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Department for Environment Food & Rural Affairs

Defra NANR271

UK-wide Support Infrastructure for Low Frequency Noise Sufferers ('LFN Network')

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Foreword

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Executive Summary

The project was set up to meet a need for improved treatment of Low Frequency Noise (LFN) complaints in cases where no noise source could be found. Such cases can be highly distressing for the complainant and difficult to handle by the Environmental Health Officers (EHOs) concerned and so tend to result in disproportionate use of resources. The hypothesis is that, irrespective of the (unknown) cause of the LFN perception, the perception may be lessened through application of techniques specifically adapted from the field of tinnitus and hyperacusis therapy. The aim of the project was therefore to establish, on a trial basis, a national network of treatment centres for sufferers of LFN located within the existing network of tinnitus clinics in the UK.

A network of nine audiology centres was established, including eight with a good geographical spread in England and one in Scotland. A treatment protocol, specific to LFN cases, was then developed through discussions with the centres and a referral pathway was also established. Each centre made contact initially with EHOs in one or two local authorities in their vicinity to offer the service which was widened to a larger catchment area if sufficient referrals were not forthcoming.

Fourteen subjects took part, eleven of which were referred from EHOs, the remaining three being self-referred. Outcome measures were based on a combination of validated questionnaires for general health, anxiety, depression, tinnitus handicap (with LFN substituted for tinnitus) and hyperacusis, combined with visual-analogue scales specifically developed for LFN to measure the pitch and loudness of the perceived LFN and the associated distress. Qualitative and open questions were also used.

Potential benefits to EHOs of being able to make referrals were evaluated by semi-structured telephone interviews in which five EHOs participated. Generally, EHOs were very positive about the service and wanted it to continue. It was clear that LFN cases require significant resources which can be reduced if the referral service is available. Audiologists' experience was evaluated in a similar way: they were generally willing to take part in the scheme and wanted it to continue and there was a feeling that they would have liked more referrals to get more experience in the use of the protocol.

The results showed a mixed picture with some clients, three in particular, showing improved scores across a range of measures with little or no benefit for others and a

worsening for one case. The improvement of some clients is positive given the lack of options available for this client group, however, the success of the approach can be considered partial at best.

The questionnaire scores indicated that individuals taking part were significantly agitated, stressed and distressed. Those individuals with LFN complaint have a significant clinical need although in the main they were not clinically anxious or depressed.

The model proposed of stress and increased auditory gain is a plausible explanation for the symptoms noted in LFN cases. In particular, the involvement of the sympathetic autonomic nervous system, and of the emotional brain, is likely to be a faithful representation of the clinical situation.

A number of useful signposts for future development were derived. First, EHOs as well as audiologists should ideally receive training in best practice to help them to handle the particular sensitivities of LFN cases. More awareness and information for GPs is also recommended. A simplification of the referral route, potentially going direct to the audiologist rather than via the GP would also be beneficial.

A strong argument for the continuation of the service is that some EHOs are now taking the initiative in contacting audiologists independently to refer LFN complainants in 'No Noise Found' cases. Without adequate training things could be made worse but access to a specific LFN protocol and associated training is likely to increase the chances of success significantly. It is recommended that existing guidance for EHOs be extended to include details of audiology services, guidelines for EHOs in making referrals and reference to the LFN treatment protocol.

Using data from the study two independent estimates of the incidence rates of LFN cases can be derived. It is estimated that there are up to 160 complainants per year in the NHS corresponding to 0.32 cases per 100 thousand per year. The incidence rate based on referrals made by EHOs is 1.01 per 100 thousand per year within local authorities. It is not known to what extent, if any, these populations overlap.

Contents

1 Introduction

Many Environmental Health Officers (EHOs) in the UK, and indeed around the world, receive occasional complaints about low frequency noise (LFN). Whilst such cases are thought to be few in number, they can be difficult for EHOs to handle and extremely distressing for the complainant who feels that they are besieged by a noise that they cannot ignore or shut out. The disturbance can be so severe that complainants frequently resort to extreme measures, like sleeping in a car or garden shed, to try to avoid the noise. EHOs admit that LFN cases can be as baffling for them as for the sufferer. Few cases are satisfactorily solved and some end up in an investigation by the Ombudsman.

In some cases a source of environmental LFN is identified, usually by an EHO, and there is then a chance of a solution by noise control. However, in a proportion of cases, perhaps as high as 70%, no noise can be identified that could be responsible for the complainant's reaction and, in the absence of a clearly identified source no action is possible by the EHO. However, it is not necessarily a straightforward matter for them to close the case at this point. First, to be confident that there is no external cause of the complainant's distress, the EHO needs to prove the absence of a sound which is never straightforward, even with modern monitoring equipment. Secondly, an EHO may not be comfortable to send away a distressed client without having been able to help them. Lacking a decisive closure, the complainant will often continue to contact the EHO simply through lack of alternatives. The result can be a cycle of frustration which consumes the EHO's resources while providing no real prospect of a resolution for the complainant.

Against this backdrop, this project has been conceived so as to help provide an alternative, and more helpful course of action for the complainant in cases where no source is found.

Why LFN sufferers are so distressed and provide such vivid descriptions of sounds that cannot be measured or heard by others remains a mystery. However, we can perhaps gain some understanding through analogy with tinnitus (ringing in the ears) and hyperacusis (abnormal sensitivity to sounds): note that there is no implication that LFN perception in 'No Noise Found' cases is linked to either of these conditions. Tinnitus sufferers are in some ways in a similar predicament to LFN sufferers in that they may be distressed by a noise they cannot get rid of. Modern tinnitus treatments

have developed considerably in the last decade due to advances in auditory neuroscience and improved understanding as to the role of auditory gain and attention in disturbance by sounds. The key elements of modern treatment are, firstly, to establish a compelling framework of understanding, i.e. for the sufferer to form a clear picture that the sound is not harmful to them, and secondly, relaxation therapy. Through careful application of these techniques the perception of the tinnitus can be softened leading to an improvement in the quality of life, see (Andersson, Baguley, McKenna, & McFerran, 2004).

This leads to the hypothesis underpinning this project which is that, irrespective of the (unknown) cause of the LFN perception, the perception may be lessened through application of techniques specifically adapted from the field of tinnitus therapy. It is hoped that the lessened perception would lead to an improvement in habituation and hence in the quality of life for complainants. The potential advantages for the EHO are that they would be able to offer genuine assistance, and more complete 'closure' in cases where action is not possible within their remit. It is hoped that this would prevent the frustration of sufferers and the disproportionate use of EHO resources that currently characterises LFN cases.

In the UK there is now a wealth of experience within a network of tinnitus clinics that could help LFN sufferers, and, indirectly, EHOs. The concept of the LFN Network is to tap into this resource for the benefit of LFN sufferers and EHOs. The aim of the project is therefore to establish, on a trial basis, a national network of treatment centres for sufferers of low frequency noise located within the existing network of tinnitus clinics in the UK. In order to realise this aim the objectives were:

- To identify a network of NHS Tinnitus Clinics that are prepared to assess and treat people with a complaint of low frequency noise in the absence of a measurable signal
- To produce a protocol for the assessment and treatment of such individuals
- To train these centres in methods of the identification of complaints of low frequency noise, low frequency tinnitus, and hyperacusis in this population
- To devise and publicise a pathway for referral of such individuals
- To monitor the operation of the network for a 12 month period.
- To report upon the effectiveness of the trial and to make recommendations for future development, or otherwise, of the network.

One common public misconception is the idea that LFN can cause physiological damage, and this may contribute to the feelings of intrusion and agitation that LFN

complainants exhibit. Sound is simply a mechanical vibration in the air. It turns out that the mechanical power in environmental sound is considerably less than is often appreciated. To illustrate, consider a LF sound at a level of 70 dB which is nearly 20 dB above the average threshold of hearing threshold at 40 Hz and so would be clearly audible and disturbing to many people in a residential environment. The sound intensity of this sound would be only 0.00001 W/m^2, or ten micro-Watts per square metre. If we take the average body as having a surface area of slightly more than one square metre, then the acoustic power incident on the body at 70 dBA will be of the order of ten micro-Watts, i.e. ten millionths of a Watt, only a small fraction of which would actually enter the body in the form of vibration. To put this in context, the intensity of strong sunlight is about 1kW/m2, and the power of a typical beating heart in an adult is of the order of one Watt so the acoustic power associated with environmental sound is almost unimaginably small compared with the power of everyday occurrences and normal body processes. At first, this conclusion may appear to contradict every day experience since we often experience sounds, especially LF sounds, as 'powerful'. The apparent contradiction can be partly explained by the extraordinary sensitivity of the ear. We may also speculate that the experience of power is essentially emotional rather than physical, and that there is a role of association for example with powerful occurrences like thunder. Nevertheless, it is inconceivable that such tiny quantities of acoustic energy could cause direct physiological damage as is sometimes erroneously believed.

2 Complaints about LFN

In this chapter we first define categories of LFN and then describe how complaints are handled by local authorities. We then review literature pertaining to surveys of LFN complaints, characteristics of complaints and possible causes. Finally, we review a therapeutic approach to LFN which has some similarities to that proposed here.

2.1 Categories of LFN complaint

It will become clear in the remainder of this chapter that there are different categories of LFN complaints. In order to discuss the suitability of particular cases for inclusion in the study the categories will be further distinguished in this section. The categories and their short names are defined in Table 1.

Table 1: Categories of LFN complaint and their acronyms

	Description	**Short name**
1	A LFN noise complaint where no noise has been found (by the EHO) that could be responsible for the complaint	No Noise Found
2	A LFN complaint where LFN has been identified which correlates with the complainants' description but which is judged not to be causing a statutory nuisance by the EHO	No Nuisance
2a	As above but the noise has now disappeared	
3	A LFN complaint where LFN has been identified and is considered to be causing a statutory nuisance.	Nuisance
3a	As above but the noise has now disappeared	

The main focus of this report is cases where no noise is found that could explain the complaint. In these 'No Noise Found' cases it is assumed that all possible avenues to find a potential source have been explored and proved negative. Since there is no prospect of external control of the perceived LFN, the possibility of an approach which encourages habituation then becomes an important option to the complainant.

In other cases a LFN is identified but is not considered by an EHO to constitute a statutory nuisance ('No Nuisance' cases). In this report we do not enter into a discussion as to how they might arrive at the decision which can be quite a complicated matter. In No Nuisance cases there is the theoretical possibility that external noise control could be applied but in many, perhaps most, cases there would be no mechanism to cause that noise control to be implemented. If so, as with No

Noise Found cases, a habituation approach could be one of very few options available to the complainant. Therefore, whilst the study is primarily aimed at No Noise Found cases, there is no reason to exclude No Nuisance cases. Indeed, since greater than average sensitivity to the LFN may be a factor in the disturbance for such cases, a habituation approach appears entirely appropriate.

'Nuisance' cases are classed as those where LFN is detected and is considered to be causing a statutory nuisance. The appropriate course of action in such cases is identification and control of the source of LFN and so these cases should normally be dealt with by the EHO under usual protocols for statutory nuisance. Therefore, Nuisance cases are not considered suitable for inclusion. In practise, mitigation measures may not always be forthcoming, for example if they exceed 'best practicable means', however no separate category is introduced to cover this subset of cases which are not thought to be common.

Anecdotal evidence also suggests that there are categories, denoted 2a and 3a in Table 1, where a LFN was present but has disappeared by the time of the investigation although the disturbance continues. A likely mechanism for the delayed responses in such cases is a cycle of increased auditory gain and anxiety (see Chapter 3) which can potentially be reversed by appropriate techniques ported from tinnitus/hyperacusis therapy. Therefore, cases of this type are considered appropriate for this approach. In practise such cases are unlikely to be distinguishable from No Noise Found cases.

At this point we should also consider the ethical implications of including cases of the various types. In Nuisance cases the onus for mitigation should be firmly placed on the person causing the nuisance according to the widely accepted 'polluter pays' principle. Therefore, it would be inappropriate, indeed unethical, for referral onto the scheme to be seen as an 'easy option' in lieu of proper assessment and control of the source of LFN. A straightforward safeguard is to exclude Nuisance cases from the study.

A related issue is the need to avoid inappropriate 'medicalisation' of complainants, particularly in cases where there might be a straightforward explanation of the complaint. This issue is not always clear cut however, and it should be noted that the complainants themselves articulate their situation as being one of "illness" or physical distress. We note that the problem of medicalisation can be minimised by ensuring that all possible avenues for locating a source of LFN have been exhausted prior to acceptance onto the scheme. One way to realise this is for EHOs to follow the

'Procedure for the assessment of low frequency noise complaints' (A. Moorhouse, D. Waddington, & M. Adams, 2005a) which is designed for this purpose.

2.2 How complaints about LFN are handled

It is appropriate at this stage to describe how complaints received by EHOs about LFN are handled. It will be seen in section 7.1 that there is some variation in practice amongst EHOs. In part this will reflect the variety of cases with which they are presented (see Chapter 6) but there may also be local variations in policy. Therefore, a definitive description of the response to complaints is not possible although the underlying structure, illustrated schematically in Figure 1, is common.

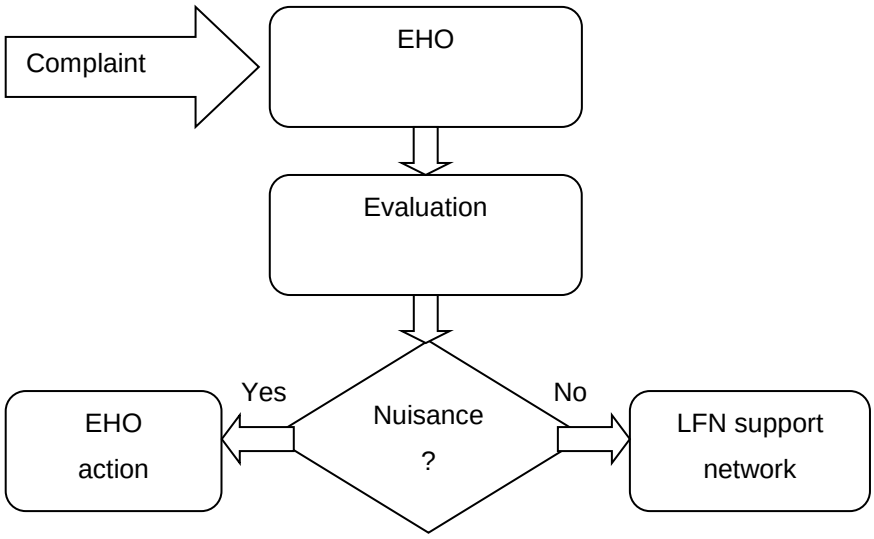

Figure 1: Schematic of the path of an LFN complaint

A local authority receiving a complaint about noise (including LFN) will usually first conduct an evaluation in order to determine whether the noise constitutes a 'statutory nuisance' (see Figure 1). Once satisfied that a statutory nuisance exists, the Environmental Protection Act 1990 requires the local authority either to serve an abatement notice, or *'to take such other steps as it thinks appropriate for the purpose of persuading the appropriate person to abate the nuisance or prohibit or restrict its occurrence or recurrence.'*

If no statutory nuisance exists then the local authority is not obliged to take further action or to investigate further and is entitled to close the file. As described in section 2.1, LFN cases of this type are the focus of the project. In practise, there are various reasons why closing an LFN case may be difficult.

First, there is the question of the criteria adopted for assessing whether the noise constitutes a statutory nuisance. For general noise complaints (not LFN), guidelines are available and there is significant experience amongst EHOs in their application and interpretation, as well as a large body of case law. Therefore, the EHO is in a reasonable position to reach a clear and informed decision. For LFN cases on the other hand this situation is more difficult. Although guideline criteria are given in the Defra guidance (A. Moorhouse, D. Waddington, & M. Adams, 2005a) these are not presented in the form of strict nuisance criteria and furthermore there is a lack of test cases so the EHO cannot be confident of the outcome should the case end up in court.

Secondly, there is the issue that if an EHO considers that the noise would not disturb an 'average' person then they would be unlikely to classify it as a statutory nuisance. This situation could occur if the complainant were particularly sensitive to the LFN. Note, as mentioned earlier, that there is no implication of unreasonableness in the case of LFN complaints - possible causes for enhanced sensitivity to LFN will be discussed in Chapter 13.

Thirdly, a characteristic of LFN complaints is the high level of distress of the sufferer and the vociferousness of the complaint. Faced with such compelling personal evidence of distress, an EHO may be inclined to question whether they had missed something and to carry out further investigations. The potential for uncertainty is exacerbated by the fact that there are various technical difficulties in measuring LFN (Leventhall, 2003).

For the above reasons, LFN complaints tend to consume more EHO resources than do other (not low frequency) noise complaints. The 'Procedure for assessment of low frequency noise complaints' (A. Moorhouse, D. Waddington, & M. Adams, 2005a) was published by Defra in 2005 so as to provide guidance to EHOs and to increase their confidence in making assessments. However, it is less familiar to EHOs than other guidance and indeed not all are aware of it, partly because LFN complaints are not everyday occurrences and partly because the guidance is not mandatory. For those unaware of the guidance, the above problems are likely to persist. Those using it should benefit from increased confidence in their decisions. However, even in these cases there remains an issue about how to help the complainant (see Figure 1) which this project aims to address.

2.3 Studies of LFN complaints

There is a large amount of literature relating to low frequency noise disturbance.

However, it is not necessary to conduct a comprehensive appraisal since good reviews are already available (Berglund, Hassmén, & Job, 1996), (Leventhall, 2003). In this section we will review published surveys of LFN complaints.

Persson and Rylander (Persson & Rylander, 1988) surveyed all 284 local authorities in Sweden with a follow up study conducted some years later amongst 41 authorities (Persson-Waye, K; Bengtsson, 2002). They found LFN complaints to constitute a significant proportion of all noise complaints. The main sources were ventilation, heat pumps and traffic. Another survey of local authorities was conducted by Tempest (Tempest, 1989) who surveyed 242 local authorities in the UK, about half the total number. From the responses he was able to estimate that there were 526 complaints per year in the UK of which 88% were solved. However, whereas cases with no obvious source (No Noise Found) are of most interest in this report, Tempest's questionnaire was aimed primarily at estimating the number of sources of LFN and possibly excluded some of the No Noise Found category.

In Poland the health effects of LFN were studied in a group exposed to LFN and a control group, matched in gender, age and living accommodation, who were exposed to similar overall noise levels but without low frequency content (Mirowska, 2001). Although few details of the analysis are given, it was concluded that LFN could be very annoying even at levels close to the detection threshold and more significantly, various (non-physiological) health effects were also claimed including creating or intensifying a depressive state, and self-reported health.

Around the same time (Persson Waye, K; Rylander, 2001) conducted a study of 279 randomly chosen persons exposed to heat pump and ventilation noise in their homes of which 108 were exposed to noise of a low frequency character and the remainder acted as a control. The health effects found by (Mirowska, 2001) were not reproduced on the whole although annoyance, disturbed concentration and disturbed rest were significantly higher in the low frequency exposed group.

A field study of eleven cases of LFN complaints was conducted in the UK by Moorhouse et al (A. Moorhouse, D. Waddington, & M. Adams, 2005a) during the development of an assessment protocol for EHOs. In three out of the eleven cases an external source of LFN was detected and in five cases no source could be found, the remaining three cases being borderline. A further six cases were investigated in order to test the protocol (A. Moorhouse, D. Waddington, & M. Adams, 2005b) in two of which a source of LFN was located, no source being found for the remaining four.

Therefore, out of a total of seventeen cases, a minimum of nine and a maximum of twelve cases fall into the category of 'No Noise Found' (see section 2.1).

A postal survey of LFN complainants was conducted in Denmark in 2002 (H Møller & Lydolf, 2002). 198 respondents reported sounds as deep humming or rumbling. Most reported hearing the sounds but others mentioned a perception of vibration either in their body or in external objects. Secondary effects such as insomnia, headaches and palpitations were often associated with the sounds. In a proportion of cases, surveys were conducted which generally showed levels to be at or below hearing thresholds. Thus, most of these would appear to be of the No Noise Found type.

Pederson et al conducted a survey in which 21 LFN sufferers participated in matching tests in which the sound from their homes was recorded and played back to them in the laboratory (Pedersen, Henrik Møller, & Waye, 2008). For seven (33%) of the subjects the annoyance was determined to be caused by a physical source. However, eight of the subjects reported a noise when none was present. These proportions are similar to the findings of (A. Moorhouse, D. Waddington, & M. Adams, 2005b) reported in the previous paragraphs in that for approximately one third of sufferers no source could be found although the disturbance continued. The authors attributed unsolved case to tinnitus, although it should be noted that this conclusion was arrived at by process of elimination without independent confirmation of the actual mechanisms. Therefore, tinnitus is one possible explanation but another mechanism could be that put forward in Chapter 3.

2.4 Characteristics and possible causes of LFN complaint

Characteristics of LFN complaints are well described in (Leventhall, 2003). Complainants tend to describe humming or rumbling often accompanied by a feeling of pressure on the ears or vibration in the body. The sound may be likened to a distant diesel engine. Most sufferers hear the noise at home, although some also hear it elsewhere, and it tends to be worse at night. The level of distress is high and complainants report being unable to escape from the sound.

Sleep disturbance is commonly reported as are dizziness, headaches, palpitations and loss of concentration. A number of health and psychological factors are also related to low frequency sound exposure in the literature although mostly the studies were conducted at higher sound levels than would be found in the home.

Typically two thirds of LFN complainants are women and the average age is around 55 (Pedersen, Henrik Møller, & Waye, 2008), (Leventhall, 2003), although this profile may not be significantly different to the profile of complainants about general noise (not LFN). 24%-40% say only they can hear the noise (Pedersen, Henrik Møller, & Waye, 2008), (H Møller & Lydolf, 2002).

In laboratory tests, LFN complainants have been found to set thresholds of acceptability closer to their hearing threshold than control subjects (e.g. their tolerance of LFN is reduced) although in absolute terms their hearing is not significantly more sensitive than an average population (Inukai, Taya, & Yamada, 2005), (A. Moorhouse, D. Waddington, & M. Adams, 2005b), (Leventhall, 2003).

Possible causes of these characteristics were systematically evaluated by (Leventhall, 2003). Abnormally acute hearing was discounted since sufferers' hearing thresholds were found to vary much like the rest of the population. Other means of perception, specifically through the skin and through resonance of the chest were not thought to be responsible since tests with profoundly deaf subjects revealed that hearing was the most sensitive mechanism of perception even at low frequency. Although chest resonance is commonly felt when exposed to loud music, the levels involved are very much higher than those found in the homes of LFN complainants.

Levels of exposure were considered too low for the symptoms to be caused by electromagnetic radiation and synaesthesia was also not considered a strong candidate. Low frequency tinnitus was thought to be a possible factor in some cases but was difficult to separate from LFN. Leventhall concluded that 'enhanced susceptibility' is a possible factor in explaining the above characteristics and this explanation is also consistent with the model proposed in Chapter 3.

2.5 Therapeutic approaches to LFN complaint

Little previous work has been done regarding the possibility of helping persons with a complaint of LFN. That which has been undertaken has been led by Dr Geoff Leventhall, and has investigated the application of Cognitive Behavioural Therapy (CBT) to LFN complaint.

Cognitive Behaviour Therapy (CBT) is based on the work of (Beck, 1976), and derives from the proposal that people can experience persistent distress because of overly negative interpretations about symptoms or sensations (MacKenna L;

O'Sullivan A, 2009). In practice CBT involves applied relaxation, positive imagery and restructuring of cognitions (beliefs). A recent meta-analysis (Hesser H; Weise C; Westin VZ; Andersson, 2011) has indicated that CBT can be applied to tinnitus, with benefits including reduction in associated distress: the perceived loudness of the tinnitus is unchanged however.

In the first of two studies, (Leventhall, Benton, & Robertson, 2008), (Leventhall, 2009) used CBT techniques in a group setting upon 9 LFN sufferers. The therapy was led by an experienced psychotherapist, and consisted of six two-hour sessions. The objectives were: *" to improve the participants' coping strategies and their quality of life, in order to relieve them from some of the distress caused by their belief that they were exposed to low frequency noise."* (Leventhall, Benton, & Robertson, 2008).

The sessions included relaxation techniques, some imaginal exposure techniques, and some aspects of Neural Linguistic Programming (NLP) were discussed. Before and after questionnaires were applied, measuring quality of life, coping strategies and specific aspects of reaction to LFN. These metrics generally improved, though no statistical analysis was undertaken.

A follow on study (Leventhall, 2009) further considered the application of CBT in the LFN complaint population, on this occasion by the delivery of an on-line course (which was supported by printed material for persons without internet access), and supporting relaxation CD material. From 53 persons who contacted the team after the course had been publicised, 46 agreed to participate, and 40 completed the initial questionnaires. 27 individuals completed the course, which represents 49% of the initial enquirers, and 67% of those who started the course. Statistical analysis of the questionnaire data from those who completed the course indicated significant improvement. The authors noted:

> *"prospective candidates for participation appear to vary in terms of their suitability for this kind of support, although we believe that most can potentially benefit. It is possible that preliminary assessment could better predict the likelihood of a positive outcome…"* (p42)

From these important studies a number of themes emerge:

- Not all those who identify themselves as LFN sufferers seeking help are able to access formal psychological therapy
- In those who can, the CBT components of informational counselling,

relaxation and of cognitive restructuring can confer improvement

- There are indications that whilst on-line or printed material can be helpful, there is a role for assessment in person in this group.

3 LFN complaint: auditory neuroscience perspectives

The aim of this chapter is to describe current auditory neuroscience understanding of human hearing and the possible implications for LFN complaints.

A modern understanding of human hearing considers not only the traditional auditory pathway, from cochlea to auditory cortex, but also the interfaces between hearing and systems of emotion and reaction. As will be described below, it is believed that these have developed due to the function of the auditory system as an early warning danger detection system, able to rapidly activate systems of reaction and arousal to an intrusion or potential danger. An underlying proposal of the project was that this understanding of hearing could be mapped on to the experience of LFN complainants, and that this might lead to a novel approach to assistance in that situation.

The traditional understanding of the anatomy and mechanisms of human hearing can be expressed as follows (see Figure 2). The pinna draws sound into the external auditory meatus (EAM), which is resonant at 3-6 kHz in the adult human. The tympanic membrane (TM) collects sounds and transmits it to the malleus, the first of the three ossicles. These (malleus, incus, stapes) are the smallest bones in the human body, and form a cantilevered bridge across the air-containing middle ear. The middle ear is ventilated through to the nasopharynx by the Eustachian Tube, which opens when the individual coughs, swallows or sneezes. The function of the middle ear system is to act as an impedance matching transformer between the vibration of sound in the EAM and the fluid within the cochlea.

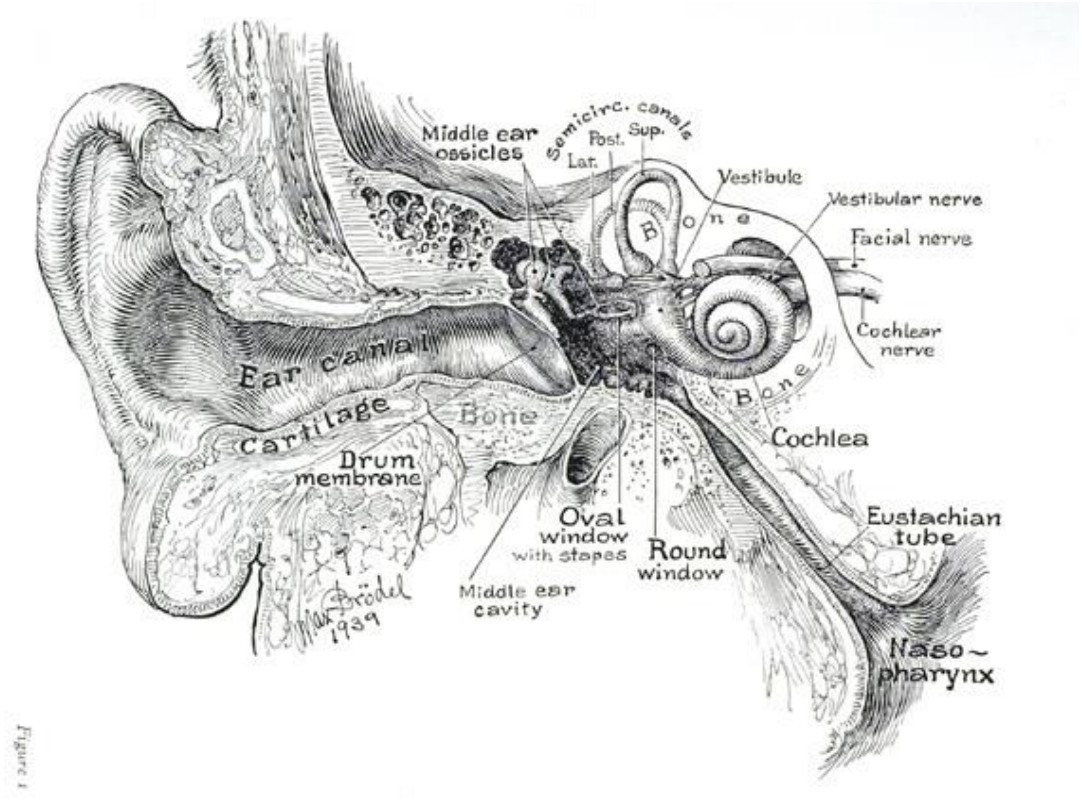

Figure 2: Figure one: The human ear (Brodel, 1946)

Cochlos is the Greek for snail, and the cochlea is a snail shell like structure which transduces sound from vibrational energy into patterns of neuronal energy that the auditory brain can interpret. About the size of a garden pea, and placed behind the eye, the cochlea has often been described as the "organ of hearing": whilst the function of the cochlea is fundamental to hearing, this description does not do justice to the functions of the auditory brain.

Within the spiral coil of the cochlea (Figure 3) there is a central membrane (the basilar membrane) that vibrates with sound, and for a sine wave a standing wave forms with high frequency sound stimulating the basal turn, and low frequency sound stimulating the apicial turn. This counterintuitive arrangement is best understood with the analogy of a skipping rope run along a gym floor: fast (high frequency) undulation dies out quickly, only activating the first few feet of the rope, whereas slower (low frequency) undulation whips up the far end of the rope.

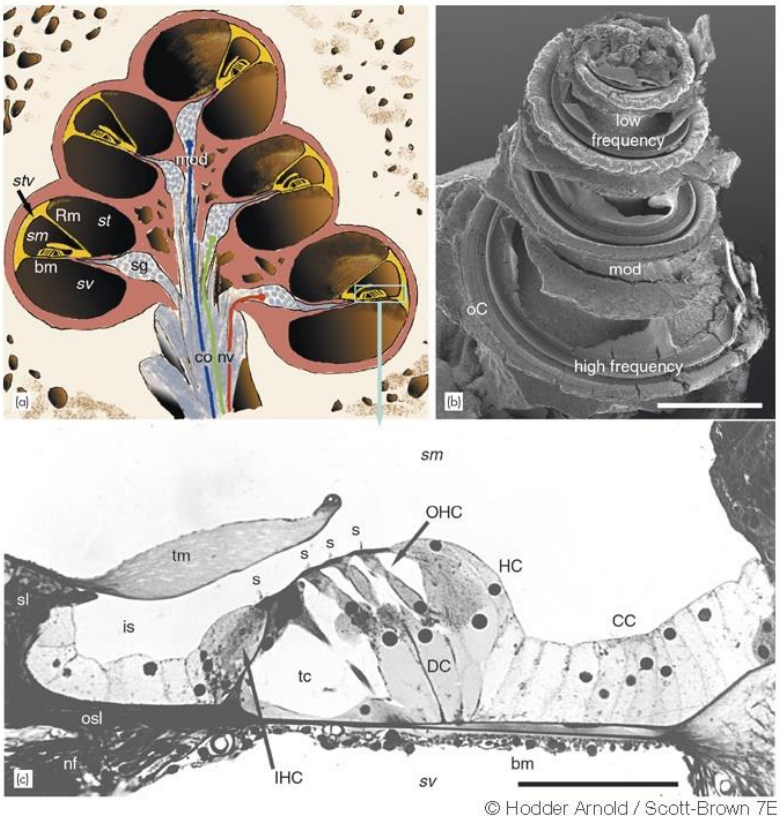

Figure 3: A schematic cross section of the cochlea in situ. The cochlear duct, sectioned in five places, contains three longitudinal chambers, scala tympani (st), scala vestibuli (sv) and scala media (sm) bounded by Reissner's membrane (RM), the basilar membrane (BM) and the stria vascularis (sv). The central bony axis of the spiral, the modiolus (mod) contains the spiral ganglion (sg) composed of bipolar neurones that peripherally innervate the hair cells and centrally form the cochlear nerve (co nv). Afferent fibres representative of low (blue), middle (green) and high (red) frequency illustrate the tonotopic arrangement within the nerve/ The sensory epilthelium is indicated by the blue box in one section. (b) scanning electron micrograph of a dissected guinea pig organ of Corti (oC) showing its location spiralling around the modiolus (mo). As indicated, high frequency sounds are detected near the base of the spiral, and low frequencies near its apex. (c) light micrograph of the region represented by the blue box in (a). The basilar membrane (bm) stretches from the osseous spiral lamina (osl) to the spiral prominence. Nerve fibres (nf) enter through the osl, underneath the spiral limbus (sl) and inner sulcus (is). The organ of Corti lies on the basilar membrane and contains one row of inner hair cells (IHC) separated by the tunnel of Corti (tc) from three rows of outer hair cells (OHC) Stereocilia (s) project from the hair cells towards the tectorial membrane (tm) which has retracted from its contact with outer hair cell stereocilia during the processing for histology. The outer hair cells are supported by Dieter's cells (DC) and outside of both are Hensen's cells and Claudius's cells (cc). From Furness D, Hackney C (2008) Form and ultrastructure of the cochlea and its central connections, in Gleeson MJ, Clarke RC (eds) Scott-Brown's Otolaryngology 7th E, figure 226.10 permission granted.

Within the basilar membrane are two types of specialised nerve cells that are involved in the transduction of sound in different ways. These are entitled "hair cells", and this name has passed into popular parlance, but is entirely a misnomer as they resemble hair in neither appearance nor structure. There are two such types of hair cells, named "inner" and "outer" for their position relative to the centre of the spiral coil of the cochlear. The inner hair cells (IHC) (Figure 4) are highly sensitive to the sound induced vibration of the basilar membrane, and are tuned to specific frequencies. The outer hair cells (OHC) (Figure 5) are, in contrast controlled by innervation down from the brain – and until recently this was not a well understood function. It now transpires that the role of the OHC is to optimise the response of the cochlea to low intensity sound: and that this is accomplished by the OHC having a motile function. An analogy is again useful: imagine an IHC as a small child bouncing lightly on a trampoline (as if in response to low intensity vibration). A big brother (e.g. an OHC) joins him, and the smaller child bounces higher and higher: so the contribution of the OHC means that IHC are more responsive to sound of low intensity. This active mechanism of the cochlea was missed by early in-vitro investigations of cochlear physiology as it requires IHC and OHC, and is sufficiently robust as to generate a measurable amount of sound from the cochlea (otoacoustic emissions, which are used to test the cochlear function of newborn babies).

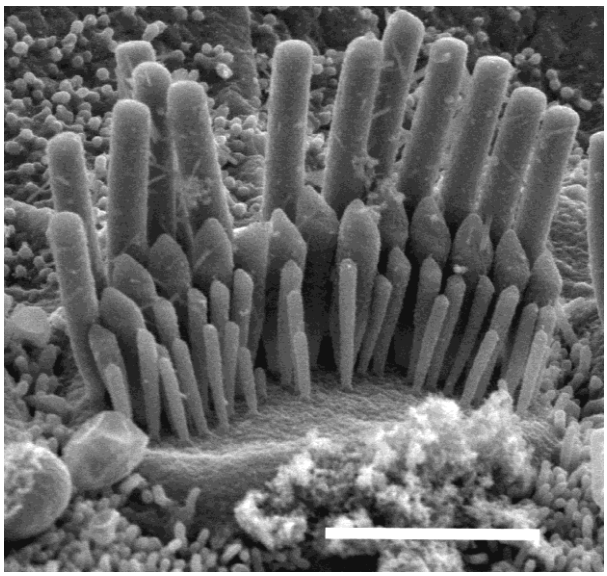

Figure 4: Scanning electron microscopic view of the stereociliary bundle of a mouse inner hair cell. The stereocilia are tiny hairs projecting from the top of the hair cell and arranged in rows of increasing height across the bundle, forming a relatively linear array. Scale bar = 2 um. Previously unpublished image provided by Prof DN Furness and Prof CM Hackney, University of Keele.

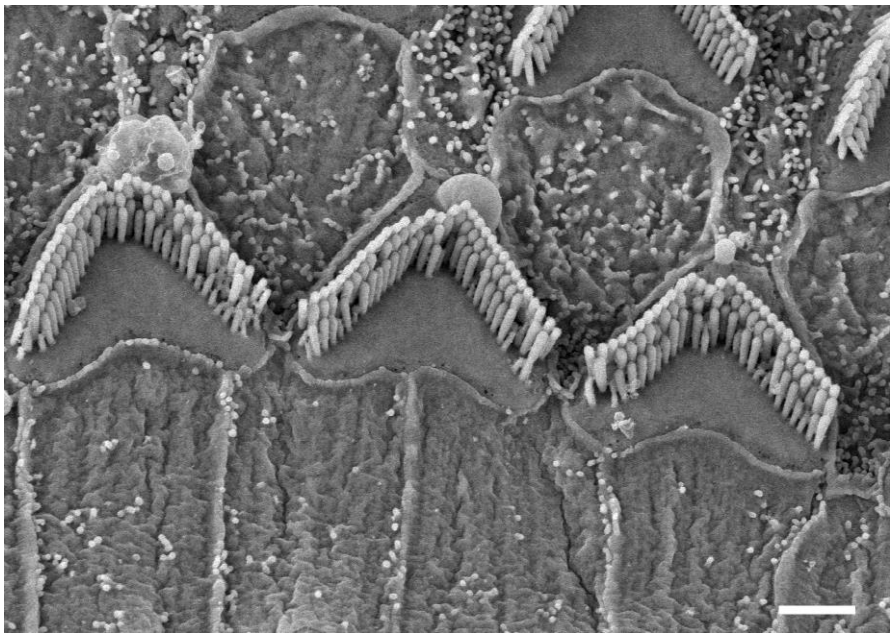

Figure 5: Scanning electron microscopic view of several stereociliary bundles of mouse outer hair cells. The stereocilia are arranged in rows of increasing height like those of the inner hair cell but forming a W-shaped array. Scale bar = 2 um. Previously unpublished image provided by Prof DN Furness and Prof CM Hackney, University of Keele.

The IHC synapse with cochlear (auditory) nerve fibres, and signals are then transmitted into the central auditory system. Key structures have been identified within the brainstem (Figure 6) concerned with the localisation of sound, and within the midbrain with the perceived intensity and importance of sound. The flow of sound continues up into the auditory cortex, where meaning is ascribed to sound, and the association cortical areas have a function in the interpretation of speech and music.

This, or similar, would have been the description of the auditory pathway until recently. A modern understanding would also want to consider the connections between brainstem hearing centres and systems of reaction and arousal. Specifically, these involve the sympathetic autonomic nervous system, which instigates a fight or flight reaction to a threatening sound, and the reticular formation, which regulates arousal and sleep under the influence of sound. One only has to briefly consider how sounds affect human arousal and agitation to see how fundamentally these interactions between hearing and reaction can influence human arousal and behaviour. An example of this is the immediate agitation and arousal associated with thinking one has heard the footstep of an intruder in the hallway when lying in bed at night. These interactions occur below the level of the ascription of meaning in the sense of speech or music, but are able to recognise sound as potentially intrusive or threatening. In the case of predators, sound generated by a successful animal would be of very low

intensity, and a potential prey animal would need a vigilant auditory system to detect and rapidly react to the sound.

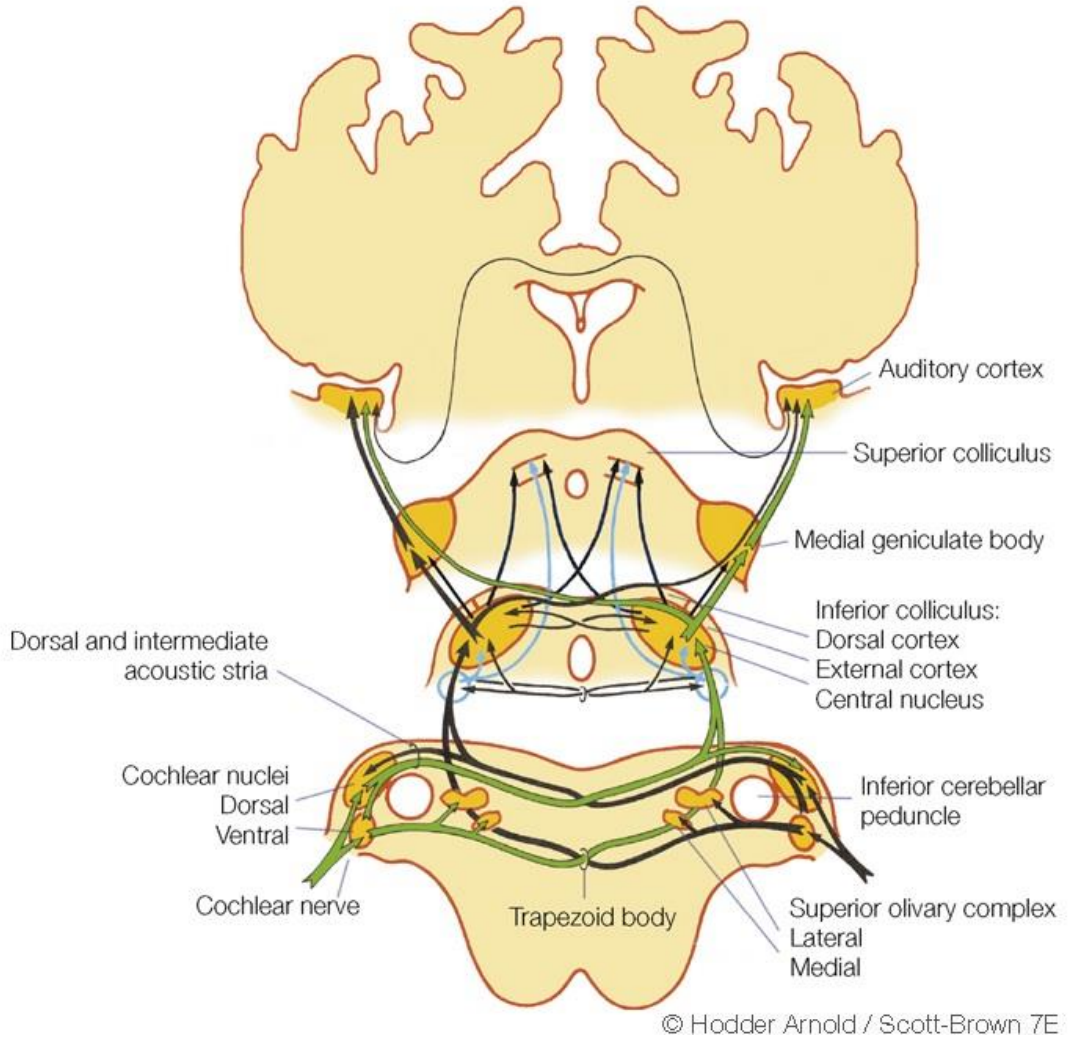

Figure 6: The ascending auditory pathway. Schematic diagram of the auditory pathway represented in slices of the cerebellum (upper), midbrain and brainstem. The main nuclei between the cochlea and cortex are shown (orange), the major pathways from each cochlea are coloured black and green respectively. More minor pathways are represented with finer arrows. From Furness D, Hackney C (2008) Form and ultrastructure of the cochlea and its central connections, in Gleeson MJ, Clarke RC (eds) Scott-Brown's Otolaryngology 7th E, figure 226.2 (a) permission granted.

This view of human (and mammal) hearing has largely derived from the study of patients with troublesome tinnitus. Such persons can be very agitated and distressed, and the extent of their distress bears little relation to the cause or matched intensity of their tinnitus (see (Andersson, Baguley, McKenna, & McFerran, 2004) for review). Whilst many people who experience tinnitus seem not to be troubled by it, those who are become to exhibit a perplexing mixture of agitation, poor concentration and

insomnia, and there is a consensus that this is best explained by models that invoke links between the auditory system and the emotional brain. Whilst there is no one-off intervention that inhibits the perception of tinnitus percepts completely and permanently (hence "no cure"), there are therapies involving sound, counselling and relaxation that can improve quality of life in such cases. What such approaches hold in common is their invocation of the principle of habituation: that being the process by which human senses filter out background and non-threatening stimuli (including sound). Habituation avoids humans being overwhelmed by sensations such as the shoes on ones feet, or the shirt on ones back: and also allows people to live next to noisy railway lines or near airports whilst largely unaware of the noise.

The usual components of tinnitus therapy are detailed in Table 2. Whilst individual clinicians and therapists may give different emphases to some elements over others, there is an emergent consensus that by understanding the situation, and by moderating the adverse reaction to the tinnitus, that quality of life can be improved. The delivery of such therapy can also vary: self help literature is popular, see (McKenna L; Baguley DM; McFerran, 2010) for example, internet delivery of therapy has been trialled with variable success (Kaldo et al., 2008), (Abbott et al., 2009), and group therapy can be undertaken (Searchfield G, Magnusson J, Shakes G, Biesenger E, 2011). Empirical evidence for the effectiveness of these varied approaches to tinnitus therapy is sparse, and it remains usual practice for therapy to be delivered on a one to one basis with 80% of UK clinician delivered tinnitus therapy delivered in this manner (Hoare, Gander, Collins, Smith, & Hall, 2010).

Table 2: Components of therapy for tinnitus

Understanding: may also be called *counselling,* and involving specific descriptions of a persons hearing, and the mechanisms of tinnitus, and the development of associated distress
Management of reaction: often some form of relaxation therapy, and techniques to reduce anxiety
Sleep management: may involve the use of bedside environmental sound generators, and techniques to improve sleep quality (sometimes called *sleep hygiene*)

Another symptom that is often associated with tinnitus is that of hyperacusis, in which a person finds that sound intensities that many people can easily tolerate are uncomfortably loud and distressing. Such people often withdraw from everyday

activities and relationships, and become fearful of sound, which can further exacerbate the problem. It is presently thought that the central sensitivity of the auditory system is dynamic: meaning that it can change according to the sound environment. Thus in very quiet surroundings auditory sensitivity (or gain) is maximised, and in louder surroundings it is minimised. In persons with hyperacusis the proposal is that central auditory sensitivity is consistently on maximum, and unable to change dependant upon surroundings, so that sound of even moderate intensity is perceived as loud and distressing. The discomfort evoked may make the person distressed and anxious (modulated by the sympathetic nervous system), which further increases the sensitivity of the auditory system.

How then can these understandings of tinnitus and hyperacusis inform an understanding of LFN complaint? From the description in Chapter 2 it will be apparent that there are some marked similarities between the experiences of troublesome tinnitus and hyperacusis, and of complaint of low frequency noise in the absence of any measureable stimulus. The distress may be substantial, and involve agitation, anxiety and irritability. The signal itself may be small, or may be the perception of unremarkable levels of environmental LF sound exacerbated by increased central auditory gain. It appears that there may be a vicious circle between the LF perception and the distress that this evokes. As with tinnitus and hyperacusis there is no suggestion that either the person's belief that they are experiencing significant LF noise, or that the distress evoked are not genuine: clearly they can both be very substantial and life defining.

From these reflections it is possible to propose how LF perception and associated distress can develop (Figure 7). In Figure 7a the relationship described above between hearing and systems of reaction is illustrated, and in Figure 7b the pleasurable effect of listening to music is shown. The situation in which unremarkable LF environmental sound is filtered by the auditory system, and thus evokes no emotional or behavioural reaction is illustrated in Figure 7c: essentially the system has habituated to whatever background activity there is. In a person in whom this filtering has failed and/or in whom there is increased auditory sensitivity to LF environmental sound (thus a similar situation to hyperacusis, but to LF sound only), substantial emotional and physical responses may develop, and may further exacerbate the LF awareness, and these vicious circles are illustrated in Figure 7d.

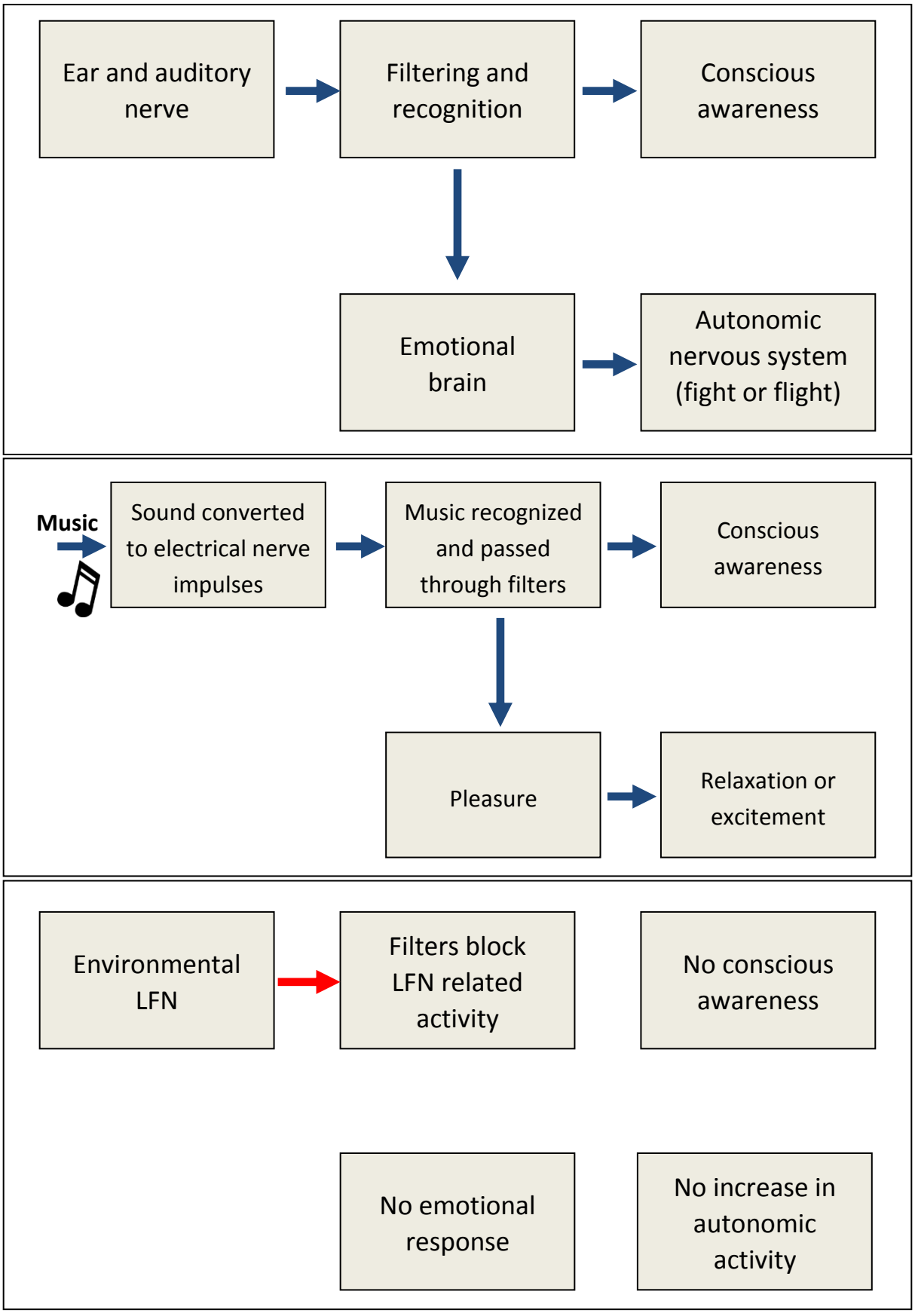

Figure 7a, Figure 7b, Figure 7c

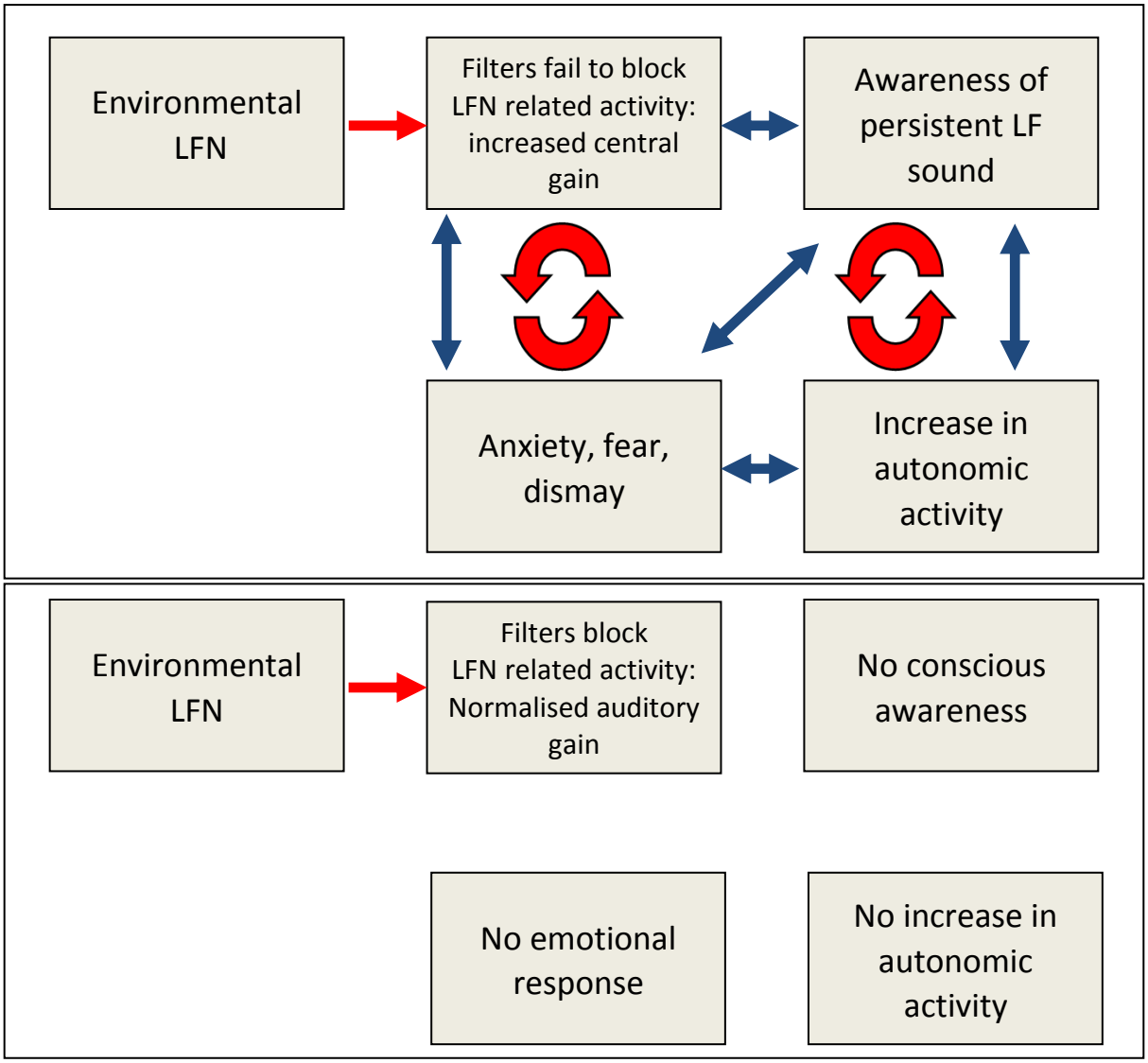

Figure 7d, e: Schematic diagrams of the development of distress and arousal to a perceived sound and to LFN. Adapted from (McKenna L; Baguley DM; McFerran, 2010) permission granted

The similarities between LFN complaint and the experiences of people with tinnitus and hyperacusis may lead to an opportunity to improve the situation. As described above, whilst the ability to completely inhibit tinnitus eludes the clinical world, therapies do exist to promote habituation. Figure 7e illustrates what may occur if a person with LFN associated distress were able to habituate to their LFN perception.

Thus, Figure 7 defines the hypothesis for this study and provides the justification for the use of tinnitus and hyperacusis approaches for use with LFN complainants.

4 Survey of LFN complaints in an audiology context

The first step in the setting up of the trial network was to identify suitable tinnitus treatment centres. For this purpose a UK-wide survey of audiology clinics was undertaken. A total of 289 letters were sent to Audiology Heads of Service inviting recipients to take part in the study and requesting the following information:

- Number of tinnitus patients seen per year:
- Number of hyperacusis patients seen per year:
- Number of LFN complaint patients seen in last year:
- How many of the LFN cases (if any) were referred from an Environmental Health Officer

From the 289 letters sent, 44 replies were received (15%) of which 37 (13%) wanted to take part in the study. This positive response, somewhat higher than would generally be expected from an unsolicited survey, is in itself an interesting statistic: it reveals a willingness amongst tinnitus specialists to engage with LFN complainants to an extent that might surprise many EHOs. Of the 17 departments who did not wish to take part 11 did not give a reason. Of the remaining six, three expressed interest in the study but were unable to take part due to being new in their post, conflict of interest or having no referrals to offer. Two declined due to low staffing and discontinuation of the audiology service and the remaining one wanted further information to make a decision.

4.1 Results and analysis

The estimated number of cases from the 32 centres who provided information is summarised in Table 3. Note that one centre reported 10-15 LFN cases per year which seems implausible since the next highest number was five and the average less than one. Excluding this figure gives a total of 34 cases from 31 centres for LFN, an average of 1.1 cases per therapist.

Table 3: Estimated number of cases seen by therapists in the 32 audiology centres which provided data in the survey.

	Tinnitus cases	**Hyperacusis cases**	**LFN cases**
Total	6,431	752	34
Average per therapist	214	21	1.1

The responses were used to select the centres with most experience of tinnitus and hyperacusis cases. Initially, seven centres were selected in the autumn of 2008, one of

which later withdrew. This met the target of 4-6 centres as specified in the research proposal. Later in the study it became apparent that the number of LFN cases being referred by EHOs was lower than expected. In order to increase the number of participants a further three centres were recruited, two of which had been shortlisted in the initial survey and one of whom who had subsequently heard of the project and asked to be included.

Nine centres eventually participated in the study, eight from England and one from Scotland which gave a reasonable coverage as shown in Figure 8.

Figure 8: Location of audiology centres taking part in the study (map from http://learnhistory.org.uk/)

4.2 Estimate of the number of LFN cases nationally

If one were to consider that the centres that did not complete the questionnaire had no patients with LFN complaint, then it would be the case that the national incidence of LFN complaint leading to referral to Audiology was 34. This would be a lower number than the total number of people with LFN complaint as some may have declined referral to an Audiology Clinic.

Using the survey responses it is possible to make a tentative estimate of the number of LFN cases nationally in a given year. Hoare et al (Hoare, Gander, Collins, Smith, & Hall, 2010) identified 351 clinicians within the NHS in England who either manage or directly provide clinical services for people with tinnitus, of whom 138 returned questionnaires indicating that they were presently active in that field. This number exceeds the number of Audiology Clinics (289 in our survey), and so some will be working in centres with more than one tinnitus-active Audiology clinician. If we make the assumption that the average figure obtained from the survey responses, i.e. 1.1 case per active therapist (n=138), is applicable across England then the estimate of cases nationally is 160. Assuming the population of England to be around 52 million this corresponds to an incidence rate (number per 100 thousand of population) of 0.32

In fact it seems likely that the audiologists who responded to the survey were more likely than average to have had experience of LFN cases. Therefore, this figure is likely to be on the high side as an estimate of the number of cases nationally within NHS clinics.

4.3 Conclusions from survey

To conclude this chapter, the results of the survey revealed a willingness amongst audiologists to engage with LFN complainants that might be counter-intuitive to many EHOs. Secondly, a tentative estimate of the number of LFN cases within the NHS in England is 160 per year which is likely to be on the high side, corresponding to an incidence rate of 0.32.

5 The LFN Network

The aim of this chapter is to describe how the trial LFN network was set up and how the protocol was developed and implemented.

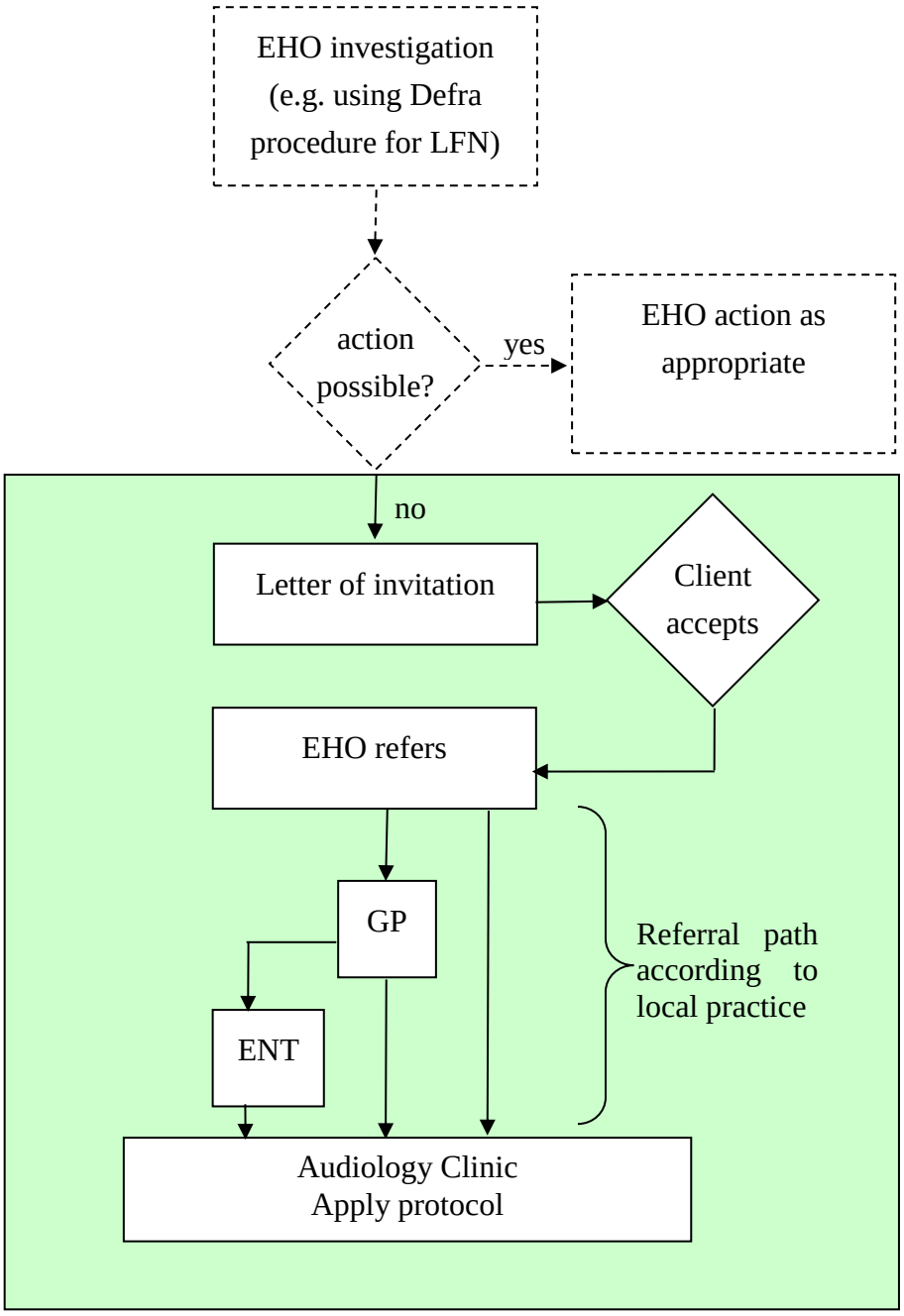

Figure 9: Schematic of referral pathway

5.1 Referral pathway

The LFN network referral pathway is outlined schematically in Figure 9 and consists of the following steps:

- The client registers a complaint about LFN with their local EHO
- The EHO investigates the complaint, preferably using the Defra LFN

procedure (A. T. Moorhouse, D. C. Waddington, & M. D. Adams, 2005a)

- If the case is judged to be a Nuisance case (see section 2.1) the EHO proceeds with their usual protocol
- If the case is judged to be a No Noise Found or a No Nuisance case (see section 2.1) the EHO informs the Client and offers participation in the study (EHO referral letter)
- The client has 28 days to accept the offer
- Upon the Client's acceptance of the offer, the EHO refers the Client to their GP (EHO letter to GP) with a copy to the Audiology centre and enclosing an information sheet for the GP (GP information sheet)
- The GP refers the Client to the Audiology Centre (possibly via ENT according to local practice)
- The Audiologist applies the LFN protocol (see section 5.4).

5.2 Recruitment of participants

Once audiologists at the centres had been trained and ethical approval had been obtained participants could be recruited onto the study. Audiologists contacted EHOs in their area to make them aware of the study. Initially, all audiologists contacted one or two nearest local authorities and in two cases this resulted in sufficient numbers of referrals. In other cases, once it became evident that insufficient case studies were forthcoming, publicity was widened to include a region, comprising around ten local authorities approached via local environmental noise groups. Despite publicity being spread to a wider area than originally anticipated, the number of cases to some centres was still fewer than expected. Whilst this is disappointing from the point of view of testing the protocol, it does provide evidence that the problem is perhaps not as widespread as often thought.

Once contact had been established, EHOs then identified complainants and, if appropriate, made them the offer of taking part in the study. In addition, a number of complainants who had not been referred by EHOs also heard about the study and asked to take part. In the later stages of the project the ethical approval was modified so as to allow these self-referred clients to participate.

A total of 11 clients were referred by EHOs and 3 arrived by independent means giving a total of 14.

5.3 Training

Training was provided to audiologists at two training sessions, the first in November 2008 and the second in February 2010. The latter was organised so as to allow three

new centres to take part in the study in an attempt to increase the numbers of case studies.

The training consisted of the following sessions:

- Sharing of background experience and good practice
- A history of LFN complaints
- An auditory neuroscience perspective on LFN complaints
- Introduction to the project
- Administering the therapy
- Delivering the therapy

During the first workshop the treatment protocol was developed which is described in the following section.

5.4 Protocol and clinical interventions

The main points of the therapeutic approach were developed during discussion at the first workshop in November 2008 and consisted of:

- The exclusion of treatable disease by clinical history (Table 4), otoscopy, audiometry (performed according to British Society of Audiology Recommended Procedures, (British Society of Audiology, 2004)) and ENT opinion as local protocols dictated
- Discussion of the distress and agitation evoked by the perceived LFN
- Environmental sound therapy to reduce the starkness of the signal
- Relaxation therapy to reduce the arousal and agitation associated with the signal
- Identification of those individuals with clinically significant anxiety and/or depression and referral to Psychological Services (using the Hospital Anxiety and Depression Scale, (Zigmond & Snaith, 1983))

Table 4: Themes in clinical history

• Onset of problem • Duration of problem • Description of noise perceived • Beliefs around source of noise • Hearing abilities • Previous ear disease • Impact upon sleep • Impact upon mood • Impact upon quality of life

The envisaged course of therapy typically was to consist of three visits, the first of 1 ½ hours and subsequent appointments of around one hour.

One novel test, referred to as the 'Kenyon Quiet Room Protocol', was developed specifically for the project. It was designed to determine if the client became aware of their LFN within a quiet room which could indicate low frequency tinnitus as a cause.

The LFN treatment protocol is given in Appendix 3 and the Kenyon quiet room test protocol in Appendix 4 (although no results from the latter are presented due to too few tests having been conducted). Informed consent was taken by the audiologist at the first appointment. A copy of the consent form is reproduced in Appendix 2.

The following outcome measures were adopted and performed at the start and end of therapy:

a. Hospital Anxiety and Depression Scale (HADS) questionnaire (Zigmond & Snaith, 1983)
b. Tinnitus Handicap Inventory (THI) questionnaire (Newman, Jacobson, & Spitzer, 1996), but substitute LFN experience for the concept of tinnitus
c. Hyperacusis was measured using a validated 14 item self report questionnaire (Khalfa et al., 2000).
d. EQ−5D questionnaire (*EuroQol--a new facility for the measurement of health-related quality of life. The EuroQol Group*, 1990)
e. Visual analogue scales for: LFN loudness, pitch and distress (Figure 10).

Items a, c and d are validated self-report questionnaires measuring respectively, anxiety/ depression, hyperacusis and general quality of life. Item b is a validated questionnaire to measure the handicap due to tinnitus, but the words 'Low Frequency Noise' were substituted for 'tinnitus'. At the present time there is no specific questionnaire for LFN complaints available and the above group of validated

questionnaires were selected that each catch one aspect of the LFN complaint experience. Item e was developed specifically for the study in order to measure loudness and pitch of the LFN pre and post treatment, as well as the level of distress and is shown in Figure 10.

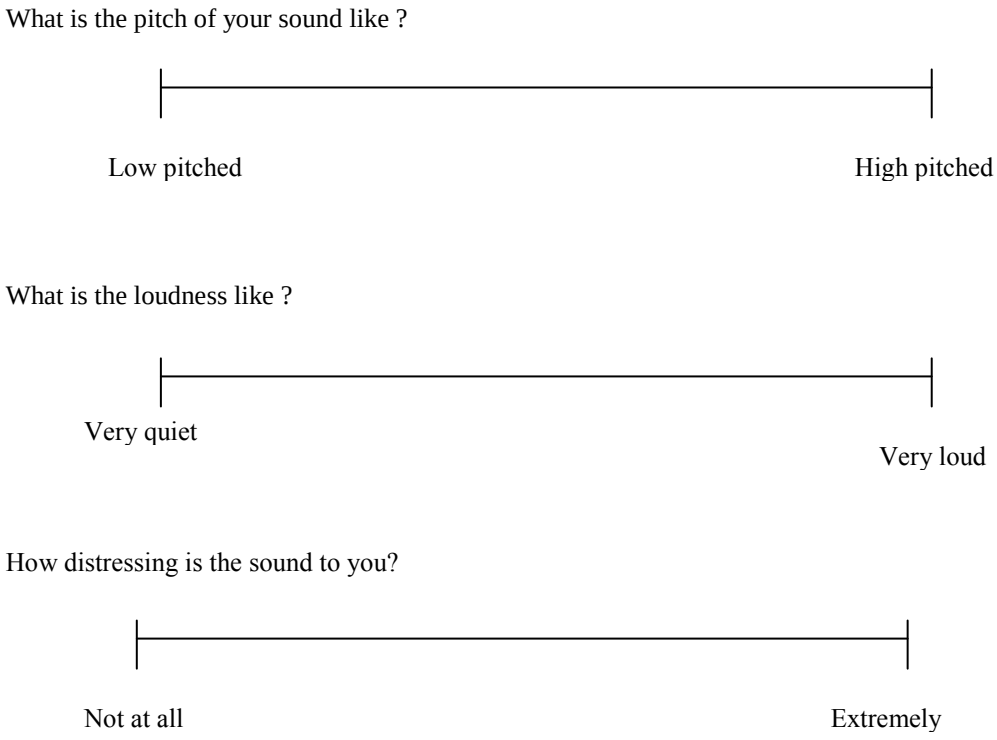

Figure 10: Visual analogue scales developed for use in the study

Qualitative, open questions on: the quality of life, things that impact on quality of life and changes to quality of life since start of therapy were also included as part of the case history.

Therapy was deemed to be complete when the Audiologist and the subject felt that significant progress had been made, and when further appointments were unlikely to add to that. Communication with the General Practitioner was as per local protocols.

To ensure anonymity, a coding system was developed in which clients were identified by a code letter and number. Any data transferred out of the clinic was identified only by the code.

Ethical approval for this multi-centre study was granted by Cumbria & Lancashire B Research Ethics Committee (reference number 09/H1016/86) and additionally by local Research and Development Committees in all sites.

6 Results of trials

In this chapter we present results of the trials, starting with demographic and qualitative data obtained from case notes and then summarising the results of the questionnaires.

6.1 Demographics

A total of fourteen individuals took part in the study, eleven of whom were referred from EHO's to the LFN network and three of whom were self-referred.

Table 5: No of referrals by centre

Centre	**A**	**B**	**C**	**D**	**E**	**F**	**G**	**H**	**I**
Referrals	2	5	2	2	1	0	1	1	0

The mean age of participants was 62 years (range 35-87 years, standard deviation 13.4 years). 8 (58%) of the participants were female and 6 (42%) male. These gender and age distribution figures are broadly consistent with previously reported figures, where an average age of 55 is reported for LFN sufferers, with two thirds female (Leventhall, 2003).

The average length of the complaint prior to seeing the audiologist was 17 months (range 9 to 31 months, standard deviation 8 months). The maximum number of appointments was 5 with a mean of 3 per case.

Table 6: Summary of audiometric data for participants

Hearing loss	Number	% of sample
Nil	2.00	14.29%
Mild	7.00	50.00%
Moderate	1.00	7.14%
Severe	0.00	0.00%
Not available	4.00	28.57%

Audiometric data was available for most cases, the results of which are shown in Figure 11 and summarised in Table 6: 14% had no hearing loss, 50% mild, 7% moderate and none had severe hearing loss: broadly speaking this is consistent with the age profile of the subjects.. This finding is consistent with previous studies which have also reported no particular differences between the hearing of LFN sufferers and that of the general population (Pedersen, Henrik Møller, & Waye, 2008), (Inukai,

Taya, & Yamada, 2005), (A. Moorhouse, D. Waddington, & M. Adams, 2005b).

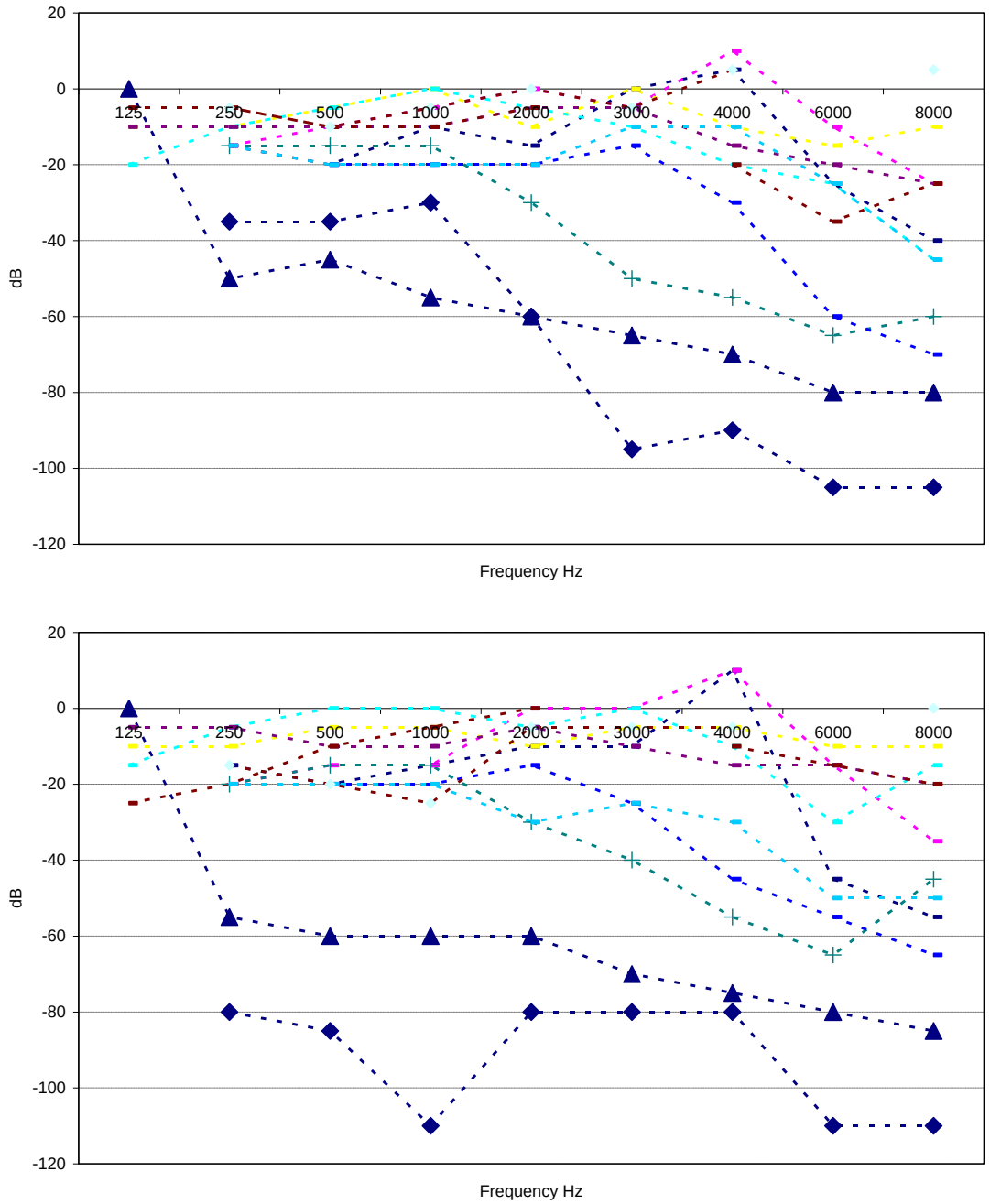

Figure 11: Participant audiograms: upper - right ear, lower - left ear

Nine of the participants (75%) were married or had been married (one was widowed) with no responses for the remainder. In 4 cases (29%) the partner was said to be aware of the sound and in 7 cases (50%) they were not with no record for the remaining cases.

From the population of the districts from which the complainants were referred we can calculate incidence rates of LFN complainants, i.e. the number of referrals per 100 thousand of population. The total population over six districts for which data is available is 1,093,718 from which 11 referrals were made giving an incidence rate of 1.01. This figure is of similar order to the estimated incidence rate for LFN complainants within the NHS in England (see section 4.2). The maximum incidence rate in any district was 2.36. Assuming the population of England as 52 million as above, the average incidence rate would give an estimate of the total number of cases in England as 520. This is likely to be an over estimate: first, no data was provided for districts from which there were no referrals so these populations were not counted in deriving the incidence rates. Secondly, some of the cases had been going on for more than a year, so the incidence rate should perhaps be interpreted as the number of cases being handled at any one time rather than per year.

6.2 Qualitative data

Half of the complainants had a clear idea about the origin of the perceived LFN, the remainder being unsure although all had thought about various possibilities. The likely sources mentioned were digital TV, factories or works, neighbours using machinery, fish tanks or hot tubs, water pipes or heavy duty pumps, telecommunication masts and refrigerators.

EHOs investigated the complaint in all but one case which was self-referred and generally made measurements in the complainants' property. In some cases investigations were also carried out in neighbouring properties or by the utilities companies. In half of the cases measurable LFN was recorded but was not considered actionable by the EHO (No Nuisance cases). Other cases were assessed as No Noise Found.

Some notes were taken of the participants' medical history. As might be expected in a group of this age profile, some, but not all, reported current and previous health issues. Relevant conditions reported include labyrinthitus, brain surgery, Seasonal Affective Disorder (SAD), whiplash and general reports of headaches and pressure on the ears.

Sleep disturbance was significant with 12 subjects (86%) reporting disruption to sleep no results being recorded for the remaining 14% of cases. We can therefore conclude that sleep disruption is of significance for this client group. Generally, the LFN disturbance was perceived as being worse at night and in some cases, only present at

night. Some participants reported getting anxious or worked up before going to bed and even 'dreading' going to bed knowing that they would have to listen to the noise. Measures to try to help sleep included sound generating devices issued by the audiologist (which generate soothing, masking sound) and which were reported to be helpful. A similar type of intervention was to use a radio which was reported to help sleep. Some subjects were reliant on medication to sleep. Some participants had been wearing ear plugs which they were advised to discontinue.

The influence of the perceived LFN on mood was also reported in some cases. Some participants reported finding it draining and trying to avoid being in the home as much as possible. Others said that as the source was a mystery any 'sense of peace' was gone and it felt like the noise was intruding on personal space.

6.3 Results from questionnaires

Charts of pre- and post-treatment scores (where available) for each of the measures are shown in

Figure 12 to Figure 16. Note that the dotted lines joining the data points do not indicate any relationship between subjects but are to help distinguish the before and after results. An improvement for the EQ5D is an increase in scores and for the HADS, THI and Khalfa questionnaires as well as the VAS loudness and distress scales it is a decrease in scores. The VAS 'pitch' results are informative rather than evaluative. Therefore, in total there are seven separate outcome measures.

The most convincing changes seen in Figure 12 to Figure 16 are for subjects A1, D2 and G1. The scores for these subjects move predominantly in a favourable direction with one or two exceptions (there is no improvement in the THI score for D2, VAS scores for A1 or Khalfa for G1). For other subjects there is no change in the scores that seems to be particularly noticeable or consistent. One could even argue a slight worsening of the scores in some cases, for example B4. Thus overall, the charts present a mixed picture with some clients apparently deriving some benefit whilst others did not improve and possibly even experienced a slight worsening. Given the low numbers of subjects, a statistical analysis of the significance of the scores is not appropriate, however, some qualitative observations may be of value.

First, note that the block of subjects B1-B5 were fairly consistent in showing no improvement or a slight worsening. It was later discovered that these clients, all referred from a single local authority, were probably given the impression by the EHO that they were being referred for tinnitus therapy. It had been intended to avoid any inference or presumption that clients were suffering from tinnitus, first, since this is

not necessarily the case and secondly because any sense that they were being labelled as tinnitus sufferers might lead clients to feel that they were being blamed for their own predicament and turn them against the therapy. Whilst the audiologists had been trained to avoid such inferences and have well-developed skills in presenting their therapy to different client groups, the EHOs on the other hand were not given specific training in how to make the referrals and are less used to dealing with clients with sensitive issues of this type. Therefore, it is possible that this group of clients did not engage with the therapy because of a misunderstanding that they were being treated for tinnitus rather than specifically for LFN. Of course it is not possible to guess how things might have turned out had they been handled differently at the referral stage, nevertheless, this experience emphasises the delicacy of the situation and points to an important lesson from the trials, i.e. that clearer instructions should be provided to the EHOs making the referral.

A second point worthy of note is that D1's scores showed a worsening for all measures except general health. In particular, the HADS scores for both anxiety and depression were sufficient to move from a category of 'cause for concern' to one of 'probable clinical case'. This change in category only occurred for this one subject and it is not known what, if any, other factors were involved in creating this shift. Nevertheless, we cannot discount the possibility that the experience of the therapy may be negative for some clients. It should be noted that there is a risk of worsening when a person attempts to address tinnitus, perhaps due to the attention paid to the symptoms.

A third point is that the most convincing cases of improvement, A1, D2 and G1 as mentioned above, corresponded by and large with the most experienced tinnitus therapists. This suggests that greater experience, unsurprisingly, is more likely to produce positive results. However, clearly the therapist is not the only factor involved since D1's scores showed, on balance, a worsening when working with the same therapist as D2.

To summarise, the success of the approach was mixed as might be expected. Nevertheless, the improvement of some clients is positive, particularly in view of the limited alternative options available for this client group. We can infer, again not surprisingly, that the experience of the therapist and the details of the referral are important factors in the potential success of the approach.

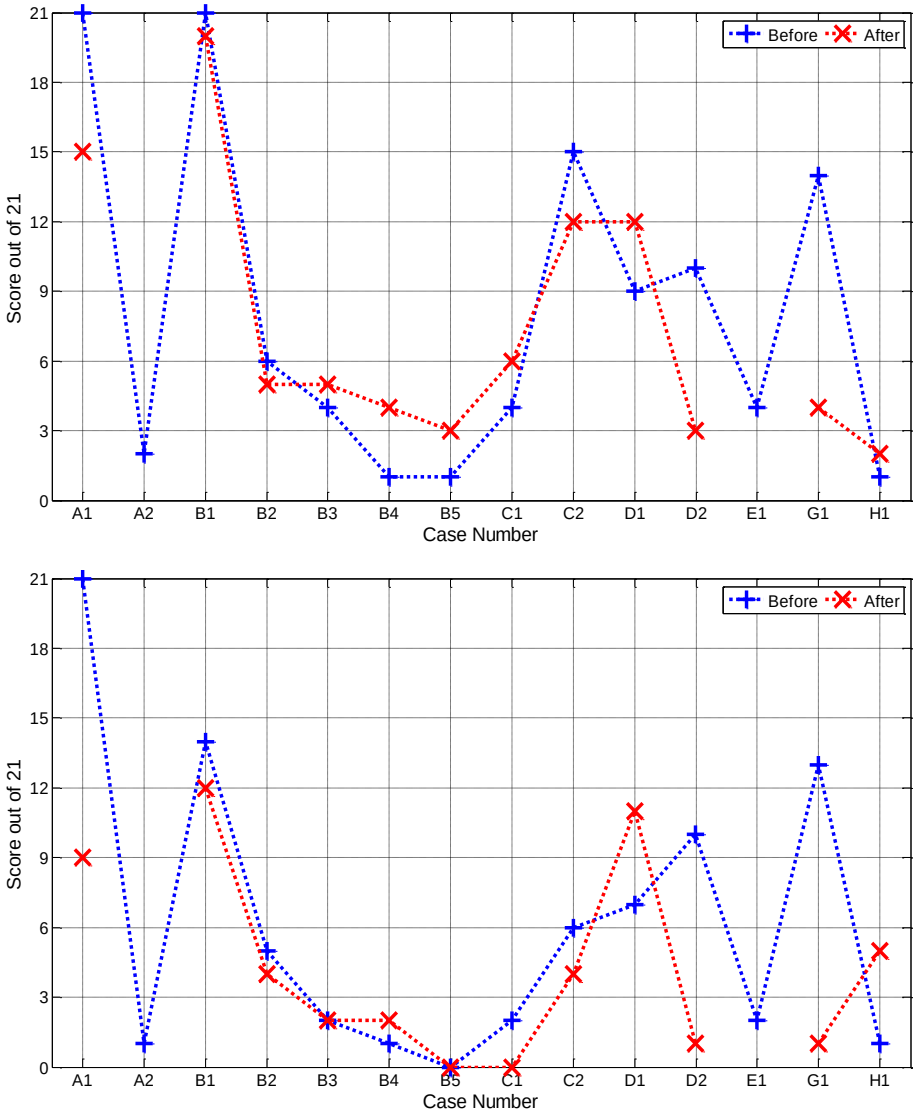

Figure 12: Hospital Anxiety and Depression Scale (HADS) scores: upper – anxiety, lower - depression

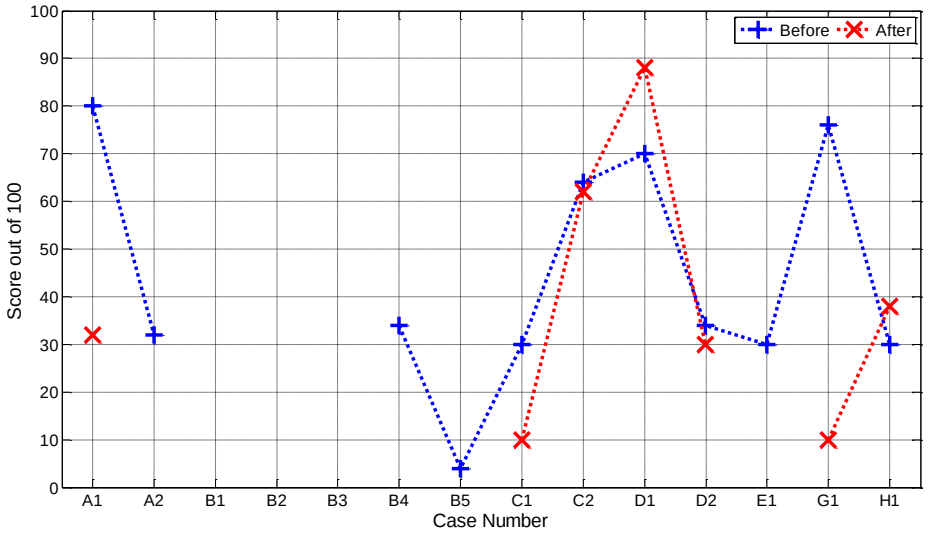

Figure 13: Tinnitus Handicap Inventory (THI) scores

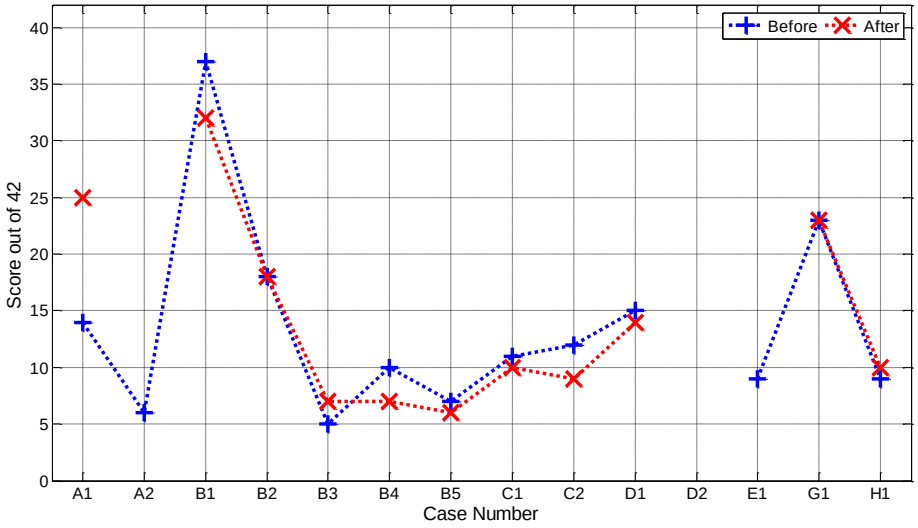

Figure 14: Khalfa hyperacusis scores

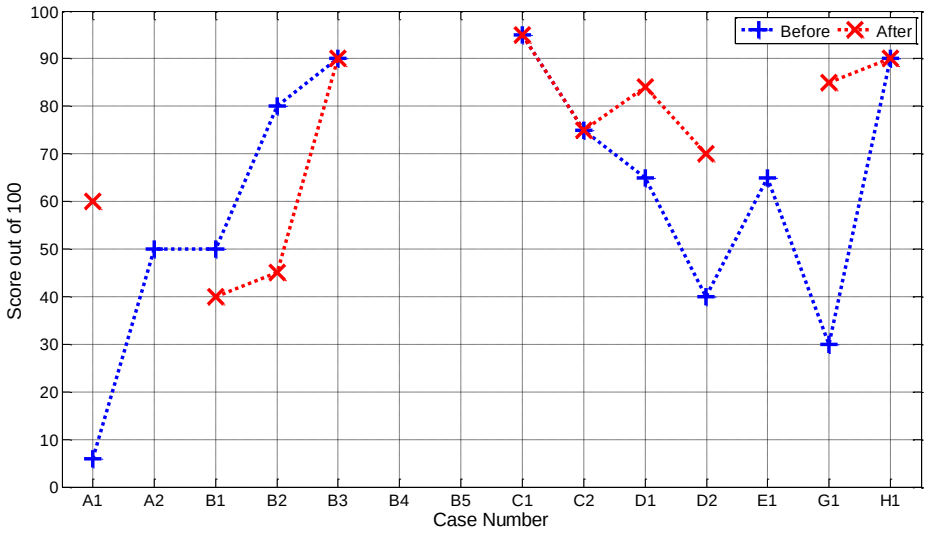

Figure 15: EQ5D health scale scores

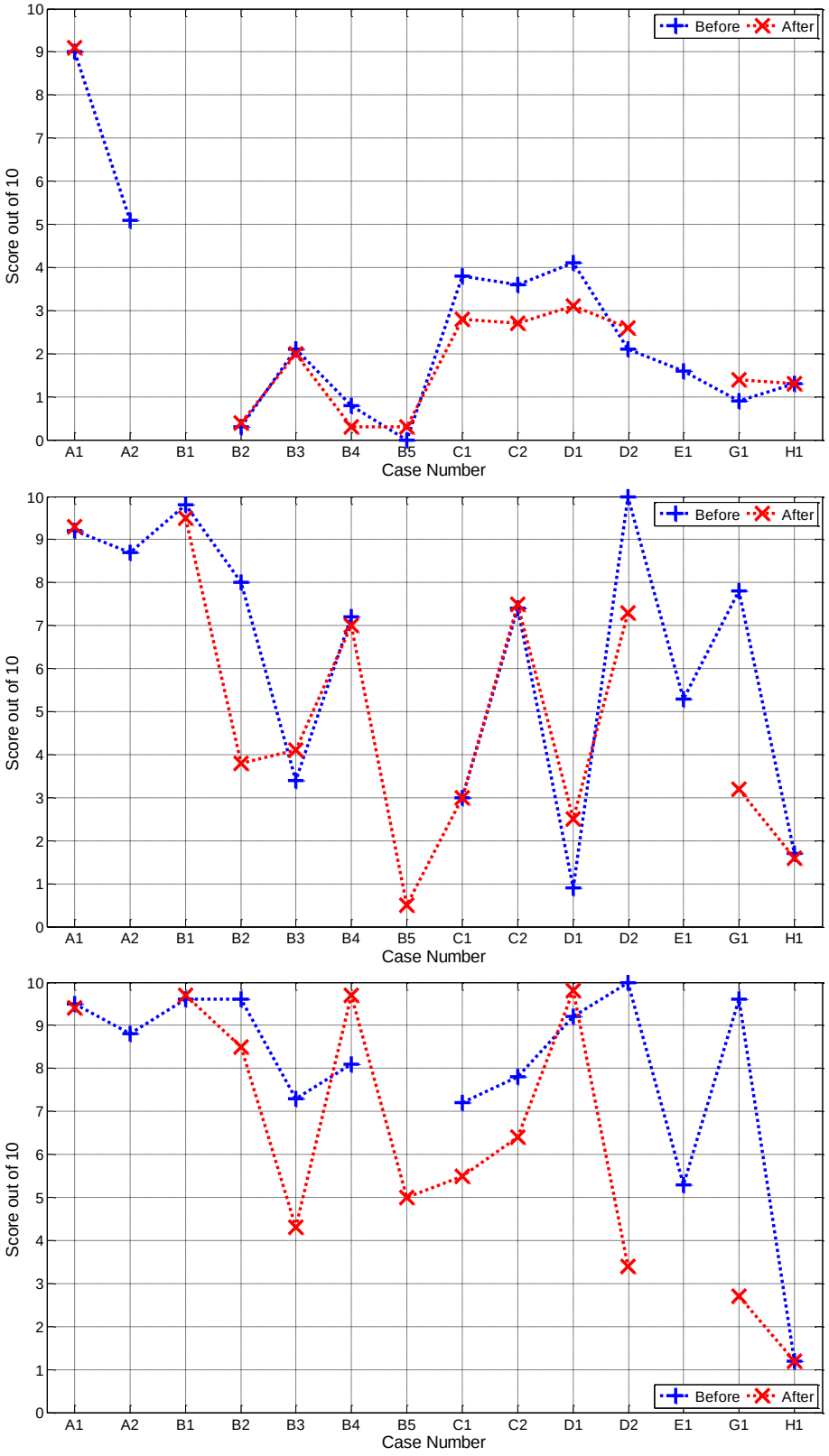

Figure 16: Visual Analogue Scale scores: from top to bottom, scales are for pitch, loudness, distress.

7 Feedback from EHOs and audiologists

The aim of this chapter is to evaluate the success or otherwise of the LFN network from the point of view of the two sets of professionals who worked together to make the referrals and to carry out the protocol, namely the EHOs and audiologists.

As well as a potential improvement in sufferers' quality of life, as discussed in the previous chapter, there are important potential benefits to EHOs in terms of their ability to deal more effectively with LFN cases. It was explained in the project brief that EHO benefits might be expected to include improved client satisfaction, improved EHO morale and reduced demand on EHO resources. It was not felt appropriate to 'measure' client satisfaction in the case studies since adequate information would be expected to become available through the case notes and questionnaires from audiologists. However, the key performance indicators for the project included the latter two potential benefits. Therefore, an evaluation of the effect on EHO resource use and morale by means of semi-structured interviews is included in section 7.1.

The project brief did not specifically include an evaluation of audiologists' experience but it became evident throughout the course of the project that this could provide valuable information for evaluating and improving the network. Therefore, an assessment of audiologists' experience is also included in section 7.2.

In order to prevent potential bias in the responses due to familiarity an independent research consultant[1] was commissioned to carry out an evaluation amongst both sets of professionals. The remainder of this chapter consists of the independent reports received from the consultant.

7.1 Semi-structured interview with EHOs

In this section we report the evaluation of EHO resource use and morale. Neither of these benefits is easily quantified. First, 'morale', although clearly important, is not a precisely measurable concept. Secondly, improved use of EHO resources is also difficult to quantify because LFN cases vary considerably in their details, so it will not be possible to establish a clear reference value for 'typical' resource use for this type of case. For this reason an approach based on semi-structured questionnaires has been adopted to evaluate both factors.

[1] Alison Fleming of TheResearchBox

All EHOs who had made referrals during the project were contacted and requested to take part in the survey. None declined to take part although some were no longer in post by the time of the survey. A total of five EHOs took part in the surveys. This is a small sample but revealed some interesting findings. The interview structure is given in Appendix 5.

7.1.1 General Background

There were variations in the number of general noise cases dealt with per year by each authority. Where a respondent had access to the statistics for the department, it was easier to obtain the information i.e. if they were a manager as opposed to a technical officer who could only really talk about their own case load.

It appeared that at the department level there were typically between 200 and 500 general noise complainants a year depending on the size of the council. Of these, around 10-15 would be described as Low Frequency Noise (LFN) complaints. Individual officers were typically dealing with around 30-40 general noise complaints with around 2-3 of these being LFN at any one time. Generally, a combination of No Noise Found, No Nuisance and Nuisance cases (see Section 2.1) would be expected amongst the LFN cases but authorities were not asked to provide a breakdown.

Part of the difficulty was that LFN complaints have not been registered as such until recently and then only by some. The audiology referral project has helped people to classify them separately. Prior to this they were described as tinnitus cases or just cases that had been closed because they could not be considered a nuisance. It was therefore difficult to obtain statistics of cases dealt with before and after the referral service came into being. From their experience though, it was usual to have one or two cases ongoing in a year. All respondents remembered having an LFN case prior to the case in question.

Similarly many authorities did not know on average how much resource was taken for the LFN cases. Two out of the five did keep such information but were not able to access it for this research. It seemed that a typical (not LFN) noise complaint would take three visits, several phone calls and a few letters. In contrast, LFN cases would typically take much more than this, including night visits, more letters, many phone calls, meetings at the authorities' offices and would be much more labour-intensive.

Two out of the five authorities have got to the position of avoiding this amount of work early on when they are fairly sure that the case is *'a tinnitus case'*.

These authorities had taken more of a view to stop the case early by saying there was little to be done because the sound levels recorded were not sufficient to be causing a nuisance. This was prior to the commencement of the audiology referral service. Those authorities who carry on with the complaint take more of a well-being and quality of life point of view. Sometimes, no matter what the philosophy of the authorities, the individual would be so insistent and distressed that the individual officer felt duty-bound to carry on with the complaint. However, in some cases the officer would feel that no matter what they did the complaint would still continue.

This latter type of complainant was unlikely to be affected by the new referral service and so often 'successful resolution' would not happen or they would have to take a view on closing it. However, handling of the more genuine LFN type of complaint was generally found to be much improved from the EHO's point of view by having the referral system. Different authorities had introduced the idea of the referral service at different stages in the process: one had used it almost immediately after one visit and others used it later on after more investigations such as a night visit.

However, in three out of the five authorities it was not possible to suggest whether the complainant had found a resolution because the officer has received no feedback from the audiologist as to the success of the treatment. These cases technically were regarded as still open but if there is no return from the complainant the cases will be closed. *"I don't know if it was successfully resolved."*

It is worth noting at this stage that the main reason for lack of feedback to the EHO from the audiologists may have been related to the need to comply with data protection rules. However, these restrictions appear to be limiting the effectiveness of the referrals, at least from the EHOs' point of view, and it would therefore be worthwhile to consider how full two-way communication between the EHO and audiologist can be allowed should the network be continued.

7.1.2 Specific cases

Respondents seemed reluctant to talk about specific cases apart from the one in question but it was clear that previous cases had taken up much more time.

"If we had understood it better, I could have just said no to all those visits (32). Each time she slightly changed how she described it so it was always regarded as a 'fresh

complaint'.

"Well, I mainly deal with industrial work."

"I had a case a couple of years ago and one of the things that clinched it was she described the noise finally as coming out of water from a stream under the house. Well, I know that sound doesn't travel through water. She had tinnitus but refused to go to an audiologist, she was too embarrassed or her pride or something."

The following describes (paraphrased) some of the cases that were referred to an audiologist

– *the case was a lady in a detached property. We did a frequency analysis and there were only low levels at low frequencies and it was under the criteria so it was not a nuisance. It was never substantiated but she said she could not sleep, that it was keeping her awake and she was so tired. She had to change rooms from her husband so it was causing problems between them. The family said they could faintly hear it but not really. It was on quite a main road but I checked the mobile phone masts, there was an old telecoms box and there was a new generator at the school but nothing. I mentioned that there was a research trial and than they might have mechanisms to help her cope with the noise and that by helping she was also helping other people. She seemed quite keen on it and I was pleased that I could offer her some comfort.*

– *the case was from a repetitive complainant and we visited many times. She was vociferous, said she had a swelling tongue, giddiness and headaches at night. It was below 20 decibels and the only noise we could hear was an aerator for a fish tank next door but it was so low it was no nuisance so we can't do anything. We have suggested the audiologist but not heard anything. We have not closed the case yet.*

– *we had a lady who said the noise 'felt like the end of the world' it was like 'roaring flames'. We suggested she went to the doctors and the audiologist and she said "you have changed my life thank-you!" She went quite willingly when we said it was for research.*

– *we had an example of a resident who said she heard rumbling which got louder at night. She thought it was the local factory which is quite big but the husband could not hear it. We made night time visits but it was not enough to register*

a nuisance. We used the Salford questionnaire but we had some Data Protection issues, passing on the name. It was quite good eventually we got the results back and it aided our investigation. We thought it was her asthma but it turns out she is sensitised to a certain frequency. She was given ways to cope and manage and the case was closed, No Noise Found.

– *she was convinced that the mobile phone station was making the railings in the corridor of the block of flats rattle. It started on May the 7th last year and now two of the adjacent neighbours have become complainants. We have had measuring equipment in all their houses. We have tried the middle of the night but we can't find anything. Unfortunately, (name of audiologist) couldn't find anything either! I have invited them all to come to our offices tomorrow so I can play back the tapes to them. I am getting wound up just telling you about it now!*

– *We've had the file for five years and she is quite agitated. In the first house we had the hand-helds* [sound level meters] *and it was only 120/125* [Hz]. *The lady can hear music and is accusing a young boy. He is adamant he is not playing music but she wouldn't listen. She was accusing him when he was away on holiday! Then she moved to a bungalow and said she could hear music, now it was Salvation Army music and one day we watched to see the neighbour and she was dressed as a Punk going to College so I doubt that she would be in to that kind of stuff. We can't really do anything because it seems to be coming from within the house.*

7.1.3 Main perceived benefits of the referral service

One of the main benefits of the service appears to be putting the situation into a formal procedure with a recognised category. This makes the interaction between complainant and officer less emotive when it comes to making the referral suggestion. Most respondents were now able to refer to the complaint as an LFN case or to say that it is part of the procedure to at least discount this as a possibility before making more on-site investigations. Most organisations recognised that it had been necessary to tread very carefully *'if you say they've got tinnitus they will just throw you out the door."*

> *"One of my case officers said 'she may have tinnitus' and she threw him out of the door!"*

> *"There was one case where a complainant had already had an audiologist because she was partially deaf but the audiologist had said that she had*

> *particularly sensitive hearing. We assume he/she meant she had become 'sensitised' but we are not sure. Anyway, they then continued to use this as ammunition as to why she could hear the noise and the officers couldn't 'I've got very sensitive hearing you know!"*

So the service has raised awareness to the extent that in one authority they now categorise LFN complaints separately from the start and give it credence. There is an awareness raising that has been caused by the pilot.

> *"It will help us draw a clear line under the case and know when to stop investigating."*

> *"It is good to be able to say that there is a professional audiolgist who might see if there is a medical reason rather than 'oh the Council is telling me I'm hearing things in my head!"*

> *"It is a very good thing from my point of view; it might not eliminate many people but it gives us another avenue and some space!"*

> *"It has been very hard to find out where the noise is coming from. People are getting quite distressed and it is nice to be able to refer them on further to something."*

Another benefit appears to be to be able to offer the service as a 'method of coping', almost like a counselling service. This seems to be appropriate given the level of distress involved.

7.1.4 Effect on resources

In an atmosphere of job reduction it was felt that workloads would be getting worse. The LFN cases mean that officers have to go out at night and then they turn up late the following day for work. In one case, 32 visits had been made. For department managers, losing capacity during the day is of obvious concern.

The referral service meant that the number of visits could be reduced to the property but also that the sound measurement equipment would not have to be 'tied-up' measuring sound which has already been shown to be too low. It appeared that the demand for equipment in these departments is high.

"I think it will make an amazing difference to be able to put the file to bed and also to be able to recognise it next time."

"It means one visit rather than three, maybe three phone calls and a letter."

Respondents also felt that if the service continued it would give them confidence to pursue the option earlier in the process thus saving resources. One or two officers said they often had a 'gut feel' about the cases being 'tinnitus' from the first phone call, *'you can tell a bit from the sound they describe, often bells, trains or fairground music'* but the confidence and training is not there to be assertive as well as sensitive after the first measurement visit. There appeared to be less awareness of sensitisation to specific frequencies than there was about tinnitus.

7.1.5 Effect on morale

On the whole the LFN cases were felt to be more stressful with a lot of pressure to make decisions. The complainants are clearly very emotional and their level of distress is high. When the measurement indicates No Nuisance or No Noise Found, then the officer may be treated quite aggressively. Over a long period of time it can make the officer almost doubt their own judgement which leads to a lowering of morale. However, it was difficult for people to quantify whether the referral service had helped their morale.

"It is stressful, you tend to over investigate because they seem so genuine."

"In a very minimal way, from the one case I benefited".

"I think it has had a neutral effect. Obviously, if we had more cases, we would be able to stop earlier in the investigation and I was pleased from a personal point of view."

"It is really stressful. She doesn't accept that I can't accept there is a noise. She is vigorously convinced and they are not receptive people".

"It is frustrating, we can't do anything but it goes on and on and on. She is traumatised and it affects her quality of life."

The EHOs were not quick to say that this was an effect but it was clear as they spoke

that it was because, (a) they knew how stressful such complaints were and (b) the option of foreshortening the process had to de facto reduce the time spent on such cases. The prospect of genuinely helping the complainant could also be said to influence morale.

7.1.6 Overall perceived success

All respondents wanted the service to continue, although they felt they would need more experience of it to give a full evaluation. They could see how it would develop and how more cases could be referred as awareness is raised amongst departments. Of course, some had difficulty measuring 'success' because they had not yet heard back from the audiologist (as mentioned earlier this was mainly due to data protection issues).

The main improvements that they wanted were: better feedback system, more GP awareness raising, some jargon-free information to give to complainants, advice on Data Protection and training.

> *"We have a policy of 3 visits, it is like 3 strikes and you are out so this was the end of the line and it came at just the right time."*

> *"I would like to see it continuing because it is a good resource to be able to offer."*

> *"I would like feedback because I do not know the outcome."*

> *"I would like more feedback from the audiologist so we know how to recognise it next time."*

> *"It fits with our corporate goals on health and wellbeing."*

> *"I think it would be really good if the service continues so people don't have to suffer. It is good for us to refer people further because a couple of time I have tried to explain the problem to Doctors and they don't seem to know about it! They only seemed to know about the ringing in the ears but it is not always ringing."*

> *"I have limited training. It is only a part of what I do."*

7.1.7 DEFRA Procedure reference NANR45

One of the authorities used the DEFRA procedure comprehensively but had had to amend it for the purposes of the study by adding a section on data protection to allow the details to be released (see Appendix 6). They had worked together with the Health Care Trust to develop the wording.

Apart from this one proactive council, the others were not using the procedure. One had read it and decided that they 'weren't doing anything wrong'. And the others were very vaguely aware of it but had not used it. One requested for it to be sent for his information.

7.1.8 Summary

Not all departments gathered statistics on LFN cases but the numbers appear to be low. Authorities vary as to whether they will pursue cases after nuisance noise levels have been dismissed. Not all had received feedback from the audiologist about the result but the complainant did not always return. Possibly the information is not released back to the authority due to data protection.

The audiologist referral service has raised awareness about LFN but the sample is too small to tell whether it has really gathered momentum. All respondents were very positive about the service and wanted it to continue because such cases were felt to be stressful and resource-intensive. It was felt to be good to be able to offer another option for people and there are pro-active authorities who now see it as part of their health and wellbeing strategy.

A number of useful signposts for future developments has emerged from this evaluation, specifically that raising awareness amongst GPs and EHOs would be beneficial. The former could be achieved by articles in GP journals such as the BMJ. The latter could be achieved by a combination of measures:

- articles in EHO trade journals
- presentations at national EHO meetings

Finally, awareness amongst audiologists and generally could be achieved with articles on key websites such as those of the British Tinnitus Association (BTA), Institute of Acoustics (IoA) and perhaps the Royal National Institute for the Deaf (RNID).

7.2 Semi-structured interview with audiologists

As a follow-up to the research conducted on Environmental Health Officers (EHOs) and their experience of the Low Frequency Noise referral trial, The Research Box also interviewed the audiologists involved in the study. All bar one of the audiologists who participated in the study were interviewed to allow them to give confidential feedback.

As an overview, most of the audiologists were pleased to have taken part in the trial but, as a result of a very low number of referrals being received, thought that the study did not have sufficient volume of cases to enable them to give solid feedback.

> *"gathering referrals has been really difficult."*
> *"it was a bit varied"*
> *"there were not enough referrals for the period of the study"*

Nevertheless, they can see the benefits of the work for individuals who experience LFN from other cases they have had direct from GPs or from previous experience. The main benefits for complainants appear to be in the improved ability to cope with the distress levels cause both by the noise and by the feelings of 'being persecuted'.

The fact of having a formal treatment which is a recognised condition helped people to 'normalise' their situation. The coping strategies of relaxation techniques also helped people to reduce the anxiety associated with noise.

> *"they are in a state of 'hyper-vigilance'".*

> *"it has reduced their distress and given them a non-judgmental environment to talk about their problems."*

There were hardly any cases that had gone through the process where the complainant had benefited by a reduction in the level of noise heard, although a few hours more sleep was mentioned.

> *" She benefited in a wider understanding of her situation and that she was not persecuted but a chronic sufferer. Didn't change her (sound) situation one iota!"*

> *"I don't think she came to an acceptance."*

In theory therefore, the audiologists felt that the system should be 'fantastic' but the research had identified too few complainants.

In one authority where a few referrals had been made, there were concerns on the part of the clients and the audiologist that the referral had been made to 'get the case off their hands' and that the proper paperwork had not been forthcoming.

> *"the clients didn't know why they were here, there was no documentation."*

One pro-active audiologist had conducted some awareness raising work with his local authority and felt there was good EHO relations, however, most found that the EHOs needed more help to understand the issues.

The principal areas of concern were that (a) the protocol could be seen to be too complex for someone without training to complete: the protocol may start off simply but become more complicated (b) the EHOs need more training in the interpersonal skills required to deal with such clients (c) there was a difference in the measurement scale used by the EHO cf. the one required by the protocol (d) some audiologists had a poor relationship with the EHO departments.

> *"the quality of the access of the relationship with the EHOs was dreadful. Essentially they don't have to do anything legally"*

> *" a good idea but we have struggled to engage the EHOs"*

> *"I have excellent links with the local EHO team."*

> *"they need more empathy with what the patients are telling them."*

> *"they are too blunt with people."*

Nevertheless, the referral trial has established some better contact between EHOs and audiologists as a good starting point but it needs re-enforcing. Specifically, clarification as to what information could be shared between the audiologist and EHO is indicated. In principle, the audiologists thought they could give general feedback, if it was allowed eg a basic feedback form could be sent post intervention but that ethical approval might take time.

Another potential barrier contributing to the lack of referrals was thought to be the number of stages involved in the referral process ie being too lengthy, too many. A few thought that the GP as an intermediary was not necessary and that this might have put people off going any further.

Most audiologists felt that the training given was very adequate but that in some cases it was too late or too long before their first referral (or not used at all). However, many felt that the skills they already had and their knowledge levels were quite high. Several had just used the same techniques they use for tinnitus. Therefore they felt "confident in the technique' which they knew but did not have "enough of a bank of experience". Emailing the University had been useful for on-going support but they felt that the protocol could be simplified. It was clear that some audiologists needed to re-visit it (maybe a podcast would be useful).

Another skill area that might benefit from further development with these clients was felt to be learning how to deal with their levels of distress and account for any potential areas of mental health needs ie if the complainant was depressed or needed referring. Comfort levels here were not always high and the main difference between a patient with tinnitus and the LFN referral was that they felt there was an external source (obviously) with an element of perceived deliberate intent. Of course more experience would have been gained with more referrals.

On the whole respondents thought that tinnitus/hyperacusis was similar to low frequency noise in terms of the symptom profile presented but that they needed handling very differently. It was thought useful to have joint terms that could allow for both situations because some clients felt comforted by not being in one or the other camp. The techniques were also felt to be similar for both in that they involve helping people to 'disregard the sound' whereas the emotional symptoms had to be handled differently.

Respondents said they would continue with the system as they are interested in the subject matter but if the cases aren't being referred it would seem immaterial. Clearly, there was felt to be more awareness raising to do both with EHOs, but also with GPs and the protocol would need to be simplified to reduce referral barriers.

> *"Yes, if the research indicates that it was of benefit because it is an interesting client group."*

"I am quite happy to see the patients"
"I have no objections."
"Yes, quite happy"

8 Evaluation and discussion

The number of referrals received by the participating Audiologists was lower than expected. There are several potential factors that may have contributed to this. Firstly, there were challenges in developing discussions between EHOs and Audiologists (see Chapter 7), and in some centres good relationships were only becoming evident by the closing stages of the project. There are also indications that some LFN complainants may have been reluctant to attend an Audiology based service, certain as they were that their issues derived from an external source of LFN rather than their reaction to sound (if indeed an LFN were present). Additionally, some may have found the concept that using tinnitus therapy based techniques implied that their experience was of tinnitus (see Chapter 6 and 7) which may have been upsetting. However, it may also be that the prevalence of LFN complaint is lower than has previously been estimated (Tempest, 1989) and is often assumed. Such an over estimate might occur when previous cases of LFN complaint involved people who were highly distressed and that were difficult (or not possible) to resolve, and hence were highly memorable.

What has been demonstrated however is that those individuals that were referred were highly distressed. Metrics of distress and handicap all indicated a clinical population that was agitated and distressed by their situation, and self report of length of complaint evidenced a situation that was chronic and long-standing. Whilst not large in number, those individuals with LFN complaint have a significant clinical need.

The HADS is a credible and robust screening tool for the identification of clinically significant anxiety and/or depression. The fact that only a small proportion of LFN subjects scored above the threshold ($x>10$) for such symptoms indicates that psychological ill-health was not marked in the cases studied. These individuals were significantly agitated, stressed and distressed – but in the main, were not clinically anxious or depressed.

The overall impression from the results is mixed but the fact that some of the subjects (three in particular) appeared to benefit from the intervention is positive, particularly given the limited options available to this client group. Further research would be required to confirm these benefits, ideally through a more quantitative study, although this would present challenges not least because of the small and diverse nature of the client group. Identifying a larger, possibly international, sample might be the only way to detect quantifiable robust impacts and/or benefits.

What remains unknown is the extent to which further ongoing intervention might

have resulted in further improvement, and also the extent to which any improvement that was achieved would be sustained. It would be feasible to calculate the average cost of the intervention based on the cost of an hour of a NHS Band 7 Audiologist times the approximate mean number of three appointments. Measuring the cost effectiveness of the LFN network was not a specific aim of this project, but is should be noted that a series of ongoing appointments with an Audiologist would have a cost within the local health economy. It has been indicated in Chapter 7 that at present EHO's are expending far more time than 3 hours on some such cases.

The lower than expected demand for the services of the LFN network may cause one to consider that fewer centres need to develop expertise in this area than the number involved in this study. Arguing against this might be the indication of some reluctance of persons to attend such a service, which may increase with distance. A solution might be for an LFN intervention protocol to be available for Audiologists, applied locally when cases arise. Whether this would allow clinicians to develop sufficient experience and expertise to deal with these challenging situations is open to debate however.

In Chapter 3 a model for the development of LFN associated distress was proposed. It should be considered whether the data collected is congruent with this perspective. High levels of distress and handicap in the subject population were evidenced, as were some individuals with significant anxiety. These are indications that the proposed involvement of the sympathetic autonomic nervous system, and of the emotional brain, are likely to be a faithful representation of the clinical situation. The suggestion that a feedback loop exists between such activation and increased awareness of, and associated distress with a perception of LFN is harder to evidence. The variable experience of subjects was indicated by some responses to the VAS (e.g. "at my worst", "at my best"), so some modulating process is likely. It did not fall within the scope of the present study to investigate what factors might be involved in such modulation, but the proposal that a feedback loop between stress /agitation and noise awareness exists may have some value.

In the recent study of Leventhall and colleagues (Leventhall, 2009), described in Chapter 2, a computerised Cognitive Behavioural Therapy (CBT) course was applied to persons suffering from LFN exposure. Statistically significant improvements in a questionnaire measure of coping ability were demonstrated, though there was a significant drop-out rate (13 of 40 individuals who started the course, 33%, or 26 of 53 enquirers, 49%), and an intention to treat analysis (e.g. considering drop-out

subjects as if they had no change after treatment) was not performed. The authors noted that among the drop-outs were some of the most distressed individuals, and that these persons might need "special attention and extra help" (p57) to be able to access therapy. Those that completed the course were thus a self-selected group to whom this approach was acceptable. Even so, it appears that computerised CBT has a value in the LFN complaint population.

This is germane to the present study, in that it is potentially possible that the two approaches could be combined. The present study indicates that Audiology based therapy provides a context in which people with LFN complaint can be assessed, treatable Audiological conditions can be excluded, and where some (modest) improvement can be made in some individuals. Individuals with high distress can be identified, and support put in place for them. If one considers that the high levels of stress in this patient population may be a factor that reduces the efficacy of intervention, then the use of computerised CBT may be beneficial in addressing that aspect of the LFN complaint experience. Further research is needed to consider this possible approach to optimising interventions for this group of people.

9 Conclusions

Using data from the study two independent estimates of the incidence rates of LFN case can be derived. It is estimated that there are 160 complainants per year in the NHS corresponding to 0.32 cases per 100 thousand per year. The incidence rate based on referrals made by EHOs is 1.01 per 100 thousand per year within local authorities. It is not known to what extent, if any, these populations overlap.

From the survey response there is a willingness of the audiology community and tinnitus specialists in particular to engage in LFN cases. However, fewer cases than expected were referred which is thought to reflect the low incidence rates.

From the EHO perspective, it is difficult to quantify the benefit of being able to make referrals. Although there seemed to be some initial difficulty in forming a working relationship with an audiologist, the EHOs who had made referrals were generally very positive about this possibility and wanted the scheme to continue. It is clear that LFN cases require significantly more resources than other noise complaints and that the opportunity to refer to a more qualified specialist (and to help the complainant) could help to reduce this burden.

Regarding benefits of the treatment protocol to LFN complainants, the mean outcome measures from six out of seven separate outcome measures (questionnaires) moved in a favourable direction, with the remaining one showing no change. This suggests an overall improvement, however, statistical significance was only achieved for one of these measures (and then at the $p<0.05$ level rather than $p<0.01$). Overall, a larger statistical sample would be required to confirm the benefits. The general impression from the results is that some of the subjects (three in particular) benefitted from the intervention with others showing little change, although no statistical test of this hypothesis has been conducted due to the small sample size. The factors likely to influence success are the quality of the referral by the EHO, the quality of the audiology input and the attitude of the complainant.

The individuals taking part were significantly agitated, stressed and distressed – but in the main, were not clinically anxious or depressed. Psychological ill-health was not marked in the cases studied.

The model proposed of stress and increased auditory gain is a plausible explanation for the symptoms noted in LFN cases. In particular, the involvement of the sympathetic autonomic nervous system, and of the emotional brain, is likely to be a

faithful representation of the clinical situation.

A number of useful signposts for future development were derived. First, EHOs as well as audiologists should ideally receive training in best practice to help them to handle the particular sensitivities of LFN cases. More awareness and information for GPs is also recommended. A simplification of the referral route, potentially going direct to the audiologist rather than via the GP would also be beneficial.

A strong argument for the continuation of the service is that some EHOs are now taking the initiative in contacting audiologists independently to refer LFN complainants in No Noise Found cases. Without adequate training things could be made worse but access to a specific LFN protocol and associated training is likely to increase the chances of success significantly. It is recommended that existing guidance for EHOs be extended to include details of audiology services, guidelines for EHOs in making referrals and reference to the LFN treatment protocol.

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Appendix 1: documents approved by the Research Ethics Committee

The documents used in the protocol are listed in Table 7 and are presented in the following pages.

Table 7: List of documents approved by the Research Ethics Committee

Document	***Filename***
Protocol	LFN treatment protocol
Participant Information Sheet	Infosheet
Participant Consent Form	Consent form
Letter of invitation to participant	EHO referral letter
GP/Consultant Information Sheets	GP information sheet
Quiet room protocol	Quiet room test
Letter to GP	EHO letter to GP
Questionnaire: HADS	HADS
Questionnaire: Khalfa Hyperacusis	Khalfa
Questionnaire: Tinnitus Handicap Inventory	THI
Questionnaire: Visual Analogue Scales	VAS
Questionnaire: EQ-5D	EQ 5D

Appendix 2: Consent form

Participant Identification Number for this trial:

CONSENT FORM

LREC Reference Number: 09/H1016/86
Title of Project: Low frequency noise network
Name of Researcher: ……

Please initial box

1. I confirm that I have read and understand the information sheet dated 01.08.09 (NANR271/ infosheet/ 2) for the above study. I have had the opportunity to consider the information, ask questions and have had these answered satisfactorily. ☐

2. I understand that my participation is voluntary and that I am free to withdraw at any time without giving any reason, without my medical care or legal rights being affected. ☐

3. I understand that relevant sections of my medical notes and data collected during the study, may be looked at by individuals from the University of Cambridge, from regulatory authorities or from the Cambridge University NHS Hospitals Foundation Trust, where it is relevant to my taking part in this research. I give permission for these individuals to have access to my records. ☐

4. I understand that some things I say to the audiologist may be quoted anonymously in project reports. I give permission for anonymous quotes to be used. ☐

5. I agree to my GP being informed of my participation in the study ☐

6. I agree to take part in the above study. ☐

_____	_____	_____
Name of Participant	Date	Signature
Name of Person taking consent	Date	Signature

When completed, 1 for patient; 1 for researcher site file; 1 (original) to be kept in medical notes

Appendix 3: LFN treatment protocol

Low Frequency Noise Network
Low Frequency Noise Treatment Protocol
Version 2. 13th August 2009

Application of Tinnitus/Hyperacusis Therapy to Low Frequency Noise Complaints

Author: Dr Baguley D.M.; Moorhouse A.T.; Husband T.G.
Number of Sections:
Date Validated: Validating Body:
Reviewer:
Updated:
Review Date:

Procedure Name: Low Frequency Noise Treatment Protocol

Description: Trial procedure for assessing and treating Low Frequency Noise complaint utilising a modified Biopsychosocial model of treatment for Tinnitus

Location: Audiology Department

Patient Category: Patients referred directly from Environmental Health Officer after completion of the Defra 'Procedure for the assessment of low frequency noise complaints'. Only patients for whom no external source of sound has been identified in this procedure can be referred for treatment as part of this trial

Protocols: Human Resources: Audiologist/Hearing Therapist participating in Low Frequency Noise research programme. Consent of local Ethics Committee to proceed. Cooperation of ENT consultant willing to assess LFN patient medically.

Appointment Time: 80% of patients seen within four weeks of the date of referral from an EHO

Waiting Time: 100% seen within twenty minutes of appointment time

Assessment and Treatment Time:

1st Appointment	-	One ½ Hours + ½ Hour Admin
2nd Appointment	-	Six weeks later – ¾ Hour+ ¼ Hour admin
3rd Appointment	-	Six weeks later – ¾ Hour + ¼ Hour admin

Probable discharge point at 3rd appointment therefore total time per patient = Four hours

Set-up Equipment:

- Calibrated Clinical Audiometer
- THI, EQ-5D, Khalfa Hyperacusis , HADS questionnaires, VAS questions
- Audiology sound proof test booth
- Otoscope
- Environmental sound therapy device
- Cambridge Muscle Relaxation CD
- Patient consent form to release anonymised data

Patient Management:

1) INTRODUCTION: Explanation of low frequency noise complaint and counselling about mechanisms of low frequency noise perception and of associated distress. Outline the assessment and treatment pathway, time commitment and likely outcome. Remind patient that they are taking part in a research programme and gain consent for their data to be used as part of the study

2) PATIENT HISTORY: Take full verbal history from patient including:

ONSET: When and how did it start, sudden or crescendo or still escalating

PRESENT SITUATION: Frequency of awareness, perceived cause, any actions that have been taken, any prior knowledge or reading, any pre-existing Tinnitus, Household members/visitors aware of noise,

IMPACT: Health/psychological, analogue scale of annoyance (1 – 100), sleep disturbance, work/relationships

EHO INPUT: Credible report?, involvement of other agencies (noise consultants/police/mental health services)

GP OPINION: Any other medical conditions, Hyperacusis, phonophobia's

ENT OPINION: Any evidence of otological pathology in LFN people

ONGOING OBSERVATION: Throughout the course of the treatment practitioners should monitor any signs of an increased LFN awareness in patients participating in the trial. Consideration should be given to terminating the treatment if concerns persist and the research coordinators should be informed

Examples of open Questions

How long have you been aware of these sounds?

What time of day are you most aware of these sounds?

What do you think may be the cause of these sounds?

Are there any other sensations you are aware of when the sounds begin?

What, if anything have you tried so far to help with these sounds?

Apply:

- EQ-5D Health Questionnaire
- THI Questionnaire with explanation of relevance to LFN perception
- Visual Analogue scale questions:
    - What does the pitch of your Tinnitus sound like?
    - What is the loudness like?
    - How distressing is the sound to you?
- Khalfa Hyperacusis questionnaire
- Hospital Anxiety & Depression Scale
- The Kenyon Quiet Room Assessment Protocol

3) DIAGNOSTIC ASSESMENT:

- AC including 125Hz if calibrated
- LDL's with caution
- Tympanometry not including ART's

Treatment: Desensitization Approach to Low Frequency Noise Complaint
Usual Tinnitus pathway of:

- Explanation (Therapy/Counselling)
- Relaxation with Cambridge CD
- Sound Enrichment using Sound Oasis ideally & pillow if required
- Minimize over time any use of hearing protection

Final Treatment Session: Will usually be at 3rd appointment

Re-apply all questionnaires

Consider careful reassessment of LDL's

Graceful withdrawal if treatment not successful, consider further support from GP or formal psychological support if required with support of ENT colleague.

Reporting:
Report as A1,2,3,etc dependent on centre
All data including qualitative to be anonymised prior to sending

Inform both Andy Moorhouse & Dave Baguley when journey with each patient begins
Give informal feedback if required, i.e. additional information not otherwise covered in protocol relevant to the client
Complete spreadsheets for data entry using supplied passwords

Standards:

- BSA Recommended test procedure for PTA
- BSA Recommended test procedure for LDL

Local: All participating Audiologists must conform to their Trust's general policies and procedures and the conditions required by the local Ethics Committee

National: Audiometers are calibrated to BS 2497 Part 5:1988 for AC and BS 6950:1988 for BC, traceable to the National Physical Laboratory Measurement Standards.

Tests are conducted in sound treated rooms complying with Department of Health and Society Security Engineering Division Standards (1976).

Sound-proof rooms comply with Department of Health and Society Security Directorate of Works Operations Audiology Test Room Qualification Report NAS11/.

Routine surveillance of equipment complies with DHSS B700.

Results are correctly documented in accordance to BSA Guidelines (British Journal of Audiology 23, 265-266).

Health and Safety at Work, etc. Act, 1974, is implemented.

WHC (80)10 Confidentiality of Medical Records is implemented.

Appendix 4: Kenyon quiet room test protocol

Low Frequency Noise Network
Quiet room protocol
Version 1. 11 June 2009

Five minutes in hearing test booth for LFN patients

Materials

Sound treated Audiology test room

Pen

Paper

Timer

Aim

Determine if patient becomes aware of their LFN within 5 mins

Determine if patient becomes aware of any internal sound / tinnitus

Are there any similarities between how they react physically or emotionally to sounds heard in the room and LFN at home?

To produce examples you can use when explaining central gain / filtering.

Carefully worded introduction

(not mentioning tinnitus, or implying that the sounds are imagined)

We are aware that hearing sensitivity varies greatly from person to person. Some people can hear sound where others cannot. Before we discuss how we can desensitise ourselves to unwanted sounds I would like to get a better idea of what you are hearing.

I would like you to sit quietly in this room for 5 minutes listening carefully for any sounds you may pick up on. Please list any sounds you hear on the sheet of paper in front of you. The door will not be locked at any time and **I will be back in five minutes / I will be here in the room with you**.

Hearing aids – in or out?

If the patient has hearing aids but hears the LFN without hearing aids being in test them for 5 mins with the hearing aids removed and switched off - to avoid distracting

feedback. This should allow for more central gain and would be similar to a quiet bedroom at night

If the patient only hears LFN with their hearing aids in let them keep the hearing aids in & switched on for 5 minutes. Then repeat test with hearing aids removed and switched off. Also check the hearing aids are functioning correctly and set appropriately – no hum, buzz or no over amplification at low tones.

View list of sounds

Questions -

Are any of the sounds you heard the same or similar to the low frequency noise you have heard in your home?

Of the other sounds on the list, have you noticed any of these sounds before today?

If yes - where and when?

Are you more sensitive to sound in your left or right ear?

Also – How did you feel when you heard these sounds? Did you notice any physical sensations? (Look for anything relating to anxiety, breathing, and muscle tension? & are these similar to what is reported at home in response to the LFN?)

Contra indications / safety concerns

Claustrophobia

** - We need to be able to see the patient in the event that they need help during the five minutes. If the test room has an observation window – observe from outside. If there is no observation window you will need to sit quietly in the room with the patient.

Appendix 5: Structure for interviews of EHOs

TOPIC GUIDE
Project 4224: University of Salford
Telephone Depth Interview (15 mins)
Introduction

EHO Name:
Subject reference no:
Audiologist to whom referred:

Interviewer name:
Date of Interview:

[Researcher explains that the interview is confidential, is subject to the MRS Code of Conduct and that comments will not be attributed to them unless they give express permission]

General Background

- How many cases do they deal with in general per year?
- Were they involved in any LFN cases prior the case (s) in question?
- Do they know how much resource is taken for an average case? How is this measured, manhours etc?
- What percentage of cases is successfully resolved currently? and prior the referral system?

Specific cases

- Please can you briefly describe the LFN cases you dealt with prior to the case in question?
  - how easy/difficult were the cases to resolve?
- Please, now could you describe the case which was referred to an audiologist?
  - how easy/difficult was the case?
  - how did the case progress?
- What do they see as the main benefits of the referral service, if any?

- What effect, if any, has the opportunity to refer complainants to the audiology service had on your use of resources for these cases?
- What effect, if any, has the opportunity to refer complainants to the audiology service had on your morale?
- Overall, would they judge that the referral service is worth continuing/has been a success or otherwise?
- Did you apply the "Procedure for the assessment of low frequency noise complaints" Defra reference NANR45?
- Q If not, were you aware of the procedure?

Appendix 6: Data protection amendment to DEFRA LFN guidance

The following amendment to the 'Procedure for assessment of low frequency noise complaints' (A. T. Moorhouse, D. C. Waddington, & M. D. Adams, 2005) was used by one of the local authorities in order to facilitate exchange of data between EHO and audiologist.

I understand that the above information has been gathered for the purpose of a noise complaint investigation and that XXXX District Council will share this information with the Audiology Department of XXXXX Healthcare NHS Foundation Trust (XXHFT) to assist its investigation. I agree that XXHFT will share its findings with XXXX District Council in order to ascertain whether there is sensitivity to particular frequencies or to establish whether there is a medical reason to explain what I am experiencing. This information and information gathered from SDHFT will be stored by the Council at its offices in XXX and will normally be retained for a period of 5 years and will be used only for this investigation and not for any other purpose. In the event that a noise abatement notice is served in relation to this complaint details will be kept on file indefinitely.