Evaluation of Live Voice Auditory Training in a Randomised Controlled Trial of Existing Hearing Aid Users

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Research Protocol

Version 1.3

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1 Project Outline

1.1 Contact Details

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1.2 Project Personnel and Collaborators

The Principal Investigator will complete initial planning, invite participants to participate in the project, manage all assessment and final appointments, analyse the data, write the initial report and disseminate the results.

The first co-applicant will contribute to initial planning, provide support for the application, provide advice on managing all financial aspects, provide advice on other clinical and research aspects, and contribute to the write-up and dissemination of results. The second and third co-applicants will provide support to the research design and write-up. Audiologists from the Wrexham Maelor Hospital Audiology Department will assist with data collection and highlighting possible participants to the Principal Investigator.

1.3 Identification of Project

One of the main challenges faced by people with hearing loss is understanding speech in noisy environments. Hearing aids can be of some benefit in these situations; however, in isolation they are unable to fully overcome the problem. If the hearing-impaired listener is unable to understand conversations in everyday listening environments they risk becoming socially withdrawn and isolated.

Auditory training involves structured practice listening to a variety of stimuli and is gaining support as an alternative to hearing aids or a supplementary intervention. Many of the auditory training programmes currently available are administered using a computer which may not be appropriate for many older hearing-impaired adults who do not have access to computers. There is therefore a need to develop a non-computerised auditory training intervention which can be delivered easily in the person's home.

The research question is; does repeated practice improve speech perception in everyday challenging listening environments for experienced adult hearing aid users? The study aims to explore whether a novel auditory training programme, which involves having conversations in the presence of a competing speaker, can improve patient outcomes. Hearing aid users will complete a baseline speech and cognition assessment and then undertake a four-week training programme at home. Their speech perception and cognitive abilities will then be evaluated again.

2 Research Protocol

2.1 Research Aims and Objectives

This study will form a randomised controlled trial (RCT) investigating the effect of a novel auditory training intervention. The primary aim is to explore whether the training programme can improve speech intelligibility in noise for experienced adult hearing aid users. A secondary aim is to investigate the effect of training on self-reported listening and cognitively demanding tasks, as cognition has been shown to mediate speech perception.

2.2 Literature Review

2.2.1 Limitations of Hearing Aids in Challenging Listening Environments

It has long been established that people with hearing impairment have greater difficulty understanding speech in challenging listening environments than do normally hearing listeners. Listening to speech in background noise is one of the main complaints among hearing aid users. In the EuroTrak survey (Hougaard and Ruf, 2011), "use in noisy situations" showed the lowest levels of satisfaction among UK hearing aid users, with a net satisfaction score of just 23%. While modern hearing aids can improve the audibility of the speech signal they are unable to eliminate unwanted background noise or overcome suprathreshold deterioration in the hearing system such as declining central auditory processing, impaired frequency and temporal resolution (Plomp, 1986). As such, the signal received by hearing-impaired listeners is degraded to such an extent that perception of speech in background noise is often severely affected. Hearing aids alone are unable to provide sufficient improvement in this challenging listening environment to give high levels of user satisfaction. These low levels of satisfaction may lead to low use of hearing aids which costs the NHS valuable resources every year. The difficulties that listeners face also make it more difficult for them to participate in social interactions which may result in them becoming socially withdrawn and isolated (Shinn-Cunningham and Best, 2008).

2.2.2 Auditory Training

Hearing aids are not the only intervention available to audiologists. As well as hearing aids, the Quality Standards for Adult Hearing Rehabilitation Services (Scottish Government, 2009) also advocate the use of non-instrumental interventions in individual management plans. Auditory training has been used for a number of years as part of an aural rehabilitation programme for patients with hearing loss (Musiek, 2006). It can be described as a process of teaching the brain to listen through active engagement with sounds, and results in improvements on the trained task (Henshaw and Ferguson, 2013b). However, for auditory training to be an effective intervention for people with hearing loss, any improvements in trained tasks need to generalise to functional benefits in real-world listening. The most direct way to achieve this is to train on a task for which improvements are most important to the individual.

Auditory training as a management option is most commonly used in children and adults who have been diagnosed with Auditory Processing Disorder. Patients with Auditory Processing Disorder often have normal hearing thresholds and the effects of auditory training on patients with peripheral hearing difficulties have been less consistently researched. Auditory training may take the form of analytic training, whereby bottom-up processes such as phonetic or temporal perception are directly trained, or synthetic training focusing on improvement in spoken language comprehension (Musiek et al., 2007). Reports in the literature as to the effectiveness of each approach are mixed. In a systematic review of the literature, Sweetow and Palmer (2005) concluded that synthetic training generated the greatest improvements in speech perception compared to analytic training. However, phoneme discrimination training (analytic) has more recently been linked to improvements in cognitive processing which may give additional benefit to patients in complex listening environments (Ferguson et al., 2012).

Auditory training programmes are designed in line with learning theory. Wolfle (1951) learning theory states that in order for a training task to be effective the participant must be actively involved in the task. There should be variation in the practice task to maintain motivation and adaptation. Wolfle also states that the duration of the practice time should be suitable relative to the task that is to be learned. The most important factor of learning theory is that immediate feedback is available as to the participant's performance on the task. Sweetow and Sabes (2006) also note that a comprehensive training programme should be cost-effective, interactive, practical and easily accessible. Ideally the training programme should be suitable for delivery within the home environment. The task should be sufficiently challenging as to maintain interest and provide scope for learning, however not so difficult as to restrict learning opportunities, induce fatigue and discourage participation. Reinforcement and feedback on task performance should be provided throughout.

2.2.2.1 Auditory Training Programmes Currently Available

Based on these principles a number of structured auditory training programmes are commercially available. A summary of commonly used programmes is given in Table 1. The LACE training programme is currently given to some Hearing Therapy patients in Betsi Cadwaladr University Health Board in order to improve their listening skills. Although these programmes are often used in the UK, Phonomena is the only

programme which was designed and developed here. This means that with other programmes, the speech stimuli used often have American accents which can increase the listening demand for users (Mattys et al., 2012). As can be seen in Table 1, training programmes require a large amount of commitment from the user to practice the tasks a few times per week for long periods of time. A systematic analysis by Henshaw and Ferguson (2013a) showed that compliance with programmes during research studies was relatively high (between 70 and 80%) however these results were not consistent with a clinical study involving users of the LACE programme in America where programme compliance was only 30% (Sweetow and Sabes, 2010). This suggests that the compliance rates shown in small scale research projects may not be representative of the clinical picture at large. While a computerised programme is beneficial as it can be carried out at home while providing real-time training information to the monitoring clinician via the internet, this delivery method may not be appropriate for all hearing-impaired listeners. In a survey of adults aged 50-74 years, Henshaw et al. (2012) showed that computer use varied with age. Computer and internet use was 81.0% and 60.9% respectively for the younger adults (aged 50-62 years) but reduced to 65.4% and 29.8% respectively for the older adults (aged 63-74 years). The mean age of patients attending for hearing reassessment in Betsi Cadwaladr University Health Board is 73.37 years. While these statistics do not discount computerised service delivery as an option, particularly in future as computer literacy increases, alternative delivery methods need to be available for many hearing-impaired listeners.

2.2.2.2 Effects of Auditory Training

Studies evaluating the effect of LACE have shown positive results on a range of measures in the US (Sweetow and Sabes, 2006; Song et al., 2012; Olson et al., 2013) however the effectiveness of the programme for our patient group has yet to be evaluated. Following a four-week training programme using LACE statistically significant, and more importantly clinically significant, improvements in speech intelligibility in noise performance were reported by Sweetow and Sabes (2006) on the QuickSIN test (see Section 2.2.3 for a description of QuickSIN). These improvements were maintained 8 weeks post-intervention. Improvements were also seen on the Hearing in Noise Test (HINT) but these did not reach significance. Olson (2013) demonstrated improvement on the QuickSIN following LACE training with a large effect size (0.8) for experienced

Table 1. Summary of commonly used auditory training programmes

Name	Aim	Format	Population	Stimuli	Adaptive	Time	Reference
Earobics	Improve spelling, reading and language comprehension	Computerised	Children and adults	Recorded speech	Adaptive	15-20 minutes, 3 times per week	www.earobics.com
FastForWord	Improve speed of auditory language processing and reading abilities	Computerised	Children and adults	Speech and non-speech stimuli		30 minutes, 5 days per week, 3-4 months	www.innovative-therapies.com
Phonomena	Improve auditory discrimination, phonemic awareness and build language skills	Computerised	Children		Adaptive		www.mindweavers.com
Listening and Communication Enhancement (LACE)	Improving listening skills	Computerised	Adults	Stimuli: Speech - sentences Processes: speech in noise, cognitive tasks, compressed speech	Adaptive	20 minutes, 5 times per week, 4 weeks	Sweetow and Sabes (2006) www.laceuk.co.uk
Dichotic Inter-aural Intensity Difference	Improving binaural separation and integration	Non-computerised, normally in clinic	Children and Adults	Stimuli: speech - digits, CV pairs and sentences Task: dichotic listening	Difficulty level set by clinician	15-30 minutes, 3-4 times per week, 2-3 months	Weihing and Musiek (2007)
Differential Processing Training	Improving auditory awareness and attention, and language comprehension	Non-computerised, CD workbook	Children	Speech and non-speech stimuli Auditory process: Dichotic listening, temporal patterning, auditory discrimination	Increasing difficulty level		Wingett (2007)

hearing aid users such as those to be used in the present study. Song et al (2012) have also reported significant improvements on the QuickSIN and HINT tests following LACE training.

For a training programme to be considered successful, on-task training effects should be associated with improved functional performance. There is increasing emphasis on the importance of cognitive abilities in the maintenance of auditory performance (Rönnberg et al., 2008; Shinn-Cunningham and Best, 2008). Studies have shown the influence of working memory (Rönnberg et al, 2008) and selective attention (Shinn-Cunningham and Best, 2008) on auditory performance in challenging listening situations. A successful auditory training programme should show off-task learning effects on cognitive performance. Many auditory training programmes (including LACE) involve training on a number of different auditory and cognitive processes however there has been little research into the effect of auditory training on cognitive performance (Henshaw and Ferguson, 2013a). Sweetow and Sabes (2006) reported improvements on the Listening Span Test and Stroop Colour Word test which assess working memory and selective attention following LACE training however it is unknown which aspect of the training had the greatest effect on performance. Henshaw and Ferguson (2013b) showed improvement in performance on a competing speech task and a dual task of listening at a challenging SNR following a phoneme-discrimination-in-noise training task. The effect of auditory training on cognitive abilities warrants further research.

The effects of auditory training are thought to occur due to the neural plasticity evident in the human brain (Willott, 1996; Tremblay and Kraus, 2002; Tremblay, 2003; Song et al., 2012). Neural plasticity refers to “alterations in the physiological and anatomical properties of neurons in the brain in association with sensory stimulation or deprivation” (Tremblay and Kraus, 2002, p93). Sensory stimulation has been shown to bring about neural changes in the central auditory system in both animal (Recanzone et al., 1993) and human studies (Kraus et al., 1995; Ponton et al., 1996). Systemic changes in the central auditory system are associated with improvements in behavioural performance (Recanzone et al., 1993, Song et al., 2012). Song et al. (2012) found that changes in the auditory brainstem response, and the concomitant improvement in performance, following LACE training were retained at six months following the intervention showing that the anatomical and behavioural changes of auditory training are maintained long-term. Since sensory stimulation alone has been shown to induce neural alterations

(Ponton et al., 1996) it is theorised that repeated exposure to challenging stimuli should bring about changes in behavioural performance.

As well as the objective improvements listed above, there have also been improvements in self-reported hearing abilities following LACE training shown in the literature. Sweetow and Sabes (2006) found a reduction in reported handicap on the Hearing Handicap Inventory for the Elderly and improvement on the Communication Scale for Older Adults. The participants from Olson (2013) also reported a benefit on training measured using the International Outcome Inventory – Hearing Aids and International Outcome Inventory – Alternative Intervention questionnaires. However, no reported improvement was seen for these participants on the Speech, Spatial and Qualities of Hearing Questionnaire. While improvements on objective measures of speech perception and cognitive performance are important, the effects of these improvements on reported abilities in real-world listening environments are also key to improving the quality of life for patients with hearing loss.

2.2.3 Speech Intelligibility in Noise Objective Measure

The QuickSIN (Killion et al., 2004) was developed as a shortened and improved version of the Speech in Noise Test (Etymotic Research, Inc, 1993 cited in Killion et al., 2004). The QuickSIN includes 12 lists of six IEEE sentences which the participant has to repeat back. The sentences each contain five key words and are presented in four-talker babble. The QuickSIN is an adaptive test using a descending paradigm to establish the participant's signal-to-noise (SNR) loss. SNR loss is the dB increase in the signal-to-noise ratio required by the participant in order to identify 50% of the stimuli correctly relative to a person with normal hearing (Etymotic Research, Inc., 2006).

The QuickSIN may be used clinically to assess the benefit of amplification, or of different hearing aid features, on the patient's ability to understand speech in noise (Taylor, 2003). The QuickSIN has also been shown to be a sensitive tool for investigating the effects of auditory training on speech intelligibility in noise performance (Sweetow and Sabes, 2006; Olson et al., 2013). As discussed in Section 2.2.3 in a recent study by Olson et al. (2013) a large effect size (0.8) was shown on the QuickSIN for experienced hearing aid users following a period of LACE training. This recommends the use of this measure in the current study. The QuickSIN will be administered pre-and post-intervention to

investigate the effect of the training on participants' speech intelligibility in noise performance.

2.2.4 Self-report Measures

The Hearing Handicap Inventory for the Elderly (HHIE; Ventry and Weinstein, 1982a) will be used to evaluate the subjective effect of the training intervention. The HHIE is designed to assess the social and emotional impact of a hearing impairment on older adults. The questionnaire includes 25 questions and users are asked to mark each question "Yes", "No" or "Sometimes". The questionnaire is scored out of a possible 100, with 1-16 indicating no handicap, 17-42 indicating mild to moderate handicap, and 43-100 indicating significant handicap (Ventry and Weinstein, 1982b). Subtotal scores can also be calculated for emotional (12 items, maximum score 48) and situational items (13 items, maximum score 52). The HHIE is a highly reliable measure with good content validity (Ventry and Weinstein, 1982b). The tool is aimed at older adults aged 65 and over which makes it a relevant tool for use in the BCUHB population. As reported above in Section 2.2.2.2, significant improvements were shown on the HHIE following LACE training (Sweetow and Sabes, 2006). The use of the HHIE in the current study will enable comparison of results to previous research.

The Glasgow Hearing Aid Benefit Profile (Gatehouse, 1999) is commonly used throughout Audiology in both research and clinical practice. It assesses auditory disability, handicap and hearing aid benefit through by asking patients to rate their performance on four pre-set listening situations and up to four self-selected listening situations. Of particular interest in this study is the self-reported disability in the most challenging pre-set listening situation: Having a conversation with several people in a group. Previous research (Ferguson et al., in press) has used this question in isolation to assess the effect of an auditory training programme.

2.2.5 Cognitive measures

2.2.5.1 Competing Speech Task

The Modified Coordinate Response Measure (MCRM) is a measure of speech intelligibility based upon the Coordinate Response Measure described by Bolia et al (2000). The Coordinate Response Measure has been widely used in studies of

informational masking (Brungart, 2001; Eddins, 2012). The original task was designed for use in research with military personnel including call signs such as “Baron” or “Hopper” within the stimulus sentence. This study uses the modified task utilised by Henshaw and Ferguson (2013b) which replaces the call signs with animals. Stimuli take the form of “show the [animal] where the [colour] [number] is” with a total of six possible monosyllabic animals, six colours and eight numbers (1-9 excluding 7). Two sentences are spoken simultaneously by a female (target) or male (distractor) voice and participants are asked to identify the colour and number spoken by the female talker. The participant’s speech reception threshold (SRT) is measured using an adaptive staircase method.

Henshaw and Ferguson (2013b) identified the MCRM as an outcome measure which is sensitive to the functional benefits seen on an auditory training task using phoneme discrimination in noise. Performance on the MCRM was correlated with self-reported listening difficulties and working memory performance (Henshaw and Ferguson, 2013b). This inclusion of this measure within the present study will enable the assessment of off-task learning effects of the training programme.

2.2.5.2 Dual Task of Listening and Memory

The dual task of listening and memory was designed to assess listening effort (Howard et al, 2010). It consists of a five digit memory task and a speech-in-noise repetition task. The method used in this study was described by Henshaw and Ferguson (2013b). Participants are asked to memorise five digits displayed visually. They are then given a list of five AB words (Boothroyd, 1968) presented in ICRA sic-talker babble at 0dB SNR and asked to repeat each word immediately. They are then asked to recall the original five digits. Henshaw and Ferguson (2013b) showed an effect of phoneme discrimination in noise training on the dual task in the challenging 0dB SNR condition when compared to performance in quiet or at -4dB SNR. There was evidence of altered resource allocation in this condition as there was a reduction in performance seen on both the digit recall and word repetition task in relation to the quiet condition. This reflects improvements in complex cognition following training. Henshaw and Ferguson (2013b) identified the dual task of listening and memory as a measure sensitive to the effects of auditory training when undertaken at a sufficiently challenging level (0dB SNR).

2.2.6 Gaps in Knowledge

- The proposed approach to auditory training (detailed in Section 2.5.6) has not previously been reported in the literature and therefore it is unknown whether this format of intervention will be effective in improving speech perception.

- It is also not known what the effect of this approach to auditory training will have on cognitive performance, which has been shown to be an important factor in understanding speech in background noise.

2.3 Research Questions

Primary – Does repeated practice improve speech perception in everyday challenging listening environments for experienced adult hearing aid users?
Secondary – Does repeated practice listening to speech in the presence of a competing speaker affect the cognitive performance of experienced adult hearing aid users?

2.4 Hypotheses

H_0 - There will be no significant improvements in speech-intelligibility in noise, cognition and self-reported hearing abilities for experienced adult hearing aid users in either the experimental or control group.

H_1 - Auditory training will result in significant improvements in speech intelligibility in noise, cognition and self-reported hearing abilities of experienced adult hearing aid users (experimental group). These improvements will be significantly greater than for participants who do not receive the auditory training programme (control group).

2.5 Research Design

2.5.1 Participant Selection and Exclusion Criteria

This study will recruit existing hearing aid users attending for a reassessment appointment in the Wrexham Audiology service. They will have a need in their personal plan relating to improved speech perception in noise despite adequate aiding. Participants will have four-frequency average hearing thresholds greater than 20 dB HL. Participants will be recruited alongside a regular communication partner, either somebody who lives with them or who visits daily and is willing to complete the training programme with them. All participants (hearing aid users and communication partners)

will also fulfill the following criteria: fluent and comfortable conversing in English, able to access the Wrexham Maelor Hospital Audiology Service, able to attend initial and follow-up appointments together, no significant self-reported memory problems or neurological problems. Participants should not have any reported colour-blindness. Participants will be aged between 65 and 85 years in order to reflect the main population of the BCU Audiology department. This is based on the mean age of patient attending for reassessment (75.37 years) ± one standard deviation (13.19 years) rounded to 5 years. The inclusion of this criterion also helps to reduce the effect of ageing on results as it has been found that auditory training is more effective in younger people due to better neural plasticity (Baran, 2007). Any participants who do not meet these criteria will be excluded from the study.

2.5.2 Sample Size

Based on the research design below an a priori sample size calculation has been carried out using the reported effect size of 0.8 on the QuickSIN from Olson et al. (2013). An effect size of 0.8 indicated that 25 participants are needed in each group to give a power of 80% at 5% significance.

2.5.3 Research Design and Group Allocation

This study will be a randomised control trial investigating the effect of a repeated practice listening to speech in the presence of a competing speaker on a variety of outcome measures. Participants will be randomly assigned to either the control or training group. Randomisation will be carried out using a dynamic adaptive allocation algorithm (Hoare et al., 2013) with an allocation ratio of 1:1. Two stratification variables will be used for the randomisation: age (<75 years : $\underline{\geq}$75 years) and sex (male : female). The experimental group will carry out the training programme detailed in Section 2.5.6 while the control group will be given a placebo intervention.

2.5.4 Recruitment

A flow-chart detailing the recruitment pathway can be viewed in Figure 1. Potential participants and their communication partners will be identified by the Audiologist during

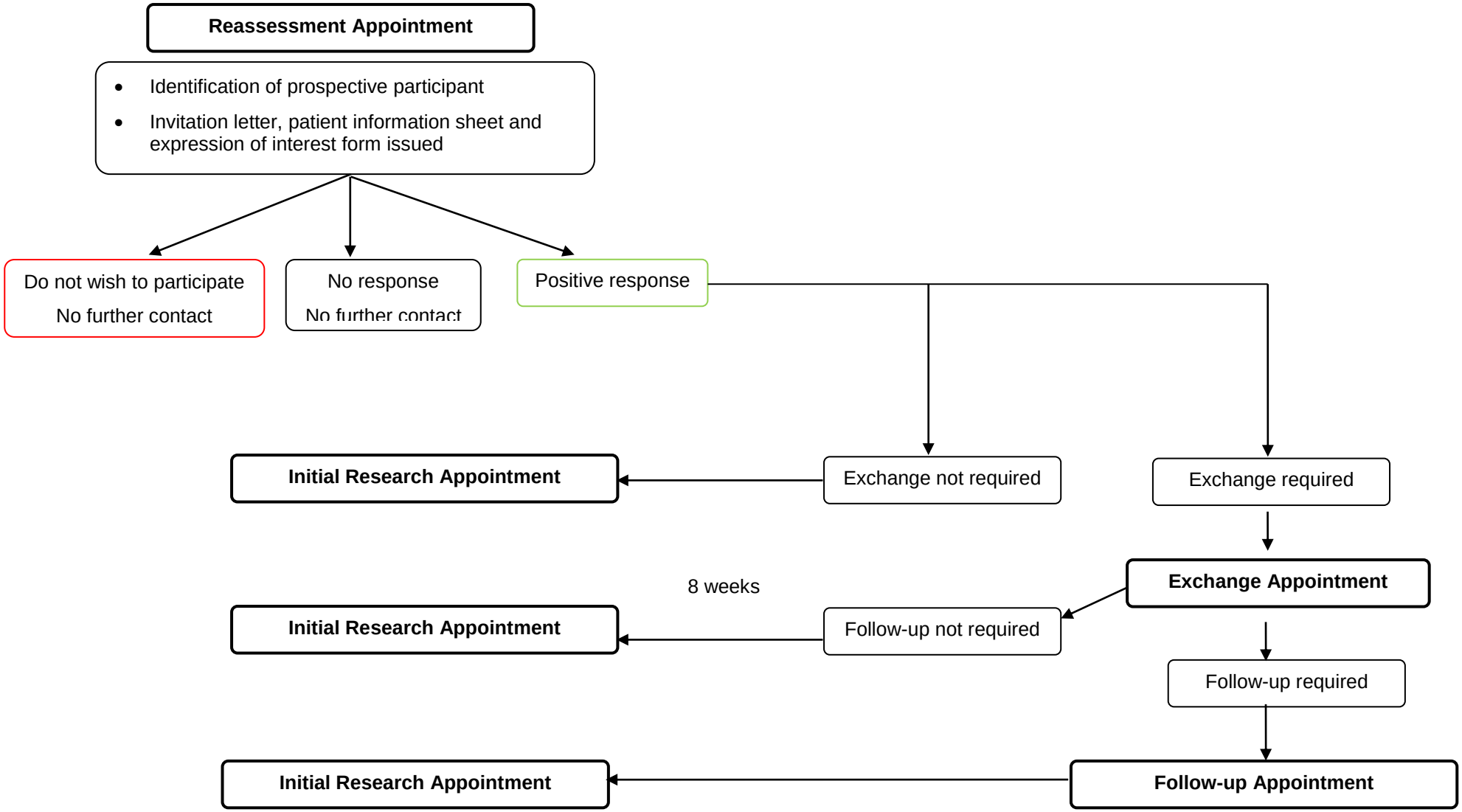

Figure 1 Recruitment pathway

their reassessment appointment. These participants will be given an invitation letter, the patient information sheet giving details of the study and exclusion criteria, an expression of interest form and a stamped addressed return envelope. If the patient replies that they do not wish to take part they will not be contacted again. If the patient and their communication partner are willing to participate and pass the exclusion criteria, a research appointment will be booked with the Principal Investigator or a Research Audiologist. If the patient's hearing aid has been exchanged but they do not require a hearing aid follow-up, a research appointment will be booked for them 8 weeks after their exchange appointment in order to allow time for acclimatisation to any hearing aid alterations. A poster will also be displayed in the waiting room of the Wrexham Audiology Department to alert patients to the existence of the research project.

2.5.5 Research Appointment Pathway

The research appointment pathway is shows in Figure 2. Participants and their communication partner will be asked to attend two 60 minute research appointments at the Wrexham Maelor Hospital Audiology Department. If possible, the first of these appointments will be linked to their hearing aid follow-up appointment (if required) as part of their Adult Hearing Pathway. The participant will be telephoned by the Principal Investigator at an agreed time two weeks after the initial research appointment to check on their progress. Any additional advice or support given during this telephone call will be noted by the Principal Investigator. The second research appointment will be arranged four weeks after the initial appointment in order to complete the final assessment.

The participant's general hearing aid follow-up and their initial research assessment will be completed separately if they are booked to coincide. Once the follow-up appointment is concluded, including completion of the patient's Personal Plan, the participant will be given a five minute break before the initial research assessment will begin.

At the start of the initial research assessment the content of the study will be explained and informed consent obtained. Three copies of the consent form will be completed; one for the participant's own records, one which will be scanned and added to the Audiology Patient Management System (Auditbase), and one copy which will be kept in a locked cabinet in the Principal Investigator's office at Wrexham Maelor Hospital for a period of six months following the end of the study. A subjective listening check of the participant's hearing aid/s will be carried out to ensure that it is functioning correctly.

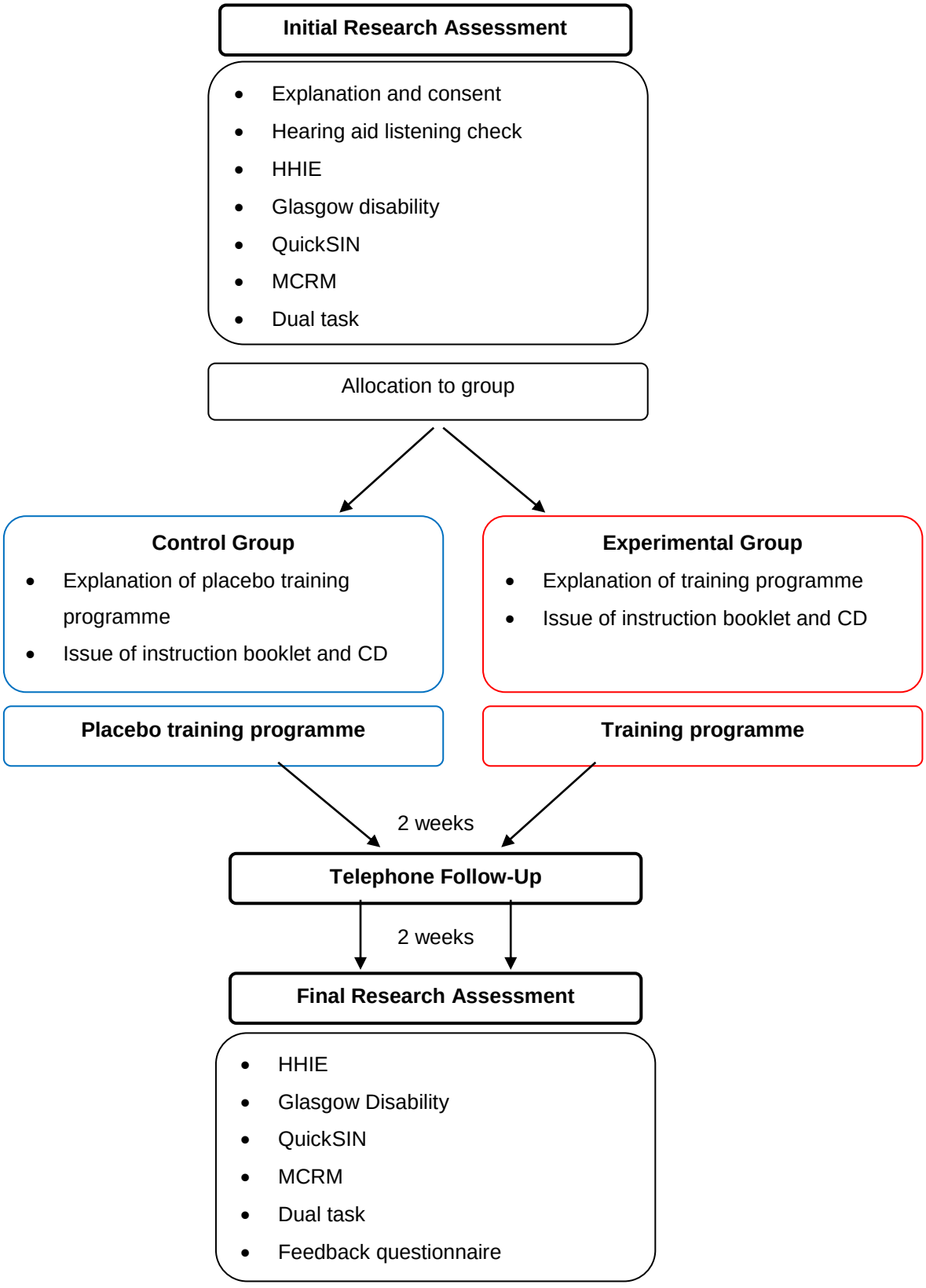

Figure 2 Research Appointment Plan

The participant will then complete the HHIE and Glasgow disability question. Their SNR loss will be measured using the QuickSIN and they will then complete the MCRM and dual task. The participant and their communication partner will be given a full explanation of the training programme or placebo programme, given the training workbook and will be provided with the CD containing the noise or placebo stimulus and the compliance letter. They will also be given the training diary to complete at home.
The final research appointment will take place four weeks after the initial research assessment. During this appointment the outcome measures of QuickSIN, HHIE, Glasgow disability, MCRM and dual task will be completed in order to obtain final performance on these measures. The participant and their significant other will also be given a questionnaire to obtain their feedback on the training programme.

2.5.6 Training Programme

The training programme used in this study will focus primarily on improving speech perception in noise. Participants will have a conversation with their communication partner in the presence of a single competing speaker presented in soundfield for 30 minutes, five times per week for four weeks. The training schedule used in this study is based on the well documented regimen used in the LACE training programme. The single-talker distractor will be formed of a selection of 30 minute extracts from four English language commercially available audiobooks. A range of male and female distractors will be used. A single-talker distractor has been chosen as studies have shown that the informational masking from an intelligible single-talker has a greater effect on performance than the energetic masking from speech-shaped noise (Brungart, 2001). These extracts will be recorded onto a CD which will be provided to the participants in order for them to complete the training programme at home. At the end of each 30 minute extract a tone will sound to alert the participant that the training session for that day is complete. Participants will be instructed to play the CD at a level which is challenging but comfortable (i.e. not too loud).

As previously stated, compliance for clinically administered auditory training programmes has previously been low. In order to improve compliance a spoken letter will be given to the participants after the tone at the end of their training session. An incentive will be given to participants completing the training programme by being entered into a prize draw to win £25 book tokens for gathering all of the letters.

The placebo training programme undertaken by the control group will involve the same period of training but in quiet. They will be given a blank CD which is segmented into 30 minute sections with the tone and compliance letter given at the end of the training session.

All training, placebo and intervention, should be carried out while the participant is wearing their hearing aid/s. If the participant has multiple programs for different listening environments they should complete the training while listening in the program most suited to the training situation i.e. everyday listening for the control group and background noise for the experimental group.

2.5.7 Involvement of Service Users in Study Materials

Current service users were consulted on the concept and design of the study. All documentation to be provided to participants has been reviewed by users to ensure that it is clear and understandable and their comments have been incorporated.

2.5.8 Tools to be Used

All aspects of research appointments will be in addition to routine appointments that hearing aid patients would have attended. Research appointments will include the following components which will be carried out for all participants:

- *Research introduction and consent* – approximately 5 minutes at initial research assessment

A full explanation of the purpose of and procedure for the study will be provided and participants will be given the opportunity to ask questions. Potential participants will be informed that they can withdraw from the study at any time, without offering an explanation or affecting their ongoing care. If they are willing to participate, a written consent form will be signed by the patient.

- *Otoscopy* – approximately 2 minutes at both research appointments

Bilateral otoscopy will be carried out to ensure that participant's ears are healthy and clear of wax. If wax removal is required then this will be arranged on the day.

- *Hearing aid listening check* – approximately 5 minutes at both research appointments

A listening check will be performed on the participant's hearing aid/s to ensure that they are functioning correctly.

- *Self-report* – approximately 10 minutes at both research appointments
    - Hearing Handicap Inventory for the Elderly

      The HHIE will be administered in written form. Participants will be provided with the questionnaire and asked to mark their answer of "Yes", "No" or "Sometimes" in the relevant box. Their questionnaire will be scored by the researcher
    - Glasgow Disability

      Participants will be asked the disability question of the Glasgow Hearing Aid Benefit Profile Part 1 for situation 4 (Having a conversation with several people in a group) only. This will be provided in written form and they will be asked to rate their difficulty level as "No difficulty", "Only slight difficulty", "Moderate difficulty", "Great difficulty" or "Cannot manage at all". Their response will be recorded by the researcher.
- *Speech intelligibility testing* – approximately 10 minutes at both research appointments

Three QuickSIN lists will be administered in the soundfield while the participant is wearing their hearing aids. The stimulus will be set to a level which is reported to be comfortable by the participant. Different lists will be administered at the initial appointment and final appointment. Participants will be required to repeat back the sentence which they have heard and the researcher will record how many keywords were repeated accurately. The QuickSIN will be scored by the researcher.

- *Cognitive measures* – approximately 20 minutes at both research appointments
    - MCRM

      The MCRM will be administered using Matlab. The level of the stimulus will be set to a level which is comfortable for the participant. The participant will be presented with the visual display represented in Figure 3 and will use the mouse to select the appropriate number-colour combination. Speech reception thresholds (SRT) are measured using an adaptive 1-up 1-down staircase method consisting of eight reversals. The SRT is calculated based on the average of the last two reversals.

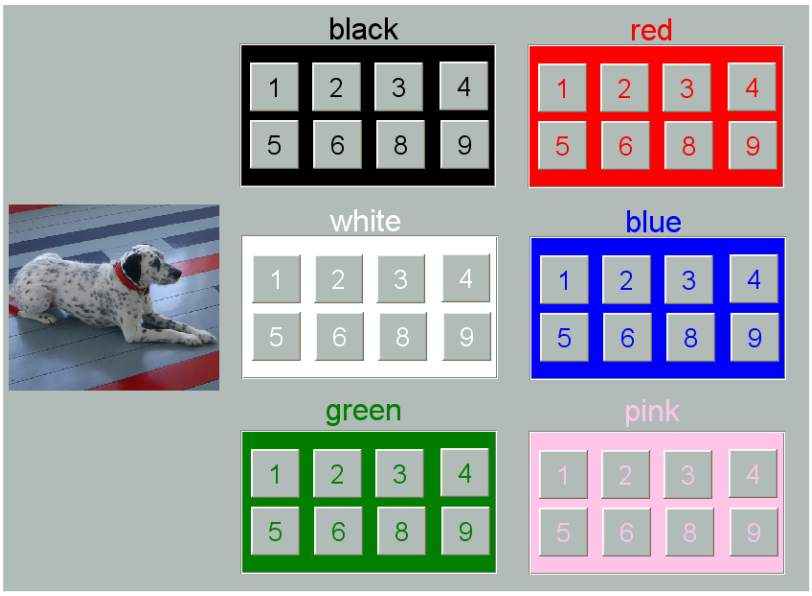

Figure 3 Visual display for participant response during MCRM task

- Dual task

  This test will be administered using PsychoPy. The stimulus level will be set by the participant at a level which is comfortable. The word task will initially be presented in isolation in order to establish single task performance. Participants will be required to immediately repeat the words that they heard and these will be scored by the researcher. The word task will then be administered sandwiched between the digit task to measure dual task performance. Participants will type the numbers that they recall using the keyboard. Four word lists will be presented in both the single and dual task conditions. The single and dual tasks will be administered twice at the initial appointment to allow for practice however only the second administration will be scored. In the single task there is a maximum possible score of 20 correct words. In the dual task there is a maximum possible score of 20 correct words and 20 correct digits. The dual task score is calculated by summing the total correct words and digits. The dual task decrement will be calculated by comparing performance on the single and dual task.

- *Introduction to training programme and issue of training materials* – approximately 20 minutes at initial research appointment

The participant and their communication partner will be given verbal instructions giving details of all aspects of the training programme. They will be issued with written instructions and a copy of the training CD. Participants in the experimental group who will

be undertaking training in noise will practice setting the level of the distractor to an appropriate level.

- *Feedback questionnaire* – approximately 5 minutes at final research assessment

Participants will complete the written feedback questionnaire in order to obtain their opinion of the training programme. This includes questions on the ease of undertaking the programme, and any changes that they would recommend for future. The questionnaire has been adapted from one commonly used during research at the NIHR Nottingham Hearing Biomedical Research Unit.

2.5.9 Training of Staff

Minimal staff training will be required for this study. Recruiting Audiologists will be briefed in the aims and methods of the study. They will be advised as to the inclusion and exclusion criteria in order to enable identification and recruitment of potential participants. They will be informed of the need to maintain participant confidentiality. The Principal Investigator and Research Audiologists will undertake refresher training in the use of speech and cognitive tests.

2.6 Data Collection

2.6.1 Extraction of Data

Data extracted from the patient management system (Auditbase) and completed assessments and questionnaires will be entered into an Excel spreadsheet. The data to be collected is shown in Table 2. Anonymised data, accessible only by the research team, will be stored for five years following completion of the project. The project will be completed once the last participant has carried out their final appointment.

2.6.2 Measured Outcomes and Data Analysis

An ANCOVA will be used to assess any main effects of time or group on participants' performance on the QuickSIN, HHIE, Glasgow disability, MCRM or dual-task performance using initial performance on the QuickSIN as a covariate.

Table 2 Data to be collected during study

Data	Source
Age	At initial appointment from Auditbase
Gender	At initial appointment from Auditbase
Four-frequency average hearing levels	At initial appointment from Auditbase
Number of hearing aids (plus aided ear if unilateral fitting)	At initial appointment from Auditbase
Average hours of hearing aid use per day	At initial appointment from Auditbase
Initial HHIE	At initial appointment
Initial Glasgow disability	At initial appointment
Initial QuickSIN SNR loss	At initial appointment
Initial MCRM score	At initial appointment
Initial single task sore	At initial appointment
Initial dual task score	At initial appointment
Final HHIE	At final appointment
Final Glasgow disability	At final appointment
Final QuickSIN SNR loss	At final appointment
Final MCRM score	At final appointment
Final single task score	At final appointment
Final dual task score	At final appointment
Compliance	At final appointment from training diary

3 Project Considerations

3.1 Benefits

3.1.1 Local Benefits

For the participants involved, if the intervention is shown to be successful they may experience improvements in their ability to understand speech in background noise. This may ultimately improve the quality of their interactions in challenging listening environments and improve their quality of life. There is evidence to suggest that learning from auditory training programmes can generalise to other listening skills (Henshaw and

Ferguson, 2013b) and so they may also experience improvement in other communication situations.

Involving the participant's regular communication partner in the training programme may increase their awareness of the difficulties faced by the patient. This in turn could motivate them to use a greater range of hearing tactics in these challenging listening environments, thereby improving the communication experiences of both the patient and themselves.

This study will provide research evidence for the completion of Higher Training Scheme modules and state registration for the Principal Investigator and material for continuing professional development.

Further research based on this study could be used to augment and improve the existing adult rehabilitation programme provided by the Audiology department by providing an additional non-instrumental management option. It could lead to the development of a user-friendly at home training programme for improving speech perception in noise for hearing-impaired or normally hearing listeners.

3.1.2 National and International Benefits

The results from this study could inform the future national use of training programmes as a non-instrumental intervention in audiological rehabilitation. If the programme is found to be effective it could encourage other departments to use at home speech in noise training as an alternative to other more expensive computerised or clinician-led training programmes. It could also be expanded in order to be incorporated into a rehabilitation programme for patients with confirmed or suspected auditory processing disorder, either with normal hearing or with hearing loss. Being patient-led, rather than clinician-led, this programme also ties in with the current national emphasis on patients taking ownership of their condition and being more involved with decisions regarding their treatment.

3.2 Limitations of Study

A limitation of this study is that the potential for bias in the selection of participants. Although all staff will be given training on the inclusion and exclusion criteria there may be variation in the development of each patient's individual management plan by clinicians meaning that needs may not be phrased in a way which could be interpreted as relating to improved speech perception in noise or complex listening situations. The

participant sample may also be limited to patients with reasonably high levels of motivation to improve their listening skills and therefore compliance with the training programme may be greater than could be expected for those with low levels of motivation. Motivation has been linked to better outcomes on training programmes (Musiek et al., 2007) and therefore the results of this study could over-estimate the effectiveness of this training intervention for the general patient population.

As the training programme is patient-led, carried out in the patient's home environment, there is limited control from the researcher as to the way that the training is undertaken by individuals. Although instruction is given regarding noise levels etc. the participant's judgment of "comfortable" or "challenging" may differ and this could lead to variability in the application of training programme between individuals.

This study does not include a measure of on-task learning. This relates to any improvements on the training task i.e. listening to their communication partner in the presence of the specific training distractor. On-task training effects are widely reported in the literature and it is therefore likely that similar effects will be shown in the current study, however the research design does not enable inclusion of a measure of on-task learning due to the patient-led, non-computerised, at home approach.

3.3 Ethical Issues

Full ethical approval will be sought from the North Wales Research Ethics Committee (Central and East). Fully informed consent will be obtained from all participants prior to inclusion in the study. Participants will be able to withdraw from the study at any time. All tools used in the study have been previously used in research or clinical practices within Audiology. If the training programme is found to be effective it will be offered to all participants in the control group.

3.4 Risk Limitation

This study has been designed incorporating measures to mitigate any identified risks.

Noise exposure will not exceed the maximum daily noise exposure limits (85 dB A for 8 hours) as testing and training will not exceed 30 minutes per day. Noise levels should not exceed 85 dB A during testing and training. Participants will not be exposed to noise levels which they find uncomfortable. Hearing aids will be optimally set using compression and output limiting in order to ensure that output levels do not exceed

unsafe limits. The research team will meet regularly to monitor progress and address any unforeseen issues that may threaten to compromise the project or patient care.

3.5 Confidentiality and Data Protection

All data relating to this study will be gathered and stored in line with the Trust Data Protection Policy.

The data will be recorded on Excel spreadsheets and will be analysed using Excel and SPSS. Participants will be issued with a unique project identification number and their study data will be recorded anonymously against this number. A separate Excel spreadsheet cross-referencing the project identification number against their patient identification number will be stored under password protection, accessible only to the research team. All data will be stored on the departmental server under password protection. Patient identifiable information will be stored for 3-6 months after the end of the research project, while anonymised information will be stored for 5 years before being destroyed.

4 Project Management

4.1. Time Scale

Figure 4 gives the proposed timescale for the research project.

4.2 Research Costs

A breakdown of the costs involved in the project, confirmed by the Finance Department, can be found in Table 3. The study has been awarded a BSA Applied Research Grant meeting all costs.

4.3 Impact of Research on Normal Workload

This study forms part of a clinical training programme for the Principal Investigator whose time is externally funded. Therefore, the time spent by the Principal Investigator on this project is not included in the summary of costs.

Data collection is expected to take 100 hours of clinical time. Research Audiologists will be involved in data collection, undertaking three-quarters of the total research appointments (the remaining quarter will be covered by the Principal Investigator). Part of the funding for this research will be used to backfill lost clinical sessions. The cost of the

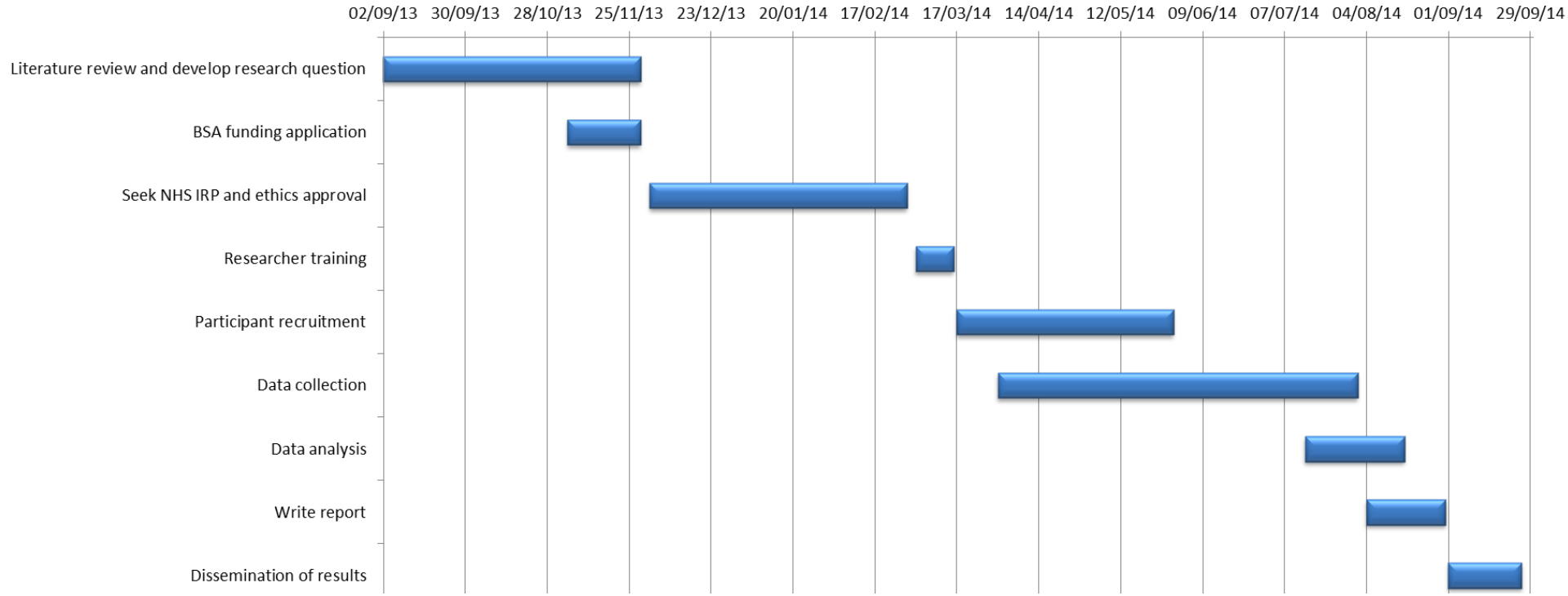

Figure 4 Gantt chart showing timescale of project

Table 3 Costs involved in the research project

	Cost (£)	Justification
Staff costs	1753.73	Backfill of clinical time lost through project: Mid-point Band 6 Audiologist, 75 hours x £18.77 including on-costs Mid-point Band 8 Audiologist, 10.5 hours x £32.95 including on-costs As completion forms part of a clinical training programme for the Principal Investigator all time spent on aspects of the project are covered under the terms of the training programme and are therefore not included in the staff costs. NHBRU staff researchers' time is funded by the NIHR.
Materials and consumables	115	Stationary (paper, envelopes etc.): £12.50 Postage: £37.50 Recordable CDs: £40 Voucher for prize draw: £25
Travel	1420	Travel costs for additional journeys undertaken by research participants: 25 participants with 1 additional journey, £10 per journey 25 participants with 2 additional journeys, £10 per journey Travel for meetings between researchers £670
Apparatus and equipment	125	Purchase of QuickSIN
Total	3413.73	

additional workload generated by this study have been included in the above research costs (see Table 3).

4.4 Dissemination

Results will be disseminated through a written report which will be submitted to the Trust. The results will be presented at the annual British Society of Audiology conference, in line with the terms of the research grant. An article will also be published in the British Society of Audiology magazine, Audacity, in line with the terms of the research grant. It is anticipated that this will be followed by publication in a peer-

reviewed scientific journal. A poster of the project will also be displayed within the Audiology reception area to share results with service users.

5 References

Baran, J.A., 2007. Managing (Central) Auditory Processing Disorders in Adolescents and Adults. In G.D. Chermak and F.E. Musiek eds, 2007. *Handbook of (Central) Auditory Processing Disorder: Comprehensive Intervention.* San Diego: Plural Publishing. Ch 9.

Bolia, R.S., Nelson, W.T., Ericson, M.A. & Simpson, B.D., 2000. A speech corpus for multitalker communications research. *Journal of the Acoustical Society of America,* 107, 1065-66.

Brungart, D.S., 2001. Informational and energetic masking effects in the perception of two simultaneous talkers. *Journal of the Acoustical Society of America,* 109 (3), 1101-1109.

Eddins, D.A., 2012. Psychometric properties of the coordinate response measure corpus with various types of background interference. *Journal of the Acoustical Society of America,* 131 (2), EL177-EL183.

Etymotic Research, Inc., 2006. *QuickSIN™ Speech-in-Noise Test*. Illinois: Etymotic Research, Inc

Ferguson, M.A., Henshaw, H., Clark, D.A. & Moore, D.R., 2012. Auditory training improves listening and cognition in complex conditions. *International Journal of Audiology,* 51, 220-227.

Ferguson, M.A., Henshaw, H., Clark, D.A. & Moore, D.R., in press. Benefits of phoneme discrimination training in a randomized controlled trial of 50-74 year olds with mild hearing loss. *Ear and Hearing.*

Gatehouse, S., 1999. Glasgow Hearing Aid Benefit Profile: Derivation and validation of a client-centered outcome measure for hearing-aid services. *Journal of the American Academy of Audiology,* 10, 80-103.

Henshaw, H., Clark, D., Jang, S. & Ferguson, M., 2012. Computer Skill and Internet Use in Adults Aged 50-74 years: Influence of Hearing Difficulties. *Journal of Internet Medicine Research,* 14, e113.

Henshaw, H. & Ferguson, M.A., 2013a. Efficacy of individual computer-based auditory training for people with hearing loss: a systematic review of the evidence. *PLOS ONE,* 8 (5), e62836.

Henshaw, H. & Ferguson, M.A., 2013b. Proceedings of ISAAR 2013: Auditory Plasticity – Listening with the Brain. 4th symposium on Auditory and Audiological Research August 2013, Nyborg, Denmark. Edited by T. Dau, S. Santurette, C. Dalsgaard, L. Tranebjærg, T. Andersen, and T. Poulsen. ISBN: 978-87-990013-4-7. The Danavox Jubilee Foundation, 2014.

Hoare, Z.S.J, Whitaker, C.J., Whitaker, R., 2013. Introduction to a generalized method for adaptive randomization in trials. *Trials,* 14, 19.

Hougaard, S., & Ruf, S., 2011. EuroTrak I: A consumer survey about hearing aids in Germany, France and the UK. *Hearing Review,* 18(2), 12-28.

Howard, C.S., Munro, K.J., & Plack, C.J., 2010. Listening effort at signal-to-noise ratios that are typical of the school classroom. *International Journal of Audiology,* 49, 928-932.

Killion, M.C., Niquette, P.A., Gudmundsen, G.I., Revit, L.J., & Banerjee, S., 2004. Development of a quick speech-in-noise test for measuring signal-to-noise ratio loss in normal-hearing and hearing-impaired listeners. *Journal of the Acoustical Society of America,* 116(4), 2395-2405.

Kraus, M., McGee, T., Carrell, T.D., King, C., Tremblay, K., & Nicol, T., 1995. Central auditory system plasticity associated with speech discrimination training. *Journal of Cognitive Neuroscience,* 7, 25-32.

Mattys, S.L., Davis, M.H., Bradlow, A.R. & Scott, S.K., 2012. Speech recognition in adverse conditions: A review. *Language and Cognitive Processes,* 27 (7/8), 953-978.

Musiek, F.E., 2006. Auditory training and CAPD: A short history. *The Hearing Journal,* 59(8), 52.

Musiek, F.E., Chermak, G. and Weihing, J., 2007. Auditory Training. In F.E. Musiek and G.D. Chermak eds., *Handbook of (Central) Auditory Processing Disorder: Comprehensive Intervention Volume 2.* San Diego: Plural Publishing. Ch. 4.

Olson, A.D., Preminger, J.E. and Shinn, J.B., 2013. The Effect of LACE DVD Training in New and Experienced Hearing Aid Users. *Journal of the American Academy of Audiology,* 24, 214-230.

Plomp, R., 1986. A signal-to-noise ratio model for the speech-reception threshold of the hearing impaired. *Journal of Speech and Hearing Research,* 29(2), 146-154.

Ponton, C.W., Don, M., Eggermont, J.J., Waring, M.D. & Masuda, A., 1996. Maturation of human cortical auditory function differences between normal-hearing children and children with cochlear implants. *Ear and Hearing,* 17(5), 430-437.

Rencanzone, G.H., Schreiner C.E. & Merzenich, M.M., 1993. Plasticity in the frequency representation of primary auditory cortex following discrimination training in adult owl monkeys. *Journal of Neuroscience,* 13(1), 87-103.

Rönnberg, J., Rudner, M., Foo, C. & Lunner, T., 2008. Cognition counts: A working memory system for ease of language understanding (ELU). *International Journal of Audiology,* 47(S2), S99-S105.

Scottish Government, 2009. *Quality Standards for Adult Hearing Rehabilitation Services*. Edinburgh: Scottish Government.

Shinn-Cunningham, B.G. & Best, V., 2008. Selective Attention in Normal and Impaired Hearing. *Trends in Amplification,* 12(4), 283-299.

Song, J.H., Skow, E., Banai, K. & Kraus, N., 2012. Training to Improve Hearing Speech in Noise: Biological Mechanisms. *Cerebral Cortex,* 22(5), 1180-1190.

Sweetow, R.W. & Sabes, J.H., 2006. The Need for and Development of an Adaptive Listening and Communication Enhancement (LACE™) Program. *Journal of the American Academy of Audiology,* 17, 538-558.

Sweetow, R.W. & Sabes, J.H., 2010. Auditory training and challenges associated with participation and compliance. *Journal of the American Academy of Audiology,* 21, 586-593.

Sweetow, R. & Palmer, C.V., 2005. Efficacy of Individual Auditory Training in Adults: A Systematic Review of the Evidence. *Journal of the American Academy of Audiology,* 16, 494-504.

Taylor, B., 2003. Speech-in-noise tests: How and why to include them in your basic test battery. *The Hearing Journal,* 56(1), 40-43.

Tremblay, K.L., 2003. Central auditory plasticity: Implications for auditory rehabilitation. *The Hearing Journal,* 56 (1), 10.

Tremblay, K.L. & Kraus, N., 2002. Beyond the ear: central auditory plasticity. *Otorinolaringology,* 52, 93-100.

Tyler, R.S., Perreau, A.E. & Haihong, J., 2009. The Validation of the Spatial Hearing Questionnaire. *Ear and Hearing*, 30 (4), 466-474.

Ventry, B.E. & Weinstein, I.M., 1982a. Hearing Impairment and Social Isolation in the Elderly. *Journal of Speech and Hearing Research,* 25, 593-599.

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

Weihing, J. & Musiek, F., 2007. Dichotic Interaural Intensity Difference (DIID) Training – Principles and Procedures. In D. Geffner & D. Ross-Swain (Eds.), *Auditory Processing Disorders – Assessment, Management and Treatment*. San Diego: Plural Publishing.

Willott, J.F., 1996. Physiological Plasticity in the Auditory System and its Possible Relevance to Hearing Aid Use, Deprivation Effects and Acclimatization. *Ear and Hearing,* 17(3), 66S-77S.

Wingett, K., 2007. Differential Processing Training Program. Illinois: LinguiSystems.

Wolfle, D., 1951. Training. In Stevens, S.S. (Ed). *Handbook of Experimental Psychology.* New York: John Wiley.