this section I will discuss the change talk and its variations in more details.

Evoking is one of the key principals of MI and refers to identifying and exploring the change talk. In the other words, actively helping the patient to explore and verbalise their own reasons for change and ideas about how change should happen. This is in contrast with educating the patient about change without paying attention to what they already know or have achieved so far (Miller & Rollnick 2012).

One way of evoking change talk is to ask open ended questions to which change talk is the answer. For instance at the interview segment above the author help the patient to envisage a changed future by asking “If you could hear better in those situations, how would it be like?”. This is an Open Question to which some sort of change talk will be the answer. Not surprisingly, the patient’s response was a form of change talk expressing his desire to change “I’d be much happier with”. Then the author offered couple of Complex Reflections on patient’s desire to change e.g., “Because you are an active person” to which the patient’s response was another form of change talk expressing his reason to change “it’s an impediment to being fully involved in what’s going on, especially socially”.

At this stage the author started to plan to talk about his ideas with regard to what can be done to help the patient. In MI exchange of information needs to be delivered in a certain way that it doesn’t assert the expert role and maintain the engagement and collaborative nature of the session. In MI and client-centred counselling, it important to realise that it is the patient who has the ultimate solution and the counsellor’s role is to help him to find it. So the attitude should be that I have some expertise about hearing aids and aural rehabilitation, and the patient is expert about his own strength, weaknesses, styles, life, and circumstances. Therefore, I need to

match my information to what the patient needs. In what follows the author provides some information and at the same time support patient's autonomy by conveying to him that he is person that makes the final decision and he doesn't have to follow the author's suggestions.

CLINICIAN: So I have some idea in terms of how you might be able to actually make an improvement in terms of the noisy environment. [Giving Information]

This is just my opinion. So feel free to agree or disagree. [Emphasis Autonomy]

PATIENT: OK.

CLINICIAN: I think that, there are some technical adjustments that I can make on the hearing aids so it doesn't amplify the background noises as much as it does now. [Giving Information]

PATIENT: OK, that's good.

CLINICIAN: The other thing is that I think that perhaps with the way that you use the hearing aids, some of the nerves in your ears and your brain do not get enough stimulation. So there are some unused resources in your brain and your ears at the moment. Whenever you use the hearing aid they start getting stimulated. [Giving Information]

PATIENT: Fair enough, OK, so the more I use them, the better it would be, yes, yeah. OK, that makes sense.

CLINICIAN: That's right, but I do not want to, this is a decision that is your decision and I cannot make this for you even if I wanted to. I am not really here to persuade you to do anything. In fact if you feel that I'm trying to persuade you, stop me. [Emphasis Autonomy]

PATIENT: No, no, no, I'm willing to try, to experiment just to see, yeah.

CLINICIAN: So you are not afraid of experimenting or trying? [Simple Reflection]

PATIENT: No, not at all, not at all.

CLINICIAN: There are different ways that people do this and I was wondering if, would that be OK if I tell you what other people's experience. [Seeking Collaboration]

PATIENT: Sure.

CLINICIAN: So you can think for yourself what would be. [Emphasis
Autonomy]

PATIENT: Of course, of course.

CLINICIAN: Some people use the hearing aids, they put them on when they
get up in the morning and then keep it on all the time during the day and take
it out at night when they go to bed. [Giving Information]

PATIENT: OK.

CLINICIAN: That gives the ears enough time to get acclimatised, to get used
to the sounds. [Giving Information]

PATIENT: OK, fair comment.

CLINICIAN: Some other people, they do the same thing, use it from the
morning to the evening when they go to bed, but they take the hearing aid out
a few times during the day to just give themselves a break. And they clean
the hearing aids with some disinfecting wipes, and then put them back in
after half an hour. [Giving Information]

PATIENT: OK.

CLINICIAN: There is also third option, which some people try to increase
the use of hearing aid step by step on gradual basis, so start from the lower
and then gradually build it up. [Giving Information]

PATIENT: OK, yeah.

CLINICIAN: And so what do you think would be a feasible thing for you to
do? [Open Question]

PATIENT: Well I think probably, realistically, probably the third option
where I progressively try to increase the use would probably be the best one
for me, I think.

I wouldn't like to say, yes I'll wear them morning to evening because, well I
mean I know in the evenings I won't, if I watch television for an hour or so
then they'll come out because I can't really use the headphones and hearing
aids together.

CLINICIAN: Exactly.

PATIENT: So I think, yeah, the third option would be the best, sort of step
wise maybe increase the use of them. I mean I can leave them in when I'm
using the computer, put on some music maybe as background and use them
then.

CLINICIAN: That's actually correct, it is again my own opinion, feel free to disagree, but even when there is no, like you using, typing on your computer there is still some background noises that can get picked up and keep the stimulating going. [Autonomy Support and Giving Information]

PATIENT: Yes, so I can, maybe some music will be a good idea, I mean sometimes I do but maybe I could do that more, yeah, there's no reason why not, yeah.

CLINICIAN: So you kind of have a positive attitude toward this. [Affirmation]

PATIENT: I try, I try. *Laughter*

At the segment above, the author used an approach called elicit-provide-elicited (EPE) in order to provide some information. EPE approach ensures that the information you provide is sandwiched between asking patients views, concerns or permission (Rollnick et al. 2008). Eliciting should happen prior to providing information and it means to encourage the patient to think about the information that you are planning to discuss. In order to elicit in the above interview segment, the author first said that he has some ideas that he liked to share and then emphasised patient's autonomy by saying "This is just my opinion. So feel free to agree or disagree". Autonomy support is one of the key attitudes originally described by Carl Rogers (Rogers 1962) and is embraced deep in the roots of MI. Carl Rogers believed that human nature is positive and forward moving and when given the essential therapeutic conditions (e.g., unconditional positive regard, empathy, transparency etc) people will naturally grow in positive direction (Rogers 1962). To support patient's autonomy the clinician should honour and respect their irrevocable right and capacity of self-direction (Deci & Ryan 1985; Miller et al. 1993).

In response to the author's statements, the patient showed an interest in listening to his suggestions. Then the author provided some information about the possible technical adjustments which needed to be taken on the patient's hearing aids as well as the importance of consistent use of hearing aids. In response to this information, which effectively was highlighting the fact that the patient didn't use his hearing aids consistently and more effort was needed on his side, the patient seemed to be agreeable but he didn't offer any change talk (i.e., he didn't say that I will do it). At this point the author thought that the patient may be feeling under an obligation to

agree while he may not be completely ready for it. Therefore, he offered further support for his autonomy by saying “this is your decision and I cannot make this for you even if I wanted to. I am not really here to persuade you to do anything. In fact if you feel that I'm trying to persuade you, stop me”. Here, the author gave permission to the patient to disregard his suggestions which paradoxically had led to the patient taking note of the advice and offering a change talk “I'm willing to try, to experiment just to see, yeah.” In MI it is very important to recognise change talk when you hear it and to evoke and respond to it when it occurs (Moyers et al. 2010). The idea is that when a change talk is offered by the patient the clinician should focus on it by asking open questions, giving affirmation, reflecting and providing reflective summaries on what the patient has said. These will often yield additional or more detailed change talk (Miller & Rollnick 2002).

The author identified the change talk and offered a Simple Reflection “So you are not afraid of experimenting or trying?” which led to further change talk “No, not at all, not at all [I am not afraid of trying it]”. This Simple Reflection was the last step, elicit, in the EPE approach because it provided a space for the patient to process and respond to the information provided.

Then the author started another EPE. He elicited by asking permission to talk about other people's experiences “There are different ways that people do this and I was wondering if, that would be OK if I tell you what other people's experience”. Then he provided information in the form of 3 options. Providing options emphasises on patient's autonomy and seek collaboration (Miller & Rollnick 2002). Next, he elicited by asking “what do you think would be a feasible thing for you to do?” This conversation moved forward to the point that the patient offered a change talk “maybe I could do that more, yeah, there's no reason why not, yeah” and the author identified the change talk and provided an affirmation “you kind of have a positive attitude toward this.” At this stage in the session it seemed that both the author and the patient had a shared sense of direction. In the other words, both the clinician and the patient were working collaboratively in order to improve patient's hearing aid use. Consistent with the metaphor used by MI pioneers this interview did look like the “ballroom waltz” rather than “wrestling” (Miller & Rollnick 2013). MI involves 4 stages: Engaging, Focusing, Evoking, and Planning. At this stage in the interview, engagement was achieved; focus on enhancing hearing aid use was clear, change

talk was repeatedly evoked so it was the time for planning and further strengthening of the change talk.

CLINICIAN: So if you, at the end of this session, if you do decide to start using the hearing aids more consistently, and decision is yours, how confident you are on a scale of zero to ten that you can actually do this? [Emphasis Autonomy and Closed Question]

PATIENT: Oh I think eight out of ten. Yeah, no, if I say I'll do it, I'll try and do it, yes, yeah.

CLINICIAN: You are a determined person. [Affirmation]

PATIENT: Yeah, I have a strong pride still, yeah, yeah.

CLINICIAN: If you feel that this is the right thing, you will do it? [Complex Reflection]

PATIENT: Yeah, sure, yes, no, no, I'll do it all right.

CLINICIAN: So how do you want to do this, what would be the exact plan, like when you are going to start? [Open Question]

PATIENT: Well I'll certainly put them on first thing in the morning, I usually do that anyway, and if I'm involved in the computer, which I am most days for a few hours, then I will use them, put on the background music. Afternoons, if I'm out in the garden or doing work around the house I don't always have them on, especially if I'm using noisy instruments, but maybe for some of that time I could put them on, yeah, but not in the evenings, except, I mean, for evening meals and, you know, when we're having dinner, then yes they can stay on, yeah, but the exception would be late in the evening when I have my headphones on, yeah.

CLINICIAN: You like to put them in, in the morning. [Simple Reflection]

PATIENT: Yeah.

CLINICIAN: When you, what time that would be? [Closed Question]

PATIENT: Oh, half past eight something like that.

CLINICIAN: Oh, quite early, yes. [Simple Reflection]

PATIENT: Well

CLINICIAN: And then for how long you want to keep them in for that period of time? [Open Question]

PATIENT: Oh, I can keep them in to midday, that's not a problem.

CLINICIAN: So around 12 o'clock [Simple Reflection]

PATIENT: Yeah, yeah, yeah, or even longer maybe, yes I mean there's no reason why I can't keep them in until after lunch.

CLINICIAN: And then that would be like? [Closed Question]

PATIENT: Two o'clock maybe.

CLINICIAN: And then

PATIENT: Afternoon, we'll see. I mean it depends on the activities, if I'm driving or doing noisy work then I may not leave them in, yeah.

CLINICIAN: So, you like it to be flexible. [Complex Reflection]

PATIENT: Yeah, yeah.

CLINICIAN: So to match with your own lifestyle. [Complex Reflection]

PATIENT: Yeah.

CLINICIAN: You do not want to commit to something that you may not be able to do. [Complex Reflection]

PATIENT: Absolutely not, no.

CLINICIAN: That, what you have set out it seems, it does make sense to me. [Affirmation]

PATIENT: Good, yeah, that's all right.

CLINICIAN: I think that's very good step forward. [Affirmation]

PATIENT: Yeah, OK, yeah.

CLINICIAN: As we said it might take time to get used to the sound of hearing aid, specifically this is more important when you are in outside situations. [Giving Information]

PATIENT: Yeah.

CLINICIAN: What is your plan for meetings or socialising etc? [Open Question]

PATIENT: Oh, I'll leave them in, yes, I mean if you think you can make them more suitable then certainly I'll wear them on those occasions, yeah. I mean it doesn't bother me wearing them, I mean I haven't got any sort of concern about that in terms of appearance or anything, I'm quite happy to wear them and most people I know now know I wear them, so it doesn't bother me, so leaving them in during social gatherings is OK with me, that's not a problem.

CLINICIAN: You don't feel embarrassed using them? [Complex Reflection]

PATIENT: No, no I feel more embarrassed if I don't pick up on conversation or feel left out of conversation, yeah, it's the lesser of two evils.

CLINICIAN: You have a practical approach [Complex Reflection]

PATIENT: Yes.

CLINICIAN: If there is a problem you want a solution. [Complex Reflection]

PATIENT: Sure, yeah, yeah.

CLINICIAN: And you're not too much worried about appearance or things like that. [Simple Reflection]

PATIENT: No, no, no I'm not a beauty queen or anything.

CLINICIAN: And then you said your friends already know that you that you have hearing aids. [Simple Reflection]

PATIENT: Most of the family know and, yeah, sure, unless they're blind.

CLINICIAN: It's not something that you can see easily you know, you have to look for them. [Giving information]

PATIENT: No, no it doesn't bother me anyway, it's there, yeah.

At the segment above the author asked an evoking question that "So if you, at the end of this session, if you do decide to start using the hearing aids more consistently, and the decision is yours, how confident you are on a scale of zero to ten that you can actually do this?". He also emphasised patient's autonomy by saying that "the decision is yours". Then the patient said that I will try to do it, change talk. The author identified the change talk and offered an affirmation "you are a determined person". The author reflected on most of the change talks offered by the patient. Then the author moved on to planning. Planning involves developing commitment to change and formulating a specific action plan. The author asked "So how do you want to do this?". Patient explained his views. Then he offered reflections to patient's change talks on the one hand, and asked probing questions to draw a clearer picture of patient's plans on the other hand. This encouraged the patient to offer even more change talk. According to MI theory, the more patient talk about change, the more the likelihood that they change. During this process the author stayed with the change talk and helped the patient in developing a plan. In addition, the author helped the patient to explore possible barriers and how he might go about managing them by exploring patient's thoughts on appearance and stigma of hearing aid.

Throughout the process the author identified patient's strength in character and resources and acknowledged them through offering affirmations. This is very important because it is the patient who needs to make the change so the clinician should help them to mobilise their resources and feel more confident that they can do it. The main aim of MI is evoke patient's own motivations for change and give them a voice. Therefore in the segment below the author continued evoking by introducing another topic.

CLINICIAN: I'm doing research on hearing aid use. I did a survey on 2,000 people with the sort of hearing loss that you've got and I have a percentage of the use of hearing aid which I like to share that with you and ask for your opinion. [Seeking Collaboration]

PATIENT: All right.

[The author displayed the pie diagram below (Figure 2.1) on the computer monitor] In most people here, so there were 8% that they don't use the hearing aids at all, and 5% use it less than an hour a day, and 13% one to four hours, 18% four to eight hours and the green area, more than eight hours a day. [Giving Information]

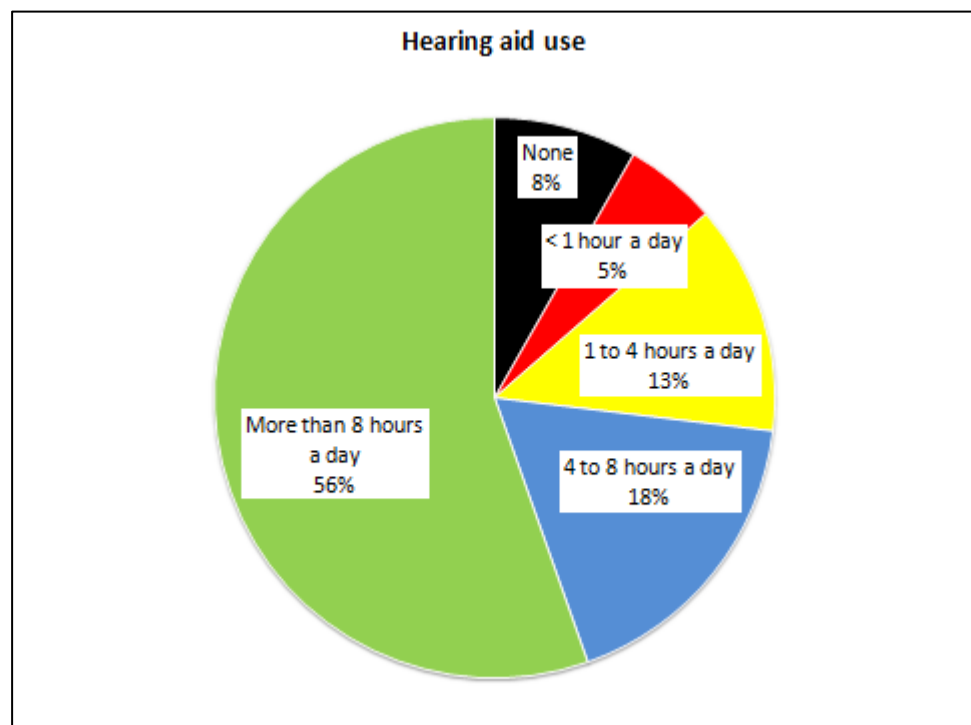


Figure 2.1: Hearing Aid use in NHS (Aazh et al. 2015).

PATIENT: Right, OK.

CLINICIAN: Where do you think you would fit? [Open Question]

PATIENT: Probably with the 18%

CLINICIAN: The blue area.

PATIENT: I'm surprised that people wear it as long as eight hours, OK, but 56%, OK, no I think I would be in the 18%, yeah, yeah.

CLINICIAN: OK, so you are in the middle ground if you like. [Complex Reflection]

PATIENT: Yeah, I think so, I'm average. *Laughter*

CLINICIAN: You have made a lot of progress from not having the hearing aid to the point you are using it. [Affirmation]

PATIENT: Sure, sure.

The author used EPE approach in the segment above. He elicited by asking "...I like to share that with you and ask for your opinion". He provided by showing the pie diagram. Then he elicited by asking "Where do you think you would fit?". The result was astonishing as the patient started comparing himself with others and wondering why many people use their hearing aids more often than he does "I'm surprised that people wear it as long as eight hours, OK, but 56%, OK". People usually like to be consistent with the majority. The pie diagram showed to him that there is room for improvement. Next the author asked more evocative question "why people use their hearing aids more than 8 hours a day". The answer to this question was expected to be the reasons for consistent hearing aid use or the change talk.

CLINICIAN: And you know because you were using the hearing aids and there are some certain difficulties

PATIENT: *Respondent indicates agreement*

CLINICIAN: And there are other things also you use for TV and things like that, which are different kinds of solutions if you like. [Simple Reflection]

PATIENT: Sure, yeah, yeah.

CLINICIAN: Why do you think these people actually use their hearing aids more than eight hours a day? [Open Question]

PATIENT: Why do they do that? I think probably because they maybe have the same sort of environment I think. I think they're probably older people that are maybe not going into different environments and sort of stressing their, or testing their hearing under different situations.

CLINICIAN: OK.

PATIENT: They're probably less, no that wouldn't be fair to say less sociable, but you know, I mean I recognise that hearing aids can only compensate for hearing loss up to a certain extent, and so perhaps these people are not actually in different environments where the hearing, hearing aid is not so useful. I'm just speculating.

CLINICIAN: Yes, so you mean it kind of matches their lifestyle? [Complex Reflection]

PATIENT: Yes, it's a lifestyle *match*, yes that's a good way of putting it actually, yes, yeah, and I think they're probably older, they're probably, let's say more sedentary, more isolated and therefore they're not encountering situations where the deficiency of the hearing aid would frustrate them perhaps.

CLINICIAN: OK.

PATIENT: I'm just speculating.

CLINICIAN: Exactly, it does, you know, it's, I don't actually know the differences in the lifestyle and things, yes. [Giving Information]

PATIENT: No, I don't either of course, but you know.

Although the author expected to hear some change talk (e.g., they like to hear better, hearing is important to them, they are more sociable, etc.) in respond to his question on why 56% of people use their hearing aids more than 8 hours per day, the patient did not offered any change talk. At this point, in order to avoid any discord and restoring the working alliance, the author shifted focus away from the diagram and to the patient's own desire for improvement.

CLINICIAN: But you, at the moment, you are *about here*? [Closed Question]

PATIENT: Something, yeah, probably, yes, yes.

CLINICIAN: But you kind of are prepared to make some improvement? [Complex Reflection]

PATIENT: Yeah I'm moving more towards probably the six hours, yeah, let me see, *twelve to four*, yeah I think I could maybe move to the six hours a day, yeah. CLINICIAN: It has to be, is your own decision and whatever you feel is right for you. [Emphasis Autonomy]

PATIENT: Yeah, well even six hours would be a 50% improvement maybe.

FN

CLINICIAN: Any improvement is good. [Affirmation]

Respondent and interviewer both talk at once

PATIENT: Yeah.

CLINICIAN: And you were thinking that if the hearing aids are performing better in noisy places that would be an encouragement for you? [Simple Reflection]

PATIENT: Oh absolutely, if I can get, if the hearing aids perform better I'll definitely use them more, well more each day, in fact as I mentioned, I would even be prepared to go private and spend some money if I thought that it would improve my ability to pick up conversations with a noisy background.

CLINICIAN: The quality of sound is the main factor? [Complex Reflection]

PATIENT: Absolutely, yeah, yeah, yes, yeah.

CLINICIAN: OK.

PATIENT: You know if the hearing aids can be more selective, for my purposes, then that would be better in terms of what they're picking up, but I don't know, I mean obviously that depends on the sophistication of the hearing aids, because I know, there are different ones that pick up different bands I think, isn't that correct, and you can adjust them I think.

CLINICIAN: We can adjust them, they're flexible, we can adjust them *and, yes* [Giving Information]

PATIENT: Yeah, OK, well that would be good, yeah.

CLINICIAN: And, what do you think would be the advantages of using hearing aids more consistently, because you were saying you are open to making an improvement in that. [Open Question]

PATIENT: Yeah, well, greater involvement, less frustration.

CLINICIAN: OK, is the outcome? [Complex Reflection]

PATIENT: Yes, the outcome would be better from my point of view, yes, and probably also for the people I'm interacting with, because they're then getting through to me.

CLINICIAN: That's right. They may get frustrated if they have to repeat something. [Complex Reflection]

PATIENT: Yes, if they think I'm not really understanding them, that's frustrating for them, yeah, sure.

In the above segment the author reflected on patient's desire to improve his hearing aid use and asked some questions which generated plenty of change talk (e.g., "I am probably moving more towards the 6 hours"). Then the author focused on technical improvements on hearing aids and asked how the patient is planning to use his aids if they get adjusted and perform better. In respond, patient offered more change talk. For instance patient said that the advantage of using his hearing aids more consistently would be "greater involvement, less frustration" and if he doesn't use hearing aids people may think that "I'm not really understanding them, that's frustrating for them". These are examples of change talk stating the reasons for change. So the patient seemed to be ready to use his hearing aids if they perform better. The author was thinking that even if he adjust the hearing aids the patient still needed to use them regularly in order get used to them, without which no amount of adjustments could guarantee a better outcome. So his next task was to clarify this with patient and seek his reaction.

CLINICIAN: That's right, yes. This, because this is a, if you like, a transition from using the hearing aid, if you like, part time, to using it a bit more consistent. [Simple Reflection]

PATIENT: Yeah, right.

CLINICIAN: And this is something, there are many different factors that can discourage you. [Giving Information]

PATIENT: Yeah, yeah.

CLINICIAN: What do you see within yourself that you think can help you to make this a successful change? [Open Question]

PATIENT: Well I mean I think I will have the enthusiasm and drive to have a better outcome, a better result, I mean that would be it really, I'd be motivated to achieve better results, yeah.

Before talking about the challenges ahead, the author planned to strengthen patient's confidence that he can do this change. The idea in MI is that the patient is the source of ideas about how change could be accomplished. The patient is expert about their own strengths in character and resources. In order to strengthen his confidence the

author asked “What do you see within yourself that you think can help you to make this a successful change?”. In respond to this patient offered a change talk stating his self-perceived ability to achieve it. This important because people need to have some confidence that they can change prior to commit to making the change.

CLINICIAN: The result of the technical adjustments is quite important for you. How about if takes time to work? [Complex Reflection and Open Question]

PATIENT: Yeah.

CLINICIAN: Because as we were talking about this it takes time to get used to the sound of hearing aids. [Giving Information]

PATIENT: Yeah, I mean if that takes time, so be it, yes, I'm prepared to give that a trial, a go, and if it succeeds well that'll convince me to continue, sure.

CLINICIAN: OK, some people say *wait* I want immediate improvement, otherwise they get discouraged. [Giving Information]

PATIENT: Yeah, yeah, yeah, no, no, I'm willing to give it time to work, yeah, sure.

CLINICIAN: And how long you are prepared to give them time to get used to them? [Open Question]

PATIENT: Well, weeks rather than months, you know, I'd be prepared to give it let's say a month and see, see what it's like after a month.

CLINICIAN: OK.

PATIENT: Yeah, I mean I, if it's a question of activating certain nerve complexes that's, it does take time, I realise that, yeah.

CLINICIAN: That's true, so you have a good understanding about the ear and the nerves. [Affirmation]

PATIENT: Yeah, yeah, so I mean I know nerve recovery and nerve impulses don't happen instantly, yeah. Well you lose them instantly, but regaining is not necessarily something that happens overnight.

CLINICIAN: It's a kind of retraining them to understand. [Giving Information]

PATIENT: Yeah, yeah, yes, OK.

Respondent and interviewer both talk at once

PATIENT: Get my brain working better, that's the negative side of it, if I could do that also I'd be very pleased.

CLINICIAN: It's the hearing part of it [Giving Information]

PATIENT: Yeah, we'll just work on the hearing, yeah.

CLINICIAN: So you're determined that you can actually give it another chance. [Complex Reflection]

PATIENT: Oh yes, absolutely, yes. Is there a big penalty if I don't?

Laughter

CLINICIAN: There is, as I said, this is, whatever you do is the right thing. [Emphasis Autonomy]

PATIENT: No, no, the incentive would be for me to have a more satisfactory outcome of the, yeah, so that would be sufficient.

CLINICIAN: OK, and, well thank you very much for being open and honest about how you feel. [Affirmation]

PATIENT: Well it's to my benefit I think.

After eliciting some thoughts about patient's strength in character, the author encouraged the patient to explore what he is prepared to do in terms of using his hearing aids consistently in order to get used to them. This is different from telling the patient that he should use his hearing aids x amount of time per day. Instead, he asked "how long you are prepared to give them time to get used to them?". To which a change talk was the patient's respond "I'd be prepared to give it let's say a month and see".

Please note, that if the author had told the patient that you need to use your hearing consistently for 1 month in order to get used to them, the patient response probably would have been a "yes" but it may not necessarily be an indication of patient's intrinsic motivation for change. As discussed earlier, in MI it is important for patient to make the argument for change not the clinician. In the interview segment above, whenever change talk happened the author responded to it by offering a reflection, affirmation or asking a question about it. At the same time the author emphasised patient's autonomy by conveying to him that whatever he decides is going to be the best for him.

In the segment below, the author initiated the process of closing the interview by giving some indications that he needed to make some technical adjustments on the hearing aids. However, he did not rush to close the session and did evoke further change talk by asking the patient about his plan. In MI it is important to help the patient to talk about change, so once you evoke change talk you would need to stay with the change talk by offering reflections, questions, and affirmations. As the result it created a lot of mobilising change. For instance the patient said “I’ll start tomorrow” which indicates a movement toward action. Then the patient offered even a stronger change talk “Well it’s the soonest I can do it, I mean, well *even* what’s left of today, yeah, sure” which indicated that he is doing something in the direction of the change. This is what happened in the segment below.

CLINICIAN: So I, what I think that I will do, I will spend some time in looking into hearing aids and see what adjustments I can make.

PATIENT: That's fine.

CLINICIAN: Before I do that, I just wanted to know that once I do those all things and we are both happy about how they operate, what would be your plan in terms of using them, exactly what is it that you are going to do?
[Open Question]

PATIENT: Well, as we’ve discussed, when I get out bed, well it won’t be immediately I get out of bed, but first thing in the morning I’ll put them on, I’ll try to continue through until after lunch, I might even use them some afternoons, but as the day progresses then probably they will be less used, but I think I can push it maybe from around four hours to six hours minimum, per day.

CLINICIAN: OK.

PATIENT: That would be my objective anyway, see how it goes.

CLINICIAN: That's fantastic, and it takes a lot of determination to do things that. [Affirmation]

PATIENT: Well we’ll see, we’ll see.

CLINICIAN: When are you going to actually do this? [Closed Question]

PATIENT: Oh, I’ll start tomorrow.

CLINICIAN: Why are you choosing tomorrow? [Open Question]

PATIENT: Well it's the soonest I can do it, I mean, well *even* what's left of today, yeah, sure.

CLINICIAN: OK, so you're a kind of a person that if you think that you set your mind, you want to do something you do not want to delay it. [Complex Reflection]

PATIENT: That's right, yeah.

CLINICIAN: Not like a person who wants to stop smoking, from next week, after this pack etc

PATIENT: Mañana. No, no, no, no I'm an instant reaction, yeah, semi instant. *Laughter*

CLINICIAN: I'm glad to hear that, and thank you very much for letting me to record this. [Affirmation]

PATIENT: No, that's quite all right, that's quite all right.

CLINICIAN: And I can now switch this off and start adjusting the hearing aids.

END OF RECORDING

7.8 Aim

Aim and objectives of the project will be described in each research paper. Here a general summary of the aims and objectives are provided.

The main aim of this project is to evaluate the feasibility of undertaking a randomised controlled trial on the effect of MI in facilitating hearing aid use in individuals with hearing impairment who do not use their hearing aids on a regular basis.

7.9 Objectives

The objectives of this feasibility study are grouped into four main categories: (1) estimating the extent of non-regular use of HAs, (2) feasibility of the MI intervention, (3) feasibility of the research procedures, and (4) exploring how people make sense of their experience of taking part in the research using qualitative data.

7.9.1 Estimating the Extent of Non-regular Use of Hearing Aids

1. To conduct a service evaluation survey in order to examine the rate of non-adherence to hearing aid use for patients fitted with hearing aids at the Royal Surrey County Hospital (RSCH) between January 2011 and January 2012.
2. To determine factors associated with non-regular use of hearing aids.

7.9.2 Feasibility of the Intervention

1. To assess whether achieving competency levels in delivering MI is feasible through the training per protocol.
2. To assess whether it is feasible to deliver MI with high fidelity and consistently in an outpatient audiology clinic.
3. To assess whether the intervention is successfully received by patients.
4. An intervention is only feasible to be included to a full scale trial if it shows some benefit over the control group hence one of the feasibility aims of pilot RCT is to explore estimation of possible effects of MI by comparing a) the number of hours that a hearing aid is used as measured via data logging, b) self-reported benefit from amplification, c) generic health-related quality of life, d) change in cognitive coping strategies, and e) change in hearing aid use and communication from the perspective of significant others at 1 month after intervention between patients who receive MI combined with standard care and patients who receive standard care only.

7.9.3 Feasibility of the Research Procedures

1. To estimate recruitment rate by assessing the proportion of eligible individuals who respond to research invitation mail shot.
2. To estimate the consent rate by eligible individuals to take part in the study and to be randomised to any of the two arms.
3. To estimate the proportion of participants randomised to each research arm and received interventions in accordance with the protocol.
4. To estimate the retention rate by assessing the proportion of participants who attended the final interview session at 1 month post intervention and provide outcomes.
5. To assess suitability of the outcome measurement tools.

7.9.4 Exploring How People Make Sense of Their Experience of Research Using Qualitative Data

1. To explore whether the intervention and research procedures were acceptable to patients.
2. To explore people's accounts with regard to factors that influenced their hearing aid use during the process of the research.

8 Chapter Three: Research Paper 1

London School of Hygiene & Tropical Medicine
Keppel Street, London WC1E 7HT
www.lshtm.ac.uk

Registry
T: +44(0)20 7299 4646
F: +44(0)20 7299 4656
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SECTION A – Student Details

Student	Hashir Aazh
Principal Supervisor	Kiran Nanchahal
Thesis Title	Feasibility of conducting a randomised controlled trial on the effect of motivational interviewing in facilitating hearing aid use

If the Research Paper has previously been published please complete Section B, if not please move to Section C

SECTION B – Paper already published

Where was the work published?	Int J Audiol		
When was the work published?	March 2015		
If the work was published prior to registration for your research degree, give a brief rationale for its inclusion	no		
Have you retained the copyright for the work?*	No	Was the work subject to academic peer review?	Yes

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For multi-authored work, give full details of your role in the research included in the paper and in the preparation of the paper. (Attach a further sheet if necessary)	HA conceived the idea, developed the protocol, obtained the appropriate approvals and permissions, conducted the data collection, analyzed the data and prepared the final report. DP assisted in data collection, analysis and writing the final report. KN assisted in preparing the protocol and overseen the analysis and contributed to the final report. BCJM assisted in data
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Student Signature: Harut Aslan

Date: 20/10/15

Supervisor Signature: Nanchochal

Date: 20/10/15

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Hearing Aid Use and its Determinants in the UK National Health Service: A Cross-Sectional Study at the Royal Surrey County Hospital

Hashir Aazh^{1,2}, Deepak Prasher¹, Kiran Nanchahal², and Brian C.J. Moore³

¹. *Audiology Department, Royal Surrey County Hospital NHS Foundation Trust, Egerton Road, Guildford, GU2 7XX, UK*

². *Department of Social and Environmental Health Research, London School of Hygiene & Tropical Medicine, London, WC1H 9SH, UK*

³. *Department of Experimental Psychology, University of Cambridge, Downing Street, Cambridge, CB2 3EB, UK*

Correspondence: Hashir Aazh, Audiology Department, Royal Surrey County Hospital, Egerton Road, Guildford, GU2 7XX. Email: hashir.aazh@nhs.net

Abstract

Objectives: The aim of this study was to investigate the rate of and factors contributing to non-adherence to hearing aid use in the UK National Health Service.

Design: A cross-sectional postal questionnaire survey.

Study Sample: A questionnaire, including the International Outcome Inventory for Hearing Aids was sent to all patients fitted with hearing aids at the Royal Surrey County Hospital between 2011 and 2012 (N=1874). 1023 questionnaires were completed and returned (response rate of 55%).

Results: 29% of responders did not use their hearing aids on a regular basis (i.e., used them less than four hours per day). Non-regular use was more prevalent in new (40%) than in existing patients (11%). Factors that reduced the risk of non-regular use included bilateral versus unilateral amplification, and moderate or severe hearing loss in the better ear. 16% of responders fitted with bilateral amplification used only one of their hearing aids.

Conclusions: The level of non-regular use of hearing aids in NHS found in this study was comparable to those for other countries. Additional support might be needed for patients at a higher risk of non-regular use.

Key words: Hearing aids, Hearing aid use, Satisfaction, Survey

Abbreviations:

BTE Behind the ear

ES Effect size

GP General Practitioner

IOI-HA International outcome inventory- hearing aids

NHS National Health Service

OR Odds ratio

PTA Pure tone average

REM Real ear measurement

SD Standard deviation

There are many studies supporting the benefits of hearing aids in improving health-related quality of life for people with hearing impairment (Bertoli et al, 2009; Kochkin, 2010; Vuorialho et al, 2006). Based on a meta-analysis, Chisolm et al (2007) reported that hearing aids have a robust, medium-to-large effect on hearing-related quality of life, with a mean between-subjects effect size (ES) of 2.1 (95% confidence interval, CI = 0.5-3.6). However, several studies reported that many owners of hearing aids do not use them regularly and do not achieve an improved quality of life (Stark & Hickson, 2004; Vuorialho et al, 2006; McCormack & Fortnum, 2013; Davis et al, 2007).

Although it is useful to determine whether a hearing aid is used regularly, there is no widely agreed definition of regular use (Perez & Edmonds, 2012). In this study non-regular use of hearing aids is defined as use of less than four hours per day. The proportion of non-regular users varies across studies conducted in different countries (Table 1): 27% and 58% in two Australian studies (Hickson et al, 2010; Stark & Hickson, 2004), 42% in Finland (Vuorialho et al, 2006), 28% in Nigeria (Olusanya, 2004), 13% to 31% in four studies conducted in the USA (Kochkin, 2005; Kochkin, 2010; Takahashi et al, 2007; Williams et al, 2009), 25% in Switzerland (Bertoli et al, 2009), 33% in Sweden (Brännström & Wennerstrom, 2010), and 23% in China (Liu et al, 2011).

TABLE 1. Estimation of amount of hearing aid usage in different countries

Study	N	Country	Age (years): Mean (SD) or Median (range)	Fitting type	Hearing aid usage
Stark and Hickson (2004)	93	Australia	72 (8.6)	45% binaural.	14% >8 hrs per day 28% 4 to 8 hrs per day 31% 1 to 4 hrs per day 15% <1 hr per day 7.5% < 1 hr per week 4.3% never
Olusanya (2004)	99	Nigeria	46 (16 to 89)	99% binaural	51% >8 hrs per day 21% 4 to 8 hrs per day 16% 1 to 4 hrs per day 8 % <1 hr per day 4% never
Kochkin (2005)	1511	USA	71	not reported	74% > 4 hrs per day 26% < 4 hrs per day
Vuorialho et al. (2006)	98	Finland	77 (61 to 87)	0% binaural	58% > 2 hrs per day 32% < 2 hrs per day 10% infrequent, if ever
Takahashi et al. (2007)	164	USA	73 (36 to 96)	not reported	65% >8 hrs per day 12% 4 to 8 hrs per day 19% 1 to 4 hrs per day 4 % <1 hr per day 0 never
Bertoli et al. (2009)	8707	Switzerland	74	61% binaural	49% >8 hrs per day 25.8% 4 to 8 hrs per day 20% 1 to 4 hrs per day 3% <1 hr per day 2% never
Williams et al. (2009)	73	USA	73 (22 to 94)	91% binaural.	61% >8 hrs per day 22% 4 to 8 hrs per day 14% 1 to 4 hrs per day 3% <1 hr per day 0 never
Hickson et al. (2010)	1653	Australia	not reported	78% binaural	51 % >8 hrs per day 23 % 4 to 8 hrs per day 17% 1 to 4 hrs per day 6% <1 hr per day 4 % never *
Brännström & Wennerstrom (2010)	224	Sweden	66 (24 to 94)	40% binaural	40 % >8 hrs per day 27 % 4 to 8 hrs per day 21 % 1 to 4 hrs per day 9 % <1 hr per day 3% = never *
Kochkin et al. (2010)	3174	USA	70	not reported	New users: 36% < 4 hrs per day Experienced users: 12% < 4 hrs per day
Liu et al. (2011)	1049	China	61 (14)	33% binaural.	43% >8 hrs per day 34% 4 to 8 hrs per day 20% 1 to 4 hrs per day 2% <1 hrs per day 1% never *

* Personal communication. Mean or median ages are given depending on the information provided in the original publication.

There is no recent study of hearing aid use for National Health Service (NHS) patients in the United Kingdom (UK). Previous studies had small sample sizes (N<150) and were conducted when analog hearing aids were issued by the NHS. These studies reported the prevalence of non-regular use of hearing aids as 43% to 45% (Stephens, 2002; Davis et al, 2007). There tends to be less benefit from analog

than from digital hearing aids and, given the widespread use of digital hearing aids in recent years, there may have been changes in the usage of hearing aids (Bertoli et al, 2009). Hearing aid use in the UK may also differ from that in other countries due to differences in service delivery models between the NHS and the health services in other countries. The main differences are described below.

1) *Hearing aids and fitting protocol*: NHS hearing aids are mainly digital behind-the-ear (BTE) hearing aids. Bilateral hearing aids are offered to all patients with bilateral hearing impairment (unless there are medical contraindications), although the patient may choose to have only one hearing aid. The choice of hearing aids is limited. In other countries, patients may have the choice of several hearing aid makes and styles. However, as shown in Table 1, binaural hearing aids were not routinely offered in these countries at the time when these studies were conducted. Moreover, in some of these surveys, a large proportion of patients received analog hearing aids (Kochkin, 2005; Olusanya, 2004; Stark & Hickson, 2004; Vuorialho et al, 2006).

Under the NHS system, qualified audiologists perform audiological assessment, dispense hearing aids and provide instructions and counselling. In some countries, medical doctors evaluate the need for hearing aids and decide on the appropriate type of hearing aid while others undertake the fitting and counselling.

Under the NHS system, a fitting session can last up to 60 minutes and several sessions of adjustment and support may be provided. Real-ear measurements (REM) are performed routinely according to the British Society of Audiology recommended procedure (BSA, 2007). With regard to post-fitting support, patients are advised to attend a walk-in hearing aid service clinic to deal with straightforward problems (sessions last approximately 15 minutes). If the problem is not resolved, the patient is offered a review appointment (30-60 minutes) for further adjustments or consideration of a different type of hearing aid. Patients may also be provided with advice on other assistive listening devices and hard of hearing social support groups.

The duration of fitting sessions and the number of follow-up sessions varies considerably across other countries.

2) *Financial support*: In the UK, the NHS covers the full cost of hearing aids. In some countries the costs may be met partly or fully by health insurance, although

often this covers only a single hearing aid. In other countries, patients pay out of their own funds.

The aims of this study were to investigate: (1) the extent of non-regular use of hearing aids dispensed and fitted in an NHS hospital in the UK; (2) audiometric and demographic factors influencing non-regular use; (3) factors influencing adherence to bilateral amplification when provided; and (4) factors influencing the benefit obtained from hearing aids, assessed using the International Outcome Inventory for Hearing Aids (IOI-HA; Cox & Alexander, 2002).

Methods

Study Design and Procedures

A cross-sectional postal questionnaire survey was conducted for patients who received hearing aids from the Audiology Department, Royal Surrey County Hospital (RSCH), Guildford, UK. The hospital has a catchment area of 320,000 people. According to the service level agreements at the RSCH all patients who need hearing aids should be referred via their general practitioners (GPs). This includes new patients, existing patients, and patients referred by Ear, Nose & Throat (ENT) or other professionals. The Audiology Department receives approximately 55 referrals per week from GPs for hearing aid fitting. Between October 2012 and November 2012, a questionnaire was posted to all patients fitted with hearing aids between January 2011 and January 2012. The IOI-HA, a seven-item inventory for assessment of hearing aid outcomes, was the main assessment tool. In addition, patients were asked whether they owned one or two hearing aids and, if the latter, whether they used both aids. Other questions related to the number of days per week they used their hearing aids and reasons for non-regular use if they did not use their hearing aids every day (see Appendix 1 for details). A cover letter was included assuring patients that their answers would remain confidential and would have no effect on their future care. They were asked to return the completed survey within two weeks, using the pre-paid envelopes provided. No further prompts were sent to patients. Demographic details of the participants, comprising address, age, gender, and hearing thresholds, were imported from records held in the electronic database of the Audiology Department. The data were anonymised prior to statistical analysis.

The survey was approved by the Research and Development department at RSCH (Ref: 13DEV0001), the NRES Committee - North of Scotland (Ref: 13/NS/0041) and the research ethics committee of the London School of Hygiene and Tropical Medicine (Ref: 6421).

Study Population

Between January 2011 and January 2012, 1920 patients were fitted with hearing aids at the RSCH, forty six of whom were deceased at the time of the survey. The survey was sent to 1874 people. The average age of the patients was 74 years (standard deviation, SD = 15 years, range 17 to 105 years). Forty eight percent of patients were male (n=899). The mean pure-tone average (PTA) audiometric threshold at the frequencies 0.25, 0.5, 1, 2, and 4 kHz was 47 dB (SD =19 dB) for both the right and left ears. Data concerning audiogram types and underlying aetiology were not collected.

Data analysis

Group differences were assessed using t-tests and chi-square tests. Logistic regression was used to assess factors associated with non-regular use of hearing aids (i.e., less than four hours use per day). Variables that were significantly different between regular and non-regular users were included to the model as independent variables. These variables were:

- 1) PTA of better and worse ears. The severity of hearing loss was categorised based on the values of the PTA at the frequencies 0.25, 0.5, 1, 2, and 4 kHz as recommended by the British Society of Audiology (BSA, 2004): Mild (20-40 dB HL), Moderate (41-70 dB HL), Severe (71-95 dB HL) and Profound (>95 dB HL). Responders with PTAs better than 20 dB were classified as “Better than 20 dB”, this group typically presented with a mild high-frequency hearing loss.
- 2) Bilateral versus unilateral fitting.
- 3) The slope of audiogram between 1 and 4 kHz (in the better ear, worse ear and averaged across ears). Participants were grouped according to whether

this slope was steep, “40 dB or over”, or “less than 40 dB” for the better ear, the worse ear and the mean across ears. A slope of 40 dB over a two-octave range is comparable to the slope of 20 dB per octave that has been considered as steep by several authors (Aazh & Moore, 2007).

- 4) Age group: based on the overall spread of age and in order to have comparable numbers in each group, participants were divided into three age ranges (under 70, 70-80, over 80).
- 5) Logistic regression analysis was also used to examine the determinants of non-adherence to bilateral use. The variables that were significantly different between adherers and non-adherers to bilateral use were included in the model as independent variables. These variables were:
 - 1) Interaural asymmetry: participants were grouped according to whether the difference in PTA between the right and left ears was “over 20 dB” or “20 dB or less”. This was based on research suggesting that people with an audiometric asymmetry greater than 20 dB may not benefit from bilateral amplification (Boymans et al, 2009; Dillon, 2001).
 - 2) PTA for the worse ear, with the same classification as in (1) above.
 - 3) Age group, with the same classification as in (4) above.

A multiple linear-regression analysis was conducted to examine the factors associated with the total IOI-HA score. The variables were PTA in the better ear, bilateral versus unilateral fitting, interaural asymmetry, mean slope of the audiogram across ears, difference in slope across ears, age, and gender. The analyses were restricted to responders with complete data on all variables required for a particular analysis.

Results

Responders versus non-responders

A total of 1023/1874 questionnaires were returned, a response rate of 55%. Responders (mean age = 75, SD = 17 years) were slightly but significantly older than non-responders (mean age = 73, SD = 13 years) ($p = 0.0034$). There was no significant difference in PTA of the better ear between responders (mean = 42, SD =

16 dB) and non-responders (mean = 41.5, SD = 18 dB) ($p = 0.36$). Figure 1 shows the means and SDs of the hearing thresholds at 0.25, 0.5, 1, 2, 4, and 8 kHz for the responders. The mean absolute value of the difference between the PTA values for the right and left ears was 11 dB for both responders and non-responders (SD = 14, SD = 15, respectively) ($p = 0.76$). The mean of the slope of the audiogram across the ears (hearing threshold at 4 kHz minus hearing threshold at 1 kHz) was 24 dB (SD = 16) for the responders and 23 dB (SD = 15) for non-responders ($p = 0.09$). The mean of the absolute value of the difference in slope between the two ears, a measure of the interaural asymmetry in slope, was 10 dB (SD = 10) for both responders and non-responders ($p = 0.43$). There was no significant difference in the proportion of women among responders (490/977, 50%) and non-responders (485/897, 54%) ($p = 0.09$).

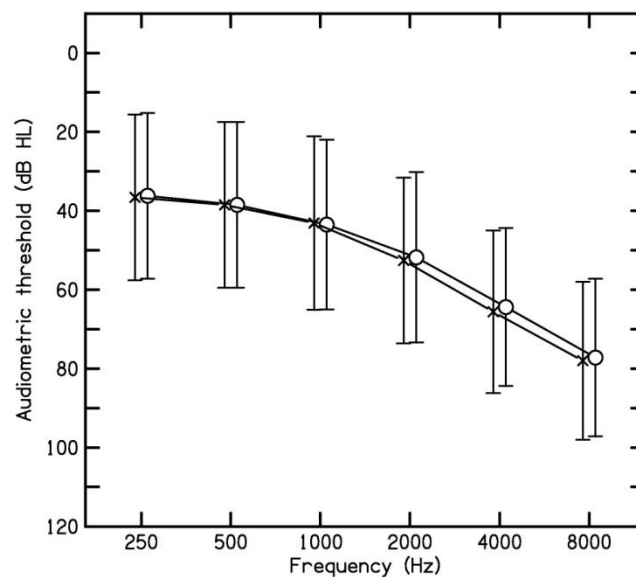


Figure 1. Means and SDs of the hearing thresholds at 0.25, 0.5, 1, 2, 4, and 8 kHz for the right and left ears of the responders (N = 977).

Sixty three percent of the responders (N = 610) were new patients and 37% were existing patients. PTA of the better ear was 38 dB (SD = 14) for new patients and 48 dB (SD = 16) for existing patients ($p < 0.001$). The mean PTA of the worse ear was 48 dB (SD = 18) for new patients and 60 dB (SD = 19) for existing patients ($p < 0.001$). The mean slope of audiogram across the ears was 24 dB (SD = 16) for

new patients and 21 dB (SD = 15) for existing patients ($p = 0.0008$). There were no significant differences in age ($p = 0.41$), interaural asymmetry ($p = 0.12$) or distribution of male/female ($p = 0.92$) between new and existing patients.

Hearing aid use (hours per day) and its determinants

71% of responders reported that they used their hearing aid(s) on a regular basis (i.e., more than 4 hours a day). The prevalence of non-adherence to regular use was 39.5% (252/638) for new patients but only 10.7% (41/383) for existing users. 22.6% (144/638) of new patients used their hearing aids less than 1 hour per day. Hickson et al (2014) suggested that successful hearing aid use requires a minimum of one hour of daily use and at least moderate self-reported benefit from hearing aids in the situations where it is most desired to hear better. On this basis, approximately 27% (174/638) of new patients failed to meet the criteria for successful hearing aid use.

The most frequent reason given for non-regular use of hearing aid was “Noisy situations are disturbing”(165/276), followed by “I can manage without the hearing aids” (108/276), “I experience negative side effects (e.g., rashes, itching, pain, build-up or wax)” (74/276), “The hearing aid has poor fit and is not comfortable”(63/276), “I have difficulties with management” (52/276), “I receive no or very little benefit” (52/276), “I don’t like the look of my hearing aid” (30/276), “It makes me feel old” (27/276), and “others” (147/276).

Forty five percent of those with a single hearing aid were non-regular users, but less than 25% of those with bilateral aids were non-regular users ($p < 0.001$). Less than half (44%) of those with PTA < 20 dB in their better ear, who typically had a mild high-frequency hearing loss, used their hearing aids more than four hours per day, while 17% of those classified as having moderate hearing loss in their better ear used their hearing aids less than four hours per day. As shown in Table 2, non-regular users had less hearing loss in both their better and worse ears than regular users. Interaural asymmetry, as measured by the difference in mean PTA or slope of the audiogram across ears, was similar for regular and non-regular users. However, the slope of the audiogram was steeper for non-regular than for regular users, for the better, the worse ear, and the average across ears. There was no significant difference in the proportion of women between regular users (361/699, 52%) and non-regular users (127/276, 46%) ($p = 0.09$).

TABLE 2. Characteristics of non-regular and regular users of hearing aids

	< 4 hours per day (N=276)	> 4 hours per day (N=699)	Difference (95% CI)	<i>p</i> value
	Mean (SD)	Mean (SD)		
Better ear PTA, dB	34 (12)	45 (16)	-11 (-12.9 to -8.7)	<0.001
Worse ear PTA, dB	44 (17)	56 (19)	-11 (-13.9 to -8.8)	<0.001
Difference in PTA across ears, dB	10 (15)	11 (14)	-0.57 (-2.6 to 1.4)	0.57
Slope better ear, dB	26 (17)	23 (16)	3.4 (1.1 to 5.6)	0.003
Slope worse ear, dB	27 (17)	22 (16)	5.0 (2.7 to 7.2)	<0.001
Mean slope across ears, dB	27 (15)	23 (14)	4.3 (2.3 to 6.3)	<0.001
Difference of slope between ears, dB	10 (10)	10.5 (10)	-0.4 (-1.8 to 1.0)	0.5
Age, years	74 (12)	76 (13)	-1.9 (-3.7 to -0.19)	0.03

TABLE 3. Characteristics associated with non-regular use of hearing aids (N = 942)

Variable	Prevalence (%) of non- regular use of hearing aids (N)	Unadjusted Odds Ratio (95% CI)	<i>p</i> value	Adjusted* Odds Ratio (95% CI)	<i>p</i> value
PTA in better ear					
Better than 20 dB	56% (27)	1		1	
Mild hearing loss	38% (175)	0.5 (0.26 to 0.9)	0.02	0.7 (0.34 to 1.4)	0.3
Moderate hearing loss	17% (71)	0.2 (0.1 to 0.3)	<0.001	0.3 (0.15 to 0.7)	0.006
Severe hearing loss	7% (3)	0.05 (0.01 to 0.2)	<0.001	0.2 (0.05 to 0.9)	0.035
Profound hearing loss	-	-		-	
PTA in worse ear					
Better than 20 dB	67% (2)	1		1	
Mild hearing loss	45% (127)	0.4 (0.04 to 4.5)	0.5	1.1 (0.1 to 14.1)	0.9
Moderate hearing loss	24% (126)	0.2 (0.02 to 1.8)	0.13	0.8 (0.06 to 10)	0.9
Severe hearing loss	12% (15)	0.07 (0.01 to 0.8)	0.03	0.4 (0.03 to 5)	0.5
Profound hearing loss	16% (6)	0.1 (0.01 to 1.2)	0.07	0.4 (0.03 to 6.1)	0.5
Fitting					
Unilateral	45% (71)	1		1	
Bilateral	25% (208)	0.41 (0.29 to 0.58)	<0.001	0.4 (0.27 to 0.7)	<0.001
Slope of the better ear					
<40 dB	26% (206)	1		1	
≥40 dB	37% (70)	1.7 (1.2 to 2.3)	0.003	1.3 (0.7 to 2.2)	0.4
Slope of the worse ear					
<40 dB	26% (202)	1		1	
≥40 dB	39% (74)	1.9 (1.3 to 2.6)	<0.001	1.3 (0.7 to 2.2)	0.4
Mean slope across ears					
<40 dB	26% (213)	1		1	
≥40 dB	40% (63)	1.9 (1.3 to 2.7)	<0.001	1.1 (0.55 to 2.3)	0.7
Age (years)					
under 70	33% (89)	1		1	
70-80	30% (105)	0.9 (0.64 to 1.26)	0.53	0.98 (0.7 to 1.4)	0.9
over 80	23% (82)	0.62 (0.44 to 0.88)	0.008	0.97 (0.6 to 1.5)	0.9

* Adjusted for other variables in the table.

Table 3 shows both unadjusted and adjusted odds ratios (ORs) derived from the logistic regression models, together with significance values. The OR represents the odds that an outcome will occur given a particular condition (e.g. an interaural asymmetry ≤ 20 dB), compared to the odds of the outcome occurring when that condition does not apply (e.g. an interaural asymmetry > 20 dB). The adjusted OR for a given variable takes into account the influence of all the other variables in the regression model. In what follows, we consider only the adjusted OR, which will be referred to as OR for brevity. Factors associated with non-regular use of hearing aids were a moderate or severe hearing loss in the better ear (OR = 0.3, 95% CI: 0.15 to 0.7, $p = 0.006$; OR = 0.2, 95% CI: 0.05 to 0.9, $p = 0.035$, respectively), and having bilateral versus unilateral amplification (OR = 0.4, 95% CI: 0.27 to 0.7, $p < 0.001$). There was no significant effect of age or slope of the audiogram.

Factors influencing bilateral versus unilateral fittings

Out of the 986 people responding to the question “Do you own a hearing aid for one or both ears?”, 84% (828) had bilateral hearing aids and 16% (158) had one. The mean PTA of the better ear was 43 dB HL (SD = 14) for people who were fitted bilaterally (N = 796) and 34 dB (SD = 19) for those with one hearing aid (N = 150) (46 responders who returned their questionnaires anonymously were excluded from this analysis as their PTA record could not be retrieved); the difference in PTA between groups was significant ($p < 0.0001$), showing that bilateral fitting was more common for those with greater hearing loss.

The mean difference between the PTA values for the right and left ears was 23 dB (SD = 21) for responders who had a single aid (N = 150) and 8.4 dB (SD = 11) for those who were fitted bilaterally (N = 796) ($p < 0.0001$). Forty four percent of responders with an interaural asymmetry of more than 20 dB were fitted unilaterally, while only 10.5% of those with an asymmetry of 20 dB or less were fitted unilaterally ($p < 0.0001$). Despite the mean PTA across ears being greater for those fitted bilaterally than for those fitted unilaterally, the mean PTA of the worse ear was higher (57 dB, SD = 28) for responders who were fitted unilaterally than for those fitted bilaterally (52 dB, SD = 17) ($p = 0.0007$). Sixty two percent of people with profound hearing loss in the worse ear were fitted with one aid. Overall, these results indicate that a large interaural asymmetry was associated with a reduced

likelihood of bilateral fitting. This is understandable, as a large asymmetry is often considered as a contraindication for bilateral amplification (Dillon, 2001).

Factors influencing the rate of adherence to bilateral use

Of the 813 people who responded to the question “If you own hearing aids for both ears, do you wear both or only one?”, 84% (N = 683) reported that they used both aids. The prevalence of non-adherence to bilateral use was about 17% (82/479) for new patients and 14% (48/334) for existing patients ($p=0.3$).

There was no significant difference between unilateral and bilateral users in PTA of the better ear ($p = 0.23$), mean slope of the audiogram across ears ($p = 0.07$), difference of slope between ears ($p = 0.7$), and gender distribution ($p = 0.5$). People who used both of their hearing aids were, on average, 2.4 years younger than those who only used one ($p = 0.04$). The PTA of the worse ear was 7.8 dB higher for non-adherers than for adherers (95% CI: 4.4 to 11.1, $p<0.001$). Also, the interaural asymmetry was 6.1 dB larger for the former than for the latter (95% CI: 3.7 to 8.4, $p<0.001$). One-third of responders who had an interaural asymmetry greater than 20 dB used only one hearing aid, while only 13% with an asymmetry of 20 dB or less used only one aid ($p<0.0001$).

Table 4 shows both unadjusted and adjusted ORs derived from the logistic regression model, together with significance values. Respondents with an interaural asymmetry greater than 20 dB had nearly three times the odds of using only one of their hearing aids compared to those with an interaural asymmetry of 20 dB or less (OR = 2.8, 95% CI: 1.5 to 5.1, $p = 0.001$). Being aged over 80 years was associated with non-adherence to bilateral hearing aid use (OR = 2.0, 95% CI: 1.1 to 3.5, $p = 0.016$). Those having profound hearing loss in the worse ear had nearly seven times the odds of using only one of their hearing aids compared to those who had mild hearing loss in their worse ear (OR = 6.7, 95% CI: 2.2 to 20.5, $p = 0.001$).

TABLE 4: Factors associated with non-adherence to bilateral use (N=781).

Variable	Prevalence of (number) using only one hearing aid	Unadjusted odds ratio (95%CI)	<i>p</i> value	Adjusted odds ratio (95%CI)	<i>p</i> value
<hr/>					
Interaural asymmetry					
≤20 dB	13% (91)	1		1	0.001
Interaural asymmetry >20 dB	33% (32)	3.2 (1.9 to 5.2)	<0.001	2.8 (1.5 to 5.1)	
PTA in worse ear					
Better than 20 dB	-	-			
Mild hearing loss	10% (21)	1		1	
Moderate hearing loss	16% (70)	1.7 (1.01 to 2.8)	0.045	1.4 (0.8 to 2.3)	0.3
Severe hearing loss	19% (21)	2.2 (1.1 to 4.2)	0.20	1.2 (0.5 to 2.5)	0.7
Profound hearing loss	58% (11)	12 (4.5 to 34.4)	<0.001	6.7 (2.2 to 20.5)	0.001
Under 70 years	12% (23)	1		1	
70-80 years	15% (44)	1.4 (0.8 to 2.3)	0.25	1.50 (0.9 to 2.7)	0.14
Over 80 years	19% (56)	1.8 (1.1 to 3.1)	0.03	2 (1.1 to 3.5)	0.016

Significant *p* values for the adjusted OR are given in bold font.

IOI-HA scores and their determinants

Table 5 summarises responses to the 7 items on the IOI-HA for the 1021 people who returned their IOI-HA. The majority of responders (67%) felt that their hearing aid(s) helped quite a lot or very much, and that the hearing aid(s) made their enjoyment of life a lot or very much better (62%), but 21% reported that they still had quite a lot or very much difficulty. The mean total score was 26.2 (SD = 6.4) out of a maximum score of 35. The mean total score on the IOI-HA was 2.2 units higher for existing users than for new patients (95% CI: 1.4 to 3, $p < 0.001$).

TABLE 5. Summary of responses to the 7 items on the IOI-HA (N = 1021)

Item	Summary of IOI-HA question	Answer	Number (%) of participants
1	How many hours per day do you use the hearing aid(s)? (Use, Mean = 4.0, SD = 1.3)	None	106 (10%)
		Less than 1 hour a day	54 (5%)
		1 to 4 hours a day	133 (13%)
		4 to 8 hours a day	177 (17%)
		More than 8 hours a day	551 (54%)
2	How much has the hearing aid helped? (Benefit, Mean = 3.7, SD = 1.3)	Helped not at all	105 (10%)
		Helped slightly	68 (7%)
		Helped moderately	171 (17%)
		Helped quite a lot	322 (32%)
		Helped very much	355 (35%)
3	How much difficulty do you STILL have? (Residual activity restriction, Mean = 3.4, SD = 1.2)	Very much difficulty	84 (8%)
		Quite a lot of difficulty	136 (13%)
		Moderate difficulty	295 (29%)
		Slight difficulty	333 (33%)
		No difficulty	173 (17%)
4	Do you think your present hearing aid(s) is worth the trouble? (Satisfaction, Mean = 4.0, SD = 1.3)	Not at all worth it	77 (7.5%)
		Slightly worth it	70 (6.9%)
		Moderately worth it	132 (13%)
		Quite a lot worth it	236 (23%)
		Very much worth it	506 (50%)
5	With your present hearing aid(s), how much have your hearing difficulties affected the things you can do? (Residual participation restriction, Mean = 3.6, SD = 1.3)	Affected very much	84 (8%)
		Affected quite a lot	131 (13%)
		Affected moderately	190 (19%)
		Affected slightly	323 (32%)
		Affected not at all	293 (29%)
6	With your present hearing aid(s), how much do you think other people were bothered by your hearing difficulties? (Impact on others, Mean = 3.7, SD = 1.2)	Bothered very much	74 (7.3%)
		Bothered quite a lot	99 (9.7%)
		Bothered moderately	204 (20%)
		Bothered slightly	314 (31%)
		Bothered not at all	330 (32%)
7	How much has your present hearing aid(s) changed your enjoyment of life? (Quality of life, Mean = 3.8, SD = 1.1)	Worse	45 (4.4%)
		No change	106 (10%)
		Slightly better	213 (21%)
		Quite a lot better	341 (33%)
		Very much better	316 (31%)

Mean scores (SD) are also given for each item.

A linear regression model (N=994) showed that there was a significant association between hearing aid use and total score on the IOI-HA. In this model, the mean score on the IOI-HA for people who reported that they did not use their hearing aids at all was taken as the baseline value; this value was 14.1 (95% CI: 12.7 to 15.4). The model predicted the increases in the IOI-HA score for other groups compared to the baseline group.

Relative to non-users, the mean IOI-HA score was higher by 6.9 (95% CI: 5.3-8.6, $p < 0.001$) for occasional hearing aid users, by 10.7 (95% CI: 9.1-12.3, $p < 0.001$) for those who used hearing aids 1-4 days per week, by 12.6 (95% CI: 11.1-14.2,

$p < 0.001$) for those who used hearing aids at least 5 days per week, and by 14.5 (95% CI: 13.2-15.9, $p < 0.001$) for those who used hearing aids every day.

Finally a multiple linear regression model ($N = 946$) showed that higher scores on the IOI-HA were associated with higher (worse) PTA values, bilateral fitting, and a shallow audiogram slope. A 1-dB increase in the mean PTA in the better ear was associated with an increase in IOI-HA score of 0.04 (95% CI: 0.013-0.066, $p = 0.004$). Bilateral fitting was associated with an increase in IOI-HA score of 2.4 (95% CI: 1.13-3.6, $p < 0.001$) relative to unilateral fitting. A 1-dB increase in mean slope of the audiogram across ears was associated with a reduction in IOI-HA score of 0.04 (95% CI: 0.07 to 0.006, $p = 0.02$). There was no significant linear relationship between the total IOI-HA score and interaural asymmetry ($p = 0.7$), difference in slope across ears ($p = 0.1$), age ($p = 0.9$), or gender ($p = 0.5$).

Although three of the variables in the regression model were significantly associated with scores on the IOI-HA, the model accounted for only 4.2% of the variance in the total IOI-HA scores. This suggests that factors not considered in the model contribute to the perceived benefit of using hearing aids.

Discussion

Prevalence of non-regular use of hearing aids and its determinants

The results showed that 29% of people who were fitted with NHS hearing aids used their hearing aids less than four hours per day. Despite the differences in service delivery models, the prevalence of non-regular use of hearing aids in this sample is comparable to that found in Australia (Hickson et al, 2010), Finland (Vuorialho et al, 2006), Nigeria (Olusanya, 2004), the USA (Kochkin, 2005), Switzerland (Bertoli et al, 2009), Sweden (Brännström & Wennerstrom, 2010), and China (Liu et al, 2011).

Non regular use was more prevalent for new patients (40%) than for existing patients (11%). This is consistent with the survey findings of Kochkin (2010), who reported that 36% of 884 new patients and 12% of 1141 existing users used their hearing aids for less than 4 hour per day.

Among new users, 27% did not meet the criteria of Hickson et al (2014) for “successful” use. Twenty three percent of new patients used their hearing aids less than 1 hour per day, which indicates that a large proportion of hearing aids fitted

under the NHS remained unused, a waste of publicly funded NHS resources. Approximately 500,000 new patients are fitted with hearing aids every year across the NHS (Davis et al, 2007). The average cost of the treatment, including the assessment and the cost of hearing aids, is about £350 per person (Department of Health, 2012). Even with a very conservative definition of unsuccessful hearing aid outcome as “use less than 1 hour per day”, there are probably about 130,000 unsuccessful users per year, corresponding to about a £45,000,000 waste of NHS funding per year. The exact societal cost of untreated hearing impairment as the result of non-use or unsuccessful use of hearing aids is not clear but untreated hearing loss has been associated with reduced ability to communicate, social withdrawal, depression, problems with employment and reduced quality of life, all of which have a substantial financial impact on social welfare and medical care systems (Hjalte et al, 2012; Davis et al, 2007).

These considerations indicate a need for urgent action to develop interventions that can improve hearing aid use and outcome. Motivational interviewing seems to be a feasible intervention in facilitating hearing aid use but further effectiveness trials are needed prior to its use in routine clinical practice (Aazh, 2014).

In our sample, the PTAs of the better and worse ears in the existing patients were significantly higher than those of new patients which could contribute to the greater use and benefit from hearing aids of the former. It is difficult to compare this result with results of other studies, because they either excluded existing users from their surveys (Brännström & Wennerstrom, 2010; Stark & Hickson, 2004; Vuorialho et al, 2006; Hickson et al, 2014) or did not compare the audiometric characteristics and prevalence of non-regular use between existing and new users (Bertoli et al, 2010; Bertoli et al, 2009; Davis et al, 2007; Stephens, 2002; Cox & Alexander, 2002; Kochkin, 2005; Hickson et al, 2010; Williams et al, 2009).

Our results showed that regular hearing aid use was more likely for bilateral than for unilateral users. This is consistent with the results of Bertoli et al (2010), who reported that non-regular use was significantly associated with unilateral amplification. Our model for non-regular use did not reveal any significant effect of age. This is consistent with the outcome of a recent systematic review, which concluded that there is no influence of age on hearing aid use (Knudsen et al, 2010).

In contrast to Staehelin et al (2011) and Bertoli et al (2009), who reported a higher prevalence of non-regular use among males, in our study there was no significant effect of gender on hearing aid use.

Bilateral versus unilateral use

Sixteen percent of respondents in our study who were fitted with bilateral hearing aids reported that they used only one of them. Previous studies based in the UK (Chung & Stephens, 1986; Brooks & Bulmer, 1981) and Sweden (Kojbler et al, 2001) showed slightly higher rates of non-adherence to bilateral use, ranging from 19% to 33%. The discrepancy may be due to the fact that the earlier studies were for people fitted with analog aids, although methodological differences and differences in service delivery models may have contributed.

Cox et al (2011) reported that people who preferred unilateral aiding indicated that their hearing was “good enough” with one hearing aid and that aiding the second ear did not yield sufficient benefit to justify bilateral use. Boymans et al (2009) reported that the decision to use only one hearing aid was most frequently based on the hearing capacity of the unaided ear; this could either be adequate without amplification or too poor to give any benefit with amplification. If this is the case, unilateral users should typically have greater interaural asymmetry than bilateral users. Our model for non-adherence to bilateral use supports this idea, in that the best predictor of using only one hearing aid for those fitted bilaterally was an interaural asymmetry in PTA greater than 20 dB.

In our study, adherers to bilateral use were, on average, 2.4 years younger than non-adherers, and the prevalence of non-adherence was highest for those who were over 80 years old. These findings are consistent with reports that elderly individuals prefer and perform better with unilateral than with bilateral hearing aids (Chmiel et al, 1997; Henkin et al, 2007).

In summary, our results and those of earlier studies suggest that people fitted bilaterally are less likely to use both aids if they have a marked interaural asymmetry in PTA and are over 80 years old. The clinical implications of this are unclear. One

might argue that it is not cost-effective to fit such people bilaterally. If are fitted bilaterally, they may need additional counselling and support (Kelly et al, 2013).

IOI-HA scores and their determinants

The total score for the IOI-HA indicates the overall effect of amplification on hearing-related quality of life. In the present study the mean total score was 26.2 (SD=6.4). This is comparable to scores reported in other countries in similar surveys (Brännström & Wennerstrom, 2010; Kramer et al, 2002). The total score on the IOI-HA was significantly higher for existing users than for new patients. This is consistent with the findings of Hickson et al (2010) who also reported that, compared to new patients, existing patients showed higher scores on the IOI-HA. Contrary to this Williams et al (2009) reported that the difference in IOI-HA score between new and existing users was not statistically significant.

Although it is debatable how often a person should use their hearing aid(s) to achieve the maximum benefit from amplification (Laplante-Levesque et al, 2013; Perez & Edmonds, 2012), our results showed that IOI-HA scores increased with increasing amount of hearing aid use and that bilateral users gained more benefit than unilateral users. This result is consistent with recent studies showing that self-reported benefit from amplification is greater for bilaterally than for unilaterally aided users (Most et al, 2012; Cox et al, 2011). However, Boymans et al (2009) found no significant difference between unilateral and bilateral groups. The discrepancy may be due to the inclusion criteria used by Boymans et al (2009). Unlike the present survey, which included all types of hearing loss, they excluded individuals for whom the better ear PTA was less than 35 dB and individuals with an interaural asymmetry in PTA greater than 20 dB. This would have excluded a large number of unilateral users.

Cox et al (2011) assessed preference for one or two hearing aids for 94 patients in a US veteran population. Forty six percent of the patients preferred using one hearing aid rather than two at 2 to 4 months post-fitting. Consistent with our study, they found that people who preferred to use two hearing aids had better scores on the IOI-HA and the abbreviated profile of hearing aid benefit (APHAB; Cox & Alexander, 1995). They did not find significant differences in reported daily hearing aid use between those who used one hearing aid and those who used two, whereas we found

that non-regular use was higher for those who were unilaterally aided. The discrepancy may be related to their inclusion criteria. Unlike our study, their participants all had mild to moderate hearing loss and symmetrical audiograms.

In summary, the overall beneficial effect of amplification on self-reported hearing-related quality of life increases with increasing PTA in the better ear and with decreasing slope of the audiogram, and is greater for bilateral than for unilateral hearing-aid users. However, the model accounted for only 4.2% of the variance in scores. This is consistent with other studies that highlighted the importance of non-audiological factors in achieving success with hearing aids (Hickson et al, 2014; Meyer et al, 2014).

Study limitations

The true extent of non-regular use of hearing aids in the NHS may be larger than found in our survey. Studies that compared digitally recorded usage time with self-reported use suggest that patients tend to under-report non-regular use (Taubman et al, 1999). It is possible that responses to questionnaires are biased toward what responders believe is socially acceptable or toward what they believe to be desired by the investigators (Choi & Pak, 2005).

Another possible source of bias is related to the retrospective nature of the survey. The IOI-HA requires patients to recall the problems that they had prior to obtaining their current hearing aid(s), in order to judge the benefits provided by the aid(s). People may misjudge the severity and impact of past medical conditions (McPhail & Haines, 2010).

In this study, selection bias was minimised by sending the survey questionnaire to all patients fitted with hearing aids during a one-year period. However, the response rate was only about 55%. People who are generally pleased with their hearing aids and the service provided may be more likely to return their questionnaires than those who are dissatisfied. This bias could have been reduced by contacting non-responders and encouraging them to return their questionnaires, but that was not done due to resource limitations. However, demographic characteristics did not differ for responders and non-responders.

Conclusions

The overall prevalence of non-regular use of hearing aids was 29%. However, the prevalence was much higher for new patients, 40% of whom reported using their hearing aids for less than four hours per day and 23% of whom reported using their hearing aids for less than one hour per day.

Non-regular use of hearing aids was associated with PTA in the better ear and unilateral versus bilateral amplification.

Sixteen percent of people who were fitted bilaterally used only one hearing aid. Non-adherence to bilateral use was associated with an interaural asymmetry in PTA over 20 dB and an age of over 80 years. The improvement in self-perceived hearing-related quality of life produced by hearing aids, as measured using the IOI-HA, increased with the amount of use of hearing aids, with bilateral versus unilateral fitting, and with the degree of hearing loss in the better ear. Additional audiology and counselling support might be needed for patients who are at a higher risk of non-regular use based on their audiometric and demographic characteristics.

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Appendix 1: Questions additional to the IOI-HA that were included to the survey questionnaire.

When was your present hearing aid fitted? _____ (Month/Year)

When was your very first hearing aid fitted? _____ (Which Year?)

Do you own a hearing aid for one or both ears?

- a) One ear
- b) Two ears

If you own hearing aids for both ears, do you wear both or only one?

- a) Only one
- b) Both

Many people use their hearing aid regularly and many people do not. How many days per week do you use your hearing aid(s)?

- a) Not at all
- b) Only occasionally
- c) Some days (1 to 4 days per week)
- d) Most days (at least 5 days per week)
- e) Every day

If you don't use your hearing aid most days, please indicate the reason (tick all that apply)

- a) I don't like the look of my hearing aid
- b) I receive no or very little benefit
- c) I find that noisy situations are disturbing
- d) I have difficulties with management (e.g. volume control, putting the aid on)
- e) The hearing aid has poor fit and is not comfortable
- f) I experience negative side effects (e.g. rashes, itching, pain, build up of wax)

- g) It makes me feel old
- h) I can manage without a hearing aid
- i) Other reasons

9 Limitations of the Research Paper 1

The aim of this section is to highlight the limitations of the research paper entitled: Hearing Aid Use and its Determinants in the UK National Health Service: A Cross-Sectional Study at the Royal Surrey County Hospital.

There are several limitations in this study as described below:

1- The determinants of hearing aid use that were examined in this paper were mainly audiometric ones. A significant limitation of the study is that non-audiometric factors that are thought to be related to hearing aid use were not considered. As shown in previous studies, the self-reported hearing problems, patient's attitude toward hearing aid, stigma of deafness, and patient's readiness and motivation are important determinants of non-regular use of hearing aids (Knudsen et al. 2010; Abdellaoui & Tran Ba Huy 2013; Vernon & Pratt 1977; Babeu et al. 2004; Laplante-Levesque et al. 2014a; Laplante-Levesque et al. 2013a). It is possible that if such non-audiometric factors were measured and added to the regression models, the results would have been different. Future studies need to include both audiometric and non-audiometric factors associated with hearing aid use and outcome.

2- There was a relatively low response rate to the survey (55%). The responders and non-responders were similar in terms of the demographic variables that were measured. However, non-responders may differ from responders in some important ways that were not measured, and this could be a source of bias.

3- In this study, 'non-regular use' of hearing aids was defined as use as less than 4 hours use per day. As discussed earlier in chapter 2 this is debatable.

4- In this paper, t-test is used to compare the means of the audiometric variables and age between regular and non-regular users. A secondary analysis on the data using the skewness and kurtosis normality test (D'Agostino et al. 1990) rejected the hypothesis that these variables were normally distributed. Hence, using t-test may not be the best of choice of statistical analysis. The outcomes of the analysis published in Table 2 in the above chapter have now been double checked by the Wilcoxon rank-sum (Mann-Whitney) test, and its results did not change. This is reassuring and consistent with the idea that the t-test and linear regression model are

considered as typically robust for violations of the normal distribution when the sample size is large (e.g., $n > 50$) (Lumley et al. 2002).

10 Chapter Four: Research Paper 2

London School of Hygiene & Tropical Medicine
Keppel Street, London WC1E 7HT
www.lshtm.ac.uk



Registry
T: +44(0)20 7299 4646
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Student	Hashir Aazh
Principal Supervisor	Kiran Nanchahal
Thesis Title	Feasibility of conducting a randomised controlled trial on the effect of motivational interviewing in facilitating hearing aid

If the Research Paper has previously been published please complete Section B, if not please move to Section C

SECTION B – Paper already published

Where was the work published?	Int J Audiol		
When was the work published?	September 2015 [Epub ahead of print]		
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Student Signature: Hashir Aazh Date: 20/10/15

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Feasibility of conducting a randomised controlled trial to evaluate the effect of motivational interviewing on hearing aid use

Hashir Aazh*

** Audiology Department, Royal Surrey County Hospital, Guildford, UK*

Key words: Motivational interviewing, hearing aid use, amplification, feasibility study

Abbreviations: CEMI= Client evaluation of motivational interviewing, CERQ= Cognitive Emotion Regulation Questionnaire, COSI= Client Oriented Scale of Improvement, GHABP= Glasgow Hearing Aid Benefit Profile, HADS= Hospital Anxiety and Depression Scale, IOI-HA= International Outcome Inventory for Hearing Aids, IOI-HA-SO= International Outcome Inventory for Hearing Aid for the Significant Other, MI= Motivational interviewing, MISC= Motivational interviewing combined with standard care, MITI= Motivational interviewing treatment integrity assessment tool, RCR= Readiness to Change Ruler, RCT= Randomized controlled trial, REM= Real ear measurement, SC= Standard care, WHO-DAS II = World Health Organisation's Disability Assessment Schedule II

Correspondence: Hashir Aazh, Audiology Department, Royal Surrey County Hospital, Egerton Road, Guildford, GU2 7XX. Email: hashir.aazh@nhs.net

Abstract

Objectives: The aim of this study was to evaluate the feasibility of conducting a randomised controlled trial (RCT) on the effect of motivational interviewing (MI) on hearing aid use.

Design: This was a pilot single-blind, randomised parallel-group study conducted in the UK.

Study Sample: Thirty-seven adult patients who reported using their hearing aid(s) less than 4 hours per day were randomised to MI combined with Standard Care (MISC) (n=20) and Standard Care only (SC) (n=17).

Results: Of 220 patients invited, 37 were enrolled giving the recruitment rate of 17%. One participant withdrew giving the retention rate of 97%. It was feasible to combine MI with SC for facilitating hearing aid use and deliver the intervention with high fidelity in an audiology setting. The measure on hearing aid use (data logging) one month after interventions favoured the MISC group.

Conclusions: This pilot study suggests that conducting an RCT on using MI for facilitating hearing aid use in people who do not use their hearing aids is feasible and that MI combined with SC may have more positive effects on hearing aid use compared to SC only.

Non-regular use of hearing aids is common. Based on a recent survey conducted in the UK National Health Service (NHS) by Aazh et al (2015), approximately 40% of new patients do not use their hearing aids regularly (i.e., less than 4 hours usage per day). This finding is in agreement with prevalence of non-adherence to hearing aid use reported in surveys conducted in other countries (Hickson et al, 2010; Stark & Hickson, 2004; Brännström & Wennerstrom, 2010).

Motivational Interviewing (MI; Miller, 1996; Miller, 1983) is “a collaborative conversation style for strengthening a person’s own motivation and commitment to change”(Miller & Rollnick, 2012, p.12). Several systematic reviews and meta-analyses support efficacy of MI on adherence to long term treatments and promoting behaviour change in management of weight loss, diabetes, physical activity, and smoking cessation (Rubak et al, 2005; Lai et al, 2010). To the author’s knowledge there is no published trial on the evaluation of MI in facilitating hearing aid use. Prior to conducting a full scale randomised controlled trial (RCT) to test the efficacy of a novel intervention in a new context it is necessary to demonstrate the feasibility of delivering the intervention and test the study methods with the population of interest. The aim of this study was to evaluate the feasibility of conducting a future full scale RCT to evaluate the effect of MI on hearing aid use in people who do not use their hearing aid on a regular basis.

Methods

Trial design

This was a pilot single-blind, randomised parallel-group study conducted in the audiology department of a teaching hospital in the UK. Participants were randomly assigned to one of two groups: MI combined with Standard Care (MISC) or Standard Care only (SC). This study was approved by the NRES Committees-North of Scotland (Ref: 13/NS/0041) and the research ethics committee of London School of Hygiene and Tropical Medicine (LSHTM) (Ref: 6421).

Participants and setting

This study was conducted at the audiology department of the Royal Surrey County Hospital (RSCH) in Guildford, UK, between May and September 2013. Eligible participants were patients aged 18 or over who were fitted with hearing aids at

RSCH between January 2011 and January 2012 and reported using their hearing aids 4 hours or less per day in response to a service evaluation survey/screening questionnaire conducted between October and December 2012. The service evaluation survey questionnaires were posted to 1874 patients, of which 1021 were returned. Invitation to take part in this study was sent to 220 individuals randomly selected (using a computer generated list of random numbers) from 293 respondents who reported that they used their hearing aids for less than 4 hours a day (details of the survey are reported elsewhere) (Aazh et al, 2015). Patients were also advised that if their partner (or significant other) would like to take part in the study they should accompany them for the first visit in order to complete a questionnaire and sign a consent form. Patients who expressed their interest in taking part in this study were offered a session with the author in order to assess them against the exclusion criteria, complete baseline measures and enrolment to the study. This session lasted up to 60 minutes.

Exclusion criteria were: (1) inability to respond reliably to pure tone audiometry, (2) inability to complete the questionnaires in English language, (3) poor manual dexterity, and (4) presence of medical contraindications for hearing aid as described by the British Academy of Audiology (BAA, 2007).

Interventions

Standard Care (SC)

SC sessions were allocated 60 minutes and involved a hearing aid review appointment with a qualified audiologist with no MI training. Audiologists who provided the SC were instructed to manage the patients in the same way as they would do in their routine clinics and no attempt was taken to standardise their activities. Consistent with the routine clinical practice, audiologists typically conducted the activities listed below based on the needs of the patient:

1. Discussed patients' problems with regard to their hearing aid use.
2. Checked comfort and suitability of hearing aid(s) and ear moulds/open tubes.
3. Problem solving, practiced using hearing aid functions, changing batteries, hearing aid maintenance, as well as insertion and removal of the hearing aid(s).

4. Real Ear Measurements (REM) (if needed, REM had already been undertaken for all patients at the time of the initial fitting as a part of the routine practice).
5. Adjusted the gain-frequency response of the hearing aid(s), feedback manager, acclimatisation setting, compression, directional microphones, loop system, and additional programmes as well as automatic applications (when needed).
6. Provided brief education and explanations with regard to (a) patient's hearing status, (b) why they need a hearing aid, (c) how a hearing aid operates and its limitations, and (d) communication strategies/assistive listening devices.
7. Advised the patient that they need to use their hearing aid(s) consistently.
8. Offered them an optional follow up appointment in one week's time.

Patients who chose to have the optional follow up appointment were seen by the same audiologist one week later. This appointment was allocated up to 60 minutes and included a follow up on hearing aid use and providing further education, practice, advice, and hearing aid adjustment (as needed).

MI Combined with Standard Care (MISC)

Patients in this group received MI combined with hearing aid review with the author who is a qualified audiologist with MI training. MISC sessions were allocated 60 minutes during which the author provided MI combined with the activities related to hearing aid review as described above. Usually the first half of the session was allocated to MI in order to explore and enhance the patient's motivation to use their hearing aids. Instructions and education were provided within the MI component when indicated. The second half was allocated to review and adjustment of the hearing aid(s). The blend of MI with hearing aid adjustment tasks was flexible and based on the needs of each patient. MI was provided based on the principles described by Miller and Rollnick (2012). At the end of the MISC sessions, patients were offered the optional follow up session. Patients who chose to have the optional appointment were seen by the author in a week's time and that appointment was allocated for up to 60 minutes. The author carried out a follow up on their hearing aid use, further MI (if needed), and further hearing aid adjustments (if needed).

MI training

The author received MI training and supervised practice prior to this study. The training involved attending a two day MI workshop. Following the workshop, the author had 30 hours of practicing MI skills in audiology clinics. These were followed by 10 hours of supervision/coaching with MI experts where the audio-recordings of the MI sessions were analysed and coded. Feedback and additional training were provided in order to improve MI skills as necessary. Finally, the training process involved 100 hours of self-directed learning (i.e., reading MI literature, and reflective practice).

Prior to the start of the study the author achieved acceptable levels of competency and skilfulness in MI. The level of MI competency which was deemed to be suitable for delivering the intervention in this project was to produce a minimum of five consecutive MI sessions which were independently coded as competent in accordance with the criteria described in Motivational Interviewing Treatment Integrity 3.1.1 (MITI 3.1.1; Moyers et al, 2010).

Outcomes

(1) Recruitment and retention

Study recruitment and retention data included the number of patients identified via the screening survey who expressed interest to take part in the study, patients meeting the eligibility criteria, participants enrolled, participants completing treatment, and participants completing the four week assessment.

(2) Suitability of outcome measures

Ease of use and whether or not the outcome measures were sensitive to between-group differences were assessed. Effect sizes for each outcome were calculated as a part of this feasibility study.

The outcome measurement tools utilised in the feasibility study were data logging on hearing aids and a range of validated self-report questionnaires. The difference in hearing aid use between baseline and one month after the intervention measured using the data logging feature on the hearing aids was recorded. This is an objective measure indicating the average number of hours that a hearing aid is used per day. As the aim of the interventions were to facilitate the overall hearing aid use (e.g.,

facilitating the use of both hearing aids for bilateral users), the average hours between right and left hearing aids was used for patients with two hearing aids.

Self-report questionnaires used for this study comprise: International Outcome Inventory for Hearing Aids (IOI-HA; Cox & Alexander, 2002), International Outcome Inventory for Hearing Aid for the Significant Other (IOI-HA-SO; Noble, 2002), Client Oriented Scale of Improvement (COSI; Dillon et al, 1997), World Health Organisation's Disability Assessment Schedule II (the short version) (WHO-DASII; WHO, 1999), Cognitive Emotion Regulation Questionnaire (CERQ; Garnefski & Kraaij, 2007), Hospital Anxiety and Depression Scale (HADS; Zigmond & Snaith, 1983), Readiness to Change Ruler (RCR; Zimmerman et al, 2000), and Glasgow Hearing Aid Benefit Profile (GHABP; Gatehouse, 1999).

The GHABP and COSI were facilitated by the researcher and completed by the patient. Part one was completed at the baseline assessment session and part two was completed at the follow up session one month after the intervention. The IOI-HA, IOI-HA-SO, HADS, CERQ, WHO-DASII, and RCR were provided to participants in pen and paper format at the baseline and follow up session one month after the intervention. These questionnaires were completed by the participants in the reception area of the audiology department without any involvement from the researcher.

(3) Acceptability of the intervention

In order to assess whether MI was acceptable to patients, the Client Evaluation of Motivational Interviewing Scale (CEMI; Madson et al, 2013) was used. The CEMI is a self-report questionnaire with 16 items which is used to assess patients' feedback about the clinician adherence to MI principles.

(4) Fidelity of MI delivery

In order to see how well or poorly MI was delivered, all sessions were audio recorded and coded using the MITI 3.1.1 (Moyers et al, 2010). Coding was conducted by an independent coder who is an MI expert and was not involved in any aspect of this research or training of the author.

The MITI is a behavioural coding system that assesses both global scores and behaviour counts within a single review of a random 20 minute segment of an MI

session recording. MITI global ratings are in the form of Likert scales of one to five and an average of 4 is recommended for competency (Moyers et al, 2010). Global ratings are designed to capture the assessor's overall judgment of the interviewer's behaviour with regard to Evocation, Collaboration, Autonomy/support, Empathy, and Direction. The interviewer's utterances are assessed using behaviour counts. The utterances that receive behaviour codes comprise (1) reflections, (2) questions, (3) giving information, (4) MI adherent (e.g., asking permission, affirmation, emphasize control, support), and (5) MI non-adherent (e.g., advise without permission, confront, direct). The criteria for adequate MI competency are: (1) reflection to question ratio of two, (2) 70% open questions, (3) 50% complex reflections, and (4) 100% MI-adherent behaviours (Moyers et al, 2010).

Sample size

This was a feasibility study so a formal sample size calculation was not required. The plan was to recruit 40 patients.

Randomisation

After baseline assessment participants who met the inclusion criteria and gave written consent to take part in the study were assigned in a 1:1 ratio to either the MISC or SC group based on a computer-generated randomization strategy. The random sequence was generated by a statistician using STATA 12 prior to commencement of the study and sent to the audiology office manager for the allocation of participants. The author, who conducted the baseline assessment and enrolled participants, was blinded to the allocation and had no role in randomisation or allocation of patients to the two groups.

Blinding

Participants were blinded to group allocation. They were unaware of any specific intervention, other than "we are investigating how to facilitate hearing aid use with two counselling and audiology support approaches. Both approaches seem to be beneficial but we do not know which one is the best. The type of counselling/ audiology support you receive will be selected randomly by a computer."

Audiologists who provided SC were unaware of the type of intervention used in the MISC group. Due to the nature of the interventions provided, treatment allocation

could not be concealed from the author after the randomisation. Therefore, the author was not blinded to the treatment allocation.

Data analysis

Descriptive statistics on recruitment and retention rates, baseline patient characteristics, acceptability and fidelity of the intervention, data logging, and self-report questionnaires are reported as percentages, means, standard deviations (SD), and 95% confidence intervals (CI).

Pearson correlations were used to assess associations between hearing aid use as measured via data logging and self-report questionnaires. Estimates of effect sizes (ES) were calculated using Cohen's *d* (Cohen, 1988). Data were analysed by the author using STATA programme (version 13).

Results

Study participants

The randomisation procedure resulted in assignment of 20 patients to the MISC group and 17 patients to the SC group. There were eight females (40%) in the MISC group and seven females (41%) in the SC group. All patients had Oticon Zest hearing aids. Sixteen people (80%) in the MISC group and nine people (53%) in the SC group had bilateral hearing aids. Baseline measures for the MISC and the SC groups are presented in Table 1.

TABLE 1. Baseline characteristics of participants allocated to motivational interviewing combined with standard care (MISC) and standard care only (SC).

Characteristics	MISC		SC	
	N	Mean (SD)	N	Mean (SD)
Age (years)	20	75 (8.8)	17	69 (13.6)
PTA of better ear (dB)	20	31 (10)	17	30 (10)
Interaural asymmetry (dB)	20	8 (9)	17	16 (23)
Slope of audiogram in the better ear (dB)	20	29 (20)	17	29 (20)
Slope across ears (dB)	20	28 (18)	17	28 (15)
Hearing aid use (hours per day as measured via data logging)	20	1 (1.4)	17	1.3 (2)
International Outcome Inventory-Hearing Aid (range 7-35)	20	17.6 (6.6)	17	18.4 (7.5)
International Outcome Inventory-Hearing aid-Significant Others (range 7-35)	9	15.7 (5.3)	10	17.8 (7)
Glasgow Hearing Aid Benefit Profile (two subscales) (%)	20		17	
<i>Initial disability</i>		41.6 (15.2)		39 (20)
<i>Handicap</i>		36.6 (26.3)		46.6 (20.8)
The short version of World Health Organisation's Disability Assessment Schedule II (range 12-60)	20	19.6 (8.6)	17	15.5 (4.8)
Hospital Anxiety and Depression Scale (two subscales) (range 0-21)	20		17	
<i>Anxiety score</i>		3.7 (4.8)		3.6 (3.1)
<i>Depression score</i>		3.9 (4.5)		1.8 (2.3)
Readiness to change ruler (range 0-10)	20	5.6 (2.9)	17	4.3 (2.6)
Cognitive Emotion Regulation Questionnaire (nine subscales) (range 4-20)	16		13	
<i>Self-blame</i>		8 (3.2)		7 (1.4)
<i>Acceptance</i>		12.2 (4.1)		12 (5)
<i>Rumination</i>		7.6 (4.2)		7.5 (3.3)
<i>Positive refocusing</i>		9.4 (5)		10 (4)
<i>Refocus on planning</i>		13 (3.4)		11 (3)
<i>Positive reappraisal</i>		12.3 (4.3)		12.3 (4.6)
<i>Putting into perspective</i>		13 (5)		13 (4.5)
<i>Catastrophizing</i>		7 (2.5)		6.5 (2.6)
<i>Other blame</i>		7.7 (3.3)		7.5 (3.4)

PTA: pure-tone average audiometric threshold at the frequencies 0.25, 0.5, 1, 2, and 4 kHz for the better ear. Interaural asymmetry: the difference between the PTA values for the right and left ears. Slope of the audiogram: hearing threshold at 4 kHz minus hearing threshold at 1 kHz for the better ear

Feasibility of the research procedures

Recruitment and Retention

Forty three people (out of 220) expressed an interest in participating and attended the baseline assessment session. Four patients did not consent to take part after attending the baseline assessment. Two patients were excluded (one had an ear infection and the other one had already increased his hearing aid use to 8 hours per day at the baseline assessment). Thirty seven people were randomised, giving a recruitment rate of 17% for the pilot RCT. All 37 patients attended their sessions as planned. One patient was lost to follow up (deceased) giving a retention rate of 97% (Figure 1).

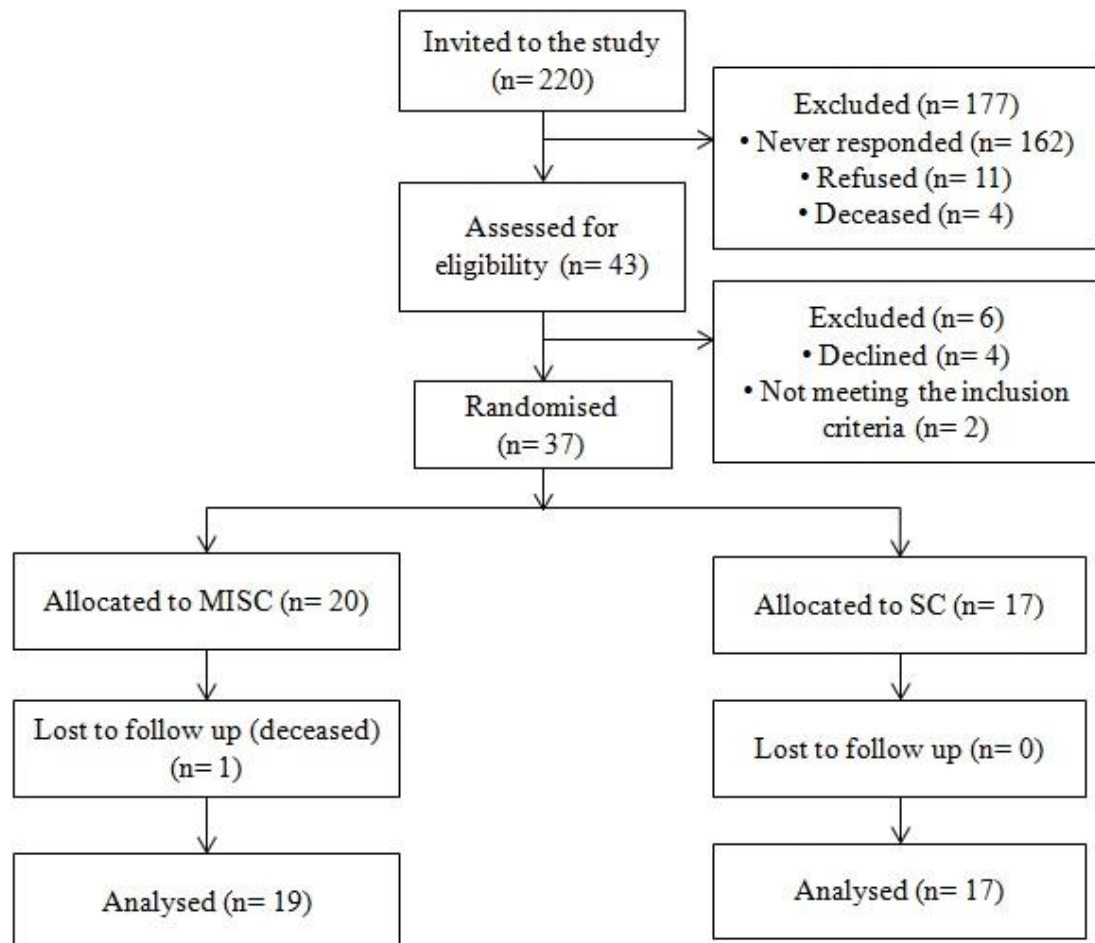


Figure 1. Study flow diagram.

Feasibility of Interventions

The length of time allocated to the interventions in both groups was enough for the tasks required. The mean time spent on patients was 37 minutes (SD=14.1) in the SC group. Due to the unstructured nature of the SC sessions it is unclear how much time was exactly spent on counselling/education component as opposed to the technical modifications of the hearing aids. The mean time spent for the MISC sessions was 52 minutes (SD=9.9). The average time spent on the MI component of the MISC sessions was 41 minutes (SD=11.2) which also included providing education when needed. Technical modifications were carried out during the remaining time when required. The optional follow up appointment was offered to all patients; 80% of patients in the MISC group (16 out of 20) and 59% of patients in the SC group (10 out of 17) attended the follow up sessions. The anticipated length for this appointment was enough for the tasks required. The mean time spent on patients for the optional follow up was 27 minutes (SD=10.5) in the SC group, and 17 minutes (SD=6.8) in the MISC group. All patients, except one, completed their final assessment with a mean time from the intervention session to the final assessment of 33 days (SD=6 for SC; SD=4 for MISC).

Suitability of Outcome Measures

All patients completed the RCR, IOI-HA, GHABP, MICI, COSI, WHO-DASII, and HADS questionnaires. However, only 78% (29/37) of the participants completed the CERQ; 22% of them felt that this questionnaire was not relevant to their hearing aid use. Nineteen significant others (51%) completed the IOI-HA-SO (49% did not have a significant other who was willing to take part in the study). Table 2 shows the changes in outcomes from the baseline to the final assessment.

TABLE 2. Changes in outcomes from baseline to final assessment (one month after intervention) and the differences between standard care (SC) and motivational interviewing combined with standard care (MISC) groups.

	SC Mean (95% CI)	MISC Mean (95% CI)	Average difference between groups Mean (95% CI)
Hearing aid use (hours per day as measured via data logging)	2.8 (1.24 to 4.27)	6 (4.26 to 7.6)	3.2 (1 to 5.36)
IOI-HA	7.5 (3.9 to 11.2)	8.3 (5.2 to 11.3)	0.73 (-3.8 to 5.3)
IOI-HA-SO	8 (2.5 to 13.5)	10.9 (4.7 to 17)	2.9 (-4.6 to 10.4)
WHO DASII	-0.4 (-1.9 to 1.1)	-1.3 (-3.1 to 0.6)	-0.85 (-3.2 to 1.5)
HADS (range 0-21)			
<i>Anxiety score</i>	-0.9 (-1.9 to 0.1)	-0.63 (-1.8 to 0.5)	0.25 (-1.2 to 1.7)
<i>Depression score</i>	-0.5 (-1.4 to 0.5)	-0.4 (-1.7 to 0.9)	0.05 (-1.5 to 1.6)
Readiness to change ruler (range 0-10)	2.3 (0.82 to 3.8)	1.6 (-0.08 to 3.2)	-0.7 (-2.9 to 1.4)
CERQ			
<i>Self-blame</i>	0.4 (-1.2 to 2)	-0.1 (-1.9 to 1.6)	-0.5 (-2.8 to 1.8)
<i>Acceptance</i>	-0.15 (-1.4 to 1.1)	0.25 (-2.3 to 2.8)	0.4 (-2.5 to 3.3)
<i>Rumination</i>	-0.15 (-1.7 to 1.4)	1.4 (0.05 to 2.8)	1.6 (-0.4 to 3.6)
<i>Positive refocusing</i>	0.7 (-1.7 to 3.1)	0.75 (-1.4 to 2.9)	0.06 (-3 to 3)
<i>Refocus on planning</i>	0.5 (-1.1 to 2)	0.06 (-3.3 to 3.4)	-0.4 (-4.3 to 3.5)
<i>Positive reappraisal</i>	-0.08 (-1.9 to 1.7)	0.06 (-1.8 to 1.9)	0.14 (-2.4 to 2.6)
<i>Putting into perspective</i>	0.8 (-0.9 to 2.5)	-2 (-3.9 to -0.12)	-2.8 (-5.2 to -0.3)
<i>Catastrophizing</i>	-0.7 (-2.3 to 0.97)	-0.8 (-2 to 0.4)	-0.1 (-2 to 1.8)
<i>Other blame</i>	-0.15 (-0.9 to 0.6)	-1.25 (-2.8 to 0.3)	-1.1 (-2.9 to 0.7)

CERQ= Cognitive Emotion Regulation Questionnaire, HADS= Hospital Anxiety and Depression Scale, IOI-HA= International Outcome Inventory for Hearing Aids, IOI-HA-SO= International Outcome Inventory for Hearing Aid for the Significant Other, WHO-DAS II = World Health Organisation's Disability Assessment Schedule II

All patients gave consent for the use of data logging in their hearing aid(s). Patients reported that the average daily use produced by the data logging system was a good estimation of their actual hearing aid use. In patients who completed the trial (n=36), there were strong correlations between data logging measurement at the final assessment and the self-reported daily use as measured by the IOI-HA (r=0.8,

$p < 0.005$), GHABP ($r = 0.7$, $p < 0.001$), and significant others report of daily use as measured using the IOI-HA-SO ($r = 0.8$, $p < 0.005$).

Data logging outcome was very sensitive to the between group differences. The mean number of hours per day that people used their hearing aid(s) increased from one hour per day ($SD = 1.5$) at the baseline to seven hours per day ($SD = 3.7$) one month after the intervention in the MISC group ($n = 19$), and from 1.3 hours per day ($SD = 2$) to four hours per day ($SD = 3.6$) in the SC group ($n = 17$). There was a large between-groups effect size of Cohen's $d = 0.98$ (95% CI: 0.3 to 1.7) for hearing aid use.

Scores on the IOI-HA, IOI-HA-SO, RCR, COSI, and GHABP showed improvement in both groups (Tables 2 and 3). There was a small between-groups ES of Cohen's d equal to 0.11 (95% CI: -0.5 to 0.8) for the IOI-HA, 0.08 (95% CI: -0.6 to 0.7) for the COSI (degree of change), -0.05 (95% CI: -0.7 to 0.6) for the COSI (final ability), 0.4 (95% CI: -0.6 to 1.3) for the IOI-HA-SO, -0.22 (95% CI: -0.9 to 0.4) for the RCR, 0.36 (95% CI: -0.3 to 1) for the GHABP (hearing aid use), and 0.25 (95% CI: -0.4 to 0.9) for the GHABP (benefit from amplification). Scores on the HADS and WHO DASII were slightly decreased (improved) in both groups (Table 3). Apart from minor changes in "rumination" and "putting into perspective" subscales in the MISC group, there were no considerable changes in the CERQ subscales between baseline and one month post intervention in either of the groups (Table 2).

TABLE 3. Outcome of the Client Oriented Scale of Improvement (COSI) and Glasgow Hearing Aid Benefit Profile (GHABP) at the final assessment (one month after intervention).

	SC	MISC	Difference
	Mean (SD)	Mean (SD)	Mean (SD)
COSI Degree of change (1-5)	3.4 (0.7)	3.5 (1)	0.1 (-0.5 to 0.7)
COSI Final ability (1-5)	4 (0.9)	4 (1)	0 (-0.7 to 0.6)
GHABP (% Use)	55 (35)	67 (34)	12 (-11 to 36)
GHABP (% Benefit)	39 (20)	45 (23)	6 (-9 to 20)
GHABP (% Residual disability)	24 (15)	18 (17)	-6 (-17 to 5)
GHABP (% Satisfaction)	46 (22)	51 (25)	5 (-11 to 21)

MI from Participant's Perspective

All patients in the MISC group completed the CEMI after their session. The mean total score on CEMI was 56 (SD= 4.3). The maximum total score for the CEMI indicating a favourable patient's feedback regarding a counselling session is 64. Therefore the scores achieved in this study indicate that the intervention was well received by the patients.

Feasibility of Conducting MI with High Fidelity in Facilitating Hearing Aid Use

All sessions were successfully coded by an independent coder using the MITI. Table 4 shows the outcome of the MITI coding for the MISC and SC sessions. The MISC sessions were coded as consistent with MI while SC did not involve any aspects of MI.

TABLE 4. Motivational Interviewing Treatment Integrity (MITI) recommended values for adequate motivational interviewing (MI) competency levels, means and SDs of coding outcomes for standard care (SC) and motivational interviewing combined with standard care (MISC) sessions and mean (95% CI) differences between groups.

	MI competency standard	SC Mean (SD)	MISC Mean (SD)	Mean Difference (95% CI)
Evocation	4	1.4 (0.5)	4.5 (0.5)	3.1 (2.7 to 3.4)
Collaboration	4	1.5 (0.6)	4.6 (0.5)	3.1 (2.7 to 3.4)
Autonomy Support	4	3.2 (0.36)	4.8 (0.4)	1.6 (1.3 to 2)
Direction	4	5 (0)	4.95 (0.2)	-0.05 (-0.2 to 0.06)
Empathy	4	1.3 (0.7)	4.3 (0.4)	3 (2.5 to 3.3)
Reflections to questions ratio	2	0.2 (0.2)	1.8 (0.5)	1.6 (1.3 to 1.9)
Percent Open Questions	70%	15% (9)	75% (13)	60% (52 to 67)
Percent Complex Reflection	50%	38% (42)	66% (8)	28% (8 to 47)
Percent MI adherent	100%	63% (0.3)	95% (0.2)	31% (0.14 to 0.49)

Discussion

In this study the feasibility of conducting an RCT on MI for facilitating hearing aid use in people who do not use their hearing aids on a regular basis was assessed. The audiologist delivering MISC was trained and achieved adequate competency levels in providing MI prior to the start of the trial. All MISC sessions were independently assessed using a reliable coding instrument in order to report the actual level of MI fidelity within the trial. MI fidelity was also documented in all SC sessions, where audiologists did not have any MI training, in order to assess the between group differences and the extent to which the provision of SC involved therapeutic aspects of MI, if any. Endpoint outcomes were measured via data logging as well as self-report questionnaires.

Recruitment, randomisation and retention

Recruitment rate was 17% which is relatively low. Generally, the initial assessment for eligibility is the biggest difficulty to full participation in RCTs, with an average of 30% of invitees failing to attend (Toerien et al, 2009). Although this study met its recruitment target which was a convenience sample of about 40 people, it is suggested to consider different approaches to increase recruitment rate for the full scale trial (Treweek et al, 2013). A Cochrane review suggested that telephone reminders to the non-respondents to the written invitations improved the recruitment rate (Treweek et al, 2013). Another method which seems to have improved recruitment rate is inviting people at face-to-face sessions (Ford et al, 2004). In many audiology centres, patients routinely are offered a follow up session four to eight weeks after the fitting. Identifying and inviting eligible participants to research at such face-to-face follow up sessions may improve the recruitment rate. Retention rate in this study was 97% which is satisfactory.

Randomisation was feasible as all participants gave consent for random allocation and it led to comparable distribution of participants into the MISC and SC groups in baseline characteristics (Table 1). However, based on the results of other studies it seems that a moderate or severe hearing loss in the better ear and having bilateral versus unilateral amplification reduce the risk of non-regular use of hearing aids (Bertoli et al, 2010; Aazh et al, 2015), hence it might be beneficial to consider the

application of stratified randomisation in future full scale trial in order to ensure that such baseline variables are evenly distributed between the groups.

Feasibility of interventions

Results of this study showed that combining MI with hearing aid related tasks in the time allocated was feasible and the MISC was acceptable to patients as measured via the CEMI. The MISC intervention was designed to combine MI and SC which is different from providing MI in addition to SC. Several components of SC (e.g., education, giving advice, and reliance on technical adjustments) were shortened and modified in order to accommodate and adhere to the MI components. Although the mean time spent on patients in the MISC group was 15 minutes more than the SC group, the mean time spent for follow up sessions in the MISC group was 10 minutes less than the SC group.

The rationale for offering the follow up session as an option was to adjust the interventions to the patients' needs. One intervention session may be enough for some patients. Consistent with this, 11 out of 37 patients did not feel that they needed to have the optional follow up session. The take up of the optional follow up in the MISC group was about 20% more than the SC group. This is potentially an important outcome as a follow up session provides an opportunity for additional support and care which can lead to improved hearing aid use. It is possible that the use of MI improved a patient's motivation to adhere to the study protocol, leading to a higher rate for acceptance/ attendance of the optional follow up session. This is consistent with other studies that suggest MI improves attendance rate in trials (Heffner et al, 2010; Smith et al, 2009). The extent to which the optional follow up session might have influenced the outcome of the interventions is not clear and there is a need for further assessment in future studies.

To the author's knowledge this was the first time that the application of the motivational interviewing treatment integrity (MITI 3.1.1) coding system was tested in an audiology context. This study showed that it was feasible to use the MITI in order to assess fidelity of an intervention that combined MI with SC (all sessions in this study were successfully coded). As all of the MISC sessions met the criteria for competency levels as measured via the MITI, it seems feasible to (1) achieve competency levels in delivering MI through the training per protocol, and (2) deliver

MI with high fidelity and consistency throughout a clinical trial for facilitating hearing aid use. However, in this study MI was delivered by one audiologist only, hence it is not clear whether the competency levels can be achieved consistently throughout a full scale trial when the intervention is delivered by several audiologists. For the full scale trial several people need to be trained to deliver the MI intervention in order to improve generalisability of the research findings. Many studies suggest that treatment fidelity can be maintained when a number of people are delivering the intervention (Bellg et al, 2004; Resnick et al, 2005). However, involvement of more than one interventionist adds more variability to the intervention delivery and possibly to the treatment effect (Apodaca & Longabaugh, 2009; McCambridge et al, 2011).

Suitability of outcome measures

All questionnaires, except the CERQ seemed to be acceptable to patients as they were completed successfully by all participants at the baseline and one month post intervention. Although patients in both groups showed improvement in the IOI-HA, IOI-HA-SO, RCR, COSI, and GHABP self-report questionnaires, the ES's were small. In contrast, hearing aid use as measured via the data logging system had a large ES in favour of the MISC group. This indicates that the data logging system is more sensitive to change in hearing aid use compared with the self-report questionnaires. In addition, use of the data logging system was acceptable to patients as all gave consent for its use and there was a strong correlation between the data logging and the self-report hearing aid use which supports the validity of this method. Based on this study and the findings from other reports, use of a data logging system seems to be feasible as the main outcome or at least in combination with self-report measures in future full scale trial (Laplante-Levesque et al, 2014; Perez & Edmonds, 2012).

Data logging is an objective measure which did not seem to be influenced by the researcher's awareness of the treatment allocation. In addition, all questionnaires were completed by the patients without interference from the researcher (except from the COSI and GHABP which were facilitated by the researcher). However, in order to improve the internal validity of the study and minimise the risk of selection bias (Pocock, 1983), the future full scale trial may benefit from assigning the

baseline assessment and the follow up outcome measurements to a person who is blinded to the treatment allocation.

The change in hearing aid use seemed to favour MISC compared to SC only. However, due to the feasibility nature of this study the outcomes were limited to one month after the intervention with no long term follow up. The full scale trial should include follow up sessions at three and six months after the intervention in order to explore the long term effects of the MISC. The gap between the SC and MISC may reduce over the time as there are several studies that suggest the relative ES's of MI decreases over time (Hetteima et al, 2005; McCambridge & Strang, 2005). In addition, the number of drop outs may increase for the longer term outcomes. These factors need to be considered when calculating the sample size for the future full scale trial.

For the data logging outcome at one month post intervention there was a large between-groups ES of Cohen's $d = 0.98$ (95% CI: 0.3 to 1.7) for hearing aid use. However, given the fact that the full scale RCT will include several interventionists and longer term outcomes, it seems reasonable to use a more conservative ES estimation of Cohen's $d = 0.60$ for MI in order to calculate sample size (Hetteima et al, 2005). On average the audiology department at the RSCH fits hearing aids for 2400 patients per year. Therefore a bulk postal screening questionnaires to patients in conjunction with a rolling recruitment where a dedicated research audiologist recruits patients via face-to-face post hearing aid fitting follow up sessions would gather a sufficient number of participants for the full scale trial.

Conclusions

This pilot study shows that conducting an RCT on MI for facilitating hearing aid use in people who do not use their hearing aid(s) on a regular basis is feasible. The measure on hearing aid use (data logging) one month after interventions favoured MI combined with SC. The findings from this study support moving forward with a larger RCT in order to establish the short and long term effects of MI combined with SC on hearing aid use.

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11 Limitations of the Research Paper 2

The aim of this section is to highlight the limitations of the research paper entitled: Feasibility of conducting a randomised controlled trial to evaluate the effect of motivational interviewing on hearing aid use.

This research paper was successful in terms of providing the standard deviations of the outcomes, willingness to randomisation, characteristics of the outcome measures, and short-term adherence which are considered as some of the key aims of feasibility studies (NIHR 2014). However, a full scale RCT needs to involve long-term outcomes and this study did not provide any data with regard to the response rate or retention rate for follow up sessions at 3, 6 or 12 months.

In this feasibility research paper the MISC intervention was delivered by only one person. Hence, it does not answer a critical question on whether it is possible to learn and deliver MI with high fidelity throughout an RCT. To answer this question, several audiologists needed to be trained and their MI skills needed to be examined against acceptable MI competencies throughout the process (Moyers et al. 2010).

Involvement of more than one interventionist adds more variability to delivery of the intervention and possibly to the treatment effect (Apodaca & Longabaugh 2009; McCambridge et al. 2011; Gaume et al. 2009; Magill et al. 2010; Miller & Rose 2009). Therefore, the effect sizes achieved in this research paper need to be interpreted in the light of its methodological limitations. This has implications for sample size calculation for the future full scale RCT which are discussed in more details chapter 6.

Finally, the recruitment rate of 17% is very low, casting a doubt on the relevance of MI for the population of interest.

12 Chapter Five: Research Paper 3

London School of Hygiene & Tropical Medicine
Keppel Street, London WC1E 7HT
www.lshtm.ac.uk



Registry
T: +44(0)20 7299 4646
F: +44(0)20 7299 4656
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Principal Supervisor	Kiran Nanchahal
Thesis Title	Feasibility of conducting a randomised controlled trial on the effect of motivational interviewing in facilitating hearing aid

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Patients' Experience of Motivational Interviewing for Hearing Aid Use: A Qualitative Study Embedded within a Pilot Randomised Controlled Trial

Hashir Aazh¹

¹. Audiology Department, Royal Surrey County Hospital NHS Foundation Trust, Guildford, UK

Corresponding author: Hashir Aazh, Audiology Department, Royal Surrey County Hospital, Egerton Road, Guildford, GU2 7XX. Email: hashir.aazh@nhs.net

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Abstract

Objective: The aim was to explore patients' accounts with regard to their experience of taking part in a pilot study evaluating the feasibility of conducting a randomised controlled trial (RCT) on the effect of motivational interviewing (MI) on hearing-aid use.

Design: This was a qualitative sub-study embedded in a pilot RCT in NHS in which participants who reported using their hearing aid(s) less than four hours per day were randomised to MI combined with audiology standard care (MISC) (n=20), and standard care alone (SC) (n=17).

An embedded mixed methods design was used in this study. 34/37 patients who took part in the pilot RCT underwent in-depth interviews one-month after the interventions. All interviews were audio-recorded, transcribed and analysed thematically.

Results: Five themes emerged in relation to the participants' perspectives about the key components of the research programme which influenced their hearing aid use. The themes comprise: (1) additional support, (2) clinician effect, (3) commitment to research, (4) research process, and (5) feeling better about self. Most people highlighted a combination of the themes related to the target interventions provided as well as the themes related to the research participation effect in general.

Conclusions:

The provision of hearing aids in the NHS may benefit from adopting a more compassionate patient-clinician relationship, additional patient education, and post-hearing-aid-fitting support. These were among the main themes which seemed to have helped people to improve their hearing-aid use. This study suggests that the general research participation effect seems to have influenced the levels of hearing-aid use in both groups. Strategies to minimise the research participation effect need to be considered in the design of the future full-scale trials.

Background

A meta-analysis showed that hearing aids (HAs) had a medium-to-large effect on health-related quality of life (Chisolm et al. 2007). Despite this, a recent study in National Health Service (NHS) in the United Kingdom showed that 29% of people (293/1021) do not use their NHS HAs regularly (i.e., use less than 4 hours per day) (Aazh et al. 2015). The non-regular use was 39.5% for new patients (Aazh et al. 2015). Previous studies in NHS also reported 43% to 45% for non-regular use (Stephens 2002; Davis et al. 2007).

In NHS, the choice of HAs is limited. In other countries, patients may have the choice of several HA makes. Despite this, non-regular use in NHS is comparable to that found in other countries: 27% and 58% in two Australian studies (Hickson et al. 2010; Stark & Hickson 2004), 42% in Finland (Vuorialho et al. 2006), 13% to 31% in four studies conducted in the USA (Kochkin 2010; Takahashi et al. 2007; Williams et al. 2009), and 25% in Switzerland (Bertoli et al. 2009). For further detail see Aazh et al. (2015).

There is no proven intervention that can successfully improve HA use in the sub-population of patients with hearing impairment who do not use their HAs consistently. Audiologists typically advise patients to use their HAs consistently throughout the day. This seems to work for majority of patients but not for this sub-population. Barker et al. (2014) conducted a Cochrane review on interventions designed to improve HA use and outcome. They included 32 studies. The interventions were mainly focused on education and communication strategies and typically involved 4-6 sessions over a period of 2-3 months (total contact time of 6-10 hours) delivered either in group or distance learning. Barker et al. (2014) did not find any evidence of statistically significant effect on HA use or on quality of life measures. Use of HAs often requires a change in behaviour which is a complex process. Simply advising people may not help them to change (Rollnick et al. 2005).

Motivational Interviewing (MI; Miller 1996) is a psychological intervention which is rooted in the client-centred counselling method of Carl Rogers (Rogers 1959) and gives great importance to both understanding a patient's internal frame of mind and exhibiting unconditional positive regard (Miller & Rose 2009). A pilot study was

conducted by Aazh (2015) in order to assess the feasibility of conducting an RCT on the effect of MI on hearing aid use. In the pilot RCT, participants were randomly assigned to one of the two groups: MI combined with Standard Care (MISC) (n=20) or Standard Care only (SC) (n=17). SC involved adjusting the hearing aids, and providing instructions and advice. MISC involved MI combined with SC tasks. The mean number of hours per day that people used their hearing aid(s) increased from 1 hour per day (SD=1.5) at the baseline to 7 hours per day (SD=3.7) one month after the intervention in the MISC group (n=19) and from 1.3 hours per day (SD=2) to 4 hours per day (SD=3.6) in the SC group (n=17). Scores on self-report questionnaires showed improvement in both groups, however the between-groups effect sizes were small (see Aazh (2015) for details). All sessions were coded by independent coders using motivational interviewing treatment integrity (MITI 3.1.1) (Moyers et al. 2010). MISC sessions were coded as consistent with MI while SC did not involve any aspects of MI (Aazh 2015).

RCTs have been described as the gold standard method for evaluating effect of a treatment (Chelimsky 1997). Prior to conducting a full scale RCT to test the efficacy of a novel intervention in a new context it is necessary to demonstrate the feasibility of delivering the intervention and test the study methods with the population of interest (Bowen et al. 2009). There is an increased recognition of embedding qualitative research in RCTs in order to gain more insights about the participants' perspectives with regard to the research procedures as well as the processes and intervening factors related to the observed quantitative outcomes (Lewin et al. 2009; Oakley et al. 2006; Bower et al. 2006). Embedded design is a mixed methods approach where the qualitative component helps the researcher to contextualise the quantitative findings and explore participant's responses to quantitative variables (Creswell 2009; Wagner et al. 2012; Pluye et al. 2009). Mixed methods design has widely been used in pilot and feasibility studies in order to produce more in-depth knowledge which can be used to inform the design of the future full-scale trials (Baral et al. 2014; Chesser et al. 2014; Iribarren et al. 2013; Secomb & Smith 2011; Fisher & Boudreau 2014; Leemans et al. 2014).

This qualitative sub-study offers an opportunity to explore participants' feedback of their experiences throughout the research and gain further insight with regard to their perspective on how the interventions influenced their hearing aid use.

Aims

The aims of this study were to explore patients' accounts with regard to the factors that influenced their hearing aid use during the process of the research.

Methods

Design

The design of this study is mixed methods where a qualitative sub-study was embedded within a pilot RCT conducted between May and September 2013 (Aazh 2015).

Ethics

This study was reviewed and approved by the NRES Committees-North of Scotland (Ref: 13/NS/0041) and the research ethics committee of London School of Hygiene and Tropical Medicine (LSHTM) (Ref: 6421). All participants gave written consent to be included to this study.

Sample

Participants were patients who took part in the pilot RCT assessing the feasibility of motivational interviewing in facilitating hearing aid use. The details of the pilot study are published elsewhere (Aazh 2015). In summary, this was a random sample selected for the pilot RCT from the population of people who indicated that they did not use their hearing aids consistently via a service evaluation survey. This qualitative sub-study was embedded within the pilot RCT. All participants who took part in the pilot RCT, except one who dropped out (36 out of 37), were invited to take part in the qualitative in-depth interviews at their final follow up session.

Interviews

The author interviewed all 34 participants between August and September 2013 at the audiology department, RSCH. The author was known to all participants as he recruited and assessed them as well as providing the intervention for the MISC group. This study was a part of the author's PhD project. The interviews lasted for up to 60 minutes and were audio-recorded. All interviews were transcribed verbatim by an independent transcription agency and provided an account of all verbal and the

audible nonverbal (e.g., coughs, cry, pause, laugh, indicating agreement, etc.) utterances.

Interviews were semi-structured and an interview guide was developed in order to prompt the questions (Appendix 1). The author used a wide range of basic counselling skills (e.g., active listening, reflecting, empathy, non-judgmental, open questions, probing, confronting, etc.) in order to build a good rapport with patients and to make them feel comfortable so they can openly talk about their ideas and concerns.

Data analysis

The method used to analyse the interview transcripts was based on the six-phase guide of thematic analysis as outlined by Braun and Clarke (2006). In order to explore the important components of the research programme from the perspective of the participants an inductive approach to thematic analysis was adopted and the themes were primarily identified at semantic level (Patton 1990).

In the first phase, the author read all the interview transcripts several times in full and checked them against the original audio recordings for accuracy. Analytic memos and annotations were taken throughout the process generating a list of ideas about potential codes as well as highlighting segments of the transcripts which were relevant to the research questions. At phase 2, segments of the transcripts relevant to the research questions were coded for potential themes. At phase 3, codes were sorted into potential themes. Codes, themes and extracts of the data are collated together ensuring that the codes and themes are closely representing the data. At phase 4, emergent themes were reviewed and refined. At phase 5, a detailed analysis for each theme was written describing its meaning and its relation with other themes in the data set. In addition, sub-themes were formed for the large and complex themes. Sixth phase included writing up an analytic narrative of the thematic analysis and providing sufficient evidence for the themes within the data (i.e., inserting the relevant data extracts). Themes were not necessarily developed based on the number of the participants identified by them but by their uniqueness and potential influence. QSR NVivo 10 was used for qualitative data analysis. Consolidated criteria for reporting qualitative research checklist was used to guide reporting of this study (COREQ; Tong et al. 2007).

Results

Participants' characteristics

There were 19 males and 15 females. Mean age was 72.2 years (SD=11.5) ranged between 34 and 92 years old. All patients had Oticon Zest NHS Behind-the-Ear hearing aids. As presented in Table 1, there wasn't any considerable difference in the baseline characteristics between the MISC and SC groups.

TABLE 1. Baseline characteristics of participants.

Characteristics	MISC	SC
	Mean (SD) N= 19	Mean (SD) N= 15
Age (years)	75 (8.8)	69 (13.6)
PTA ^a of better ear (dB)	31 (10)	30 (10)
Hearing aid use (hours per day as measured via data logging)	1 (1.4)	1.3 (2)
International Outcome Inventory-Hearing Aid (range 7-35)	17.6 (6.6)	18.4 (7.5)

This table shows the baseline characteristics of participants allocated to motivational interviewing combined with standard care (MISC) and standard care only (SC). ^aPTA: pure-tone average audiometric threshold at the frequencies 0.25, 0.5, 1, 2, and 4 kHz for the better ear.

Themes and their distributions

Five themes emerged in relation to the participants' perspectives about the key components of the research programme which influenced their hearing aid use. Number of themes which were identified in each transcript varied among participants. Most transcripts provided several themes while there were some transcripts with a single theme only. The themes comprise: (1) additional support, (2) clinician effect, (3) commitment to research, (4) research process, and (5) feeling better about self. As shown in Figure 1, the theme related to additional support was further divided into 2 sub-themes of (1) hearing aid adjustments, and (2) education, advice and counselling. The theme related to the research process was further divided into 3 sub-themes of (1) motivated by the research process, (2) negative effects, and (3) the effect outside the research team. The additional support and clinician effect seemed to be related to the target interventions provided but the commitment to research, research process, and feeling better about self were related to the general research participation effect.

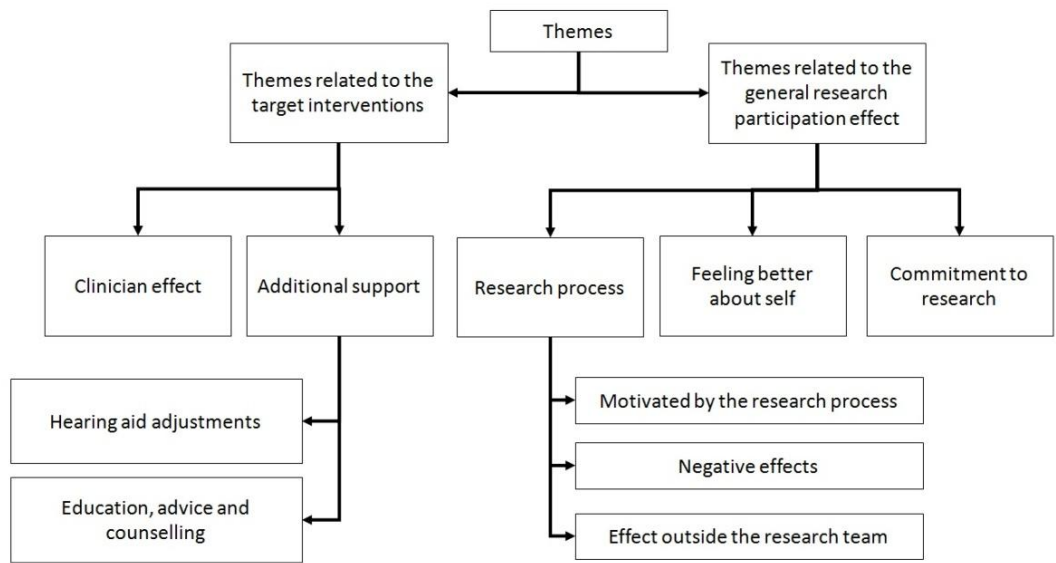


Figure 1. Themes about the key components of the research programme.

As shown in Figure 2, the most prevalent theme was the additional support which included hearing aid adjustments, education, advice, and counselling. This theme is directly related to the target interventions provided in the MISC and SC groups.

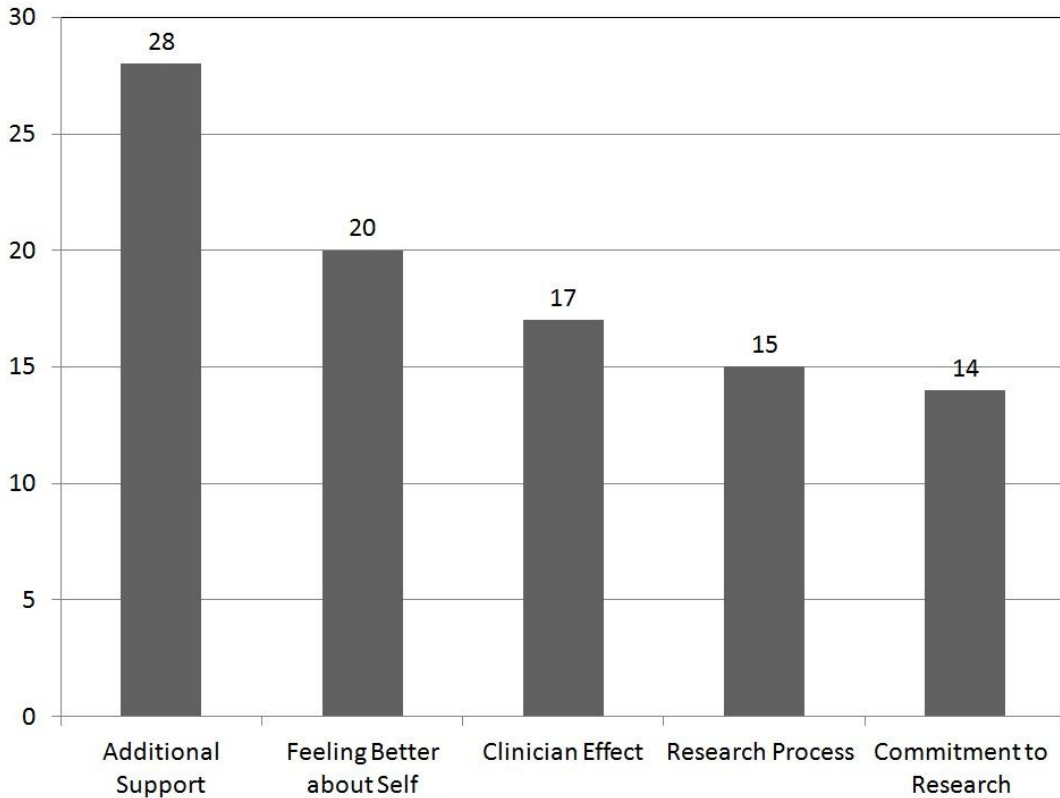


Figure 2. Number of participants identified with each theme.

Table 2 compares the distribution of the themes between the MISC and SC groups. Most of the themes are equally distributed between the MISC and SC groups. However, commitment to research is over twice as much prevalent among the patients in the MISC group compared to the SC group.

TABLE 2. Distribution of themes between MISC and SC groups.

Themes	MISC	SC
Clinician effect (17/34)	9 (53%)	8 (47%)
Additional support (28/34)		
Hearing aid adjustments (17/34)	9 (53%)	8 (47%)
Education, advice and counselling (26/34)	15 (58%)	11 (42%)
Commitment to research (14/34)	10 (71%)	4 (29%)
Research Process (15/34)		
Motivated by the research process (10/34)	5 (50%)	5 (50%)
Effect outside the research team (4/34)	1 (25%)	3 (75%)
Negative effects (5/34)	2 (40%)	3 (60%)
Feeling better about myself (20/34)	12 (60%)	8 (40%)

Theme 1: Clinician effect

Fifty percent of the patients (17/34) described that the most helpful part of the research programme was related to the audiologist's attitude. The theme of clinician effect was not necessarily linked to the specific content of the interventions provided but was rather related to the fact that a caring professional taking interest in them and exhibiting a more supportive attitude which seemed to be missing from their original NHS hearing aid fitting session. Several patients attributed the change in their hearing aid use (increased usage) to the audiologist's attitude. Eight out of nine of the participants in the MISC group and three out of eight of the participants in the SC group who were identified with this theme showed over four hours improvement in their hearing aid use.

“[the reason for improvement was] responding to the attitude and support of the staff at Royal Surrey, I include yourself.” (P15MISC)

“Well her whole attitude, seemed to be geared to, not only the study but actually helping me to use it as you have done. Only the fact that I could talk to somebody like yourself that understood what the issues were.” (P16SC)

Theme 2: Additional support

Eighty two percent (28/34) of participants felt that the research offered them some additional support to the routine care in the NHS.

Several patients pointed out that additional support to their initial NHS fitting session was needed and taking part in the research study provided an opportunity for them to receive such care and support.

“I suspect I wouldn’t have had quite the amount of time and attention that you and she have been given as a result of this research.” (P15SC)

“I think the main thing [helped him to improve hearing aid use] was the first thing I said, the after sales service which I’m getting now, well, a lot of people need more.” (P24MISC)

This theme was divided into 2 sub-themes of (1) hearing aid adjustments, and (2) education, advice and counselling. They are described in more details below.

Subtheme 1: Hearing aid adjustments

Fifty percent of participants (17/34) said that adjustment of their hearing aids helped them to use them more often. Eight out of nine of the participants in the MISC group and three out of eight of the participants in the SC group who were identified with this theme showed over four hours improvement in their hearing aid use.

“There has been a change along the lines that some of the feedback is certainly less than it was previously, which I found pretty objectionable for things like driving a car or something like that, and I wouldn’t wear hearing aids in the car because of that. Now I can wear the hearing aids and it’s perfectly acceptable, and I don’t really know I’ve got them in.” (P28MISC)

“Yes. Yeah, that, because before it was like a tinny, robot sound all the time. So now it’s much better. There’s still some distortion at times, but it’s much more of a natural voice that I hear. Whereas before it wasn’t, it was just robotic.” (P11SC)

Subtheme 2: Education, advice and counselling

Seventy six percent of the participants (26/34) felt that the education, advice and counselling contributed to their decision on using their hearing aids. Eleven out of 15 of the participants in the MISC group and four out of 11 of the participants in the SC group who were identified with this theme showed over four hours improvement in their hearing aid use. There wasn't a clear distinction between the elements of this theme. Often people described their experience of receiving "counselling", "advice" or "education" interchangeably or together. For this reason sub-themes were not created for this category.

Several participants described that gaining more information about their hearing impairment and amplification encouraged them to use their hearing aids more consistently. They felt that they were not given enough information at their original NHS fitting session.

"And it is, and then when you said that your brain needs to get used to having it communicating with it, I think that's something I didn't realise before. And the more you use it, the more your brain gets used to it and I'm sure if anybody had said that to me before, I might have taken more notice." (P32MISC)

Some participants described that instructions and advice provided by the audiologist helped them to use their hearing aids more consistently.

"And it's like, she just makes you try and build you, just says you can use it at home first and then the week after use it out and then the week after use it in the car." (P2SC)

Several patients described that the reason that they used their hearing aids was the fact that they were told to do so. However, it is not clear why they haven't complied with the same advice probably given to them at the time of their original NHS hearing aid fitting session. Often probing questions revealed that it was not necessarily the lack of information but the fact that they didn't feel that they needed to use their hearing aids was the main barrier.

Theme 3: Commitment to research

Forty one percent (14/34) of the participants linked the change in their hearing aid use to their commitment to the research programme. They expressed that the main factor which motivated them to change their hearing aid use was their participation in the research. They believed that by accepting the invitation to the research they were in fact made a commitment to use their hearing aids. In the other words, commitment to research seemed to be a key motivation for change in their behaviour of hearing aid use.

“Yeah, well I mean I was part of the research programme so I mean I wanted to give it the best opportunity, so it wasn’t, as you say, the technical adjustments at the beginning but I just wanted to give it the best opportunity over the six week period, so, yeah.” (P1MISC)

“because I committed to the research programme, I committed to using the hearing aid. Only the fact that I agreed to participate in the programme and it would be pointless my agreeing to participate in the programme if I wasn’t going to wear the hearing aid.” (P6SC)

Theme 4: Research process

Forty four percent of the participants (15/34) expressed that their interaction with the process of research influenced their decisions about their hearing aid use. This theme was mainly focused on the effects which were not necessarily limited to the interventions delivered by the audiologists. Several participants described that the main effect of the research was related to engaging with the process of research as a whole (e.g., receiving the invitation letter, completing questionnaires, initial assessment, giving consent, and follow up sessions, etc.).

The influence of the research process was not always positive and some patients expressed some negative effects as the result of engaging with the research process. Moreover, the research process effect was not always directly related to the planned components of the research programme and few patients mentioned that they received influences from outside the research team during the study period. The theme of the research process is sub-divided into 3 sub-themes of (1) motivated by the research process, (2) negative effects, and (3) effects outside the research team.

These subthemes will be described separately in the section below using the direct quotations from the transcripts to illustrate them.

Subtheme 1: Motivated by the research process

Overall 10/34 believed that engaging with the research process was the main stimulus helping them to change their behaviour. This theme was differentiated from the commitment to research because it didn't imply that they were committed to the research. Instead, they felt motivated to use their hearing aids because of getting involved in the research.

Commitment to research theme represents a conscious decision that because I am committed to the research, I also am committed to use my hearing aids. This is in contrast with the research process which represents a desire to improve one's use of hearing aids because of taking part in the research. In the other words, for those identified with motivated by the research process theme, taking part in the research created a momentum to start using their hearing aids.

For instance, one patient described that receiving the invitation to research letter triggered his motivation to use his hearing aid.

"I think the motivation for me came as soon as the questionnaire arrived [invitation to research accompanied by the Patient Information Leaflet], it started making me think about my hearing then. So I was already motivated.I was always going to do it, yeah. It was, I don't think, the only thing you could have done was be to try and demotivate me from using it." (P33MISC)

Some patients felt that the research process as a whole was the main factor not the individual tasks taken by their audiologist during the intervention sessions.

"I don't know what she [the audiologist] did that made me do that [use my hearing aid consistently], I think it was not herself, but the process, the whole situation."(P10SC)

Subtheme 2: Effect outside the research team

Twelve percent of participants (4/34) described that taking part in the research programme encouraged them to talk about their hearing impairment with

their peers, family and friends. This resulted in gaining more support from the people outside the research team.

“I now know that there are people, because I’ve talked about this hearing aid study to other people and I know there are people at the golf club who wear, because I see them now wearing their hearing aids and it doesn’t bother them and it doesn’t bother me anymore.” (P16SC)

Subtheme 3: Negative effects

The effect of the research process did not always encourage the participants to use their hearing aids. Fifteen percent (5/34) felt that various stages of the research had a negative impact on them. Some patients described that during the process of the research they felt that they were pushed into accepting that they were doing something wrong. The research components that gave them this impression were mainly the information leaflets and the assessment questionnaires.

“That is incredibly difficult, really is difficult, because I have felt some pressure during all these questionnaires, interviews, blah, blah, blah. All of this research of yours, is geared towards, the deaf person is not doing all they could to help themselves, so let’s push and nudge and prod, and try and make them, you know, get more, as much out of life as they can, hearing wise, and I don’t see it like that.”(P3SC)

The negative effects were not always directly related to the components of the research but sometime were related to the reactions of others to the patient’s participation to the study. For example one patient said that her children were discouraging her to take part in the research or to use her hearing aids.

“And they’re very negative [her children]. They say there’s nothing the matter with my hearing. They can’t see any reason why I would want to improve it. Well, I’m supposed to go home and say I’m not having it after all. That’s what would please them, isn’t it? If I go home and say I’ve changed my mind.” (P22MISC)

Theme 5: Feeling better about self

Fifty nine percent of participants (20/34) expressed that taking part in the research was a selfless act that made them feel better about their selves being able to help

others. Several participants described that their main motivation to take part in the study was to give something back to the NHS and do something good by getting involved in the research. They also seemed to feel that using their hearing aids consistently during the study period would be of benefit to the research programme hence they did their best to improve their hearing aid use for altruistic reasons.

“We’ve gained a lot from NHS. And from assistance that we’ve had and it is, it was something we could do in return. Yes dear. Something we could give back. I think that’s quite true. We just thought, what on Earth help can we possibly be? But if we could be of help, then great.” (P31SC)

Discussions

Summary of the key findings

Five themes emerged from analysing the transcripts about the participant’s accounts of the important factors in the research programme which influenced their hearing aid use. These comprise: (1) additional support: participants benefited from the additional support provided during the research, (2) clinician effect: good patient-clinician relationship, (3) feeling better about self: altruistic reasons, (4) research process: effects of various components of research beyond the target interventions, and (5) commitment to research: people felt that by taking part in the research, they were committed to the research programme and to use their hearing aids.

A combination of the themes was identified for each individual. This indicates that there was no single component in the research process that could be identified as the active ingredient.

Most people highlighted a combination of the themes related to the target interventions (i.e., additional support, and clinician effect), and to the themes related to the research participation effect in general (i.e., commitment to research, research process, and feeling better about self).

Clinician effect

There are many studies in the literature suggesting that effective clinician-patient communication and alliance are closely linked with the patient’s satisfaction and their adherence to the treatment (Hall et al. 1988; Stewart 1995; Ong et al. 1995;

Fuertes et al. 2013; Dillon et al. 1999; Dillon et al. 1997; Humes et al. 2001; Uriarte et al. 2005; Sabate 2003). Grenness et al. (2014) conducted a qualitative research and interviewed 10 hearing impaired individuals in order to assess their expectations from audiologists. The dominant theme among their participants was the clinician effect. According to their patients, without a good clinician-patient relationship all the other tasks were likely to be inefficient or to fail (Grenness et al. 2014).

It is hard to compare how people felt about the patient-clinician relationship between the MISC and the SC group because they only received either one of them. Hence, all patients were comparing their MISC or SC intervention sessions with their original NHS fitting appointment.

Although the theme of the clinician effect was equally prevalent between the MISC and the SC groups, 8 out of 9 of the MISC participants who were identified with this theme achieved over 4 hours improvement in their hearing aid use compared to only 3 out of 8 participants in the SC group.

This between-group difference may be related to the key elements of MI which are partnership, direction, acceptance, compassion, and evocation in the MISC sessions (Miller & Rollnick 2012). The similarities and differences in the clinicians' conversation styles between the MISC and SC sessions as measured independently via MITI 3.1.1 are briefly discussed below.

MISC and SC sessions achieved similar ratings with regard to the direction and compassion but their ratings were significantly different in partnership, acceptance, and evocation (Aazh 2015). Direction measures the degree to which the clinicians maintain appropriate focus on a specific target behaviour during the session (e.g., use of hearing aids) (Moyers et al. 2010). The global rating for direction was 5 (SD=0) in the SC group and 4.95 (SD=0.2) in the MISC group ($p=0.4$) (Aazh 2015). The global ratings in MITI 3.1.1 are in the form of Likert scales of 1 to 5 and average of 4 is required for MI competency level (Moyers et al. 2010). This indicates that in both the MISC and SC sessions the audiologist exerted influence on the sessions and generally did not miss opportunities to direct the patient toward the target behaviour of hearing aid use.

Compassion is to actively promote the other's welfare and give priority to other's needs. The MITI 3.1.1 does not include any measure that can assess compassion.

However, it is likely that in both groups the clinicians who delivered the interventions exhibited a more compassionate attitude compared to the usual care. This is consistent with the feedback received from the participants that appreciated the fact that a caring professional taking interest in them and exhibiting a more supportive attitude which seemed to be missing from their original NHS sessions.

Partnership refers to collaboration and power sharing between the therapist and the patient in such a way that a patient's ideas are valued and influence the direction of the session. This is in contrast to a clinician assuming the expert role and prescribing a treatment. The global rating on MITI 3.1.1 for partnership was 1.5 (SD=0.4) in the SC group and 4.6 (SD=0.5) in the MISC group ($p<0.001$) (Aazh 2015). The lower scores on partnership which was shown in the SC group indicates that the audiologists did not work towards a mutual understanding with the patient during the sessions and relied upon a one-way communication based on their expert knowledge (e.g., audiologists at SC rushed into offering solutions to the problems expressed by the patients without further exploring the possibilities, patient's strengths, motivation, ideas, feelings, etc) (Moyers et al. 2010). In contrast, the higher scores as shown in the MISC group suggest that the audiologist was curious about the patient's ideas and did not rely on authority to achieve progress. Expert knowledge was used strategically not before the patient was ready to receive it (Moyers et al. 2010). According to MI no one is completely unmotivated for change but they may be ambivalent. Ambivalence is a state of uncertainty and people can stay in that state for a long time (Rollnick et al. 2008). In MI it is important to encourage the patient to explore and verbalise their own reasons, need, desire and ability to change, as opposed to lecturing and giving them information and advice about the benefits of the change, or arguing about the negative consequences of not making the change (Miller & Rollnick 2002).

Acceptance or empathy which is embedded in MI is a key concept developed by Carl Rogers and involves (1) prizing the inherent worth and potential of every human being, (2) understanding another's internal perspective, (3) honouring their autonomy, right and capacity for self-direction, (4) seeking and acknowledging the person's strengths and efforts (Miller & Rollnick 2012; Rogers 1962; Rogers 1980). Global rating for empathy was 1.3 (SD=0.7) in the SC group and 4.3 (SD=0.4) in the MISC group ($p<0.001$) (Aazh 2015). Clinicians in the SC group were generally

achieved lower scores on empathy which means that they mainly probed for the factual information in order to offer practical solutions rather than focusing on understanding the client's perspective as described above. Although many participants appreciated the fact that the audiologists have asked them more questions and spent more time on offering solutions compared to a typical routine NHS appointments, these did not necessarily led to improved hearing aid use in majority of the participants in the SC group.

Evocation refers to actively helping the patient to explore and verbalise their own reasons for change and ideas about how change should happen. This is in contrast with educating or persuading the patient to change (Miller & Rollnick 2012). Global score for evocation was 1.4 (SD=0.5) in the SC group and 4.5 (SD=0.5) in the MISC group ($p<0.001$) (Aazh 2015). This means that in the SC group the audiologists actively provided reasons for change and education about the change without exploring client's knowledge, efforts and motivations (Moyers et al. 2010). Audiologists' enthusiasm during the SC sessions must have been greater than what the patients experienced in their original NHS hearing aid fitting sessions, which might have led to high prevalence of the theme related to the clinician effect even in the SC group. However, the improvement in hearing aid use was greater in the MISC sessions in which the audiologist worked proactively to evoke patient's own reasons for change and ideas about how change should happen (Moyers et al. 2010).

To sum up, although this qualitative sub-study shows that there are several factors that contributed to the improved hearing aid use observed in the pilot RCT (Aazh 2015), consistent with other studies (Grenness et al. 2014; Hall et al. 1988) the clinician effect seemed to be very crucial from patients' perspective. However, the clinician effect was related to greater improvement in the MISC group compared to the SC. Therefore, enhancing the patient-clinician relationship in NHS audiology through adopting an approach which is informed by MI in which audiologists actively explore patients' concerns, ideas, and motivations about hearing aid use could be beneficial in improving hearing aid use.

Hearing aid adjustments

Hearing aid adjustment was an important part of the interventions in both the MISC and SC groups. Many people expressed that hearing aid adjustments helped them to

use their hearing aids more often and there was a general sense that NHS doesn't offer enough support after the fitting of hearing aids.

The main barriers to the consistent use of hearing aids as reported by patients are often related to poor performance of the hearing aids, poor fit, and discomfort (Aazh et al. 2015; Bertoli et al. 2009; Gopinath et al. 2011; Hickson et al. 2014). Therefore, regular adjustment of the hearing aids in order to ensure that they perform well is crucial. Gopinath et al. (2011) reported that the lack of benefit from the hearing aids, uncomfortable fitting and difficulty in putting them in were the main barriers to hearing aid use. Bertoli et al. (2009) reported that the strongest factors associated with non-regular use were dissatisfaction with the hearing aid and difficulty to handle it. Hickson et al. (2014) reported that when hearing aid users were asked why they did not use their hearing aids, almost 25% described that their hearing aids did not help them to hear better, 11% reported that their hearing aids were too noisy, and 11% had difficulty managing their hearing aids. Wong et al. (2003) reported that improved performance of hearing aids in noisy environments associates with greater satisfaction with hearing aids.

Hearing aid adjustment component of the interventions provided in the MISC and SC groups was potentially very critical because it could have resolved or improved many of the above mentioned problems. However, 35% of the participants (6/17) who have made over 4 hours increase in their hearing aid use and 71% of participants (5/7) who have made between 2 and 4 hours increase in their hearing aid use did not mention the adjustments of the hearing aids as a beneficial factor. Therefore, it seems that although hearing aid adjustments are very important for some patients, it may not predict successful hearing aid use for others.

Education, advice and counselling

Several participants described that in their original NHS hearing aid fitting session they didn't receive much information about their hearing impairment and didn't fully realise the importance of consistent use of their hearing aids. Problems with the lack of information and education for patients is common in healthcare systems in most countries (Coulter & Cleary 2001). A meta-analysis found that patient's adherence to treatment was predicted by greater clinician information giving discussions (Hall et al. 1988). A more recent meta-analysis showed that non-

adherence to treatment is 1.47 times greater among individuals whose physician is poor in building rapport, empathy, and communication (Zolnierek & Dimatteo 2009). Failure in communication about the disease and treatment options are among the most frequent sources of patient's dissatisfaction (Grol et al. 1999; Grol et al. 2000; Wensing et al. 1998). A systematic review on patients priorities for the general practice care revealed that "informativeness" was among the most important priorities of patients with regard to their primary healthcare providers (Wensing et al. 1998). Patients expect their clinician telling them all they want to know about their illness and making them feel free to talk about their problems (Grol et al. 1999). A recent qualitative study in the field of audiology reported that the patients emphasised the importance of being informed about their hearing and their hearing aids capability (Laplante-Levesque et al. 2013).

In the current study, a large number of patients believed that gaining more information about their hearing impairment and amplification did encourage them to use their hearing aids more. This highlights the need to improve provision of information to patients during the first hearing aid assessment and fitting sessions in routine NHS audiology clinics. This is consistent with the results of Kelly et al. (2013) who conducted a mixed methods study in NHS in order to explore older adults experience with their new hearing aids and to identify what they believed would enable them to successfully adjust to wearing them. They found that the primary need prior and after the hearing aid fitting was information. Similar to the results of this study, their participants described that they received little information about the types of hearing aids, process of receiving audiological services, and information to help them adjust wearing them (Kelly et al. 2013).

Although the theme of education, advice, and counselling was equally prevalent between the MISC and the SC groups, 73% (11/15) of the MISC participants who were identified with this theme achieved over 4 hours improvement in their hearing aid use compared to only 36% (4/11) participants in the SC group. This between-group difference may be related to the manner in which information was provided in the MISC group. In MI an approach called elicit-provide-elicited (EPE) is used in order to provide information (Miller & Rollnick 2012). EPE approach ensures that the information provided is sandwiched between asking patients views, concerns or permission (Rollnick et al. 2008). Eliciting should happen prior to providing

information and it means to encourage the patient to think about the information that the therapist is planning to discuss. This way the patient becomes prepared and ready to receive the information which can enhance the likelihood of the change to happen.

Milstein and Weinstein (2002) suggested that simply providing information to people about their hearing impairment may not necessarily improve compliance to hearing aid use if they are not ready for this (Milstein & Weinstein 2002). In the current study, although 44% of the participants who were identified with this theme achieved over 8 hours of hearing aid use, education, advice and counselling theme was also presented in 70% of participants who achieved less than 2 hours change in their hearing aid use. Therefore, not everyone who found the information, advice and counselling useful necessarily improved their hearing aid use.

Themes related to the research participation

Commitment to research was over twice as much prevalent among the patients in the MISC group compared to the SC group. This is consistent with several studies that suggest MI improves adherence to research studies and reduce drop outs (Heffner et al. 2010; Smith et al. 2009). In the other words, the commitment to research may be a mediator for change in hearing aid use.

Selflessness or altruistic motivations has been considered as one of the most common reasons that people taking part in a medical research (Gabbay & Thomas 2004; Mattson et al. 1985; Slevin et al. 1995; Bevan et al. 1993; Larson & McGuire 1990). In this study, several participants described that their main motivation to take part in the study was to give something back to the NHS and to do something good by getting involved in the research. This is consistent with a qualitative study conducted by Canvin and Jacoby (2006) who found that patients have a sense of moral duty to take part in research. Patients expressed the wish to help others, the wish to do their bit, give something back, help the researcher, and contributing to scientific knowledge as their reasons for participation (Canvin & Jacoby 2006). McCann et al. (2010) also reported similar results. They reported that their participants expressed a willingness to help others and to contribute towards furthering the medical knowledge (McCann et al. 2010).

Commitment to research, research process, and feeling better about self seem to be related the well-established research participation effect (RPE; McCambridge et al.

2014b) which is described as the consequences of research participation as the result of the overall interaction of the participant with the research process not necessarily the target interventions under examination (McCambridge et al. 2014c). The implication of this finding is that if this was not a research programme and people simply were invited for a follow up session as a part of their routine NHS care then the true outcome of the interventions provided in both MISC and SC groups could have been different from what we observed here. This is consistent with what has been highlighted by several authors in the past (Solomon 1949; French 1953; McCambridge et al. 2014b). It has been suggested that completing self-report questionnaires, reading the research information leaflets, giving consent, being classified as eligible for a study, being observed and receive feedback may provide an opportunity to change regardless of the target therapeutic interventions (French 1953; McCambridge et al. 2014b; Solomon 1949; Godin et al. 2010; Conner et al. 2011). For instance, it has been reported that just asking people how often they ride a bicycle may increase cycling in some (Hernan 2004; Hernan & Robins 2006).

RPE can potentially inflate the levels of hearing aid use in both MISC and SC groups. For instance, in the current study due to the RPE some participants might have improved their hearing aid use to an extent beyond which no more improvement could have been made. In the other words, they reached the performance asymptotes or the ceiling effect, which is described as the level that participant's scores cannot exceed a specific value with more information, additional practice, or retests (Miller 1956; Wang et al. 2009). This could have lead have diluted the intervention effect estimates in the RCT.

It is interesting to explore how participants would react to the interventions in the absence of RPE. This way the effectiveness of the MISC intervention compared with the SC in real clinical settings can be assessed. Therefore, future studies should explore the effect of the MISC on people who are not aware of being studied. This has an ethical problem as informed consent will not be sought from the participants. However, waiving the informed consent has successfully been explored by many authors in the field of public health behavioural trails (McCambridge et al. 2013; McCambridge et al. 2014a; Hendershot et al. 2013; O'Neil 2013; Plunk & Grucza 2013; Schwab 2013; Sisti et al. 2013; Wang & Kitsis 2013; Zuraw 2013). One way of achieving this is through adopting a clustered randomised trial (CRT) design in

which hospital sites rather than individual patients are randomised to provide MISC or SC as their routine care. In CRT design, the interventions are naturally applied at the cluster level. Therefore, waiving informed consent in the CRT design should not necessarily be seen as an impediment to ethical approval as long as it is sufficiently justified to proceed without participants' consent (Giraudeau et al. 2012; Sim & Dawson 2012).

Conclusions

Five themes emerged in relation to the participants' perspectives about the key components of the research programme which influenced their hearing aid use. Most people highlighted a combination of the themes related to the target interventions provided (i.e., clinician effect, and additional support) as well as the themes related to the RPE (i.e., commitment to research, research process, and feeling better about self).

Clinical implications

Several improvements can be made in the provision of the audiological services in the NHS for patients who do not use their hearing aids on regular basis. These comprise: (1) enhancing the patient-clinician relationship through adopting MI conversation style in which audiologists actively explore patients' concerns, ideas, and motivations about hearing aid use, (2) spending more time on patient education and improving adherence through provision of information in the MI style, (3) providing additional post-hearing-aid-fitting support and follow up with regard to the adjustments of the hearing aids.

Implications for research

RPE seems to have inflated the levels of hearing aid use in both the MISC and SC groups and needs to be minimised in future full-scale trials on MI for hearing aid use. In order to minimise the RPE, the future studies should explore the effect of MISC on people who are not aware of being studied through adopting a clustered randomised trial design in which hospital sites rather than individual patients are randomised to provide MISC or SC as their routine care.

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Appendix 1:

The guide for qualitative interviews

This interview can take about 1 hour and will be tape recorded. I like this to be a relaxed conversation so you shouldn't feel under pressure at all. There is no right and wrong answers and I just like to know your opinions. All the interviews will be recorded and transcribed and all personal/ identifiable data will be removed from the transcripts and whatever you tell me will remain confidential. I will summarise the interviews from all participants and write my research paper without mentioning any names or any identifiable information.

I will be asking you questions. Please feel free to answer in any way that you like. You don't have to answer my questions. You can answer them if you like. I would like to hear your honest response. Please do not feel that you have to tell me something that I like to hear. In fact I like to hear how exactly you felt and your opinions. At the end of the interview you will get to ask any questions that you may have and I will do my best to answer all of your concerns.

Tell me about how your hearing aid use was prior to research. What were the positives and what were the obstacles?

How confident were you that you could use your hearing aids if you wanted to?

Tell me your opinion of the review sessions that you have received in this study. What were the good points and not so good points? How these could be improved to suit you better? What is your opinion about the duration and number of visits that you had in this study?

Tell me about the questionnaires that you had to complete. How did you feel about answering to all those questions at home or clinic? How did you feel about recording the hearing aid use via data logging?

From your experience what was the most important thing that you feel that you have gained by taking part in this study? What difference they made in your life and how important they are to you?

How the number of hours that you use a hearing aid could make a difference in your life? Does it really matter to you, whether you use it 4 hours a day or 8 hours a day?

Does it make any difference?

Do you have any views about those who don't use their hearing aids or do not come forward for a hearing test? What do you think about those who do?

13 Limitations of the Research Paper 3

The aim of this section is to highlight the limitations of the research paper entitled: Patients' Experience of Motivational Interviewing for Hearing Aid Use: A Qualitative Study Embedded within a Pilot Randomised Controlled Trial.

There are several limitations in this study as described below:

1- In order to improve the reliability of qualitative studies, it is recommended that the coding process to be conducted by more than one researcher (Green & Thorogood 2009b). However, the data in this paper were coded by only one person, the author. This hampers the internal validity of this study hence its results need to be interpreted with caution. Future studies need to include more than one coder in order to improve reliability of their result.

2- A lot of the data that have been collected, were not analysed. For example, in the methods section it is stated that "an account of all verbal and the audible nonverbal (e.g., coughs, cry, pause, laugh, indicating agreement, etc.) utterances," was made but there is no further mention made of this 'non verbal' data. Non-verbal cues form a significant part of the communication and are subject of an increasing medical literature reports (Hall et al. 1988). This study would have benefited from coding of the non-verbal cues in a more systematic manner to help understanding patients' perspectives.

3- Embedded qualitative studies usually involve interviews with patients in the intervention arm only (Greene 2007). This paper reported the themes which were generated from interviewing patients in both intervention and control arms. One of the aims was to look for the between-group differences in the themes which was proved to be very ambitious. Although five themes were generated, they did not distinguish the experience of patients who received motivational interviewing compared to those who received SC only.

4- This was a qualitative sub-study embedded in a pilot RCT. Results of the pilot RCT suggested that the change in hearing aid use as measured via data logging was more marked in the experimental group that underwent motivational interviewing, than in the control group. Yet, no difference was found in the themes that emerged from coding the interviews. This could mean that the coding system used was

inadequate to reveal subtle differences in behaviour change that took place during the study. In the other words, thematic analysis approach did not seem to be adequate to explain the between-group differences in this study. Future research should apply different qualitative analysis strategies (Green & Thorogood 2009b; Miles & Huberman 1994) in order to explore differences in patients experience between MISC and SC only.

5- The author is himself a clinician; he designed the study, delivered the intervention, conducted the intervention and wrote the paper. These roles might have conflicted or produced bias in the interpretation of the results. In order to minimise bias, future studies may benefit from assigning a person or few researchers who have not been involved in other aspects of the study to perform the qualitative interviews and data-analysis.

6- This paper failed to explore long-lasting changes in hearing aid use after participation in the RCT. This is also reflected by the fact that 3 of the 5 themes relate to the research participation rather than to the real life effect of the interventions received. This makes the results of this study less relevant for those wishing to obtain sustainable changes in hearing aid use in clinical practice. Future studies would benefit from longer-term follow up sessions and interviews.

14 Chapter Six: The Final Discussion

14.1 Summary of the Research Process

The aim of this feasibility project was to help estimate important research design parameters comprising (1) standard deviations of the outcome measures, (2) willingness of participants to take part in the study and to be randomised, (3) number of eligible patients, (5) characteristics of the proposed outcome measures, (6) follow-up rates, response rates to questionnaires, and adherence/compliance rates, (7) acceptability of the intervention to its target population, (8) ease of implementation as planned, (9) practicality of the intervention, (10) fidelity of the intervention to MI theory and how to deliver the intervention in a way that accommodates the requirements of the target population and context, (11) how to integrate MI with other audiological tasks. These are consistent with the definition and remit of feasibility studies as described by the National Institute of Health Research (NIHR 2014; Bowen et al. 2009).

In this section a more discussion is provided with regard to the findings of this feasibility study. The feasibility project involved a the survey study conducted to screen for eligible participants and a pilot single-blind, randomised parallel-group study with mixed methods embedded design conducted in the audiology department of the Royal Surrey County Hospital .

The feasibility project took about 2.5 years and included 7 phases:

Phase 1 (October 2012- November 2012): Screening questionnaires were posted to all patients fitted with hearing aids at RSCH in the period of January 2011- January 2012. The aim of the screening survey was to identify patients who are potentially eligible to be invited to the pilot RCT (i.e., patients report that they don't use their hearing aids on regular basis).

Phase 2 (December 2012-April 2013): Processing the returned questionnaires, extracting the data from the questionnaires and entering the data into an Excel data base.

Phase 3 (May 2013- June 2013): Invitations to research were posted to eligible patients.

Phase 4 (24th June 2013-4th September 2013): The pilot RCT was conducted (i.e., baseline assessment, consent, randomisation, interventions, outcome measurement, data collection plus qualitative interviews at one month post interventions).

Phase 5 (1st October 2013-December 2013): Quantitative data were analysed.

Phase 6 (January 2014-July 2014): Qualitative data were analysed.

Phase 7 (July 2014-December 2014): Quantitative and qualitative data were triangulated and reports written.

14.2 Findings of the Feasibility Study and Directions for Future Research

The feasibility study showed that conducting an RCT on MI for facilitating hearing aid use in people who do not use their hearing aids on a regular basis is feasible. The feasibility data are discussed in the sections below under 6 main headings: (1) feasibility of the recruitment procedures, (2) feasibility of randomisation, (3) feasibility of interventions, (4) acceptability of interventions to patients, (5) feasibility of outcome measurement tools, (6) preliminary estimation of effect sizes, confidence intervals and standard deviations.

14.2.1 Feasibility of the Recruitment Procedures

One important aim of a feasibility study is to assess whether the research site and the investigators can recruit enough patients to the full scale trial. Less than a third of the trials achieve their original recruitment target (McDonald et al. 2006). Low recruitment rate can lead to abandonment of a study or if it continues, make it subject to bias because of failure to include a representative sample of patients (Prescott et al. 1999; Ross et al. 1999). Many trials recruit fewer participants than planned (Ross et al. 1999). In this section the results of the feasibility study with regard to the number of eligible patients, recruitment and retention rates will be discussed.

14.2.1.1 Response rate to the screening postal questionnaire

The postal questionnaire survey was aimed to identify eligible patients to take part in the pilot RCT. 1021/1874 responded to the questionnaire giving the response rate of 54.5% which is better than 24% return rate in the survey conducted by others in NHS audiology departments (Kelly et al. 2013). The response rate in this study is

comparable to the average response rate of 55% in the survey assessing patient's priorities with respect to primary health care services in UK, Norway, Sweden, Denmark, Germany, Netherlands, Portugal, and Israel (Grol et al. 1999) as well as to the 56.5% average return rate in a study on patient's experiences from hospital health care in Germany, Sweden, Switzerland, and UK (Coulter & Cleary 2001).

Bulk recruitment via posting a screening questionnaire to patients fitted with hearing aids in a one-or two-year period prior to the start of the RCT project can help to identify a large number of potential patients in a short period of time. However, the response rate could be improved if the evidence-based methods proven to be effective in increasing response rates to the postal questionnaires are utilized (Edwards et al. 2002; Edwards et al. 2007; Harrison & Cock 2004; McCluskey & Topping 2011; Nakash et al. 2006; Richards 2007). For instance, Edwards et al. (2002) showed that follow up contact improved the odds of response by 1.44 (1.22 to 1.70) and providing non-respondents with a second copy of the questionnaire improved the odds of response by 1.41 (1.02 to 1.94). Nakash et al. (2006) reported that sending reminder letters and telephone contact improved the odds of response by 3.7 (2.30 to 5.97). A Cochrane review reported that the odds of response became substantially higher with follow-up contact (Edwards et al. 2007).

14.2.1.2 The number of potentially eligible patients identified via the screening survey

29% (293/1021) of those who responded to the screening survey questionnaire reported to use their hearing aids for less than 4 hours per day hence were eligible for the pilot RCT. Therefore, there seems to be a pool of approximately 300 patients per year at the RSCH who potentially are eligible for the study and may be invited for assessment against the exclusion criteria. The number of patients fitted with hearing aids at the Audiology Department, RSCH, since the survey in 2011-2012 remained approximately the same with 2275 patients in 2012-2013, 2597 patients in 2013-2014, and 2461 patients in 2014-2015.

14.2.1.3 Attended the baseline assessment

19.5% (43/220) of those invited attended the baseline assessment. Generally, the initial assessment for eligibility is the biggest difficulty to full participation in RCTs, with an average of 30% of invitees failing to attend (Toerien et al. 2009).

Although the pilot study met its recruitment target which was a convenient sample of about 40 people, it seems that it performed poorly particularly at this stage. Therefore, in order to ensure that the full scale trial will meet its recruitment target, it is suggested to consider different approaches to increase recruitment rate (Treweek et al. 2013; Thoma et al. 2010). Treweek et al. (2013) conducted a Cochrane review in order to assess effect of interventions used in clinical trials to improve recruitment. They included 45 trials with over 43 000 participants in their review. The results of their meta- analysis suggested telephone reminders to the non-respondents to follow up the written invitations improved recruitment (risk ratio=1.66, 95% CI 1.03 to 2.46; two studies, 1058 participants).

Another method which seems to have improved recruitment rate for elderly participants in a clinical trial is to conduct the screening phase at face-to-face sessions (Ford et al. 2004). For instance, in many centres patients are routinely offered a follow up session 4 to 8 weeks after the fitting of their hearing aid(s). Identifying and inviting eligible participants to research at these sessions may improve the recruitment rate.

Therefore, it is recommended that a rolling recruitment system should be utilised in conjunction with the bulk recruitment where a dedicated research audiologist perform face-to-face post-hearing aid fitting follow up sessions in order to identify eligible participants and invite them to the research. Audiology Department at RSCH fits about 55 patients with hearing aids per week hence approximately 16 eligible patients could be identified each week. Rolling recruitment can start parallel to the bulk screening 2-3 months prior to the start of the trial which could help to form a bigger pool of eligible patients.

14.2.1.4 Found to be eligible to be included to the study

95% (41/43) of those who attended the baseline assessment met the inclusion/exclusion criteria and were eligible to be included in the study.

This was better in our study compared to those reviewed by Toerien et al. (2009) who reported that on average 30% of those attending trials were found to be ineligible.

14.2.1.5 Eligible patients who gave consent and were randomised

90% (37/41) of those found to be eligible gave consent to take part in the study and were randomised. The rate achieved in this study is comparable to the rate reported in a review of 133 RCTs published in 6 major medical journals (Annals of Internal Medicine, Annals of Surgery, British Medical Journal, The Journal of the American Medical Association, The Lancet, and The New England Journal of Medicine) (Toerien et al. 2009). They reported that the median percentage of eligible participants who were randomly allocated to a treatment arm was 90% (Toerien et al. 2009). However, 25% of RCTs randomised only 77% of eligible patients or fewer and the poorest performing trial randomising only 20% (Toerien et al. 2009).

14.2.1.6 Outcome assessed

97% (36/37) of those randomised attended the final outcome assessment. This is better than the median of 93% reported by Toerien et al. (2009) among the 133 RCTs published in the 6 major medical journals. The high retention rate in this pilot phase may in fact be due to having outcomes measured in one month post-intervention as opposed to 3, 6, and 12 months post-intervention which are typically used in trials. Therefore, it seems reasonable to account for the typical 20% drop out rate when planning for sample size calculation for a full scale RCT which might involve longer follow up assessments.

14.2.2 Feasibility of Randomization

Participants were randomly assigned to one of two groups: MI combined with Standard Care (MISC) or Standard Care only (SC). The randomisation procedure was acceptable to patients and resulted in assignment of 20 patients to MISC group and 17 patients to SC group.

14.2.3 Feasibility of Interventions

The length of time allocated to the interventions (60 minutes) in both groups was enough for the tasks required.

In the pilot study, the 2 audiologists who provided the interventions in the SC group were selected based on the clinics availability, not on a random basis. They were qualified audiologists deemed to be suitable to carry out the research tasks by the

audiology department management. They were approached individually by the author and agreed to take part in the study. Patients in the SC group seemed to be extremely pleased with the services they received from them. The mean number of hours that people used their hearing aid(s) (measured via data logging) increased from 1.3 hours per day (SD=2) to 4 hours per day (SD=3.6) in SC group. This was a considerable improvement in hearing aid use which was achieved in SC. The qualitative enquiry embedded in the pilot RCT showed that the distribution of the clinician effect theme was almost equal between MISC and the SC groups. This suggests that patients in both groups felt that their clinicians were compassionate about their hearing healthcare. Clinician effect was a powerful theme in explaining the improvement in hearing aid use during the study as 65% of those identified with this theme achieved over 4-hours improvement in their hearing aid use, despite the fact that majority of them had only a mild hearing loss in their better ear.

It is possible that the selected audiologists for the SC had superior knowledge, skills, experience, or higher level of motivation in providing excellent care compared to other audiologists whom were not considered to be invited to the research. In order to address this in the future full scale trial it is recommended to send an email invitation to all members of the Audiology Department (n=30). Then select 4-5 audiologists randomly (based computer generated random numbers) to provide SC sessions from those who express interest in taking part in the study.

Prior to the start of the trial a 1-day workshop can be arranged for the audiologists in order to refresh their memory on clinical best practice with regard to the tasks involved in standard care hearing aid review sessions as well as good clinical practice in research. This can help to develop a better consistency among different audiologists/interventionists taking part in a full scale trial.

It was feasible to learn MI and achieve competency levels. It was feasible to combine audiology tasks with MI. All sessions were successfully coded by independent coders using motivational interviewing treatment integrity (MITI 3.1.1) coding tool. MI global mean scores for MISC sessions were all at competency level of 4 or above. Therefore, it is feasible to deliver MI with high fidelity and consistency throughout a clinical trial for facilitating hearing aid use. However, only one person, the author, was involved in learning and providing MI. Therefore, this

limits generalising the outcome of the feasibility study. In order to address this in the full scale trial, it is recommended to send an introductory email to all audiologists (n=30) working at the Audiology Department, RSCH, informing them about the research and the opportunity to get involved. From those who express an interest in taking part, 4-5 audiologists can be selected randomly using computer generated random numbers. These audiologists may undergo MI training in addition to the one-day workshop on good clinical practice for hearing aid review. They may provide the intervention in the MISC sessions during the RCT should they pass the criteria for competency in delivering MI.

14.2.4 Acceptability of the Interventions to Patients

All patients in the MISC group completed CEMI after their session. The mean total score on CEMI was 56 (SD= 4.3). The maximum total score for CEMI indicating a favourable patient's feedback regarding a counselling session is 64. Therefore the scores achieved in this study indicate that the intervention was well received by the patients. The qualitative study explored participant's opinion about the very basic assumption of this study that people often need further encouragement and motivational enhancement to use their hearing aids. Participants were asked whether it is a good idea to invite people back [as happened in the study], assess their hearing aids use, and encourage them uses their hearing aids more consistently. All of the participants had sympathy for the aims of the research and spoke of the pilot trial as a good idea and very beneficial for people with hearing impairment that have not got on well with their hearing aids. They also felt pleased to be a part of this research programme.

Majority of people welcomed the idea of additional support and counselling after fitting of hearing aids. Participants described that encouragement and persuasion to use hearing aids is very important. Those who used their hearing aids more consistently felt that they started to realise how helpful their hearing aids were. They believed that when they included hearing aids into their daily routine then it was easier to keep them in all day long and they were quite pleased with that.

14.2.5 Feasibility of the Outcome Measurement Tools

All patients gave consent for the use of data logging in their hearing aids. Patients reported that the average daily use produced by the data logging system was a good

estimation of their actual hearing aid use and use of this facility was acceptable to them. Therefore, use of data logging seems to be feasible as the primary outcome in the full scale RCT. All questionnaires except CERQ seemed to be acceptable to patients.

14.2.6 Training of the Interventionists for the MISC Group

Based on the experience gained during this study, a training programme for audiologists who wish to provide intervention at MISC group in the future full scale trials may involve the components listed below:

- 1- A 2-days MI training workshop
- 2- 30 hours of practicing MI skills in audiology clinics for patients who didn't use their hearing aids on a regular basis
- 3- 10 hours of supervision/coaching with MI experts where recordings of the sessions were analysed and coded and feedback and additional training were provided to improve MI skills as necessary.
- 4- 100 hours of self-directed learning (i.e., reading MI literature and reflective practice).

Prior to the start of the RCT the audiologists should achieve acceptable levels of competency and skilfulness in MI. The level of MI competency which is deemed to be suitable for delivering the intervention in this project is to produce a minimum of 5 MI sessions which are independently coded as competent in accordance with the criteria described in Motivational Interviewing Treatment Integrity 3.1.1 (MITI 3.1.1; Moyers et al. 2010).

14.2.7 Preliminary Estimation of the Effect Sizes, Confidence Intervals and Standard Deviations

As discussed earlier, it seems that data logging seems to be a feasible measure to be used as the primary outcome for the full scale RCT. There was a large between-groups effect size of Cohen's $d = 0.98$ (95% CI: 0.3 to 1.7) for hearing aid use. Therefore, using this effect size at a power of 90%, a type 1 error rate of 0.05 (two-tailed), a randomisation ratio of 1:1 and a 20% drop-out rate, a sample size of 56 participants ($n = 28$ in each group) will be required for the full scale RCT.

However, in this pilot study the MISC intervention was only delivered by one person while for the full scale trial several people would need to be trained to deliver the MI intervention in order to improve generalisability of the research findings. Involvement of more than one interventionist adds more variability to delivery of the intervention and possibly to the treatment effect. There are many studies that suggest the skills of the MI-trained practitioners who deliver interventions in RCTs varies from one counsellor to another and some of these variations influence the outcome behaviour (Apodaca & Longabaugh 2009; McCambridge et al. 2011; Gaume et al. 2009; Magill et al. 2010; Miller & Rose 2009). For instance, Gaume et al. (2009) conducted an RCT assessing the effect of counsellor's skills on the outcome of MI for patients' alcohol use 12 months post-intervention. Seven MSc level psychologists with 1 year of clinical experience received training to deliver MI in the trial. They received 7 days of formal training plus ongoing supervision and coaching from MI experts. All counsellors received uniform amounts of training and supervision. All MI sessions were audio-recorded. Independent coders assessed the recordings using Motivational Interviewing Skills Code (MISC) version 2.0 (Miller et al. 2003). MI skills according to MISC scores differed widely among counsellors. MI-consistent skills were related to better alcohol outcomes among patients at 1 year follow up, whereas the use of MI-inconsistent skills resulted in poorer outcomes (Gaume et al. 2009). McCambridge et al. (2011) also reported the influence of the counsellor's MI-skills on patient's outcome. They studied the effect counsellors' skills on outcome of MI for cannabis cessation among adolescents. Four counsellors underwent MI training and supervision in order to deliver MI in their RCT. All MI sessions were recorded. They used MITI for independently coding of the MI sessions. Their results showed some evidence of variability in achievement of cessation outcome between counsellors. Statistically significant differences across all 4 counsellors were observed for all MITI measures indicating variability in counsellor's MI skills. MI spirit and the proportion of reflections were predictive of cannabis cessation 3 months after MI (McCambridge et al. 2011).

In the pilot study, the outcomes were only assessed 1 month post intervention while in the full scale trial longer-term outcomes (e.g., 3, and 6 months) should be considered. The gap between SC and MISC may reduce over the time. McCambridge and Strang (2005) suggested that the effect of MI intervention on in

reducing drug consumption and related risks among young people deteriorated over time. A systematic review of treatment outcome literature for MI suggested that the relative effect sizes of MI decreases over time (Hettema et al. 2005). The mean effect size across all included studies was 0.77 (95% CI: 0.35 to 1.19) at 0-1 month post intervention, but it was about 0.30 (95% CI: 0.16 to 0.43) at 6-12 months post intervention. However, in studies where the additive effect of MI was tested the average effect size was 0.60 which was maintained over time (n=10 studies). In these studies patients were typically randomised to receive or not receive MI at the beginning of a standard or a specific treatment programme. The effect of MI combined with standard care on hearing aid use also assesses additive effect of MI hence it is likely that the effect size maintain over time.

Therefore, taking all into consideration, it is recommended to use a conservative estimation of $d = 0.60$ in order to calculate sample size. Using this effect size at a power of 90%, a type 1 error rate of 0.05 (two-tailed), a randomisation ratio of 1:1 and a 20% drop-out rate, a sample size of 144 participants ($n = 72$ in each group) will be required for the full scale RCT.

15 Conclusions

1. The survey study showed that despite the use of modern digital hearing aids in the NHS and application of real ear measurements based on the national guideline (BSA 2007), approximately 40% of newly diagnosed hearing impaired patients, do not use their hearing aids regularly. The improvement in self-perceived hearing-related quality of life increases with the amount of use of hearing aids, with bilateral versus unilateral use, and with the degree of hearing loss in the better ear. There is a need to develop and examine interventions that can improve hearing aid use.
2. The pilot RCT showed that MI combined with SC compared to the SC only seemed to improve the hearing aid use in patients who did not use their hearing aids on regular basis. This was a pilot study, hence due to the lack of statistical power the data analysis was mainly descriptive and the treatment effect was not established. However, the aim was to examine feasibility of conducting a full scale RCT on the effect of MI on hearing aid use.
3. It seemed feasible to combine MI with audiological tasks within the context of an outpatient audiology clinic with the aim of improving hearing aid use. MI delivered in this manner by an audiologist was judged to be consistent with the theory and protocol of MI.
4. The findings from this study support moving forward with a larger RCT in order to establish the short-and long-term effects of MI combined with SC on hearing aid use and benefit.
5. The amount of hearing aid use (data logging) seems to be a feasible measure as the primary outcome in the future RCT.
6. Although the research procedures seemed to be feasible, several approaches to improve recruitment rate has been discussed.
7. It is not clear if MI is delivered by other audiologists, it would produce the same fidelity scores and outcome as what were observed in this pilot study. Implications of this for future research have been discussed.

8. Long-term effects of MI combined with SC on hearing aid use are not clear. Implication of this for sample size calculation in future full scale RCT has been discussed.

9. Qualitative enquiry embedded in the pilot RCT revealed that participants welcomed the idea of additional support and counselling after fitting of hearing aids. Participants described that encouragement and persuasion to use hearing aids was very important.

10. The research participation effect seems to have inflated the levels of hearing aid use in both the MISC and SC groups and needs to be minimised in future full-scale trials on MI for hearing aid use. Appropriate research designs have been discussed.

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17 Appendix 1

17.1 International Outcome Inventory for Hearing Aids (IOI-HA; Cox & Alexander, 2002)

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)?

- a) None
- b) Less than 1 hour a day
- c) 1 to 4 hours a day
- d) 4 to 8 hours a day
- e) More than 8 hours a day

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 that situation?

- a) Helped not at all
- b) Helped slightly
- c) Helped moderately
- d) Helped quite a lot
- e) Helped very much

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?

- a) Very much difficulty
- b) Quite a lot of difficulty
- c) Moderate difficulty
- d) Slight difficulty
- e) No difficulty

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

- a) Not at all worth it
- b) Slightly worth it
- c) Moderately worth it
- d) Quite a lot worth it
- e) Very much worth it

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

- a) Affected very much
- b) Affected quite a lot
- c) Affected moderately
- d) Affected slightly
- e) Affected not at all

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?

- a) Bothered very much
- b) Bothered quite a lot
- c) Bothered moderately
- d) Bothered slightly
- e) Bothered not at all

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

- a) Worse
- b) No change
- c) Slightly better
- d) Quite a lot better
- e) Very much better

17.2 International Outcome Inventory for Hearing Aid for the Significant Other (IOI-HA-SO; Noble, 2002)

1. Think about how much your partner used their present hearing aid(s) over the past 2 weeks. On an average day, how many hours did your partner use the hearing aid(s)?

<i>None</i>	<i>Less than 1 hr/day</i>	<i>1-4 hr/day</i>	<i>4-8 hr/day</i>	<i>More than 8 hr/day</i>
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

2. Think about the situation where you most wanted your partner to hear better, before getting their present hearing aid(s). Over the past 2 weeks, how much has (have) the hearing aid(s) helped in that situation?

<i>Helped not at all</i>	<i>Helped slightly</i>	<i>Helped moderately</i>	<i>Helped quite a lot</i>	<i>Helped very much</i>
<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 your partner to hear better. When your partner uses their present hearing aid(s), how much difficulty does he or she **STILL** have in that situation?

<i>Very much difficulty</i>	<i>Quite a lot of difficulty</i>	<i>Moderate difficulty</i>	<i>Slight difficulty</i>	<i>No difficulty</i>
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

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

<i>Not at all worth it</i>	<i>Slightly worth it</i>	<i>Moderately worth it</i>	<i>Quite a lot worth it</i>	<i>Very much worth it</i>
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

5. Over the past 2 weeks, with their present hearing aid(s), how much have your partner's hearing difficulties affected the things you can do?

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

6. Over the past 2 weeks, with their present hearing aid(s), how much were you bothered by your partner's hearing difficulties?

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

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

<i>Worse</i>	<i>No change</i>	<i>Slightly better</i>	<i>Quite a lot better</i>	<i>Very much better</i>
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

17.3 Client Oriented Scale of Improvement (COSI; Dillon et al, 1997)

NAL
CLIENT ORIENTED SCALE OF IMPROVEMENT



Name: _____ Category: New Return
 Audiologist: _____
 Date: 1. Needs Established _____
2. Outcome Assessed _____

Degree of Change

Final Ability (with hearing aid)
 Person can hear
 10% 25% 50% 75% 95%

SPECIFIC NEEDS

Indicate Order of Significance

- Categories:
1. Conversation with 1 or 2 in quiet
 2. Conversation with 1 or 2 in noise
 3. Conversation with group in quiet
 4. Conversation with group in noise
 5. Television Radio @ normal volume
 6. Familiar speaker on phone
 7. Unfamiliar speaker on phone
 8. Hearing phone ring from another room

	Worse	No Difference	Slightly Better	Better	Much Better	CATEGORY	Hardly Ever	Occasionally	Half the Time	Most of Time	Almost Always

9. Hear from door bell or knock
10. Hear traffic
11. Increased social contact
12. Feel embarrassed or stupid
13. Feeling left out
14. Feeling upset or angry
15. Church or meeting
16. Other

17.4 World Health Organisation's Disability Assessment Schedule II (the short version) (WHO-DASII; WHO, 1999)



World Health Organization Disability Assessment Schedule II

Phase 2 Field Trials – Health Services Research
12-Item Self-Administered Version

For Office Use Only:

Center# Subject # - Time #

Day / Month / Year

- | | |
|--------------------------------|---------------------------------------|
| Pop: | Dwelling: |
| <input type="checkbox"/> Gen | <input type="checkbox"/> Independent |
| <input type="checkbox"/> Drg | <input type="checkbox"/> Assisted |
| <input type="checkbox"/> Alc | <input type="checkbox"/> Hospitalized |
| <input type="checkbox"/> Mnh | |
| <input type="checkbox"/> Phys | |
| <input type="checkbox"/> Other | |

H1	How do you rate your <u>overall health in the past 30 days?</u>	Very good	Good	Moderate	Bad	Very Bad
----	---	-----------	------	----------	-----	----------

This questionnaire asks about difficulties due to health conditions. Health conditions include diseases or illnesses, other health problems that may be short or long lasting, injuries, mental or emotional problems, and problems with alcohol or drugs.

Think back over the last 30 days and answer these questions thinking about how much difficulty you had doing the following activities. For each question, please circle only one response.

In the last <u>30 days</u> , how much <u>difficulty</u> did you have in:						
S1	<u>Standing for long periods</u> such as <u>30 minutes?</u>	None	Mild	Moderate	Severe	Extreme /Cannot Do
S2	Taking care of your <u>household responsibilities?</u>	None	Mild	Moderate	Severe	Extreme /Cannot Do
S3	<u>Learning a new task</u> , for example, learning how to <u>get to a new place?</u>	None	Mild	Moderate	Severe	Extreme /Cannot Do
S4	How much of a problem did you have <u>joining in community activities</u> (for example, festivities, religious or other activities) in the same way as anyone else can?	None	Mild	Moderate	Severe	Extreme /Cannot Do
S5	How much have you been <u>emotionally affected</u> by your health problems?	None	Mild	Moderate	Severe	Extreme /Cannot Do

Please continue to the next page ...

In the last 30 days, how much <u>difficulty</u> did you have in:						
S6	<u>Concentrating</u> on doing something for <u>ten minutes</u> ?	None	Mild	Moderate	Severe	Extreme / Cannot Do
S7	<u>Walking a long distance</u> such as a <u>kilometre</u> [or equivalent]?	None	Mild	Moderate	Severe	Extreme / Cannot Do
S8	<u>Washing your whole body</u> ?	None	Mild	Moderate	Severe	Extreme / Cannot Do
S9	Getting <u>dressed</u> ?	None	Mild	Moderate	Severe	Extreme / Cannot Do
S10	<u>Dealing with people you do not know</u> ?	None	Mild	Moderate	Severe	Extreme / Cannot Do
S11	<u>Maintaining a friendship</u> ?	None	Mild	Moderate	Severe	Extreme / Cannot Do
S12	Your day to day <u>work</u> ?	None	Mild	Moderate	Severe	Extreme / Cannot Do

H2	Overall, how much did these difficulties <u>interfere</u> with your life?	Not at all	Mildly	Moderately	Severely	Extremely
H3	Overall, in the past 30 days, <u>how many days</u> were these difficulties present?	RECORD NUMBER OF DAYS ___/___				
H4	In the past 30 days, for how many days were you <u>totally unable</u> to carry out your usual activities or work because of any health condition?	RECORD NUMBER OF DAYS ___/___				
H5	In the past 30 days, not counting the days that you were totally unable, for how many days did you <u>cut back</u> or <u>reduce</u> your usual activities or work because of any health condition?	RECORD NUMBER OF DAYS ___/___				

This completes the questionnaire. Thank you.

17.5 Cognitive Emotion Regulation Questionnaire (CERQ; Garnefski & Kraaij, 2007)

CERQ

© Garnefski, Kraaij & Spinhoven, 2001

How do you cope with events?

Everyone gets confronted with negative or unpleasant events now and then and everyone responds to them in his or her own way. By the following questions you are asked to indicate what you generally think, when you experience negative or unpleasant events.

	(almost) never	some- times	regu- larly	often	(almost) always
1. I feel that I am the one to blame for it	1	2	3	4	5
2. I think that I have to accept that this has happened	1	2	3	4	5
3. I often think about how I feel about what I have experienced	1	2	3	4	5
4. I think of nicer things than what I have experienced	1	2	3	4	5
5. I think of what I can do best	1	2	3	4	5
6. I think I can learn something from the situation	1	2	3	4	5
7. I think that it all could have been much worse	1	2	3	4	5
8. I often think that what I have experienced is much worse than what others have experienced	1	2	3	4	5
9. I feel that others are to blame for it	1	2	3	4	5
10. I feel that I am the one who is responsible for what has happened	1	2	3	4	5
11. I think that I have to accept the situation	1	2	3	4	5
12. I am preoccupied with what I think and feel about what I have experienced	1	2	3	4	5
13. I think of pleasant things that have nothing to do with it	1	2	3	4	5
14. I think about how I can best cope with the situation	1	2	3	4	5
15. I think that I can become a stronger person as a result of what has happened	1	2	3	4	5
16. I think that other people go through much worse experiences	1	2	3	4	5
17. I keep thinking about how terrible it is what I have experienced	1	2	3	4	5
18. I feel that others are responsible for what has happened	1	2	3	4	5

19. I think about the mistakes I have made in this matter	1	2	3	4	5
20. I think that I cannot change anything about it	1	2	3	4	5
21. I want to understand why I feel the way I do about what I have experienced	1	2	3	4	5
22. I think of something nice instead of what has happened	1	2	3	4	5
23. I think about how to change the situation	1	2	3	4	5
24. I think that the situation also has its positive sides	1	2	3	4	5
25. I think that it hasn't been too bad compared to other things	1	2	3	4	5
26. I often think that what I have experienced is the worst that can happen to a person	1	2	3	4	5
27. I think about the mistakes others have made in this matter	1	2	3	4	5
28. I think that basically the cause must lie within myself	1	2	3	4	5
29. I think that I must learn to live with it	1	2	3	4	5
30. I dwell upon the feelings the situation has evoked in me	1	2	3	4	5
31. I think about pleasant experiences	1	2	3	4	5
32. I think about a plan of what I can do best	1	2	3	4	5
33. I look for the positive sides to the matter	1	2	3	4	5
34. I tell myself that there are worse things in life	1	2	3	4	5
35. I continually think how horrible the situation has been	1	2	3	4	5
36. I feel that basically the cause lies with others	1	2	3	4	5

Thank you for filling out the questionnaire!

17.6 Hospital Anxiety and Depression Scale (HADS; Zigmond & Snaith, 1983)

Hospital Anxiety and Depression Scale (HADS)

Patients are asked to choose one response from the four given for each interview. They should give an immediate response and be dissuaded from thinking too long about their answers. The questions relating to anxiety are marked "A", and to depression "D". The score for each answer is given in the right column. Instruct the patient to answer how it currently describes their feelings.

A	I feel tense or 'wound up':	
	Most of the time	3
	A lot of the time	2
	From time to time, occasionally	1
	Not at all	0
D	I still enjoy the things I used to enjoy:	
	Definitely as much	0
	Not quite so much	1
	Only a little	2
	Hardly at all	3
A	I get a sort of frightened feeling as if something awful is about to happen:	
	Very definitely and quite badly	3
	Yes, but not too badly	2
	A little, but it doesn't worry me	1
	Not at all	0
D	I can laugh and see the funny side of things:	
	As much as I always could	0

	Not quite so much now	1
	Definitely not so much now	2
	Not at all	3
A	Worrying thoughts go through my mind:	
	A great deal of the time	3
	A lot of the time	2
	From time to time, but not too often	1
	Only occasionally	0
D	I feel cheerful:	
	Not at all	3
	Not often	2
	Sometimes	1
	Most of the time	0
A	I can sit at ease and feel relaxed:	
	Definitely	0
	Usually	1
	Not Often	2
	Not at all	3
D	I feel as if I am slowed down:	
	Nearly all the time	3
	Very often	2
	Sometimes	1
	Not at all	0

A	I get a sort of frightened feeling like 'butterflies' in the stomach:	
	Not at all	0
	Occasionally	1
	Quite Often	2
	Very Often	3
D	I have lost interest in my appearance:	
	Definitely	3
	I don't take as much care as I should	2
	I may not take quite as much care	1
	I take just as much care as ever	0
A	I feel restless as I have to be on the move:	
	Very much indeed	3
	Quite a lot	2
	Not very much	1
	Not at all	0
D	I look forward with enjoyment to things:	
	As much as I ever did	0
	Rather less than I used to	1
	Definitely less than I used to	2
	Hardly at all	3
A	I get sudden feelings of panic:	

	Very often indeed	3
	Quite often	2
	Not very often	1
	Not at all	0
D	I can enjoy a good book or radio or TV program:	
	Often	0
	Sometimes	1
	Not often	2
	Very seldom	3

	Scoring (add the As = Anxiety. Add the Ds = Depression). The norms below will give you an idea of the level of Anxiety and Depression.	
	0-7 = Normal	
	8-10 = Borderline abnormal	
	11-21 = Abnormal	

Reference:

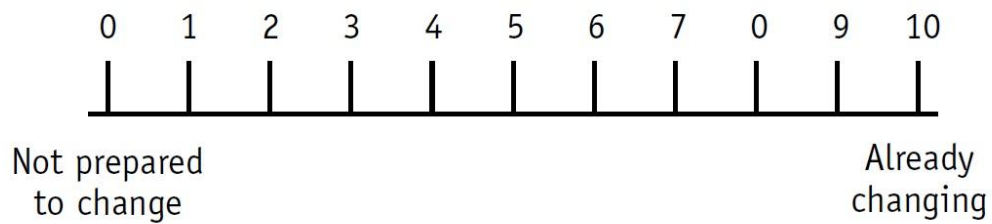
Zigmond and Snaith (1983)

17.7 Readiness to Change Ruler (RCR; Zimmerman et al, 2000)

READINESS RULER

Below, mark where you are now on this line that measures your change in _____.

Are you not prepared to change, already changing or somewhere in the middle?



17.8 Glasgow Hearing Aid Benefit Profile (GHABP; Gatehouse, 1999)

Does this situation happen in your life? LISTENING TO THE TELEVISION WITH OTHER FAMILY OR FRIENDS					
0 ___ No		1 ___ Yes		WHEN THE VOLUME IS	
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, <u>with your hearing aid</u> , how much difficulty do you <u>now</u> 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? HAVING A CONVERSATION WITH ONE OTHER PERSON WHEN THERE IS NO BACKGROUND					
0 ___ No		1 ___ Yes		THERE IS NO BACKGROUND	
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, <u>with your hearing aid</u> , how much difficulty do you <u>now</u> 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	0 ___ N/A 1 ___ Never/Not at all 2 ___ About ¼ of the time 3 ___ About ½ of the time	0 ___ N/A 1 ___ Hearing aid no use at all 2 ___ Hearing aid is some help 3 ___ Hearing aid is quite helpful	0 ___ N/A 1 ___ No difficulty 2 ___ Only slight difficulty 3 ___ Moderate difficulty	0 ___ N/A 1 ___ Not satisfied at all 2 ___ A little satisfied 3 ___ Reasonably satisfied

4__ Great difficulty 5__ Cannot manage at all	5__ Very much indeed	the time 4__ About ¾ of the time 5__ All the time	helpful 4__ Hearing aid is a great help 5__ Hearing is perfect with aid	4__ Great difficulty 5__ Cannot manage at all	4__ Very satisfied 5__ Delighted with aid
--	----------------------	---	---	--	--

Does this situation happen in your life? **CARRYING ON A CONVERSATION IN A BUSY STREET OR SHOP**
0 __ No 1 __ Yes

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, <u>with your hearing aid</u> , how much difficulty do you <u>now</u> 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? **HAVING A CONVERSATION WITH SEVERAL PEOPLE IN A GROUP**
0 __ No 1 __ Yes

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, <u>with your hearing aid</u> , how much difficulty do you <u>now</u> have?	For this situation, how satisfied are you with your hearing aid?
0__ N/A 1__ No difficulty	0__ N/A 1__ Not at all	0__ N/A 1__ Never/Not at all	0__ N/A 1__ Hearing aid no use	0__ N/A 1__ No difficulty	0__ N/A 1__ Not satisfied at

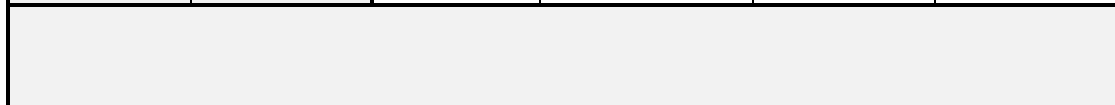
2__ Only slight difficulty	2__ Only a little amount	all	at all	2__ Only slight difficulty	all
3__ Moderate difficulty	3__ A moderate amount	2__ About ¼ of the time	2__ Hearing aid is some help	3__ Moderate difficulty	2__ A little satisfied
4__ Great difficulty	4__ Quite a lot	3__ About ½ of the time	3__ Hearing aid is quite helpful	4__ Great difficulty	3__ Reasonably satisfied
5__ Cannot manage at all	5__ Very much indeed	4__ About ¾ of the time	4__ Hearing aid is a great help	5__ Cannot manage at all	4__ Very satisfied
		5__ All the time	5__ Hearing is perfect with aid		5__ Delighted with aid

Part 2:

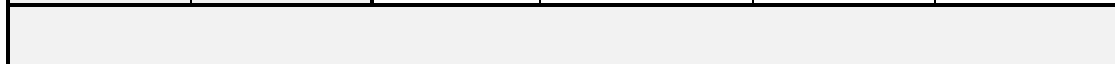
We have dealt with some of the situations which in our experience can lead to difficulty with hearing. What we would now like you to do is to nominate up to four new situations in which it is important for you as an individual to be able to hear as well as possible.

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, <u>with your hearing aid</u> , how much difficulty do you <u>now</u> have?	For this situation, how satisfied are you with your hearing aid?
0__ N/A	0__ N/A	0__ N/A	0__ N/A	0__ N/A	0__ N/A
1__ No difficulty	1__ Not at all	1__ Never/Not at all	1__ Hearing aid no use at all	1__ No difficulty	1__ Not satisfied at all
2__ Only slight difficulty	2__ Only a little amount	2__ About ¼ of the time	2__ Hearing aid is some help	2__ Only slight difficulty	2__ A little satisfied
3__ Moderate difficulty	3__ A moderate amount	3__ About ½ of the time	3__ Hearing aid is quite helpful	3__ Moderate difficulty	3__ Reasonably satisfied
4__ Great difficulty	4__ Quite a lot	4__ About ¾ of the time	4__ Hearing aid is a great help	4__ Great difficulty	4__ Very satisfied
5__ Cannot manage at all	5__ Very much indeed	5__ All the time	5__ Hearing is perfect with aid	5__ Cannot manage at all	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, <u>with your hearing aid</u> , how much difficulty do you <u>now</u> 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, <u>with your hearing aid</u> , how much difficulty do you <u>now</u> 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, <u>with your hearing aid</u> , how much difficulty do you <u>now</u> 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

17.9 Client Evaluation of Motivational Interviewing Scale (CEMI; Madson et al, 2013)

Client Evaluation of Counseling

Please rate each response on the scale below relating to your most recent session with your counselor.

1	2	3	4
Not At All	Only a Little	Some	A Great Deal

In your session, how much did your counselor:

- | | | | | |
|--|---|---|---|---|
| 1. Focus only on your weaknesses. | 1 | 2 | 3 | 4 |
| 2. Help you to talk about changing your behavior. | 1 | 2 | 3 | 4 |
| 3. Act as a partner in your behavior change. | 1 | 2 | 3 | 4 |
| 4. Helped you to discuss your need to change your behavior. | 1 | 2 | 3 | 4 |
| 5. Make you feel distrustful of him/her | 1 | 2 | 3 | 4 |
| 6. Help you examine the pros and cons of changing your behavior. | 1 | 2 | 3 | 4 |
| 7. Help you to feel hopeful about changing your behavior. | 1 | 2 | 3 | 4 |
| 8. Argue with you to change your behavior. | 1 | 2 | 3 | 4 |
| 9. Change the topic when you became upset about changing your behavior. | 1 | 2 | 3 | 4 |
| 10. Push you forward when you became unwilling to talk about an issue further. | 1 | 2 | 3 | 4 |
| 11. Act as an authority on your life. | 1 | 2 | 3 | 4 |
| 12. Tell you what to do. | 1 | 2 | 3 | 4 |
| 13. Argue with you about needing to be 100% ready to change your behavior. | 1 | 2 | 3 | 4 |
| 14. Show you that she/he believes in your ability to change your behavior. | 1 | 2 | 3 | 4 |
| 15. Help you feel confident in your ability to change your behavior | 1 | 2 | 3 | 4 |
| 16. Help you recognize the need to change your behavior. | 1 | 2 | 3 | 4 |

Thank you for your time. Your feedback is valuable. Please return this form in the folder provided to your counselor.

18 Appendix 2

Patient information leaflet

Title of project: Counselling and Audiology support in facilitating hearing aid use.

You and your partner are being invited to take part in a research study at the Royal Surrey County Hospital. Before you decide, it is important for you to understand why the research is being done and what it will involve. Please take time to read the following information carefully. Before you decide, discuss it with relatives, friends and your GP if you wish.

Ask us if there is anything that is not clear or if you would like more information. Take time to decide whether or not you wish to take part.

What is the purpose of the study?

From previous research, we know that many people do not use their hearing aids on regular basis. We are investigating how to facilitate hearing aid use with two counselling and audiology support approaches. Both approaches seem to be beneficial but we do not know which one is the best. The type of counselling/ audiology support you receive will be selected randomly by computer.

Why have I been chosen?

Last year, we posted a questionnaire to people who had been fitted with hearing aid(s) during 2011-2012 at the Royal Surrey County Hospital. Many people pointed out that they did not use their hearing aids on regular basis. 40 people from those who mentioned that they did not use their hearing aids regularly, like you, are being invited to take part in this study.

Do I have to take part?

It is up to you to decide whether or not to take part. It is completely voluntary. If you decide to take part, you may still withdraw at any time without giving any reason and your further care will not be affected.

What will happen to me if I take part?

If you agree to take part you will be seen up to 4 times at the audiology department at Royal Surrey County Hospital. The first 3 visits are weekly and the final visit is 6 weeks after your first visit.

Once we receive your express of interest form (the slip attached to the end of this leaflet), someone from audiology department will give you a call to answer your questions and arrange your first visit.

Prior to the first visit we will send you 4 questionnaires. You would need to complete them at home and bring them with you on your first visit. Completing these questionnaires will take about 20 minutes.

At your first visit you will meet with an audiology researcher who will explain the aims of the study and answer your questions. At this session you will be asked to complete 3 questionnaires and sign a consent form. This visit should last about 45-60 minutes.

At the second and third visits your audiologist will provide counselling and check your hearing aids. These visits should last between 30 and 60 minutes. At the end of each visit you will be asked to complete a questionnaire which takes about 5 minutes.

At the fourth visit, the audiology researcher will interview you with regard to your

experience during the research and you will be asked to complete 3 questionnaires. Prior to this visit we will send you 4 questionnaires which you would need to complete at home and bring with you on the last visit. The last visit should take about 60-90 minutes.

There are no side effects to the procedures involved in this study.

All interviews will be audio recorded and transcribed for analysis. All names and identifiable information will be removed from the transcripts before analysing and publishing the data. **All data will be treated as confidential.**

What about my partner (or significant other)?

Your partner or significant other is also invited to take part in this research by completing a questionnaire about your hearing before and after the study. Completing this questionnaire will take about 5 minutes. If your partner (or significant other) agrees to take part in this study she/he should accompany you for the first visit in order to ask their questions, complete a questionnaire and sign a consent form. They will also be posted a questionnaire prior to your final visit which needs to be completed at home and given to you to bring with you for the last visit.

What about expenses?

At your final visit, we will pay you £50 to cover your travel expenses.

Will my GP be informed?

If you agree to take part, we will inform your GP of your participation in the study.

What are the possible benefits of taking part?

You might find the extra audiology support and counselling provided useful. We cannot promise the study will help you, but your involvement will help us to improve the service for hearing aid users.

Will my taking part in the study be kept confidential?

If you join the study, all information that is collected about you during the course of the study will be kept strictly confidential. Details about you and any modifications on your hearing aids will be recorded in your audiology notes which will be kept confidential.

What will happen to the results?

The results will be published in medical journals. If you wish to know the results, please ask the audiology department. Results will be available in 2 years time.

Who is organising and funding the research?

This study is being run by the Audiology department at Royal Surrey County Hospital and London School of Hygiene and Tropical Medicine.

The study is being funded through an educational fellowship from National Institute of Health Research (NIHR), UK.

