Collaborative audiological and psychological intervention where tinnitus and hearing loss co-exist

by

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ABSTRACT

Title: Collaborative audiological and psychological intervention where tinnitus and hearing loss co-exist.

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Tinnitus is the perception of sound in the absence of an external sound source and is estimated to be experienced by 10-15% of the population. The majority of tinnitus patients present with some form of hearing loss and intervention aimed at reducing the effects of auditory pathology is indicated in tinnitus management. A significant number of tinnitus patients are also suffering from psychological distress. Psychological interventions aimed at addressing the emotional distress caused by the tinnitus and helping the patient to reclassify his/her thoughts and beliefs about tinnitus are becoming more popular. The optimal model for tinnitus intervention may be a team approach between audiology and clinical psychology. The objective of the study was to determine the effect of a combined multidisciplinary approach in the treatment of tinnitus, using psychological and audiological intervention methods, in comparison to a single approach on tinnitus severity.

The study followed a quantitative research approach, employing a randomised quasi-experimental within-subject, repeated measures design with a varied order of procedures. Eleven participants were assigned to three different treatment groups

based on counter-balanced assignment. Each group received in a different order psychological intervention comprising cognitive behavioural therapy (CBT), audiological intervention involving hearing aid fitting and the counselling component of tinnitus retraining therapy (TRT) and a combination of audiological and psychological interventions. Intervention periods were each two months long, with a one-month rest period between each intervention. In total, seven tinnitus assessments were conducted during the course of data collection to evaluate the changes in Tinnitus Handicap Inventory (THI) and Tinnitus Functional Index (TFI) scores, along with tinnitus pitch, tinnitus loudness, minimum masking levels (MML) and residual inhibition (RI) before and after interventions.

The results indicated that both the singular approaches as well as the combined intervention approach lead to clinically relevant shifts in the THI and TFI scores. Although the study results support the evidence for audiological intervention and for psychological intervention, it was not successful in proving that a combination of audiological and psychological intervention was more successful than a singular approach. It did, however, still indicate that a combination approach yielded clinically relevant reductions in THI and TFI scores and, therefore, that a combination approach is successful and effective. The assessment results of the psychoacoustic properties of tinnitus did not yield any relevant results, and failed to identify any patterns or trends with regard to the effect of intervention on the psychoacoustic properties of tinnitus. None of the results indicated statistical significance of the findings. The study serves as another stepping stone in the direction of tinnitus intervention to be delivered as a conscious multidisciplinary effort where psychology and audiology complement each other. Further research to determine the effects of a collaborative intervention approach for tinnitus is recommended.

Keywords

Tinnitus

Hearing loss

Tinnitus treatment

Counselling

Tinnitus Retraining Therapy

Hearing aids

Psychology

Audiology

Cognitive Behavioural Therapy

Combined approach

Anxiety

Depression

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But those who wait upon God get fresh strength. They spread their wings and soar like eagles. They run and don't get tired, they walk and don't lag behind. – Isaiah 40:31

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ACRONYMS

The list below indicate the acronyms used throughout the study in alphabetical order.

16PF5	16 Personality Factor 5th edition
BTE	Behind the Ear
CBT	Cognitive Behavioural Therapy
CHL	Conductive Hearing Loss
DCN	Dorsal Cochlear Nuclei
DSM	Diagnostic Statistical Manual of Mental Disorders
ENT	Ear-, Nose- and Throat Specialist
GP	General Practitioner
HT	Habituation-based therapy
IC	Inferior Colliculus
MCMI-III	Millon Clinical Multi-axial Inventory Third Edition
MML	Minimum Masking Levels
REM	Real Ear Measurements
RI	Residual Inhibition
RIC	Receiver in Canal
SNHL	Sensory Neural Hearing Loss
TFI	Tinnitus Function Index
THI	Tinnitus Handicap Inventory

THQ	Tinnitus Handicap Questionnaire
TQ	Tinnitus Questionnaire
TRQ	Tinnitus Reaction Questionnaire
TRT	Tinnitus Retraining Therapy
UK	United Kingdom
USA	United States of America
VCN	Ventral Cochlear Nuclei

1. INTRODUCTION

1.1 Definition of tinnitus

Tinnitus is the perception of sound in the absence of an external sound source (Henry, Dennis & Schechter, 2005), its name deriving from the Latin word “tinnire”, which means “ringing like a bell” (Baguley, 2002). It is generally described in common English as “a ringing in the ears” (Baguley, Andersson, McFerran & McKenna, 2013a). It can be perceived on one or both sides of the head, and it can be of short duration, or it can be be persistent (Tunkel, Bauer, Sun, Rosenfeld, Chandrasekhar, Cunningham et al., 2014). Tinnitus can be objective, implying that a bystander can hear it as well as the patient. Tinnitus can also be subjective, which means that it is only heard by the patient (Henry et al., 2005). A distinction is also made between primary tinnitus, referring to tinnitus that is idiopathic and may or may not be associated with sensorineural hearing loss (SNHL), and secondary tinnitus, which describes tinnitus that is linked to a specific underlying cause (other than SNHL) or an identifying organic condition (Tunkel et al., 2014).

Tinnitus is a universal and widespread phenomenon; it is estimated that tinnitus is experienced by 10–15% of the population (Henry et al., 2005; Kaldo, Haak, Buhrman, Alfonsson, Larsen & Andersson, 2013). This estimation is in line with various reports of frequent or persistent tinnitus prevalence from all over the world, including figures from the United Kingdom (UK) (10.1%), Sweden (14.2%), Germany (11.5%), Denmark (17%), the United States of America (USA) (7.9 to 14.9%), Egypt (5.17%), Japan (18.6%) and Nigeria (14.1%) (Baguley et al., 2013a). The phenomenon of tinnitus has been a longstanding subject of intrigue to scientists and clinicians, as it remains paradoxical that so many people can experience tinnitus and not be distressed, while others become so disturbed by it that they cannot function in a normal manner (Baguley et al., 2013a).

Tinnitus becomes a relevant problem when it is negatively perceived by and causes distress to the person experiencing it. The manner in which tinnitus is perceived differs among individuals. Tinnitus may be perceived in various forms, often described as a ringing, hissing, buzzing, sizzling or humming sound (Henry et al., 2005), among many reported descriptions. Some people may not attach any significance to its presence, while others may perceive it as annoying, debilitating and threatening (El-Shunnar, Hoare, Smith, Gander, Kang, Fackrell, et al., 2011; Henry et al., 2005). This "bothersome tinnitus" may lead to rippling effects affecting basic daily tasks (Newman, Sandridge, Scott, Cherian, Cherian, Kahn et al., 2011). It may cause sleep disturbances, poor concentration, difficulties in performing tasks and a variety of negative emotional reactions. The impact of tinnitus on quality of life and activities of daily living has been widely described as an obstacle to living life in a normal manner, with 1–2% of the population finding that their tinnitus impairs their daily lives to a significant extent (Baigi, Oden, Almlid-Larsen, Barrenäs, & Holgers, 2011). Across Europe, the USA and several countries in Africa and Asia, tinnitus affects generally 0.5% of people so severely that they find it impossible to lead a normal life (Baguley, McFerran & Hall, 2013b). The World Health Organization quantifies the burden of tinnitus in Western countries, estimating it to be even higher than many other well-known and recognised health problems (Zenner, Vonthein, Zenner, Leuchtweis, Plontke, Torka et al., 2013).

Tinnitus may also impact economics. As it is recognised to have a significant impact on activities of daily life, it receives attention in workers' compensation cases, albeit inconsistent among different compensation boards. In 2012, tinnitus was the most prevalent service-related disability among USA military veterans being compensated, with nearly one million veterans being awarded disability compensation in connection with tinnitus (Tunkel et al., 2014). Building a case for compensation claims due to tinnitus proves to be challenging, as there is no objective measure to verify its severity. Nonetheless, military veterans can submit their claims and in 2004 the total annual compensation amount as awarded to USA military veterans was estimated at $345,495,552 (Henry et al., 2005).

1.2. Epidemiology of tinnitus

There are no definite indications that women and men experience tinnitus differently (Andersson, 2002). Conflicting information regarding prevalence between genders have been published, although the general consensus is that prevalence in males and females are fairly similar (Baguley et al., 2013b). A recent cross-sectional study in Korea reported the adjusted odds ratio of tinnitus as higher for women (Kim, Lee, An, Sim, Park, Kim et al., 2015), while Holgers, Erlandsson and Barrenäs (2000) found their sample of tinnitus study participants to be over-representatively men, commenting that their experience was that men may be the larger group of help seekers. However, their findings did indicate that gender was not a predictor of the severity of tinnitus, or related to absence from work related to tinnitus.

Tinnitus occurs in both adults and children. However, the statistics on tinnitus in children are much less defined and receive a lesser amount of research attention, possibly because children seem to be less likely bothered by the perception (Baguley et al., 2013b). It is difficult to get reliable information from young children with regard to tinnitus symptoms, but it seems that the impact of tinnitus is consistently lower for children than for adults, which may also explain why far fewer children than adults go to tinnitus clinics (Baguley et al., 2013a). Tinnitus in children is more prevalent in those with hearing loss, whether conductive or sensorineural, but interestingly severe tinnitus is reported more in children with moderate or severe hearing loss than in those with profound hearing loss (Nodar & Lezak, 1984). Age consistently seems to be a relevant factor as numerous reports indicate an increase of annoying tinnitus with ageing up to 60–79 years, after which a plateau in the prevalence of tinnitus is observed (Henry et al., 2005; Kim et al., 2015; Shargorodsky, Curhan & Farwell, 2010). In an early study, Hinchcliffe (1961) found a tendency for tinnitus to increase in prevalence in different age groups: 21% (18–24 years), 27% (24–35 years), 24% (35–44 years), 27% (45–54 years), 39% (55–64 years) and 37% (65–74 years). The majority of tinnitus patients present with some form of hearing loss, with reportedly 70–80% of them having remarkable hearing difficulties (Henry et al., 2005). This correlates with the increased prevalence in older people, as ageing is linked to hearing loss (Baguley et al., 2013b).

1.3. Etiological factors of tinnitus

A major risk factor for tinnitus seems to be hearing loss. However, this is a complicated matter as numerous people with hearing loss do not experience tinnitus, whereas some patients with tinnitus do not present with hearing loss (Baguley et al., 2013b). Hearing loss and tinnitus therefore often coincide, but not necessarily. In the famous Heller and Bergman (1953) study, 94% of the subjects reported tinnitus within minutes after being placed in a soundproof booth, indicating that tinnitus basically becomes a universal experience in severe silence (Holgers et al., 2000). It is apparent that tinnitus is a common experience in silence and that the surrounding environmental sound may serve as a natural masker of the tinnitus. Yet, there is a consistent and unambiguous connection between hearing loss and tinnitus according to research (McFerran & Baguley, 2009). Tinnitus occurs in both patients with conductive hearing loss (CHL), but especially in those with SNHL, making SNHL (especially in the high frequencies) the dominant factor in predicting the occurrence of tinnitus (Ruppert & Fay, 2012). Considering CHL, the indications are that the occurrence of an air-bone gap on the audiogram is a risk factor for tinnitus. Furthermore, the greater the air-bone gap is, the higher the possibility of tinnitus seems to be. Tinnitus perception in CHL relates to the reduction of environmental sound input and the possibility of increased central gain in the auditory system. The bigger the air-bone gap, the greater effect it has on sound transmission through the middle ear, thereby reducing sound input and increasing the odds of tinnitus (Davis, 1995). Tinnitus is an extremely complex phenomenon and is not a disease per se, but rather reflects a symptom that can result from multiple conditions somewhere in the auditory pathways, including the ear, auditory nerve and auditory cortex (Weaver, 2014). Injuries along the auditory pathway often result in hearing loss. Therefore, there is a high correlation between hearing loss and tinnitus.

As mentioned, primary tinnitus is idiopathic and may or may not be associated with SNHL (Tunkel et al., 2014), which refers to hearing loss on a cochlear level where damage to the cochlear hair cells occurred. Hair cell damage may cause a series of events on the auditory pathway that result in the perception of tinnitus, which is discussed in detail in the section describing the mechanisms of tinnitus. Hair cell

damage occurs naturally with ageing and may cause age-related SNHL or presbyacusis (Henry et al., 2005). Noise exposure may also lead to SNHL and has been described as a risk factor for tinnitus (Galazyuk, Wenstrup & Hamid, 2012; Kim et al., 2015). Strong relations between noise exposure and tinnitus have been well documented and the recent report by Kim et al. (2015) further stressed the association of a range of various forms of noise exposure with tinnitus. Noise exposure can occur in the work place, such as factory work, military service or night club jobs (Baguley et al., 2013a). People can also be vulnerable to recreational noise exposure, especially musicians, iPod users, and people engaging in do-it-yourself activities (Baguley et al, 2013a; Kim et al. 2015).

Some drugs may induce tinnitus, although it is sometimes difficult to distinguish with certainty whether it is the condition that requires the treatment or the treatment itself that leads to tinnitus, as both are strong stimulants of the limbic system (Baguley et al., 2013a). Some drugs may have an ototoxic effect, resulting in cochlear damage. These include salicylates, which may cause outer hair cell dysfunction which is often reversible. Although it is frequently reversible, the temporary cochlear damage categorises it as primary tinnitus. The intake of salicylates may lead to interference with the motor protein of the outer hair cells, prestin, may reduce cochlear blood flow, and inhibits the enzyme cyclooxygenase. Antibiotics such as aminoglycosides can cause ototoxicity if normal therapeutic levels are exceeded, with some people showing unusually high cochlear sensitivity for them. The aminoglycosides are thought to stimulate free radical production within the outer hair cells, resulting in cell death (Chrbolka, Paluch & Alušik, 2015; Baguley et al., 2013a).

Secondary or “syndromic” tinnitus is linked to a specific underlying cause (other than SNHL) or an identifying organic condition (Tunkel et al., 2014). In these cases tinnitus management relies largely on treatment of the underlying cause.

A familiar cause of secondary tinnitus is otosclerosis, a disease of the footplate of the stapes, otic capsule and vestibular apparatus, resulting in CHL (Baguley et al., 2013a). It occurs more commonly in women and in the Caucasian race, with a prevalence varying from 0.3% to 2.1%. The theories as to why otosclerosis causes tinnitus take into account that CHL may cause deafferentation, as well as reduce the effect of environmental noises. It causes the formation of new bone which has a rich blood supply and the otosclerotic process produces small arteriovenous malformations, both leading to pulsatile tinnitus. Furthermore, the otosclerotic bone produces toxic enzymes which damage the cochlea, bony invasion of the cochlea can occur and cochlear blood supply may be altered (Baguley et al., 2013a).

Other conditions causing conductive hearing loss can be associated with tinnitus, such as wax impaction, otitis media, tympanic membrane perforations and cholesteatoma. Tinnitus related to these conditions is probably due to the decrease of sound input from the environment. These conditions are usually easily treated by Ear, Nose and Throat (ENT) specialists (Galazuyk et al., 2012; Tunkel et al., 2014).

There are many more conditions of the auditory system with a strong link to tinnitus, which is why the Clinical Practice Guidelines for Tinnitus (Tunkel et al., 2014) recommends a medical history and exam for tinnitus patients (Weaver, 2014). Ménière's disease, vestibular schwannomas, cerebellopontine angle lesions, superior semicircular canal dehiscence, and myoclonus conditions may result in secondary tinnitus (Baguley et al., 2013a).

Apart from medical conditions, mental health complications pose a risk for tinnitus. Stress, depression and unemployment have all been connected to the prevalence of tinnitus (Kim et al., 2015), with tinnitus patients reporting remarkably enhanced strain during stressful times than healthy control groups (Mazurek, Szczepek & Hebert, 2015). The severity of the tinnitus often reflects the psychological state of the patient (Chrbolka et al., 2015) and a relationship between tinnitus and psychological distress

has been observed in many studies. Research findings suggest that both attentional and emotional brain areas are linked to tinnitus activity, therefore psychological intervention is proposed as a treatment component for tinnitus (Andersson, 2002). Not all research findings agree with a direct relationship between tinnitus and psychological disorders, with some results showing a low correlation between depression and tinnitus (Ooms, Meganck, Vanheule, Vinck, Watelet & Dhooge, 2011), while other studies observe only a weak association between tinnitus and mental health (Krog, Engdahl & Tambs, 2010). Nonetheless, evidence-based practice recommends psychological consultation for tinnitus patients, especially when the Tinnitus Handicap Inventory (THI) score exceeds 38 points (Crocetti, Forti, Ambrosetti & Del Bo, 2009).

1.4. Mechanisms of tinnitus

Several underlying mechanisms are likely responsible for the generation of tinnitus, which involves different levels on the auditory pathway, as well as neural, motor and somatosensory systems and their interactions with one another (Leaver, Seydell-Greewald & Rauschecker, 2015). Structures thought to be involved in tinnitus generation include the cochlea, cochlear nuclei, cochlear nerve, auditory cortex, limbic system and autonomic nervous system.

Cochlear involvement in tinnitus is well described in various research reports (Kaltenbach, 2009; Leaver et al., 2015; Snow, 2013). Under normal circumstances, when the cochlear system is intact, stimulation or excitation of any component of the system triggers inhibition directed at the other parts of it. This phenomenon is believed to boost the ultimate signal-to-noise product. When a component of the cochlear system is damaged, the surrounding areas are subject to reduced inhibition, therefore an increase in spontaneous activity can occur in those areas (Noble, 2008). With a loss of hair cell function, the afferent neurons seem to set off irregular auditory sensations close to the frequency region of the lesion (Henry et al., 2005). Support for this theory is found in the notion that tinnitus patients generally report the pitch of

their tinnitus to be close to the frequency range of their hearing loss (Henry et al., 2005, Roberts, Eggermont, Caspary, Shore, Melcher & Kaltenbach, 2010).

The lesion in the cochlea, as described above, leads to reduced neural activity from the peripheral system, which, in turn, may cause increased spontaneous neural activity in the central auditory nervous system (Kaltenbach, 2009; Newman et al., 2011), including the dorsal and ventral cochlear nuclei (DCN and VCN), the central nucleus of the inferior colliculus (IC), and the primary and secondary auditory cortices (Galazyuk et al., 2012; Roberts et al., 2010). It seems that these structures increase their gain in an attempt to compensate for the loss of input from the cochlea, thereby developing the hyperactivity in neural firing (Galazyuk et al., 2012). Enhanced spontaneous firing rates in the DCN continue after the lesion occurred, indicating independence of the peripheral system. The spontaneous firing rate seems to increase in the hours following the lesion, not just affecting the region of the hearing loss alone (Eggermont, 2015; Galazyuk et al., 2012). Further neural activity responses relating to tinnitus origins include neural synchrony, bursting activity and reorganisation of tonotopic maps in the auditory cortex (Galazyuk et al., 2012; Roberts et al., 2010). Following acoustic trauma, abnormal bursting activity occurs in the DCN and IC of the auditory nerve. Eggermont's (2015) study on cats showed that 3–16 weeks after noise-induced hearing loss, the tonotopic map in the primary auditory cortex changed significantly. Tonotopic remapping occurs as neurons that used to be activated by output from the now affected cochlear area become recruited to accept the increased spontaneous activity from the less affected neighbouring areas (Baguley, 2013b; Noble, 2008). In light of the above descriptions of cochlear and central involvement in tinnitus, one can conclude that cochlear pathology could be the initial foundation of tinnitus, but that the subsequent surge of neural changes in the central auditory system is probably responsible for maintaining the condition (Baguley, 2013b). Intervention aimed at reducing the effects of auditory pathology is strongly indicated in tinnitus management.

Tinnitus-related differences have also been identified outside of the central auditory systems in non-auditory structures (Leaver et al., 2015; Roberts et al., 2010), particularly involving the structures of the limbic system. The limbic system was initially defined as a circuit that serves emotion, linking the hippocampal formation, hypothalamus, cingulate cortex and prefrontal cortex. Other regions implicated in emotional processing are now also considered part of the limbic system, including the amygdala and ventral striatum (Leaver et al., 2015). The limbic system contains cortical and subcortical structures that are active in processes of memory, motivation, emotion and attention. Interconnections between auditory and limbic systems are reciprocal and appear to influence the development of tinnitus (Galazyuk et al., 2012; Gunbey, Gunbey, Aslan, Bulut, Unal & Incesu, 2015). Multiple sets of behaviours have been linked to these connections, such as auditory fear conditioning, plasticity in auditory centres in response to sounds and emotional responses to verbal stimuli. The thalamus processes auditory information and regulates sleep and wakefulness cycles, awareness and physical activity. As neuronal activity related to tinnitus becomes permanent in the medial geniculate body after a hearing loss, it results in enhanced thalamic grey matter concentration, affecting the inhibition to the perception of annoying sounds (Gunbey et al., 2015). Limbic and auditory structures interact in the thalamus and the tinnitus signal that started in the auditory pathway may be wiped out by feedback from the limbic system which blocks the tinnitus signal from reaching the auditory cortex. Should the limbic system fail to stop the signal, the perception of tinnitus will occur (Snow, 2013). In addition to tinnitus-related activity, the limbic system structures have also been implicated in research concerning the regulation of emotion, affect and mood (Leaver et al., 2015) and are associated with attention, executive function and behaviour (Roberts et al., 2010). A significant number of tinnitus patients are also suffering from psychological distress (Krog et al., 2010; Udupi, Uppunda, Mohan, Alex & Mahendra, 2013), with some studies placing the numbers as high as 45% (Reynolds, Gardner & Lee, 2004). As tinnitus has furthermore been linked strongly to reports of dysfunctions in sleep, concentration, daily functioning and emotional reactions (Newman et al., 2011), the involvement of limbic and cognitive systems in tinnitus is likely and deserves consideration in treatment.

1.5. Assessment of tinnitus

Thus far, tinnitus has proved to be difficult to measure and attempts to assess tinnitus have a long and complex history. Reasons for tinnitus being difficult to assess are inconsistent test-retest reliability, fluctuations of the tinnitus percept in many patients, and the complexity of tinnitus sounds (Tyler, 2000). Due to the high prevalence of hearing loss in tinnitus patients, diagnostic audiological testing is suggested to determine the presence and type of hearing loss and the opportunity for counselling and sound therapy. A test battery of otoscopy, tympanometry, air and bone conduction thresholds, speech reception and word recognition measures may provide valuable information about the presence, type and symmetry of hearing loss, and can assist in planning the intervention and patient education. Acoustic reflex and decay testing should be considered with caution as many of these patients are having difficulty in tolerating loud sounds (Tunkel et al., 2014).

Measurement methods of the tinnitus are designed to assess either the sensory aspects of the tinnitus by means of psychoacoustic measures or the functional and emotional effects of tinnitus, by means of self-reporting questionnaires (Meikle, Steward, Griest & Henry, 2008). Psychoacoustic measurements are less popular as they require specific equipment and protocols, along with being time-consuming (Meikle et al., 2008). They are not routinely recommended in the clinical practice guidelines for tinnitus, as they are not considered helpful in diagnostics or guiding intervention plans (Tunkel et al., 2014). There is little evidence of the existence of a relationship between the psychoacoustic characteristics of tinnitus and the distress tinnitus causes in patients (McKenna, Handscomb, Hoare & Hall, 2014; Ooms et al., 2011a). Yet, depending on the form of treatment, these characteristics may be clinically relevant, especially for counselling purposes and when masking stimuli or when sound generators are to be used (Henry et al., 2005).

Assessment of the psychoacoustic properties of tinnitus includes certain aspects, as subsequently discussed (Henry et al., 2005; Meikle et al., 2008). *Pitch matching* attempts to match the perceived tinnitus sound to a pure tone as presented via the

audiometer. Although earlier it was thought that the tinnitus pitch correlates with the edge frequency of the hearing loss, one study could not find a clear relationship between the audiogram and the most prominent pitch of the audiogram (Pan, Tyler, Ji, Coelho, Gehringer & Gogel, 2009). Pan et al. (2009) also concluded in their study that patients found it difficult to match the tinnitus to a certain frequency and that some patients experience a tonal sound, while others describe it as a noise-like sound which was even harder to match to one frequency. At the pitch-matched frequency, the *loudness* of the tinnitus is determined based on the patient's perception of which intensity matches that of the perceived tinnitus. The *minimum masking level* (MML) refers to the minimum intensity level at which broadband noise will render the tinnitus inaudible. Once the MML has been determined, *residual inhibition* (RI) is measured to determine if and how the patient's tinnitus has changed and how long it takes for the tinnitus to return to its usual loudness. Of these measurements, loudness and MML measures have been found to be the most remarkably reduced following intervention for tinnitus (Meikle et al., 2008). The current study also measured these psychoacoustic properties of tinnitus to see if any noteworthy changes were observed that could be linked to the effect of tinnitus intervention.

In essence, the factor that makes tinnitus a debilitating condition is the distress it causes in the patient. Therefore, it is fundamental to interview the patient carefully to get an indication of the severity and the impact of the tinnitus. A detailed, structured interview may help the clinician to obtain information about the nature and onset of the tinnitus, together with the patient's account of how it affects his/her everyday life (Baguley et al., 2013a). Helpful tools in obtaining information about the impact of the tinnitus are found in a number of tinnitus-specific questionnaires that aim to identify the areas affected by the tinnitus and that are sensitive to the effects of treatment. Two such questionnaires were used in the current study, namely the *Tinnitus Handicap Inventory* (THI) (Newman, Jacobson & Spitzer, 1996) and the *Tinnitus Functional Index* (TFI) (Meikle, Henry, Griest, Steward, Abrams, McArdle et al., 2012).

The THI is the most widely used scale internationally for assessing a self-reported tinnitus-related handicap, as well as determining treatment outcomes. It is a subjective self-report tinnitus questionnaire with outstanding convergent validity, construct validity and test-retest reliability (McCombe, Baguley, Coles, McKenna, McKinney & Windle-Taylor, 2001). Significantly, the degree of handicap calculated according to the THI has been shown to have close correlations with both stress levels and psychopathology levels in patients (Salviatti, Macrì, Terlizzi, Melcore, Provenzano, Capparelli et al., 2013). Salviatti et al. (2013) compared the THI scores of tinnitus patients to their scores of psychopathologic distress measures and found that a THI score greater than 36 was strongly indicative of psychiatric comorbidity in patients. Their study results resemble the trends identified by Crocetti et al. (2009) whose study indicated strong correlations between THI scores and the presence of anxiety and/or depression symptoms. They recommended in-depth psychological assessments for all tinnitus patients with THI scores of 38 and more. Zeng, Li, Li, Cen, Li and Zhang (2016) found the scores of the different subscales of the THI particularly helpful in determining potential contributory underlying factors of exacerbated tinnitus. Their subjects presented raised functional subscale scores in cases of aggravated hearing loss, whereas elevated emotional subscale scores were associated with negative life events. The THI is therefore identified as a valuable tool for detecting which tinnitus patients may need psychological treatment as part of their tinnitus intervention, as was the focus of the current study.

The TFI is a fairly new 25-item questionnaire with robust psychometric validity. It was designed to be sensitive to treatment effects, to address all the key dimensions impacted by tinnitus, and to be validated to scale the negative impact of tinnitus (Henry, Griest, Thielman, McMillan, Kaelin & Carlson, 2015). It is sensitive to outcomes, making it a good tool to monitor progress and for use in research (Baguley et al., 2013a). It was aimed at improving the THI's sensitivity to changes in tinnitus severity (Fackrell, Hall, Barry & Hoare, 2015). The current study applied TFI assessments together with THI evaluations to look for comparisons in score changes with intervention and to assess if differences in the various subscale areas occur with the alterations in therapy methods.

The current study further looked into the distress experienced by the subjects by means of interviews and assessments done by a psychologist, as recommended in the Clinical Practice Guidelines for Tinnitus (Tunkel et al., 2014). As the prevalence of anxiety and/or depression disorders have especially been reported among tinnitus studies (Krog et al., 2010; McCormack, Edmonson-Jones, Fortnum, Dawes, Middleton, Munro et al., 2015), the psychologist screened for anxiety and depression in the study participants.

The first evidence-based clinical practice guidelines for the assessment of chronic tinnitus was published by Tunkel et al. in 2014. The guidelines exclude patients with secondary tinnitus, pulsatile tinnitus, and tinnitus associated with complex auditory hallucinations or hallucinations related to psychosis. A summary of the guidelines for assessment of patients with bothersome, persistent and primary tinnitus is illustrated in Figure 1.

Clinical practice guidelines for tinnitus assessment (adapted from Tunkel et al. , 2014)

Figure 1. Clinical practice guidelines for tinnitus assessment

1.6. Management of tinnitus

Approximately 8% of the population take steps to seek medical advice about tinnitus (El-Shunnar et al., 2011) and as the world-wide awareness of tinnitus is rising, so is the number help seekers (Holgers et al., 2000). A number of tinnitus treatments are being practised today. The intervention focus is often related to the origin or cause of the tinnitus as believed or understood by the practitioner (Baguley, 2006).

Therapies are designed based on the different assumed mechanisms of generation. Sweetow (2013) summarised the current treatments under three subgroups, each group focusing on a specific goal it aims to achieve. The interventions based on the "auditory modality" try to reduce the contrast of the tinnitus, those based on "limbic engagement" attempt to change the thought patterns about tinnitus, and treatments relating to "auditory-striatal-limbic connectivity" entail physical procedures on anatomic structures thought to be involved in tinnitus generation, aiming at reducing the tinnitus at the original sources. Figure 2 illustrates how certain therapy approaches and techniques fit into these three different schools of thought.

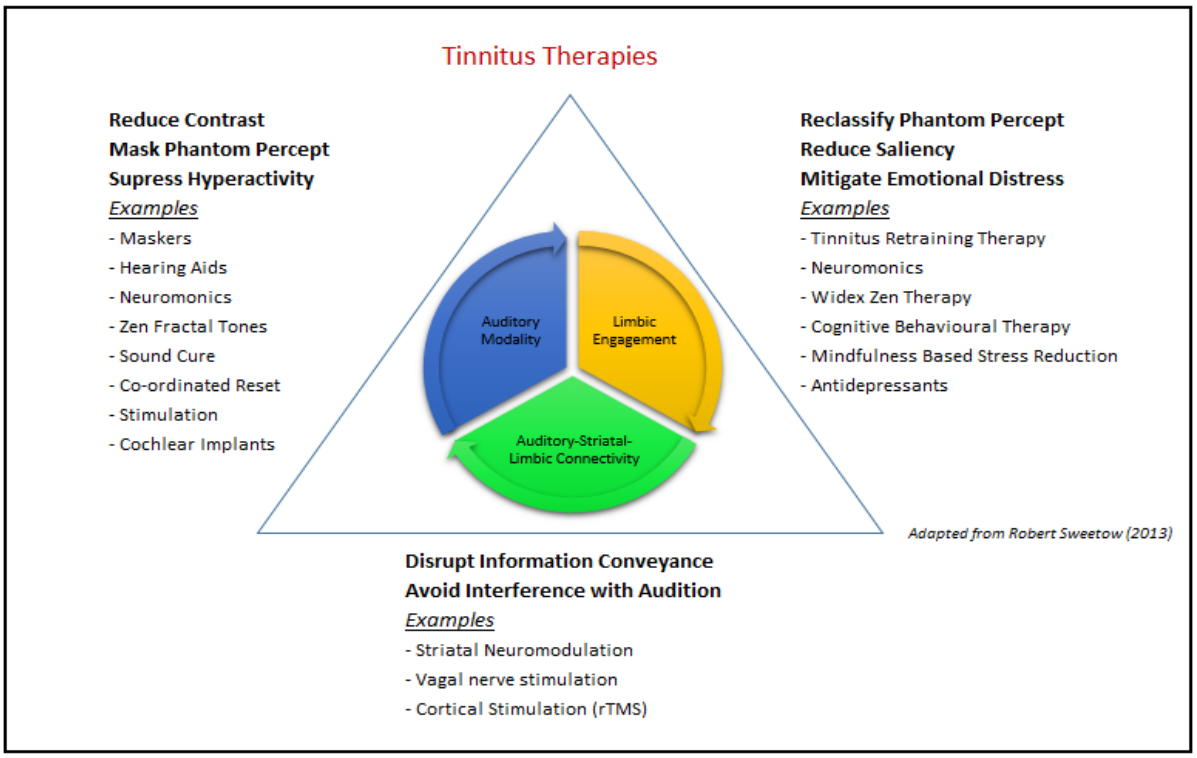

Figure 2. Tinnitus therapies (Sweetow, 2013)

1.6.1 Tinnitus intervention based on the auditory modality

Intervention may be aimed at reducing the contrast of the tinnitus, focusing on an auditory modality. This would include the use of various noise generators, hearing aids and cochlear implants. Stimulation of the hearing system may reduce the hyperactivity of the auditory system (Sweetow, 2013). The use of hearing aids as tinnitus treatment has been the dominant method of choice among audiologists for a long time (Henry et al., 2005; Hoare, Kowalkowski, Kang & Hall, 2011). While the majority of audiologists are not qualified tinnitus experts, they are aware that hearing aids may bring benefits of some sort to the patient (Henry et al., 2005). Sound can act as a masker of tinnitus, as it stimulates the auditory pathways (Holgers et al., 2000). Silence can induce tinnitus, as shown in the Heller and Bergman study (1953), where normal hearing people experienced tinnitus when placed in a quiet, sound-treated room.

The bulk of tinnitus patients do in fact also have hearing loss (Noble, 2008; Tyler, Haskell, Gogel & Gehringer, 2008). Therefore, enhancing the input of sound to the peripheral hearing system with a hearing aid may reduce the tinnitus (Holgers et al., 2000). Hearing aids may enhance the hearing of soothing sounds, increase background noise as to create a diversion of attention away from the tinnitus, give more access to other interesting sounds to direct the attention away from the tinnitus, stimulate the auditory cortex, enhance quality of life in aspects that are related to hearing difficulties, reduce the amount of attention that the patient pays to the tinnitus, and amplify ambient noises to mask the tinnitus signal (Henry et al., 2005; Henry, Zaugg, Myers & Schechter, 2008; McNeill, Távora-Vieira, Alnafjan, Searchfield & Welch, 2012). Even though many tinnitus patients will shift the blame of their communication difficulties to their tinnitus rather than their hearing loss (Tyler, Gogel & Gehringer, 2007), they may find that the stress they experience is significantly reduced as their communication improves (Tyler et al., 2008). Research indicated that the effects of subjective tinnitus have been significantly reduced after patients received hearing aids, compared to the scores before hearing aid fitting (Henry, Zaugg, Myers & Schechter, 2008).

The use of therapeutic sound is often used as part of tinnitus treatment. Sound can affect both the perception of the tinnitus, referring to the acoustic characteristics of the tinnitus, as well as the person's reaction to the tinnitus (Henry et al., 2008). The patient can be supplied with additional sound stimuli via ear-level devices, such as hearing aids, or environmental stimuli such as sound generators, radios, water features or fans (Henry et al., 2005). There are also applications that can be downloaded on mobile phones that are designed to provide soothing sounds which may relieve the tinnitus. When the sound affects the tinnitus perception, the process is usually referred to as "masking". Masking can occur either completely (making the tinnitus inaudible), partially (causing spectral changes in the tinnitus) or not at all, which does not cause any change in the tinnitus percept (Henry et al., 2008; Tyler et al., 2008). Sometimes the intention of the sound stimulation is not to alter the characteristics of the tinnitus, but rather to change the patient's response to the tinnitus. Henry et al. (2008) describes how sound can be chosen for different purposes, such as using soothing sound to promote a sense of relief, background sound to lessen the contrast between the environmental sound and the tinnitus sound, or interesting sound to direct attention away from the tinnitus and onto another sound. Sound enrichment may offer short-term relief from the tinnitus, but has no impact on the tinnitus itself (Noble, 2008). There is little, and very conflicting evidence available on the efficacy of maskers (Dos Santos, Bento, De Medeiros, Oiticcica, Da Silva & Penteado, 2014; Henry et al., 2005; Hoare et al., 2011).

1.6.2. Tinnitus intervention based on limbic engagement

Becoming more and more popular are the interventions aimed at addressing the emotional distress caused by the tinnitus and helping the patient to reclassify his/her thoughts and beliefs about tinnitus. Therapies supporting this notion include the counselling aspect of Tinnitus Retraining Therapy (TRT), Cognitive Behavioural Therapy (CBT), relaxation and the counselling programmes of Widex Zen Therapy and Neuromonics (Sweetow, 2013).

Counselling the tinnitus patient should be one of the focus points of tinnitus management, involving the discussion of tinnitus mechanisms, offering sympathy and

reassurance to the patients, and informing them about available and suitable treatment options (Galazyuk et al., 2012). Further counselling points would be avoiding excessive noise exposure, reducing stress, limiting caffeine, alcohol and tobacco intake, avoiding silence and keeping busy with meaningful tasks (Henry et al., 2005). As stress is an important risk factor in the severity of tinnitus (Baigi et al., 2011), it is sensible to offer emotional support to the patients. It has been observed that simply paying attention to patients may already have a positive effect on their tinnitus distress (Tyler, 1997). Another method to alleviate tinnitus distress is directive counselling. Directive counselling refers to structured content of the counselling directly presented to the patient by the clinician (Henry et al., 2005). It is shown to be significantly more effective than undirected self-help methods (Hoare et al., 2011).

The neurophysiological model of tinnitus (Jastreboff, 1990) serves as the foundation of TRT and suggests that the development of bothersome tinnitus does not only lie in the generation and perception of the tinnitus signal, but in the way the brain evaluates, monitors and reacts to it. Should the signal be classified as an unpleasant or threatening stimulus, it earns greater attention and analysis, which inevitably evokes emotional responses (Jastreboff, 2007). These emotional reactions should be addressed to promote successful and long-lasting management of tinnitus. The model focuses on achieving habituation, both to the reactions to tinnitus experienced and to the tinnitus signal itself (Jastreboff, 2007). To achieve habituation, a broad band sound is applied together with amplification (where indicated), which must not overshadow (mask) the tinnitus signal completely, leaving the tinnitus to remain audible to the patient so that it could be habituated to. Directive counselling helps the patient understand the tinnitus and auditory mechanisms and is aimed at gradually neutralising the negative perception of tinnitus so that habituation may take place (Hazell, 1999). Overall, TRT is mostly described as a sound and successful approach. When compared to tinnitus masking, it was indicated that tinnitus masking may bring more relief initially which remained fairly constant, but that the effects of TRT improved incrementally, leading to greater success in the long term (Henry, Schechter, Zaugg, Griest, Jastreboff, Vernon, Kaelin et al., 2006). This finding highlights the benefit of audiological counselling.

The goal of psychological treatments for tinnitus is to address the way in which the patient responds to the tinnitus, rather than addressing the tinnitus itself. Psychologists may apply techniques such as hypnosis, relaxation, biofeedback, stress management or education, with the standout treatment of choice being CBT (Noble, 2008). It has been reported numerous times that approximately 40–50% of people with tinnitus suffer from significant levels of psychological distress (Newman et al., 2011; Reynolds, Gardner & Lee, 2004). Pre-existing psychological factors such as anxiety, depression and mood disorders tend to be more pronounced in people with tinnitus than in people without complaints of tinnitus and seem to play a role in the development of negative behavioural responses to tinnitus (Andersson, Strömgren, Ström & Lyttkens, 2002; Andersson, 2002; Reynolds et al., 2004). Furthermore, the tinnitus may lead to further psychological distress such as reduced quality of life, anxiety, sleep problems, poor concentration, avoidance behaviours and emotional suffering (Andersson, 2002; Newman et al., 2011). Clinical psychologists are trained to counsel the patient presenting with these difficulties and to assist the patient to empower themselves to manage or alter their problems.

The style of CBT is counselling that assists the patient in identifying negative and inappropriate behaviours and reactions and finding ways to change them into more positive and appropriate reactions (Henry et al., 2005). It is the most widely validated psychological treatment and shows consistent signs of efficacy in tinnitus treatment (Hoare et al., 2011; Newman et al., 2011, Noble, 2008). Opposed to directive counselling, it involves close collaboration between the patient and clinician when identifying maladaptive cognitions and devising alterations and specific goals (Andersson, 2002; Wright, 2006). An underlying foundation of CBT focuses on the three major levels of cognition: full consciousness where rational decisions are made with full awareness, automatic thoughts which are not carefully assessed for accuracy and truthfulness, and schemas, the fundamental rules or core beliefs within a person (Wright, 2006). Cognitive methods of CBT apply the use of questions to guide the patient to new perspectives. The clinician asks the patient to reflect on specific aspects that guide him/her to identify cognitive errors and to find alternative ways of processing that are less disruptive. Behavioural methods of CBT involve the planning

of activities and pleasant events that would enhance quality of life and resist low energy and poor participation patterns (Wright, 2006). A typical CBT package for tinnitus treatment may include relaxation techniques, cognitive restructuring of incorrect beliefs about tinnitus, reducing avoidance and checking behaviours, encouraging mindfulness to notice their own thoughts with less distress, altering emotional reactions to tinnitus, addressing sleep hygiene and concentration difficulties, and relapse prevention strategies (Andersson, 2002; Newman et al., 2011). The patient is therefore guided and empowered to change his/her perceptions about tinnitus and to adapt his/her behavioural responses in order to experience less distress and enhanced quality of life.

1.6.3. Tinnitus intervention based on auditory-striatal-limbic connectivity

Some interventions focus on the disruption of information conveyance. These medical models include therapies of neuromodulation in the basal ganglia, vagal nerve stimulation and cortical stimulation. These approaches are very new and more research is being done to develop these techniques (Sweetow, 2013).

1.6.4. Alternative tinnitus therapies

Apart from audiological and psychological interventions, current available practices for tinnitus management include pharmacotherapy or drugs, sleep, stress-relief and biofeedback clinics, music and relaxation therapies, electrical and magnetic stimulations, ultrasound, acupuncture, hypnosis, laser treatment and ear candling (Baguley, 2013a; Henry et al., 2005; Hoare & Hall, 2011; Noble, 2008; Tyler, 1997). Up to date there is no consistent evidence for the true effectiveness of any pharmacological elements in tinnitus treatment, although antidepressants may reduce sleep problems for severely distraught patients and could be helpful in reducing anxiety and depressive symptoms often associated with tinnitus (Noble, 2008). Under extensive review, it was concluded that medications that were considered for tinnitus treatment often relieve factors associated with tinnitus rather than the tinnitus itself. This could potentially create risks of dependence that may have serious side effects

or simply do not prove any advantage over the placebo (Henry et al., 2005). A lack of clear evidence also marks the other treatments mentioned and some, such as ear candling, raise serious concerns for the patient's safety (Baguley, 2013a).

1.7. Motivation for audiological and psychological intervention in combination

Current research implies good methods in applying the audiological techniques of hearing aid fitting and directive counselling, but also shows great promise for the psychological direction of CBT as tinnitus treatment. Can we name one kind of treatment as better than the other? Noble (2008) stated that at present, no profession can claim to hold the prime position. Both fields have produced quality work in proving their relevance and progress, with strong arguments supporting their cause.

At present, there seems to be a tendency to direct tinnitus patients towards psychological treatments, suggesting that it is the leading form of intervention (McFerran & Baguley, 2009; Reynolds et al., 2004). As most tinnitus patients do present with hearing loss and because the uses of hearing aids are shown to relieve tinnitus, the audiologist does have a relevant and important role in tinnitus management (Henry et al., 2005; Noble 2008). Tinnitus cannot be explained without acknowledgement of the complexity of its mechanisms involving the peripheral and central auditory systems and their connections to the central nervous system (McFerran & Baguley, 2009).

Psychologists are not extensively (if at all) trained in auditory pathology, nor can they fit hearing aids. Therefore, as tinnitus is perceived by the patient to be an ear-related condition, the entry point of intervention must remain audiological and otolaryngological (McFerran & Baguley, 2009). Yet, we cannot deny the repeated evidence of psychological factors in tinnitus patients and the persistent distress that the tinnitus causes them (Reynolds et al., 2004). The evidence for the valuable contribution that CBT can bring in treatment should not be ignored when treating a

tinnitus patient. However, audiologists are not trained in CBT and although there are educational centres offering short courses in CBT, one cannot expect an audiologist with a fraction of a psychologist's training to perform CBT on a comparable level (McFerran & Baguley, 2009). Likewise, there is a serious shortfall of psychologists who are literate in audiology and tinnitus and who are prepared to partake in tinnitus intervention (McFerran & Baguley, 2009). Audiologists' scope of practice excludes intervention in chronic depression, personality disorders and suicidal tendencies (Tyler et al., 2008; Baguely, 2005) – factors that may be relevant in tinnitus cases. Keeping all these factors in mind, the next possibility should be considered: the optimal model for tinnitus intervention may be a team approach between audiology and clinical psychology (Noble, 2008).

1.8. Problem statement

Tinnitus is a debilitating condition affecting millions of people around the world. Its repercussions affect the domains of emotional, financial and functional well-being. Unfortunately, the ideal treatment recipe remains elusive and an urgent need for more comprehensive diagnostic and treatment guidelines is expressed (Hoare & Hall, 2010; Langguth, Kleinjung & Landgrebe, 2011). The field of tinnitus is young and lacks substantial supporting evidence (Searchfield, 2011). While the uncertainty continues, the numbers of help seekers are increasing. More and more tinnitus sufferers are reading about tinnitus on the Internet, travelling to find solutions, hearing about tinnitus through multidimensional media and discussing it. While tinnitus sufferers are becoming better informed, they are also expecting better solutions (Tyler, 1997).

Despite the growing evidence of both audiological and psychological techniques showing promise in tinnitus therapy, the referral patterns between these fields are of concern. A national survey in the UK showed that while all the audiology clinics offered their tinnitus patients audiological strategies, the provision of psychological care was variable and inconsistent (Hoare, Gander, Collins, Smith & Hall, 2010). Hoare and Hall (2011) reported that only a third of their respondents reportedly had the opportunity of referring their tinnitus patients to psychology. Furthermore, only one

third used a tinnitus questionnaire and a mere 5% screened for anxiety or depression by means of a validated questionnaire (Hoare & Hall, 2011). The field of tinnitus deserves better teamwork and more exposure on educational levels across these fields (Tyler, 1997). Tinnitus treatment requires collaboration between disciplines and research initiatives investigating a combination of strategies from different fields would be of enormous value for the future of tinnitus intervention (Baguley et al., 2003).

1.9. Rationale

There is a clear call for research evaluating the combination of audiological and psychological components in tinnitus treatment. Salviati et al. (2013) found 43.59% of the tinnitus patients in their sample to be affected by a psychological disorder and identified a THI score of over 36 to be likely to co-occur with psychological conditions that warrant psychological intervention. This correlates with the work of Crocetti et al. (2008), recommending psychological consultation for all tinnitus patients with a THI score of 38 or more after significant correlations were found between those patients' THI scores and depression and/or anxiety indicators. It may therefore be assumed that patients with THI scores greater than 36 should benefit from both audiological intervention to address the neurophysiological components of tinnitus, as well as psychological intervention to address the psychological conditions that are likely to be present. Thus far, much has been written about either type of intervention for tinnitus as a singular approach.

Audiologists are consulted worldwide about tinnitus management, especially because the majority of tinnitus patients have hearing loss (Tyler, 2000). McNeill et al. (2012) showed that hearing aids can relieve tinnitus, but they did not include psychological intervention methods in the study and only monitored the participants over a period of three months. Reynolds et al. (2004) expressed their deepest concern when they found that patients who completed their proposed tinnitus treatment still presented with continuing psychological complications afterwards. The possibility of setbacks post treatment needs to be assessed when the initial optimism achieved during intervention may have faded. Audiologists may play a valuable role in providing

counselling within the area of hearing loss (Tyler et al., 2008). In order to provide patients with a deeper understanding of their tinnitus, directive counselling methods show great promise (Hoare et al., 2011). A complete and available protocol for directive counselling can be found in the Tinnitus Retraining Therapy Counseling Guide, which is based on the Neurophysiological Model of Tinnitus (Jastreboff, 1990), and is used as an illustrated ring-bound book that assists the clinician with counselling of the patient in terms of the TRT principles. It may add great value in addition to hearing aid fitting and CBT for patients with tinnitus and hearing loss.

Psychologists are also reported to be valuable in tinnitus treatment. Recent work by Ooms, Vanheule, Meganck, Vinck, Watelet and Dhooge (2011) suggests that psycho analysis of tinnitus patients is justified, as many patients show a significant relation between the severity of their tinnitus and anxiety – both cognitive and somatic anxiety. They suggest that in line with Jastreboff (1995), anxiety could be a causal factor in tinnitus, but is also the result of an anxious reaction toward the tinnitus, thus creating a vicious circle effect. Because psychologists are suited to treat depression and anxiety, often by administering CBT, their use of CBT is also likely to be beneficial in the treatment of tinnitus (Andersson, 2002). Andersson, Porsaeus, Wiklund, Kaldo and Larsen (2005) reported that CBT is an effective treatment for tinnitus. However, in their study a standard protocol of audiological support including hearing aid fitting was not followed with participants.

None of the above-mentioned studies investigated an approach combining structured professional audiological and psychological intervention as a collaborative effort. There is a need for collaboration between disciplines and research initiatives investigating interdisciplinary teamwork could be of significant value (Baguely, Davies & Hazell, 2003). With the high prevalence of hearing loss and psychological influences in tinnitus patients (McCombe et al., 2001), comparisons between psychological or audiological intervention versus a combination of both may be of value in recommending tinnitus treatment methods in the future. In the light of the previous research outcomes that have been discussed, the proposed study asks the following

question: Does a combined psychological and audiological intervention approach result in better treatment outcomes than either method alone where tinnitus and hearing loss co-exist?

2. METHODOLOGY

2.1 Research objective

The objective of the study was to determine the effect of a combined multidisciplinary approach in the treatment of tinnitus, using psychological and audiological intervention methods, in comparison to a single approach to tinnitus severity.

2.2. Research design

This study followed a quantitative research approach, employing a randomised quasi-experimental within-subject, repeated measures design with a varied order of procedures (Fouche, Delport & De Vos, 2005). The extent to which the independent variables (the intervention methods) influenced the dependent variable (the tinnitus severity) was investigated (Struwig & Stead, 2001). A within-subject design refers to a study where the same group of subjects (the study participants) was evaluated at different time intervals (Kim, 2010). One group of participants' outcomes of intervention was compared to their own outcomes on a different method of intervention in terms of their tinnitus severity. To avoid influences of individual personality traits between different subjects on the results of the subjective tinnitus scales, no control group was implemented. This allowed for comparable contexts and individuality to be separated from the error term as each participant served as his/her own control (Kim, 2010; Trochim, 2006).

The research design used in the current study creates a bias, as it is possible that the influence of the previous intervention period could remain and impact on the measurements taken throughout the data collection. An experimental design with a control group may have minimised such bias (Fouche et al., 2005). If different groups of participants received different types of intervention, other intervention effects could not possibly interfere with the accuracy of the measurements taken. However, tinnitus severity is a subjective and personal matter. It is not perceived as and responded to

equally among different people (El-Shunnar et al., 2011; Newman et al., 2011). Many internal factors may influence the experience of tinnitus, such as the presence and varying configurations of hearing loss (Henry et al., 2005, Rupert & Fay, 2012), age (Kim et al., 2015), gender (Holgers et al., 2000; Kim et al., 2015) mental health (Kim et al., 2015; Mazurek et al., 2015), personality traits and emotional responsiveness (Andersson, 2002). A research design where different groups of participants were compared to one another could not possibly achieve exact similarity for the internal factors mentioned above. This could create another bias, as the participants in different groups may respond in a dissimilar manner to the various types of intervention, possibly due to their own internal factors. The current study attempted to avoid the influence of personal factors across different participant groups on the measurements, therefore opted to use a within-subject, repeated measures design. The order of interventions were varied for each group to minimise the bias.

2.3. Ethical considerations

The South African National Health Act (2007) provides clear guidelines for research to be conducted in an ethical manner. Where human subjects are involved in a study, ethical standards must be maintained to protect them from potential harm (Trochim, 2006). This study followed and respected these guidelines and standards, aiming to promote respect for all the participants. As commanded by the South African National Health Act (2007), ethical clearance was obtained from an established research ethics committee, in this case at the University of Pretoria, before commencing with the data collection (Appendix A). The following guidelines for ethical research procedures were carefully studied and adhered to throughout the study.

2.3.1. Informed consent and voluntary participation

Informed consent is a fundamental principle of research ethics and requires that participants are thoroughly informed about the specifics of the research procedures and that they voluntarily agree to take part without being coerced (Struwig & Stead, 2001; Trochim, 2006). In the current study the prospective candidates had to

understand that they would receive therapy to address their tinnitus at no cost. The treatments would take place over three periods, each lasting two months. These three periods involved audiological, psychological and combination approaches. They had to be willing to take part in the therapy, and be willing to travel to the relevant practices for the intervention as instructed in certain time frames. Prior to taking part in the data collection, they had to complete assessments from audiological and otolaryngological perspectives to ensure that they were suitable candidates for the study. This information was discussed with each participant by the researcher when he/she was invited to take part in the study. This was done in addition to the participant receiving an invitational letter (Appendix B) containing information with regard to the research procedures. Participants were then provided with an informed consent form (Appendix C). This form explained the title, goal and procedures of the research project. It stated that there were no known risks and discomfort associated with participation, that their confidentiality would be ensured, and that they had the right to withdraw from the study without any consequences. By signing this form, they agreed to take part voluntarily with a thorough understanding of the research process. All participants signed informed consent forms before partaking and received a signed copy of the document for themselves.

2.3.2. Beneficence and non-maleficence

This ethical principle implies that good should be done to the participants and that they should not be placed in a situation where they are at risk of physical or physiological harm (Trochim, 2006). This principle was adhered to by fitting the participants with top-end hearing aid technology and using a well-structured and trusted counselling manual founded on evidence-based practice, namely the Tinnitus Retraining Counselling Guide. To prevent harm, each hearing aid fitting was objectively validated by means of performing Real Ear Measurements (REM) for accurate gain calculations (Martin & Clark, 2003).

2.3.3 Quality of procedures

High-quality research should be a priority for all researchers. In the current study, excellence was pursued by using calibrated equipment for all measurements of the hearing system as well as the psychoacoustic characteristics of the tinnitus. The subjective tinnitus scales, including the THI (Appendix D) and the TFI (Appendix E), were selected for their good internal consistency (Crocetti et al., 2009), credibility and responsiveness to intervention-related change (Henry et al., 2015) and for producing reliable assessment data. The hearing aid fittings were objectively verified by means of REM, which is a recognised and recommended evidence-based procedure (Martin & Clark, 2003).

2.3.4 Plagiarism

The work of others may not be used without accurate acknowledgement of their contribution (De Vos, Strydom, Fouché & Delport, 2011; Struwig & Stead, 2001). All the sources that were used to contribute to the current study were acknowledged.

2.3.5 Confidentiality

The privacy of all participants must be protected when conducting research and they must be assured that identifying information will not be accessible by persons who have no direct involvement in the study (Struwig & Stead, 2001; Trochim, 2006). As the data collection for the current study involved therapy with participants and multiple measurements at different points in time, anonymity could not be achieved (Trochim, 2006). However, confidentiality was achieved by assigning a code to each participant which was used for the data-processing procedures. Only the psychologist was made aware of each participant's code as she too had an active role in the data collection procedure (De Vos et al., 2011).

2.4. Participants: Sampling and selection

2.4.1. Participants

The participant population comprised of persons suffering from tinnitus, accompanied by sensory hearing loss as evaluated by a registered audiologist. All participants presented with initial baseline scores of 38 points or more on the subjective THI (Newman et al., 1996), categorising their tinnitus as either “moderate”, “severe” or “catastrophic”. The configuration of the hearing losses was not considered for the inclusion criteria. The tinnitus and hearing loss were either bilateral or unilateral.

2.4.2. Inclusion and exclusion criteria for participant selection

Gender was not considered a factor of inclusion or exclusion in the current study. All participants in the study had to comply with the following selection criteria to avoid interference with the validity of the results by external and variable factors. To qualify for inclusion in this study, all participants had to:

a) Present with bilateral or unilateral bothersome tinnitus, scoring 38 or more points on the THI (Newman et al., 1996), therefore categorising their tinnitus as either “moderate”, “severe” or “catastrophic”. Studies suggest that patients with scores of 38 or more on the THI are likely to present with psychological conditions and should also be referred for psychological treatment (Salviati et al., 2013; Crocetti et al., 2008). The current study included both audiological and psychological intervention, therefore participants with scores of 38 or more were considered to be ideal candidates to receive the planned intervention. The THI is a subjective self-report tinnitus questionnaire with outstanding convergent validity, construct validity and test-retest reliability (McCombe et al., 2001). The THI can be reproduced and has no copyright, making it easily accessible for research application (McCombe et al., 2001). The study measured differences in the THI scores over a period of roughly nine months, after different treatment models were used, therefore the initial scores had to be indicating at least a moderate handicap in order to leave room for change. Although the TFI was also used to monitor the participants’ tinnitus severity, it was not involved in the decision of candidacy for the study.

b) Present with hearing thresholds worse than 25 dBHL at a minimum of three frequencies between 250 Hz and 8000 Hz at least in one ear, as assessed by an audiologist. Thresholds of -10 dBHL to 15 dBHL are considered normal hearing (Clark, 1981). A minimal hearing loss occurs from 16 dBHL to 25 dBHL, while 25 dBHL to 40 dBHL is classified as a mild loss (Clark, 1981). It was decided to include only patients with a hearing loss that was mild or worse so that hearing aid fitting as part of the audiological intervention could be ethically facilitated when it was certain that they presented with hearing loss.

c) Present with hearing loss of a sensory (cochlear) origin which had not appeared with a recent sudden onset. As hearing aid fittings and an intervention period of at least 9 months applied, the hearing loss had to last without being cured during this time, either by medical intervention or spontaneous recovery. Sensory hearing loss due to cochlear hair cell loss has frequently been associated with tinnitus, presumably as discordant damage of inner and outer hair cells results in imbalanced activity further along the auditory pathways (Jastreboff, 1995). A sensory hearing loss can be identified on an audiogram when there is the same amount of attenuation of both air conduction and bone conduction (Martin & Clark, 2003).

d) Be 18 years of age or older in order to provide written informed consent for participation.

e) Be literate in English and/or Afrikaans to interpret and complete the tinnitus questionnaires, informed consent form and comprehend the counselling material presented.

f) Be able to travel for the assessments and intervention for the duration of the data collection to the University of Pretoria, the researcher's audiology practice in Centurion and the psychologist's practice in Pretoria.

The focus of the treatment offered in the study was based on guidelines described for primary tinnitus (Tunkel et al., 2013), therefore the designed intervention would not be suited for secondary tinnitus due to other underlying conditions. The excluding factors may also have influenced the medical and/or emotional well-being of the participants

which could have led to absence from sessions and possible interference with judgment or feelings about tinnitus when completing the subjective THI and TFI. Therefore, prospective participants presenting with the following were excluded from the study:

a) Active vestibular disorders, as those patients were in need of medical treatment which could, together with the balance problem itself, interfere with attendance of the data collection process. Treatment of the balance disorder may impact the tinnitus to an extent that makes the participant's experience of tinnitus unstable. Vernon and Johnson (1980) found that some patients with Ménières disease whose vertigo was controlled by treatment experienced more distress from their tinnitus, as they focused more on the tinnitus after the vertigo was subdued. Such an effect could interfere with the study results by influencing the tinnitus outside of the effect of the interventions provided. Participants experiencing balance problems may also be emotionally influenced on days that the balance problem is worse, which could impact the results of the subjective THI and TFI measurements.

b) Conductive hearing loss, as many patients with CHL can easily be treated by means of wax removal, grommet insertion, perforation repair or ossicle reconstruction or replacement (Baguley et al., 2013a). Successful treatment could result in improvement in hearing (Martin & Clark, 2003). This could have interfered with the need for a hearing aid fitting for the data collection process. Due to the medical nature of conductive hearing loss, the hearing can be fluctuating which could result in unreliable hearing aid fittings.

c) Vestibular schwannomas – although 75% of this population presents with tinnitus (Baguley, Chang & Moffat, 2001) and 30% had tinnitus causing a significant handicap according to THI measurements (Humphriss, Baguley, Axon & Moffat, 2006), it was decided to exclude these patients because medical treatments could alter the tinnitus. Tinnitus frequently persists after surgical removal of a tumour, sometimes staying unchanged, sometimes becoming less pertinent and occasionally becoming even worse (Baguley et al., 2001). Although these tumours generally grow slowly (Baguley et al., 2013a), the data collection period was a minimum of nine months, which could allow changes in the tumour. Lloyd, Kasbekar, Baguley and Moffat (2010) found evidence to suggest that tinnitus occurs more in patients with actively growing

neuromas than in static neuromas. It was decided to avoid the risk of physiological factors possibly interfering with or hindering the progress of psychological and/or audiological intervention.

d) Formal tinnitus intervention received by either an audiologist or psychologist in the past six months to avoid the effects of that treatment's remaining influence on the objective and subjective tinnitus measurements. Recent treatment could interfere with the reliability as it would be difficult to ensure that the success achieved with the treatment provided during the study, instead of the success of previous treatment influences, is reflected.

2.4.3. Sampling method

The participants were chosen for participation in the study based on a non-probability quota sampling method (Maree & Pietersen, 2010a), selecting only participants who complied with very specific characteristics as outlined in the selection criteria.

Prospective participants presenting with tinnitus were referred by ENTs, General Practitioners (GPs), audiologists, psychologists or by themselves. They were asked to fill out the THI questionnaire. They underwent a full diagnostic hearing test with psychoacoustic measures of tinnitus, including pitch matching, loudness matching, MML's and RI (Meikle et al., 2008). Those who obtained recent diagnostic audiograms completed the psychoacoustic measurements of tinnitus and were retested for air conduction to ensure reliability and stability of the audiogram. When the THI scores and audiograms indicated possible candidacy, the prospective participants were verbally informed about the study, as well as provided with a written invitation. Those who were interested were referred, as is recommended, for assessment by an ENT specialist (Henry et al., 2005) to eliminate the factors mentioned for exclusion of the study. Once the participant consulted an ENT and indicated interest in partaking in the study, the informed consent was signed and the TFI was completed if not already filled out. The participant was then assigned to a group and intervention began. Due to the nature of referrals, the participants did not all start with the data collection

procedures at the same time, but rather joined the study as they were referred. The prospective participants who did not meet the selection criteria were excluded from the study, but still invited to receive the intervention.

2.4.4. Participant demographics

Seventeen participants meeting the selection criteria signed up for participation in the study. Four participants withdrew during the early stages of data collection due to time constraints and personal reasons. One participant was diagnosed with cancer before completing the first block of intervention and consequently withdrew. Eleven participants completed the full cycle of the data collection procedure and one participant completed two thirds of the data collection before withdrawing due to family responsibility issues. This participant also felt that the intervention thus far received was sufficient and that it was not necessary to continue. Due to the data being incomplete, that participant's data was withdrawn, leaving the researcher with completed data for 11 participants.

Table 1 summarises the descriptions of the participants as per group and of the total sample of participants who completed the data collection and whose data was used in the analysis. As not all participants had bilateral tinnitus, or their tinnitus perception changed dramatically, the psychoacoustic measurements were not always measured for both ears, as specified in the table by *n,* indicating the number of participants for that measurement.

Table 1. Description of participants

Description	Group A n = 5	Group B n = 3	Group C n = 3	Total n = 11
Female	3	1	1	5
Male	2	2	2	6
Mean age	53.8 years (SD: 8.2)	64.0 years (SD: 1.0)	46.7 years (SD: 11.5)	54.6 years (SD: 10.0)
Mean Pure Tone Average (PTA) (500–2000 Hz)	Right ear: 15.7 dBHL (SD: 15.1 dBHL) Left ear: 26.0 dBHL (SD: 14.1 dBHL)	Right ear: 22.2 dBHL (SD: 17.8 dBHL) Left ear: 8.30 dBHL (SD: 3.3 dBHL)	Right ear: 19.4 dBHL (SD: 15.5 dBHL) Left ear: 18.9 dBHL (SD: 14.0 dBHL)	Right ear: 18.5 dBHL (SD: 14.5 dBHL) Left ear: 19.2 dBHL (SD: 13.4 dBHL)
Configuration of audiogram	3x bilateral sloping loss 2x unilateral sloping loss	1x bilateral sloping loss 1x unilateral sloping loss 1x bilateral high frequency loss	1x bilateral sloping loss 1x bilateral high frequency loss 1x bilateral rising loss	5x bilateral sloping loss 3x unilateral sloping loss 2x bilateral high frequency loss 1x bilateral rising loss
Mean THI baseline score	62 (SD: 19.4)	66 (SD: 14.0)	78 (SD: 12.5)	67.5 (SD: 16.4)
Mean TFI baseline score	64.5 (SD: 26.6)	73.1 (SD: 6.6)	74 (SD: 16.5)	69.4 (SD: 19.2)
Mean tinnitus pitch: right ear	2666.7 Hz (n = 3) (SD: 2929.7 Hz)	7333.3 Hz (n = 3) (SD: 1154.7 Hz)	5333.3 Hz (n = 3) (SD: 3055.1)	5111.1 Hz (n = 9) (SD: 2987.2)
Mean tinnitus pitch: left ear	3150.0 Hz (n = 5) (SD: 2913.3)	7000.0 Hz (n = 2) (SD: 1414.2 Hz)	6333.3 Hz (n = 3) (SD: 2886.8 Hz)	4875.0 Hz (n = 10) (SD: 3035.1)
Mean tinnitus loudness: right ear	31.7 dBHL (n = 3) (SD: 20.8 dBHL)	71.7 dBHL (n = 3) (SD: 20.8 dBHL)	46.7 dBHL (n = 3) (SD: 23.6 dBHL)	50.0 dBHL (n = 9) (SD: 25.7 dBHL)
Mean tinnitus loudness: left ear	47.0 dBHL (n = 5) (SD: 12.0 dBHL)	57.5 dBHL (n = 2) (SD: 3.5 dBHL)	55.0 dBHL (n = 3) (SD: 13.2 dBHL)	51.5 dBHL (n = 10) (SD: 11.3 dBHL)
Mean MML: right ear	43.0 dBHL (n = 2) (SD: 41.0 dBHL)	69.0 dBHL (n = 3) (SD: 10.2 dBHL)	32.0 dBHL (n = 3) (SD: 17.4 dBHL)	48.6 dBHL (n = 8) (SD: 25.7 dBHL)
Mean MML: left ear	51.2 dBHL (n = 5) (SD: 10.0 dBHL)	67.5 dBHL (n = 2) (SD: 2.1 dBHL)	55.3 dBHL (n = 3) (SD: 14.6 dBHL)	55.7 dBHL (n = 10) (SD: 11.6 dBHL)
Mean RI: right ear	27.5 s (n = 2) (SD: 29.0 s)	25.0 sec (n = 3) (SD: 11.3 s)	5.0 sec (n = 2) (SD: 0 s)	7.0 sec (n = 7) (SD: 17.0 s)
Mean RI: left ear	12.2 s (n = 5) (SD: 15.1 s)	17.5 s (n = 2) (SD: 5.0 s)	1.7 s (n = 3) (SD: 1.2 s)	10.1 s (n = 10) (SD: 11.9 s)

Of the 11 participants, six were male and five were female. The mean age of the participants was 54.6 years (SD: 10.0). Eight participants presented with bilateral hearing loss of various configurations, while three participants presented with

unilateral hearing loss. The mean baseline scores for the subjective tinnitus questionnaires were 67.5 (SD: 16.4) for the THI and 69.4 (SD: 19.2) for the TFI.

2.5. Material and apparatus used

2.5.1. Material

Table 2 shows the material and apparatus used in the current study. The THI (Appendix D) and TFI (Appendix E) questionnaires were used throughout the study to obtain at first a baseline measurement of each participant's tinnitus severity. From there on, it was repeatedly used after intervention blocks and rest periods to monitor the tinnitus severity in order to draw comparisons between tinnitus severity before and tinnitus severity after treatments.

The directive counselling which was part of the audiological intervention was performed by using the "Tinnitus Retraining Therapy Patient Counseling Guide" (Henry et al., n.d.). This manual allowed the audiologist to show clear and simple illustrations to the participant while directing the audiologist in the content of the counselling on the back of the illustration. Utilising this manual enabled the audiologist to counsel each participant in the same manner with high consistency by means of a well-researched tool.

The psychologist conducted two personality assessments, namely the 16 Personality Factor Fifth Edition (16PF5) (Boyle, Matthews & Saklofske, 2008) together with the Millon Clinical Multiaxial Inventory Third Edition (MCMI-III) (Millon, Millon, Davis & Grossman, 2006). These two instruments enabled her to draw a personality profile for each participant and allow a more complex understanding of the psychological factors which influence the intensity of the experience of tinnitus. The results of these two instruments were not used to answer the research question or to achieve the research aims, but guided the psychological intervention of CBT.

The 16PF5 is an internationally well used and researched self-report instrument of personality assessment. South African norms are available for the fifth edition. It is based on Cattell's trait theory of personality whereby he identified 16 primary factors and a number of secondary factors.

The MCMI-III is a self-report questionnaire which is closely linked to the Diagnostic Statistical Manual of Mental Disorders (DSM). Therefore, it can indicate possible psychiatric or psychological conditions which may aggravate the experience of tinnitus. In particular, the patient's profile can show anxieties which are known to aggravate tinnitus.

2.5.2. Apparatus

Participants underwent a diagnostic hearing evaluation including the psychoacoustic measurements of tinnitus, which was conducted in a sound-treated room by means of an audiometer and insert earphones. Accompanying the measurements of thresholds and tinnitus properties were procedures of otoscopy (to examine the outer ears) and immittance measurements (to evaluate middle ear functioning) for which an otoscope and tympanometer were used.

The hearing aid fittings were performed using computers and hearing aid fitting software. The Noah 4 software was utilised to organise and store each participant's hearing aid fitting information. Top-end hearing aids from three different hearing aid companies were used, each fitted with the respective companies' software and fitting interface. Real ear measurements were performed for each fitting by means of the Interacoustics Callisto Real Ear Measurement System.

Table 2. Material and apparatus used

Process	*Material and apparatus used*
Tinnitus severity evaluation	THI TFI
Audiological evaluation and measurements of psychoacoustic properties of tinnitus	Welch Allyn Otoscope with reusable ear specula. Titan Diagnostic Middle Ear Analyzer and OAE (Calibrated on 21.1.2015) Interacoustics AD229b diagnostic audiometer (Calibrated on 21.1.2015) Insertphone 10-Ohm (3A) insert earphones (Calibrated on 21.1.2015) Radio Ear B71 bone conductor (Calibrated on 21.1.2015) Interacoustics AD629 diagnostic audiometer with insert earphones (new, calibrated 12.11.2015) 2 x 2m Audiometric Booth (Calibrated on 21.1.2015) 1.9 x 1.9 m Audiometric Booth (new, calibrated 12.11.2015) Audiometry data sheet
Amplification and sound therapy	Acer Travelmate 5742 computer Samsung S19D300 computer screen HP ProDesk Desktop computer Noah 4 software NoahLink and NearCom interfaces Widex Compass GPS hearing aid fitting software Oticon Genie hearing aid fitting software Unitron Truefit hearing aid fitting software Interacoustics Callisto Real Ear Measurement System Hearing aids: Widex D4, Oticon Alta Pro, Unitron Quantum Pro
Audiological counselling	The “Tinnitus Retraining Therapy Patient Counseling Guide” (Henry et al., 2007.)
Psychological assessment and intervention	16PF5 MCMI-III
Data organising	Microsoft Excel Dropbox

2.6. Data collection procedures

2.6.1. Experimental protocol and flow of procedures

The participants were assigned to one of either three treatment groups based on counter-balanced assignment**.** Participant one was placed in group A, participant two was placed in group B, participant three was placed in group C and so forth. For each group, the order of interventions differed, as illustrated in Figure 3.

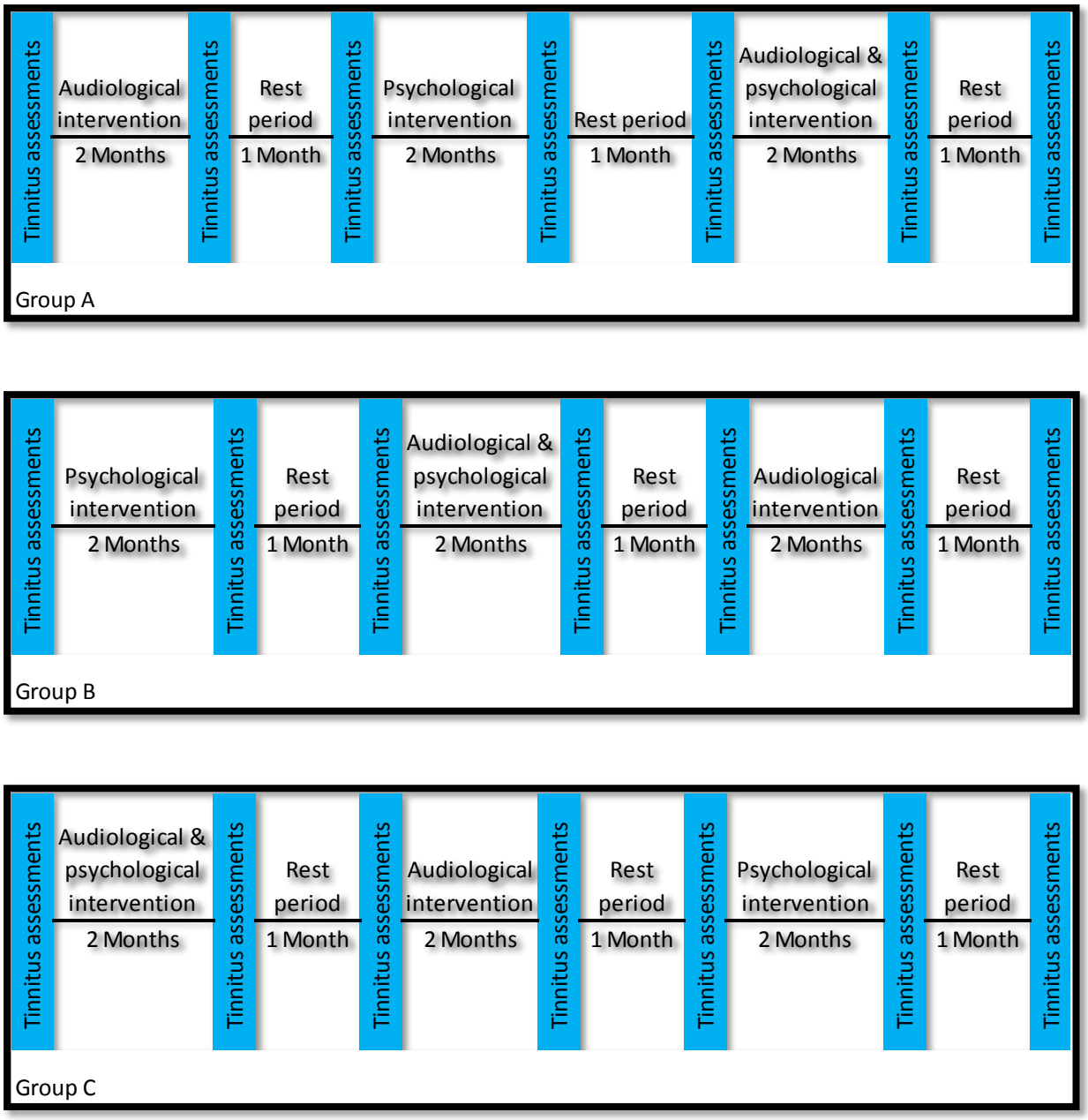

Figure 3. Course of data collection

As shown in Figure 3, the participants commenced with the first treatment for a period of two months, after which the THI, TFI and psychoacoustic measurements of tinnitus (from here on referred to as "tinnitus assessments") were conducted again. It was followed by a one-month rest period, with no intervention, after which tinnitus assessments were repeated. Intervention by means of a second treatment approach subsequently commenced for two months, again ending with the tinnitus assessments.

A second one-month rest period was taken, concluding with tinnitus assessments. The remaining (third) treatment method was then initiated for two months, the tinnitus assessments were completed again, followed by a final one-month rest period and ultimately concluding the data collection with final tinnitus assessments.

Where single approach interventions occurred, the audiologist or psychologist and participant arranged the sessions amongst themselves and the process for each intervention was followed as explained in the section for intervention procedures. In the case of combined intervention, the audiologist notified the psychologist to contact the participant after completing the first session with the participant, during which the participant was reminded of the psychology sessions that would also take place during that period. The psychologist and participant then arranged their sessions amongst themselves over the next two months, independent of the sessions that occurred with the audiologist.

This study aimed to determine the effect of psychological and audiological intervention methods for patients suffering from tinnitus. As the data collection process of the study took a minimum period of nine months per participant and included free therapy and multiple reassessments, it was decided that the intervention be performed by one psychologist and one audiologist only to enhance the consistency of the treatment and avoid the risk of incomparable and poorly standardised intervention (Hoare & Hall, 2011). The researcher owned an audiology practice and was able to use the practice's space and resources to conduct the assessments and intervention free of charge to participants. The psychological intervention was performed by a psychologist at the University of Pretoria. The data collection was therefore conducted at the offices of the respective audiologist and psychologist.

2.6.2. Assessment procedures

As illustrated in Figure 3, each participant completed a test battery of assessments a total of seven times during the data collection period, indicated as “tinnitus assessments”. Each such assessment comprised the following measurements:

a) Completion of the THI (Newman et al., 1996), which consists of 25 questions in which the patient subjectively grades the frequency or severity of different aspects of his/her tinnitus. The patient answers a question such as “Because of your tinnitus, is it difficult for you to concentrate?” with either “yes”, “sometimes” or “no”. Each answer counts either four, two or zero points, the maximum total score being 100 points. The patient’s tinnitus score then places him/her in a category of tinnitus severity, either slight (0–16 points), mild (18–6 points), moderate (38–56 points), severe (58–76 points) or catastrophic (78–100 points). The THI can be reproduced and has no copyright, making it easily accessible for research application (McCombe et al., 2001). The questions evaluate distress caused at three different components, namely emotional distress, functional interference and catastrophic thinking. This factorial structure of the three components was recently validated, and it was found that the scores of the subscales can be used reliably for data analysis (Kleinstäuber, Frank & Weise, 2015). A change of 20 points or more on the THI is considered clinically significant.

b) Completion of the TFI (Meikle et al., 2012), which was developed to assess a broad range of symptoms associated with tinnitus severity, to distinguish among patients whether the tinnitus is “no problem” or “a very big problem” and to be responsive to change in tinnitus severity. The patient is asked to rate the impact of the tinnitus on a scale of one to ten in terms of its severity, for example, “Over the past week, how strong or loud was your tinnitus?” The TFI has 25 questions and evaluates the impact of tinnitus in eight subscales, including intrusiveness, sense of control, cognition, sleep, auditory, relaxation, quality of life and emotional distress (Fackrell et al., 2015). A change of 13 points indicates a clinically significant change.

c) Measurement of the psychoacoustic properties of tinnitus per ear, including (Henry et al., 2005, Meikle et al., 2008): 1) Pitch matching was done to match the perceived

tinnitus sound to a pure tone as presented via the audiometer; 2) The loudness of the tinnitus was determined at the pitch-matched frequency; 3) The MML refers to the minimum intensity level at which broadband noise masks the tinnitus; and 4) The RI was then measured by presenting an elevated level of masking for 60 seconds in the participant's ear and recording how long it takes for the tinnitus to return to its usual loudness.

The assessment data was captured and stored according to the visiting session of the participant's timeline, where it was also indicated before or after which intervention it was recorded. The data was initially recorded on the dated tinnitus assessment forms and kept in each participant's file.

2.6.3. Intervention procedures

2.6.3.1. Audiological intervention

The audiological intervention involved two components: hearing aid fitting and directive counselling as described in the TRT method (Jastreboff & Hazell, 1993). The content of the audiological intervention sessions is summarised in Figure 4.

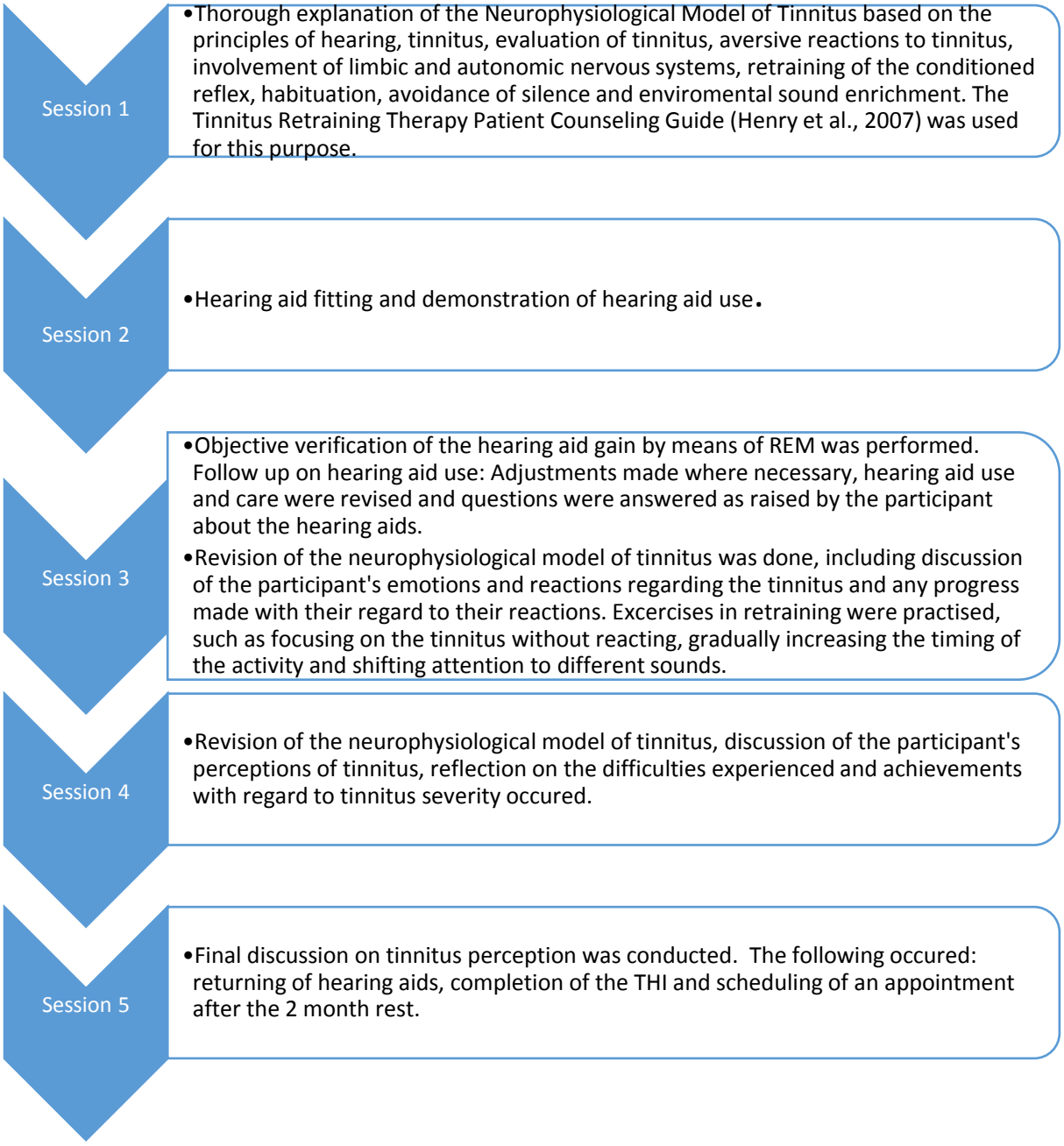

Figure 4. Audiological intervention

Hearing aid fitting

The hearing aid fitting is aimed at reducing communication stressors that may be experienced due to hearing loss (Henry et al., 2005). It also plays an important role in enriching the environment with sound, as soft sounds may be better audible to the patient. Noble's (2008) review of published evidence regarding the benefits of hearing

aid use concluded that it may reduce the prominence of the tinnitus. Hearing aid fitting was performed on each participant monaurally or binaurally, depending on which ear(s) presented with hearing loss as indicated on the audiogram. Premium range technology (at the time of the study) in the form of behind-the-ear (BTE) or receiver-in-canal (RIC) hearing aids was fitted. The participants were fitted with hearing aids after adjustments in slim tubes, receivers and domes were made to suit the ear(s) and audiogram (Martin & Clark, 2003). With the first fitting the participants were given ample opportunity to have the gain of the instrument(s) adjusted to their comfort. Thorough explanation with regard to handling the hearing aid(s), changing the batteries and taking care of the instrument(s) was given and hearing aid batteries for the duration of the intervention period were supplied. With the follow-up visit, REM were performed and the hearing aid gain was adapted where necessary (Martin & Clark, 2003).

Directive counselling

The TRT Patient Counselling Guide (Henry, Trune, Robb & Jastreboff, 2007) was used to conduct the directive counselling. Its guidelines are clearly set and the material contains comprehensible illustrations to help the patient understand the model. The key points of counselling as described in the TRT model were (Jastreboff & Hazell, 1993):

a) *An explanation of tinnitus based on the Neurophysiological model included facilitation of a deeper understanding with regard to:*
   - The ear and hearing;
   - The process of sorting auditory information into meaningful patterns before perception could take place;
   - The sub-awareness neuronal networks connections with limbic and autononomic nervous systems;
   - How emotional responses to certain sounds were remembered and became conditioned reflexes which cannot be habituated to if behaving like a survival reflex;
   - How the tinnitus signal was detected, perceived and evaluated in the brain;

- New sounds which could not be ignored until evaluated and classified by the brain;
- How the negative emotional response to tinnitus disrupted homeostasis by activating limbic and autonomic nervous system reactions;
- How the negative perception of tinnitus became a conditioned response;
- A vicious circle which has begun: the negative response was set and triggered when the tinnitus is detected, leading to limbic and autonomic nervous system activation and then leading to enhanced detection of tinnitus with a strengthening of the negative response.

b) Training the participant in changing the perception of tinnitus:

- The participant had to understand that the persistence of tinnitus was dependent on the aversive conditioned response continuing;
- His/her response could be retrained directly and consciously;
- Exercises in deliberate conscious reclassification of tinnitus, more positive reactions to tinnitus, stress relief and relaxation exercises were practised;
- The participant had to understand that there was no quick fix to manage tinnitus.

c) Training the participant to avoid silence, explaining that:

- Silence resulted in abnormal increases in auditory gain;
- Most people would experience tinnitus in silence (Heller and Bergman phenomenon);
- The environment had to be enriched with sounds 24 hours per day, as the subconscious mind remained active when sleeping.

2.6.3.2. Psychological intervention:

An eight-week course of CBT was provided to the participants. The content of the CBT focused on psychological factors which directly or indirectly aggravate the tinnitus experience. The CBT was conducted by the third author, a lecturer holding a doctorate in psychology from the University of Pretoria who has experience in treating tinnitus

patients with CBT. The researcher and the psychologist discussed the nature of the intervention beforehand, after which the psychologist went on to structure the sessions independently.

The CBT intervention was focused on helping the participants to define their difficulties and in learning skills to manage these difficulties. During a collaborative process between the participant and the psychologist, maladaptive cognitions and behaviours were identified, tested for validity and revised (Wright, 2006). Both cognitive and behavioural methods are applied in CBT intervention to achieve these goals of self-reflectance and coping. Cognitive methods include engaging in Socratic questioning (guiding the participant to active involvement in finding answers by asking questions), employing guided discovery (questions leading to the participant exploring and changing maladaptive thoughts), keeping thought change record (noting automatic thoughts and identifying associated emotions), examining the evidence, examining advantages and disadvantages, identifying cognitive errors, generating rational alternatives, and engaging in activities of imagery, role play and rehearsal. Behavioural methods involve designing activities, rating them according to pleasure or mastery, and then designing changes that will lead to greater enjoyment. Relaxation and breathing training, exposure and response prevention, and the use of coping cards also form part of behavioural methods in CBT (Wright, 2006).

The psychologist applied various components (as deemed relevant for each participant) as described by Andersson's (2002) "CBT package for tinnitus":

Information – The patient was informed about tinnitus, hearing and relevant factors.

Functional analysis – Factors influencing the tinnitus annoyance were analysed.

Applied relaxation – The participant was taught to relax and to use self-control over bodily and mental sensations.

Cognitive restructuring – The participant was taught to identify the content of his/her thoughts and to challenge or control those thoughts.

Emotional reactions – Participants were taught to manage their emotions, especially fear and avoidance, in relation to tinnitus.

Sleep hygiene – Participants presenting with sleeping problems were helped to improve bed-time habits, to restrict worry time and to relax.

Relapse prevention – A proper discussion was held with the participant to identify risk factors for worsening tinnitus and to design a coping or management plan for when it happened.

2.7. Data processing

2.7.1. Data preparation

The data gathered was organised in each participant's individual file according to date. Once all the data was collected, it was reviewed for data accuracy. The data was subsequently captured on an MS Excel database which allowed for data analysis.

2.7.2. Statistical analysis

Analysis refers to categorising, ordering, describing and summarising of data to generalise or draw conclusions about the population (Pietersen & Maree, 2010a). To obtain the raw data in numerical form for computerised data analysis, all the scores from the tinnitus assessments were organised in MS Excel. These scores were then analysed by a biostatistician who compared the scores from different groups with one another, making comparisons between the scores obtained from different intervention types, before and after scores and scores before and after rest periods. The biostatistician further compared the effect of interventions on the different subgroups of the THI and TFI. Scores were also compared according to a timeline, as indicated, and specifically according to visit. For each tinnitus assessment and comparison made, the data was analysed in terms of the minimum, mean, standard deviation, median and maximum values. Trends and patterns were searched for in order to draw conclusions.

The probability value – known as the *p*-value – indicates the probability of perceiving the precise value of the test statistics or a more extreme value (Pietersen & Maree, 2010a). The *p*-value helps to conclude whether there is a statistically significant difference or a significant correlation with the research variable according to the results. In the current study, the *p*-value was calculated by means of the non-parametric exact Wilcoxon Two-sample Paired Signed-rank Test, which is appropriate for small sample sizes, where one cannot assume that the distribution of the difference has a normal distribution in the population (Pietersen & Maree, 2010b). A *p*-value smaller than 0.05 would indicate that a statistically meaningful difference was observed. The current study compared singular approach interventions and a combination approach intervention.

2.8. Reliability

Reliability refers to the consistency, accuracy and stability with which the participants were measured (Maree & Pietersen, 2010b). Thus, if the same variable is measured under similar conditions, it should produce identical measurements (Fouche & De Vos, 2005). Reliability in this study was achieved by using standardised and well-researched assessment tools, namely the THI and TFI, to measure the outcomes. The THI is described as the best established tinnitus questionnaire, with high levels of reliability demonstrated in many populations (Kleinstäuber et al., 2015). The TFI shows strong measurement properties and high reliability and is described as a fine tool to measure changes in tinnitus severity (Meikle et al., 2012). In the current study, no control group was used in order to avoid influences of individual personality traits between different subjects on the results of the subjective tinnitus scales. This created more stability of the measurements that were compared among the groups.

2.9 Validity

Validity refers to the extent to which the measurement truthfully reflects what it intended to measure (Delport, 2005). The current study made use of the THI and TFI assessments, both of which have shown good construct validity (Kleinstäuber et al.,

2015; Meikle et al., 2012) and are described as valid tools for research purposes. Unreliable instruments pose a threat to validity (Pietersen & Maree, 2010c). Therefore, all the equipment used for the assessments and REM were calibrated to international standards before data collection in order to obtain accurate readings.

3. RESULTS

3.1. Notes on participant characteristics

Among the 11 participants who completed the full cycle of the data collection, eight (72.7%) presented with bilateral hearing loss and three (27.2%) with unilateral hearing loss according to their audiograms. Of the eight participants with bilateral hearing loss, two had asymmetry between the different ears, presenting with hearing loss only in the highest frequencies and resulting in the participants choosing to have only one hearing aid fitted. Therefore, six participants (54.6%) were fitted binaurally, and five participants were fitted monaurally as part of the audiological intervention. The eleven participants each completed two-month intervention blocks of hearing aid fitting and TRT counselling, psychological counselling, and a combination of both in various orders. All of the 11 participants completed the THI and TFI a total of seven times, however not all participants completed the psychoacoustic measurements for both ears every time, due to either absence of tinnitus in certain ears, or an inability to travel to the practice at that time (in which case the THI and TFI were completed via email communication). The number of participants for the different measurements are indicated with *n* throughout the results and discussion sections.

3.2. Changes in subjective tinnitus questionnaire scores with treatment: singular approaches versus a combined approach

Table 3 depicts the changes measured in the THI and TFI scores from pre-treatment to post-treatment for both the singular and combined intervention approaches. A lowering of 20 points or more on the THI (McCombe et al., 2001) and 13 points or more on the TFI (Meikle et al., 2012) is considered a clinically relevant improvement, indicating that the participant showed remarkable progress. This is not to be confused with statistical significance, which indicates that a statistically meaningful difference was observed when analysing the data (Pietersen & Maree, 2010b).

Table 3. Shifts in subjective questionnaire scores from pre-treatment to post-treatment: singular versus combined approaches

			n	THI (total score)	p-value	TFI (total score)	p-value
Mean (SD)	*Baseline*		11	67.5 (16.4)		69.4 (19.2)	
	Post psychological intervention	Change from Baseline	11	-33.8 (16.9)	0.3082	-27.4 (20.6)	0.1115
		Change from Rest	11	-3.3 (17.5)	0.2231	-5.1 (11.2)	0.1891
	Post audiological intervention	Change from Baseline	11	-48.5 (18.6)	0.6931	-44.0 (24.2)	0.8955
		Change from Rest	11	-31.5 (25.6)	0.1671	-26.8 (23.1)	0.3246
	Post combined approach	Change from Baseline	11	-42.9 (23.0)	-	-43.0 (26.0)	-
		Change from Rest	11	-18.2 (24.3)	-	-20.2 (24.7)	-

As indicated in Table 3, clinically relevant shifts in the total THI (McCombe et al., 2001) and TFI (Meikle et al., 2012) scores were achieved after psychological treatment (-33.8 and -27.4 points). When compared to a combined approach, larger shifts (-42.9 and -43.0 points) were obtained when the interventions were combined ($p = 0.3082$ / $p = 0.1115$). Bias was likely to occur in the study as the participants' treatment results could still influence the scores after the next intervention type over time despite the rest period that was implemented to minimise the bias. Therefore, the scores were also analysed to reflect a change from rest. The change from rest score serves as sensitivity marker that reflects the shift in scores from the previous rest period before the intervention up to the scores taken after the intervention and provides a suggested impact of the intervention provided since the participant's rest period. Using this calculation, both the THI and TFI scores decreased with the psychological (-3.3 and -5.1) and combination (-18.2 and -20.2) intervention approaches, once again showing a greater difference with the combination approach ($p = 0.2231$ and $p = 0.1898$). P-values comparing psychology versus combined intervention for the questionnaires were greater than 0.05, thus failing to indicate a significant difference between the two intervention approaches.

Relevant decreases (McCombe et al., 2001 Meikle et al., 2012) in tinnitus questionnaire scores from the baseline were also seen for audiological intervention (-48.5 and -44.0). This trend repeated when the scores were analysed as change from rest (-31.5 and -26.8). The changes were unexpectedly slightly larger for the single audiological approach than for the combination approach in both calculations from baseline (combined: -42.9 and -43.0) and from rest (combined: -18.2 and -20.2). The p-values comparing audiological versus combined interventions were all greater than 0.05, indicating no significant difference between the two approaches.

Figure 5 demonstrates the effect of single and combined intervention approaches on tinnitus questionnaire scores as measured in the current study. The figure on the left compares the baseline THI scores to the THI scores as measured after each intervention type. The figure on the right does the same with the TFI scores. In both figures the blue areas represent the 25th to 75th percentile of the data, thus illustrating the middle 50 percent of the data. Maximum and minimum values are indicated above and below the blocks, with the black line inside each block illustrating the median value.

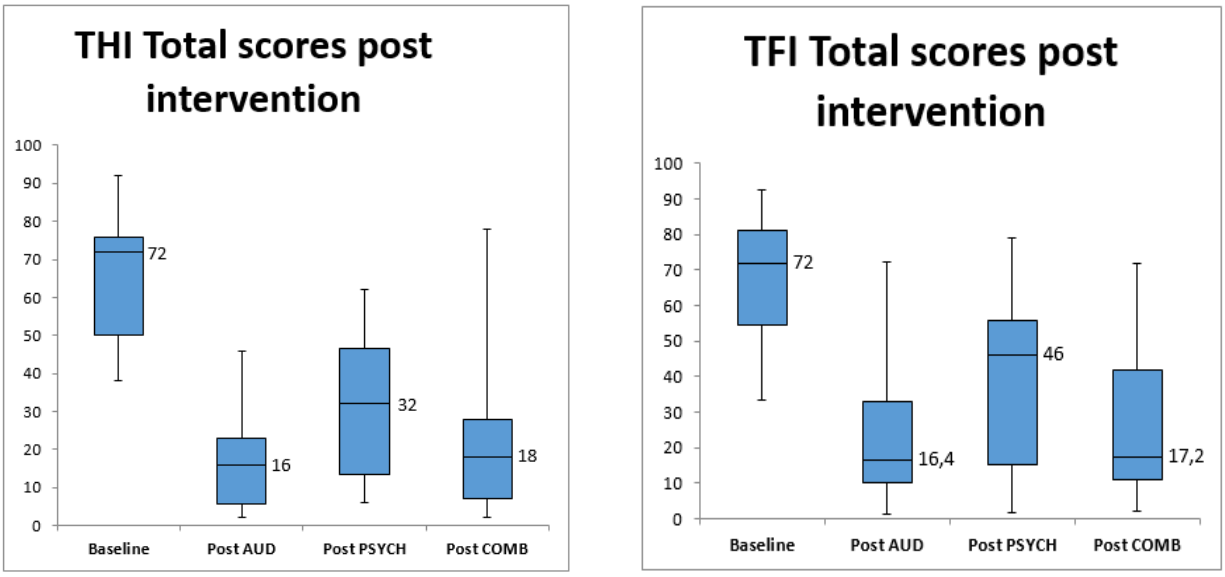

Figure 5. Changes in tinnitus questionnaires with single and combined approaches

As illustrated in Figure 5, clinically relevant reductions (McCombe et al., 2001 Meikle et al., 2012) in THI and TFI scores occurred with singular and combined intervention approaches compared to the baseline. The median is indicated with a line in each block. Combined intervention resulted in a greater reduction than the singular approach of psychology alone, but yielded similar results to the singular approach of audiology alone.

3.3. Changes in tinnitus questionnaire totals per group over time

Bias is a relevant factor in the current study as the participants' tinnitus assessments were repeatedly measured. Therefore, it was possible that the influence of the previous intervention period could remain and impact on the new measurements. As the three groups of participants each had a different order of interventions received, they are compared in terms of a time-line, to observe possible trends over time. Table 4 indicates the changes in the THI scores after each visit for the different groups who received the various interventions in alternating orders. Figure 6 illustrates the shifts in THI scores on a timeline for the different groups.

Table 4. THI total scores per visit

MEAN (SD) - THI

	Group A (n = 5) Intervention 1 = Audiology Intervention 2= Psychology Intervention 3 = Audiology and Psychology	Group B (n = 3) Intervention 1 = Psychology Intervention 2= Audiology and Psychology Intervention 3 = Audiology	Group C (n = 3) Intervention 1 = Audiology and Psychology Intervention 2= Audiology Intervention 3 = Psychology	Total (n=11)
Visit 1: Baseline	62.0 (19.3)	66.0 (14.0)	78.0 (12.5)	67.5 (16.4)
Visit 2: Post intervention 1	14.4 (17.4)	52.0 (15.6)	50.0 (26.2)	34.4 (26.0)
Change from last assessment	-47.6 (23.5)	-14 (2.0)	-28.0 (35.4)	-33.1 (26.3)
Visit 3: Post rest	18.8 (13.9)	50.7 (16.7)	58.0 (33.1)	38.2 (26.5)
Change from last assessment	4.4 (5.6)	-1.3 (3.1)	8.0 (25.5)	3.8 (12.6)
Visit 4: Post intervention 2	24.8 (21.9)	18.0 (15.1)	28.7 (15.1)	24.0 (17.4)
Change from last assessment	6.0 (22.8)	-32.7 (23.9)	-29.3(19.4)	-14.2 (27.8)
Visit 5: Post rest	16.8 (10.3)	23.3 (13.0)	38.0 (15.9)	24.4 (14.5)
Change from last assessment	-8.0 (20.4)	5.3 (23.2)	9.3 (5.0)	0.4 (18.6)
Visit 6: Post intervention 3	13.2 (8.6)	16.7 (8.1)	30.0 (11.1)	18.7 (11.0)
Change from last assessment	-3.6 (8.7)	-6.7 (15.0)	-8.0 (8.7)	-5.6 (9.7)
Visit 7: Post rest (Final)	12.8 (10.3)	24.0 (15.1)	36.0 (26.2)	22.2 (18.1)
Change from last assessment	-0.4 (5.0)	7.3 (17.9)	6.0 (15.6)	3.5 (11.7)

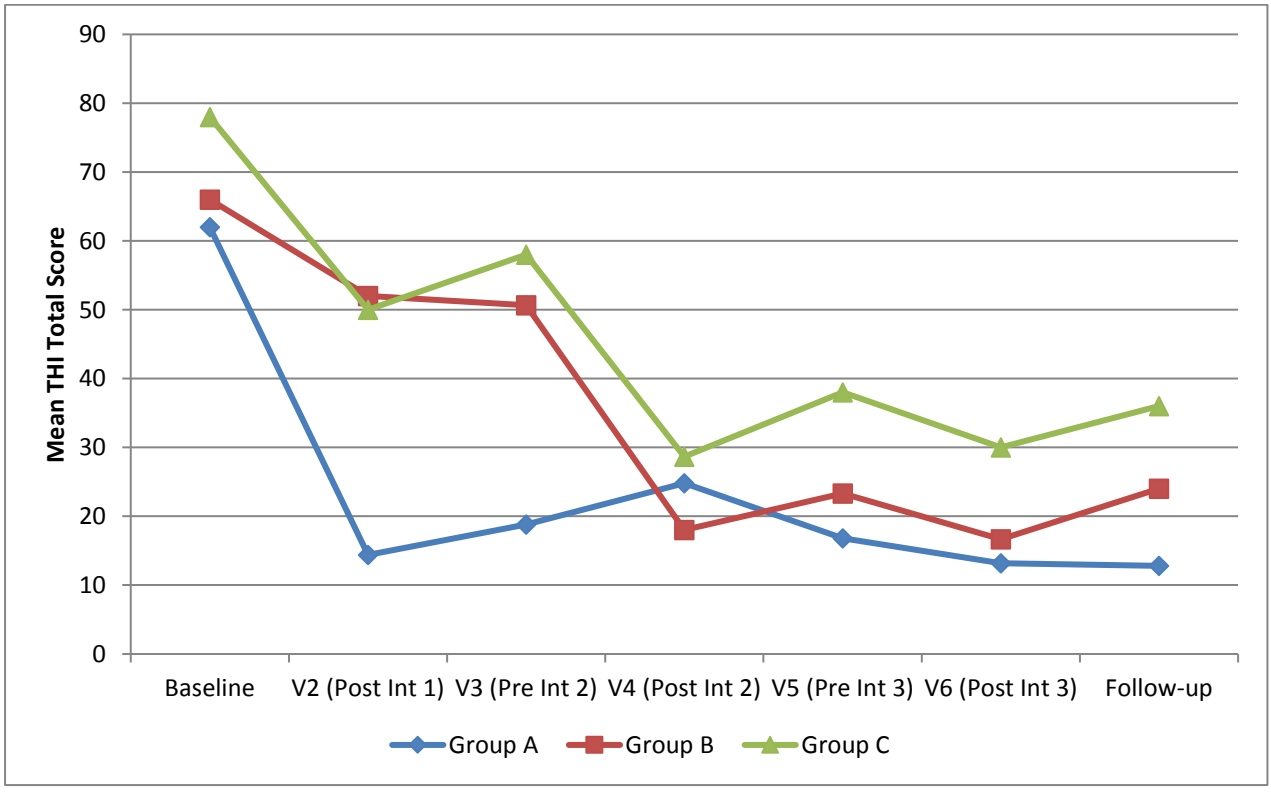

Figure 6. Timeline of mean THI total scores

As documented in Table 4 and illustrated in Figure 6, all three groups of participants had a remarkable shift from the baseline THI score after completion of their first intervention block, regardless of the type of intervention. Group A showed the largest initial decline (-47.6) in THI totals, followed by Group C (-28.0) and Group B (-14), as documented in Table 4. Groups B and C showed further decline after the second intervention, whereas Group A's scores were slightly raised after the second intervention. All three groups' THI scores showed minimal change from visits four to seven, which means that the THI scores seemed to have settled after five months. The THI scores generally increased slightly after rest periods, with the exception of Group A, whose scores showed a further decline from 24.8 to 16.8 points (Table 4) after psychological intervention and a small decrease from 13.2 to 12.8 points after the rest period when the combined psychology and audiology intervention was completed. The same trend was observed in Group B after psychology intervention was received, decreasing still after the rest period from 52.0 to 50.7 points. Group C had a consistent raise in scores after each rest period.

Table 4 shows that Group A showed the largest decline (-47.6) in THI scores after completion of their first treatment, audiology intervention, which was a singular approach. Group B had the most decline (-32.7) after their second intervention, which was the combined approach. Group C showed very similar reductions after the combined approach (-28.0) and the audiology intervention (-29.3), which were their first two interventions.

The same comparisons were made using the TFI scores. Figure 7 illustrates the shifts in TFI scores on a timeline for the different groups. Table 5 shows the changes in the TFI scores after each visit for the three groups.

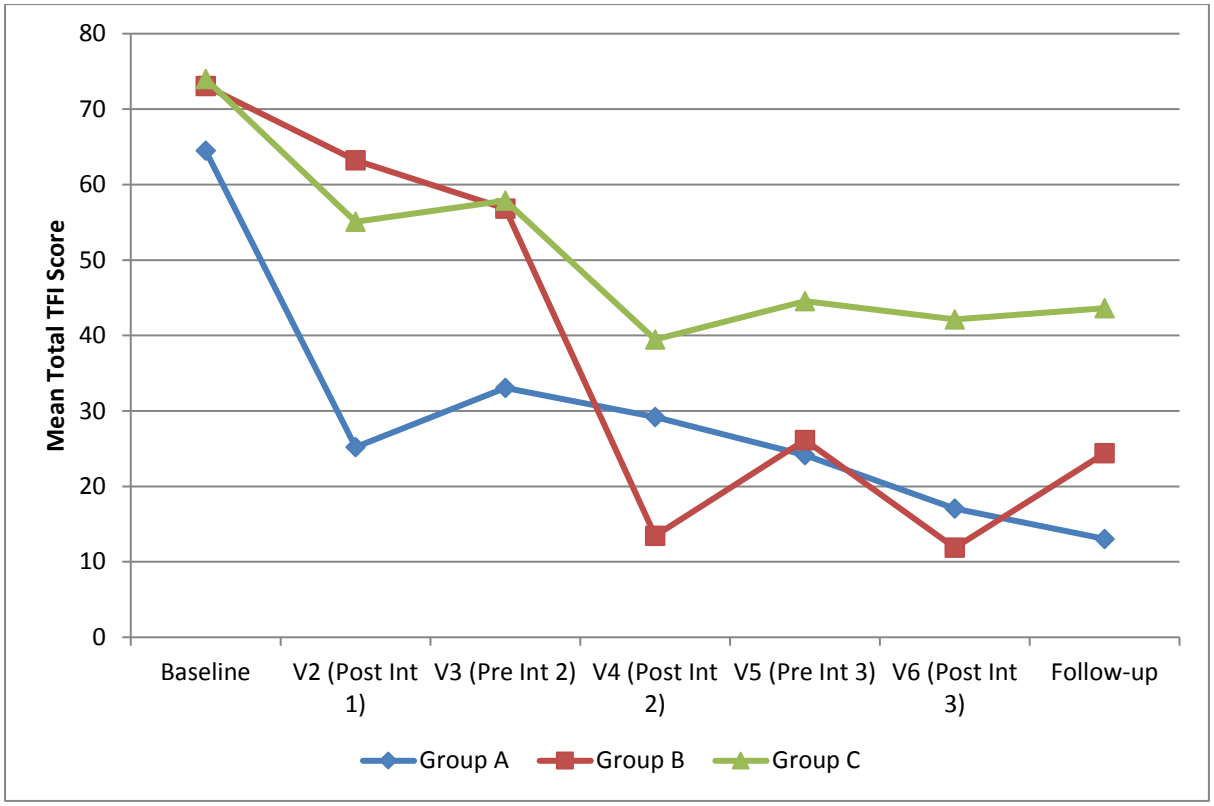

Figure 7. Timeline of mean TFI total scores

Similar to the THI results, the groups showed their largest decrease in total TFI scores over the first four visits, with the scores remaining fairly similar from visit four to seven, as illustrated in Figure 7.

Table 5. TFI total scores per visit

MEAN (SD) - TFI

	Group A (n = 5) Intervention 1 = Audiology Intervention 2= Psychology Intervention 3 = Audiology and Psychology	Group B (n = 3) Intervention 1 = Psychology Intervention 2= Audiology and Psychology Intervention 3 = Audiology	Group C (n = 3) Intervention 1 = Audiology and Psychology Intervention 2= Audiology Intervention 3 = Psychology	Total (n=11)
Visit 1: Baseline	64.5 (26.6)	73.1 (6.6)	74.0 (16.5)	69.4 (19.2)
Visit 2: Post intervention 1	25.2 (27.6)	63.2 (20.9)	55.1 (15.6)	43.7 (27.7)
Change from last assessment	-39.3 (28.4)	-9.9 (15.0)	-18.9 (31.6)	-25.7 (27.4)
Visit 3: Post rest	33.0 (23.4)	56.8 (24.7)	57.9 (20.5)	46.3 (24.2)
Change from last assessment	7.8 (9.0)	-6.4 (6.8)	2.8 (14.2)	2.6 (11.0)
Visit 4: Post intervention 2	29.2 (26.3)	13.5 (0.2)	39.5 (10.9)	27.7 (20.1)
Change from last assessment	-3.8 (10.9)	-43.3 (24.9)	-18.4 (11.1)	-18.6 (22.1)
Visit 5: Post rest	24.2 (23.0)	26.1 (17.3)	44.5 (8.8)	30.3 (19.3)
Change from last assessment	-5.0 (5.3)	12.7 (17.5)	5.1 (3.3)	2.5 (11.7)
Visit 6: Post intervention 3	17.0 (16.5)	11.9 (2.9)	42.1 (11.5)	22.5 (17.4)
Change from last assessment	-7.1 (10.0)	-14.3 (14.4)	-2.4 (10.4)	-7.8 (11.2)
Visit 7: Post rest (Final)	13.0 (14.2)	24.4 (22.5)	43.6 (17.9)	24.5 (20.5)
Change from last assessment	-4.0 (3.5)	12.5 (19.7)	1.5 (10.3)	2.0 (12.4)

As indicated in Table 5, Group A had a clinically relevant reduction of 39.3 points on the TFI after their first intervention, audiology (singular approach). Group B had a relevant reduction of 43.3 points after their combined intervention period, which was their second intervention. Group C, as with the THI, once again had similar changes after their first intervention, the combined approach (18.9 points) and their second intervention, i.e. audiological treatment (18.4 points).

Group A had one increase total score after a rest period, but otherwise showed steady decline. Group B's TFI totals increased after each rest period, with the exception of the rest period post the psychological treatment, where it continued to lower. Group C was consistent in a raise in TFI scores after each rest period.

3.4. Changes in the psychoacoustic properties of tinnitus with treatment: singular approaches versus a combined approach

Table 6 documents the shifts in various psychoacoustic properties of tinnitus per ear, from pre-treatment to post-treatment for both singular and combined intervention approaches. The values as indicated are further illustrated by means of the figures below.

Table 6. Shifts in psychoacoustic properties of tinnitus from pre-treatment to post-treatment: singular versus combined approaches

			n	Tinnitus Pitch *Right* (Hz)	p-value	n	Tinnitus Pitch *Left* (Hz)	p-value	n	Tinnitus Loudness *Right* (dBHL)	p-value	n	Tinnitus Loudness *Left* (dBHL)	p-value
Mean (SD)	*Baseline*		9	5111.1 (2987.2)		10	4875.0 (3035.1)		9	50.5 (25.7)		10	51.5 (11.3)	
	Post psychological intervention	Change from Baseline	8	0.0 (462.9)	0.8384	9	-305.6 (1424.0)	0.6704	8	5.0 (11.7)	0.5935	9	5.6 (11.3)	0.6487
		Change from Rest	8	-125.0 (1126.0)	1.0000	9	-222.2 (1201.9)	0.8614	8	-0.6 (4.2)	0.4947	9	2.2 (5.1)	0.8005
	Post audiological intervention	Change from Baseline	9	-611.1 (1364.2)	0.7835	10	-1375.0 (1845.6)	0.4718	9	1.7 (13.9)	0.8935	10	1.0 (10.75)	0.8190
		Change from Rest	9	-611.1 (1166.7)	0.7112	10	-1175.0 (1691.7)	0.3880	9	0.0 (5.6)	0.6221	10	0.5 (10.12)	1.0000
	Post combined approach	Change from Baseline	9	-555.6 (2171.5)	-	10	-475.0 (2609.9)	-	9	2.8 (20.2)	-	10	4.0 (12.7)	-
		Change from Rest	9	-611.1 (1964.7)	-	10	-500.0 (1649.9)	-	9	1.1 (17.1)	-	10	0.5 (9.6)	-
			n	MML *Right* (dBHL)	p-value	n	MML *Left* (dBHL)	p-value	n	RI *Right* (sec)	p-value	n	RI *Left* (sec)	p-value
Mean (SD)	*Baseline*		8	48.6 (25.7)		10	55.7 (11.6)		7	20.0 (17.0)		10	10.1 (11.9)	
	Post psychological intervention	Change from Baseline	7	6.7 (18.9)	0.4511	9	2.7 (11.7)	1.0000	6	-2.2 (14.8)	1.0000	9	2.2 (9.2)	0.8247
		Change from Rest	8	-1.5 (5.5)	0.2093	9	1.3 (8.6)	1.0000	8	3.4 (6.5)	0.2448	9	-0.8 (3.3)	0.6849
	Post audiological intervention	Change from Baseline	8	0.9 (20.5)	0.9581	10	-3.3 (8.9)	0.5449	7	38.6 (78.5)	0.6950	10	8.9 (15.4)	0.4614
		Change from Rest	8	-2.6 (10.6)	0.4697	10	-2.0 (6.2)	0.7047	8	11.0 (25.7)	0.4292	10	-1.0 (15.0)	0.3448
	Post combined approach	Change from Baseline	8	-2.1 (14.3)	-	10	2.3 (18.7)	-	7	26.4 (86.6)	-	9	2.9 (12.1)	-
		Change from Rest	9	4.3 (14.7)	-	10	0.0 (13.8)	-	8	20.8 (77.2)	-	9	-1.8 (6.7)	-

The p-values for all the psychoacoustic measurements when comparing singular to combined approaches exceeded 0.05, showing no statistically significant differences between the singular and combined treatment approaches.

3.4.1. Shifts in tinnitus pitch

As shown in Table 6, tinnitus pitch tended to lower after psychological intervention (0.0 Hz and -305.6 Hz) for the right and left ears, repeating that trend in the changes from rest. When compared to the combination approach, the combined intervention also resulted in lowering tinnitus pitch (-555.6 Hz and -500.0 Hz). The mean tinnitus pitch also lowered after audiological intervention (-611.1 Hz and -1375.0 Hz) across right and left ears. When comparing singular versus combined approaches, all p-values were greater than 0.05, showing no statistically significant difference between the two intervention approaches.

Figure 8 illustrates the changes in tinnitus pitch for the right and left ears with each intervention. The blue areas represent the 25th to 75th percentile of the data, thus illustrating the middle 50 percent of the data. Maximum and minimum values are indicated above and below the blocks, with the median value shown as the black line inside each block.

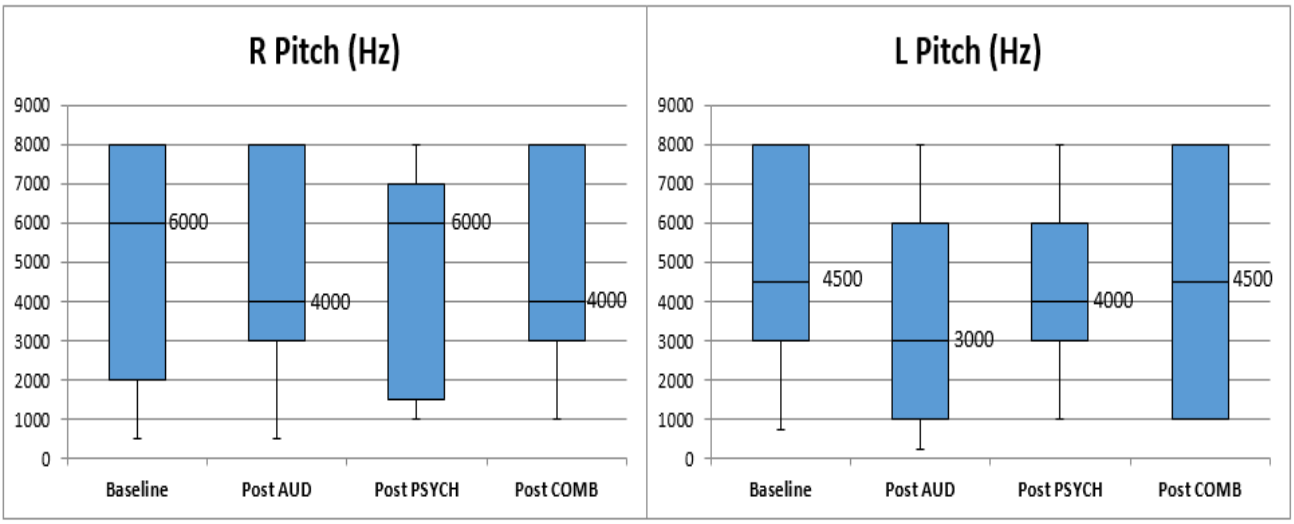

Figure 8. Changes in tinnitus pitch with single and combined approaches

Figure 8 demonstrates the general lowering of tinnitus pitch from the baseline after each intervention type. Apart from a general trend of lowering, a consistent pattern among the various intervention types across the two ears cannot be seen.

3.4.2. Shifts in tinnitus loudness

Figure 9 illustrates the changes in tinnitus loudness for the right and left ears with each intervention. The blue areas represent the 25th to 75th percentile or middle 50 percent of the data. Maximum and minimum values are indicated above and below the blocks. The median value is indicated by the black line inside each block.

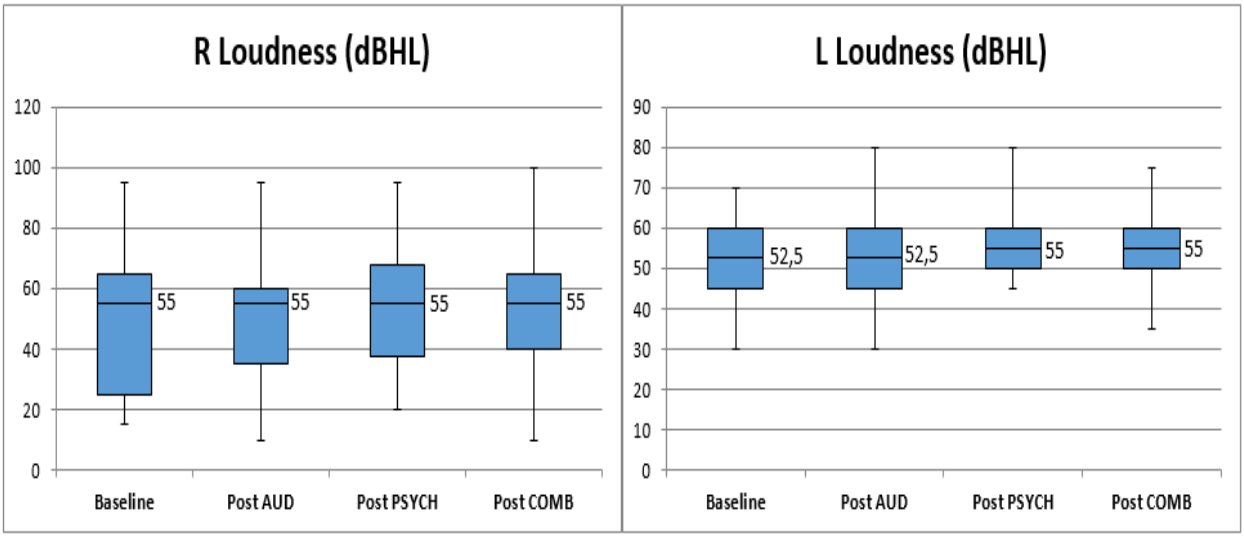

Figure 9. Changes in tinnitus loudness with single and combined approaches

When compared to the baseline, tinnitus loudness across the right and left ears increased slightly for psychological (5.0 dBHL and 5.6 dBHL), audiological (1.7 dBHL and 1.0 dBHL) and combination (2.8 dBHL and 4.0 dBHL) approaches (Table 6). However, when analysed as change from the rest period, tinnitus loudness decreased only by 0.6 dBHL after the psychological treatment was completed.

3.4.3. Shifts in minimum masking levels

Figure 10 illustrates the changes in MML for the right and left ears with each intervention. The blue areas represent the 25th to 75th percentile of the data, thus illustrating the middle 50 percent of the data. Maximum and minimum values are indicated above and below the blocks, with the black line inside each block illustrating the median value.

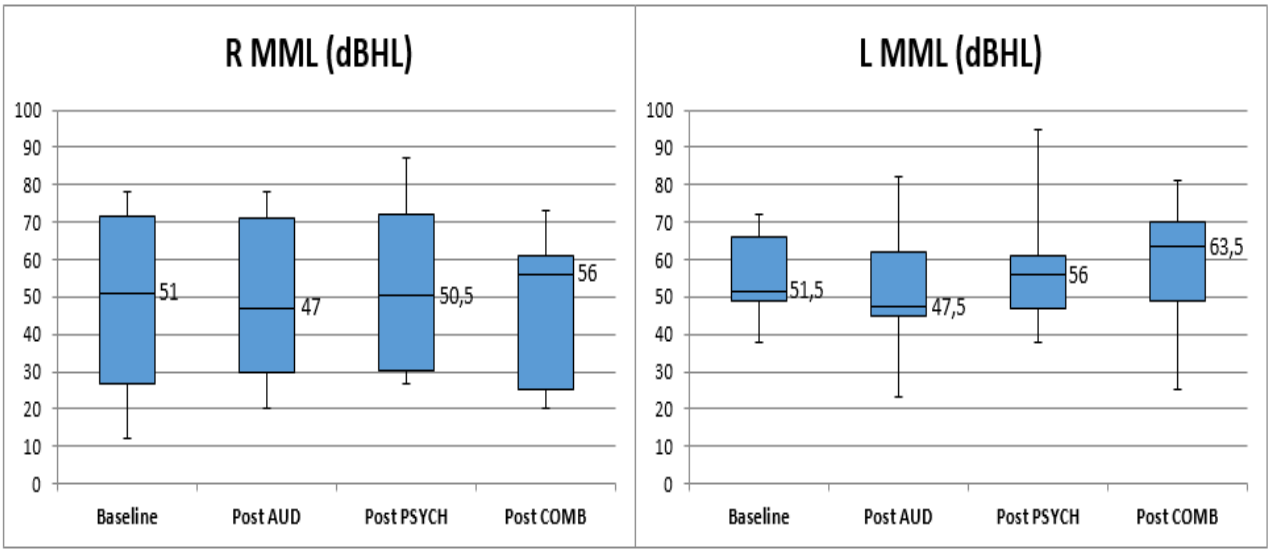

Figure 10. Changes in minimum masking levels with single and combined approaches

The MML values increased slightly for right and left ears (6.7 dBHL and 2.7 dBHL) after the psychological approach. After audiological intervention, mixed results were obtained, as MML increased slightly (0.9 dBHL) in the right ear, while decreasing in the left ear (-2.1 dBHL). The contrary happened after the combined approach, namely an increase in the left ear (2.3 dBHL) and a decrease in the right ear (-2.1 dBHL).

3.4.4. Shifts in residual inhibition

The shifts in RI as occurred in the right and left ears with the different intervention types are illustrated by Figure 11. The blue areas represent the 25th to 75th percentile of the data, thus illustrating the middle 50 percent of the data. Maximum and minimum values are indicated above and below the blocks, with the black line inside each block illustrating the median.

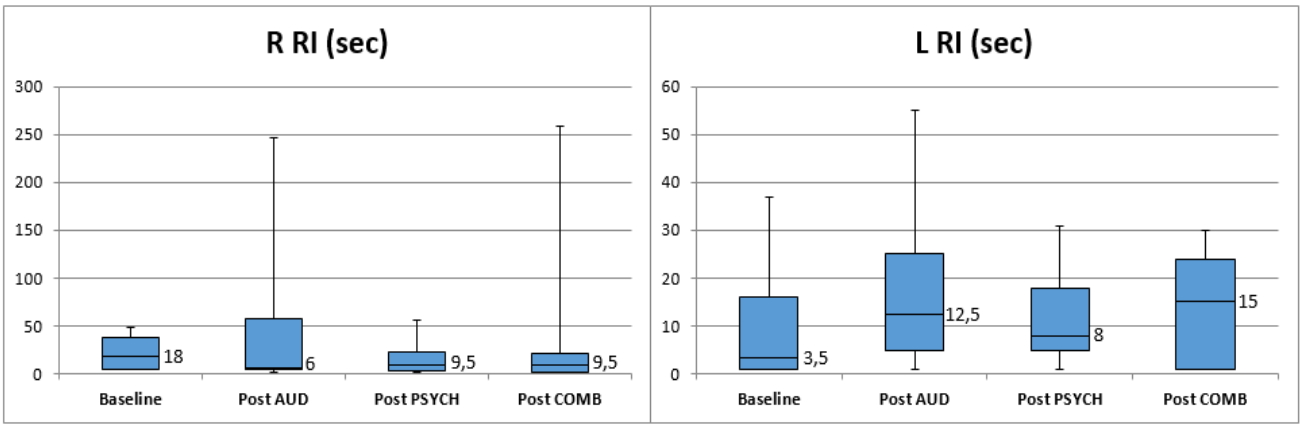

Figure 11: Changes in residual inhibition with single and combined approaches

The RI values showed a decrease (-2.2 s) in the right ear after psychological intervention while an increase was measured for RI in the left ear (2.2 s). Following the audiological intervention approach, values for RI increased across the two ears (38.6 s and 8.9 s). The same trend occurred after the combined approach, although to a slightly lesser extent (26.4 s and 2.9 s) when compared to the baseline. When analysed as change from rest, RI was slightly lowered for all three approaches in the left ear (psychology: -0.8 s; audiology: -1.0 s; combined: -1.8 s), but increased for all approaches in the right ear (psychology: 3.4; audiology: 11.0 s; combined: 20.8 s).

4. DISCUSSION AND CONCLUSION

4.1. Discussion of results

Despite the high prevalence of tinnitus and the impact it may have on quality of life, there are still no specific evidence-based protocols for its management (Tunkel et al., 2014). There are, however, strong indications of successful management by means of audiological intervention, including components of hearing aid fitting (McNeill et al., 2012), counselling (Searchfield, Kaur & Martin, 2010) and TRT (Hoare et al., 2011), as well as evidence for psychological approaches (Zachriat & Kröner-Herwig, 2004; Jun & Park, 2013), of which the most popular is CBT. Limited research is available to compare combination therapy approaches to single therapy approaches. This study compared single approaches of psychological counselling (applying CBT) and audiological intervention (including hearing aid fitting and the directive tinnitus counselling component of TRT) to a combination of these two approaches. Measurements were compared for subjective tinnitus questionnaires and psychoacoustic properties of tinnitus.

When comparing the subjective tinnitus questionnaires, it was indicated in the current study that each of the three intervention approaches had a clinically relevant effect on both the THI, thus lowering more than 20 points (-33.8; -48.5; -42.9) (McCombe et al., 2001) and the TFI, thus lowering more than 13 points (-27.4; -44.0; -43.0) (Meikle et al., 2012). Research that considered the efficacy of audiological intervention by means of tinnitus questionnaires showed the same trend. McNeill et al. (2012) concluded that hearing aid fitting reduced tinnitus distress if the fitting results in masking the tinnitus signal. The distress was measured by means of the Tinnitus Reaction Questionnaire (TRQ). Although the current study used different tinnitus questionnaires (THI and TFI), both the study by McNeill and colleagues (2012) and the current study reflect that hearing aid fitting was of value in reducing the patients' tinnitus related distress. The research report by McNeill and colleagues (2012) didn't describe tinnitus counselling as part of the intervention provided, but Searchfield et al.

(2010) specifically considered the effect of a combined counselling and hearing aid fitting approach versus the effect that counselling only had on tinnitus questionnaire scores. Searchfield and colleagues (2010) reported that the tinnitus counselling was further complemented by hearing aid fitting, as measured by the Tinnitus Handicap Questionnaire (THQ), concluding that hearing aids not only improved hearing, but also had a therapeutic effect on the participants. Their counselling was informational in terms of the origins of tinnitus, along with reassurance and advice to avoid silence. The current study applied a more formal and directive approach of counselling by using the counselling component of the TRT manual. Many studies have shown that TRT reduces tinnitus distress. Hatanaka, Ariizumi and Kitamura (2008) observed a statistically significant improvement (*p*-value: 0.0024) in THI scores just a month after TRT, comprising of counselling and sound generators, was provided, with further improvements for up to six months of active treatment. Their study did not describe hearing aid fitting as part of the intervention, but did include the use of sound generators, which the current study omitted. Although not directly comparable, the current study's results of clinically relevant improvements on tinnitus questionnaire scores with audiological counselling and hearing aid fitting is thus in line with other research.

The current study also showed shifts in the THI and TFI after psychological intervention by means of CBT. This is in agreement with other research reports. Conrad, Kleinstäuber, Jasper, Hiller, Andersson and Weise (2014) concluded that CBT is successful in reducing dysfunctional tinnitus-related cognitions. They compared different aspects of CBT, namely self-help internet-based CBT and CBT group sessions, which differ from the current study's one-on-one sessions of CBT with a psychologist. Jun and Park (2013) describe in their meta-analysis of CBT for tinnitus studies a noteworthy trend that CBT does relieve tinnitus in terms of participants' responses to tinnitus, however not necessarily the acoustical properties of tinnitus. Andersson et al. (2005) used the TRQ to measure progress for tinnitus intervention for elderly participants by means of CBT. Their results showed statistically significant reductions (*p*-value = 0.014) of tinnitus-related distress. The current study included

participants of various ages of over 18 years and should thus be compared with caution, but once again reflects the same trends of improvement with CBT.

There are a few research reports comparing CBT and audiological intervention for tinnitus. Grewal, Spielmann, Jones and Hussain (2014) conducted a systematic literature review of randomised control trials and studies and concluded that both TRT and CBT resulted in notable improvements in participants' quality of life, with additional improvements seen in depression when treated with CBT. Zachriat and Kröner-Herwig compared HT (such as TRT) to CBT in a randomised control study and also found that both approaches resulted in similar and statistically significant improvements (p-value < 0.001) in tinnitus questionnaire scores, but that CBT showed a greater improvement in general well-being and adaptive behaviour. There are currently no studies that compared a single approach (as the above-mentioned studies) to a combined approach, except for a related matter in the study by Seydel, Haupt, Szczepek, Klapp and Mazurek (2010), where TRT was modified to include components of CBT. The results showed a significant reduction of TQ scores when compared to a control group, but no comparison was made to a single method approach as in the current study. Hiller and Haerkötter (2005) did a comparison study of singular CBT intervention versus combined CBT and sound generators, finding no additive effects when adding the sound generators. As their study fitted noise generators and the current study fitted hearing aids, the results are not comparable.

Concerning the psychoacoustic properties of tinnitus, mixed results were obtained in the current study, concurring with other study results. Pitch mostly lowered with all intervention approaches, but standard deviations were large and no statistical significance was observed. Moffat, Adjout, Gallego, Thai-Van, Collet and Norena (2009) found that hearing aid fitting did result in some lowering of the tinnitus spectrum, more so for low- to medium-frequency amplification than for high-frequency amplification.

Thus far, little information about the effect of intervention on pitch matching has been published. Although intervention effects are easily measured with subjective scales, correlations with tinnitus pitch and subjective scales are not found, as shown by Degeest, Corthals, Dhooge and Keppler (2016), as well as by Rent, Bhojwani, Bhat and Unnikrishnan (2013), who could not find a relationship between tinnitus pitch and THI scores. Hoare, Edmondson-Jones, Gander and Hall (2014) reported that pitch-matching measurements are often inconsistent and influenced by test procedures and patient learning, which lead to general variability and unpredictable measures. As with the current study, Hoare and colleagues (2014) too found substantial standard deviations in their measurements. The current study could not find any significant proof of pitch changes in response to intervention other than a general trend of lowering it, which may have been influenced as mentioned above and therefore cannot serve as a reliable indicator of the effect of intervention on tinnitus pitch.

According to Meikle et al. (2008), tinnitus loudness and MMLs are considered the most useful psychoacoustic measurements to evaluate treatment effects, therefore it was expected to see substantial lowering of these scores in the study, especially since decreases were seen in the THI and TFI measurements. This was not the case in the current study however. The data indicated an unexpected slight increase from the baseline in tinnitus loudness for all the interventions. Moffat et al. (2009) found no effect of hearing aid use on tinnitus loudness and Grewell et al. (2014) as well as Jun and Park (2013) found no reduction in tinnitus loudness after CBT treatment. Dos Santos et al. (2014) did, however, find that both singular approaches of amplification alone and combined approaches of amplification with additional use of sound generators resulted in a reduction of tinnitus loudness, slightly more so for the combined intervention groups.

Once again, the value of tinnitus loudness measurement is questioned as other literature points out the shortcomings of this measurement. Hoare et al. (2014) described loudness matching results as less variable than pitch matching, however still marked by inconsistency and highly influenced by time, learning and test

procedure. Their recommendation is to disregard at least the first measure, even suggesting to select only the third measure as a baseline for acceptable reliability. This method was not applied in the current study. Despite finding slight increases in tinnitus loudness after intervention, the current study showed improvement in the THI and TFI, which makes the reliability and value of tinnitus loudness matching doubtful. This supports the findings of Degeest et al. (2016), who could not find any correlation between THI scores and audiometrically measured tinnitus loudness. Rent et al. (2013) disagreed with this as they observed a significant correlation between tinnitus loudness matching intensity and THI scores.

The current study observed the changes in MMLs with each intervention, which are regarded as valuable measurements in assessing treatment effects (Meikle et al., 2008). In the current study, mixed results of both enhanced and lowered values were recorded, which is not comparable to other research findings. The study could not find supporting evidence for studies indicating a decrease in MMLs after treatment, like Dos Santos et al. (2014) described in both their participant groups of amplification versus amplification in combination with noise generators. Dos Santos and colleagues also found that MML values were meaningfully correlated with THI scores, a correlation which is not reflected in the current study. Degeest et al. (2016) concluded that MMLs do not contribute to THI scores, which is more in line with the current study's findings.

The changes in RI with each intervention approach was inspected as well. The study results showed a trend of improved RI after intervention, but not always more so for the combined intervention approach as expected. Little has been published about RI changes after intervention and the writer is unaware of any studies comparing single and combination approaches' effect on RI in order to compare data. What is evident from the literature is another finding by Degeest et al. (2016) that RI does not contribute to THI scores. The current study could also not prove statistical significance for RI improvements and therefore it cannot confidently be concluded that a combined intervention approach yielded greater improvement in RI in participants.

The results of the current study showed that regardless of the type of intervention received, all groups had clinically relevant reductions in THI and TFI scores after their first intervention type, with two groups showing further large reductions after the second intervention, after which all three groups' THI and TFI scores remained fairly stable after the fourth visit, about four months into the data collection period. This pattern is similar to Zachriat and Kröner-Herwig's (2004) findings where their participants who received CBT, as well as the participants who received HT showed significant changes in various tinnitus questionnaires at the second visit, five weeks after the first measurements. The participants showed smaller but further decreases up to the fifth visit, six months into data collection and, from there on up to twenty-one months, results showed small increases and decreases, remaining fairly stable. For both audiological, psychological and combination approaches in the current study, the largest effect seemed to occur within the first four months and the effect remained stable. This agrees with other research reports showing long-term success with treatment. Henry, Thielman, Zaugg, Kaelin, Schmidt and Griest et al. (2017) reported that the improvements recorded after six months of adapted CBT were sustained at twelve months, Jun and Park (2013) reported the effect of CBT to be maintained over time, Searchfield et al. (2010) found that THQ scores were reduced twelve months following audiological intervention, and Henry et al. (2005) found that TRT effects improved incrementally over time up to eighteen months. Forti, Ambrosetti, Crocetti and Del Bo (2010), however, raised concern about the assumption that participants who received TRT remained satisfied, as they found that 43.5% who did not return for follow up still suffered from tinnitus.

4.2. Clinical implications

The high prevalence of tinnitus and the devastating effect it may have on the individual's quality of life mean that research into the field is relevant. There is a need for quality research in this field in order to establish reliable protocols for assessment and intervention (Searchfield, 2011). The current study aimed to investigate whether a combination of the treatment methods of audiological intervention (by means of hearing aid fitting and TRT counselling) and psychological intervention (by means of CBT) resulted in different results from a single approach. Different aspect of tinnitus

were measured during the course of the data collection, leading to various inferences regarding implications for assessment and management of tinnitus.

The results implied that the use of subjective tinnitus questionnaires is valuable in measuring the outcome of intervention (Tunkel et al., 2014; Baguley et al., 2013a). Relevant improvements in various areas of life were easily monitored by means of these scales and could be strongly recommended for use in clinical practice. In contrast with the scales, the measurements of the psychoacoustic properties yielded conflicting, variable and inconsistent results and the usefulness of these measurements are questioned (Hoare et al., 2014). In the current study, the tinnitus questionnaires revealed consistent and pertinent changes with intervention while no such pattern could be seen with the psychoacoustic measurements, therefore implying that psychoacoustic measurements do not correlate with tinnitus distress as measured by the questionnaires (Degeest et al., 2016). An important clinical implication for assessment of tinnitus reinforced by this study is that subjective outcome measures are more responsive to changes in tinnitus severity than psychoacoustic measures and should be the primary means of assessment of tinnitus (Rabau, Cox, Punte, Waelkens, Gilles, Wouters et al., 2015).

On the intervention front, the results were surprising. Although the results reinforced recommendations for audiological approaches or psychological approaches as effective tinnitus treatments, the study failed to prove with certainty that a combination of these approaches is more effective. It did, however, show relevant shifts in subjective scale scores for both the singular and combined approaches which still leads one to think that combining audiological and psychological intervention could be of benefit to the tinnitus patient. The results did not show that combined intervention is ineffective, therefore the idea of combined therapy should remain on the table for serious consideration. This is especially true for audiologists treating tinnitus patients with hearing aids and sound therapy, when it is very possible that the patient could be presenting with psychological factors (Salviati et al., 2013; Crocetti et al., 2008) and should benefit from psychology. The same is true for the psychologist treating a

tinnitus patient with CBT to reduce the negative emotions about tinnitus, when it is likely that the patient also presents with hearing loss (Baguley et al, 2013b) and may experience further improvement in tinnitus when the hearing loss is addressed with amplification (Searchfield et al., 2010) and the patient is counselled thoroughly on the mechanisms of the ear and tinnitus (McFerran & Baguley, 2009).

It is important to note that despite the observed shifts in subjective tinnitus scale scores, the current study did not measure changes in QOL aspects in the participants and, therefore cannot conclude that the intervention improved the participants' happiness or well-being. Other research has explored these aspects. Jun and Park (2013) and Grewal et al. (2014) reported statistically significant improvement in quality of life scores after CBT, while Zachriat and Kröner-Herwig (2004) described improved well-being and adaptive behaviour for both CBT and HT intervention approaches.

4.3. Critical evaluation

A critical evaluation of the study with regard to the strengths and limitations is necessary to determine the value of the research findings. A critical evaluation is helpful in recognising opportunities for further research.

4.3.1. Strengths of the study

The study used a within-subject repeated measures design (Fouche & De Vos, 2005) without a control group to avoid influences of individual personality traits between different subjects on the assessment outcomes. This allowed for comparable contexts (Kim, 2010; Trochim, 2006). A varied order of procedures was implemented (Fouche & De Vos, 2005) to minimise bias of the effect of time on the intervention outcomes.

The quality of assessment methods were high as the THI and TFI were chosen as tinnitus assessment measures, both of which have been praised for solid internal

consistency (Crocetti et al., 2009), along with credibility and responsiveness to intervention-related change (Henry et al., 2015). Calibrated equipment for all measurements of the hearing system as well as the psychoacoustic characteristics of the tinnitus was used. Reliable assessment data was accordingly achieved. Likewise, quality of intervention procedures were optimised in various ways. The hearing aid fittings were objectively verified through REMs, an evidence-based procedure (Martin & Clark, 2003), ensuring quality fittings. The audiological counselling was done by using the TRT Patient Counselling Guide (Henry et al., n.d.), thus ensuring stability and consistency in the presentation of the directive counselling to the different participants. Furthermore, the same audiologist and the same psychologist were used to conduct the assessments and interventions, eliminating inter-tester bias (Struwig & Stead, 2011). The psychologist assisting with the deliverance of intervention was "tinnitus literate" (McFerran & Baguley, 2009) and equipped to deliver counselling on ear-related matters.

4.3.2. Limitations of the study

The study is limited by the small sample size. The limited amount of suitable participants that could be recruited in a restricted time frame means that the results cannot be generalised to the general population (Leedy & Ormrod, 2001) and that the conclusions and predictions drawn from the results may not be entirely accurate (Strydom, 2005). The small sample size contributed to the results of the study not achieving statistical significance (Pietersen & Maree, 2010a). Although every effort was made to keep the three groups equal in size by means of counter-balanced assignment of participants into groups, untimely drop-outs led to unbalanced group sizes. The impact of one group's assessment results compared to another group of a different size can therefore not reflect a reliable comparison.

Another limitation is the effect of bias that cannot be ignored despite efforts to minimise the effect thereof. As participants took part in different forms of interventions and underwent frequent assessments, it is possible that the remaining effect of the previous intervention could still impact on the assessment results after the next

intervention. This was compensated for by the random order of intervention for the different groups, as well as allowing a one-month rest period in order to try and diminish the effect of the previous intervention, but as other research reports ongoing effects of interventions on tinnitus severity (Zachriat & Kröner-Herwig, 2004; Jun & Park, 2013; Henry et al., 2017), it is very likely that the first interventions impacted on the results of the last interventions. The pattern of stabilisation of the results after visit four, regardless of the intervention received, supports this suggestion of inevitable bias.

Certain aspects of the TRT counselling as offered in the audiological intervention approach may show similarities with psychological counselling, which may have ultimately influenced the results of the effect of the singular intervention approaches. Both singular approaches educated the participants on the effect of limbic engagement and emotional responses to the tinnitus (Henry et al., 2007; Wright, 2006) which may intensify the tinnitus severity.

As three intervention approaches were followed and rest periods were added in between, the data collection time period became lengthy. The intervention periods were restricted to two months each and the rest periods to one month each to fit into the planned time frame of the research project. Especially concerning psychology, these restrictions may have limited the outcomes of the results. The participants only received five sessions of CBT during each intervention block involving psychology. In other circumstances, CBT may typically have comprised five to twenty sessions (Wright, 2006). The CBT sessions were therefore possibly terminated before the participants have made optimal progress, thus not providing a true reflectance of the potential benefits of CBT for tinnitus management.

4.4. Suggestions for further research

The current study provided valuable information about the efficacy of audiological as well as psychological intervention for tinnitus. Still, there remain several unanswered questions that create opportunities for further research. To the researcher's knowledge, this was the first study to compare a singular audiological or psychological intervention approach to a combination intervention approach and therefore results were not easily comparable to other studies. In addition, the researcher chose to omit any forms of sound therapy and included hearing aid fitting for all participants as part of the audiological intervention, therefore the audiological intervention could not be classified as true TRT and consequently could not be compared to TRT studies. These factors give rise to multiple themes that should be researched and the following studies are recommended for further research:

- A similar study with a much larger sample size may provide more accurate and statistically significant results which could offer better clarity on the effectiveness of a combined intervention approach.
- A study with a similar research design, but much longer rest periods between interventions may minimise the bias that occurred in the current study, as the effects of previous interventions may then be minimised. It may be valuable to conduct such a study as the within-subject design avoids interference of personal factors among the different participants.
- The content of the audiological approach may be altered to include sound therapy which is a popular method in current audiology practice (Henry et al., 2006) to compare the study to a combined approach.
- Audiological intervention may be altered to exclude TRT counselling, as it may be similar to the psychological counselling at some levels. Instead, it could focus on hearing aid fitting and sound therapy, thereby two very separate audiological and psychological intervention methods could be compared in singular and combined approaches.
- More in-depth psychological analysis of participants may be done to look for indications that certain types of participants may respond better to one intervention approach than to another.

- A study comparing singular versus combined approaches may focus more on subjective questionnaire results together with psychological aspects for assessment, rather than including psychoacoustic measurements, to gain a greater understanding of how the intervention approaches impact on the participant's life.
- The effect of different approaches to intervention on the different subscales of various tinnitus questionnaires can be explored with much more depth so that appropriate inferences about intervention and possibly clearer guidelines for intervention can be revealed.
- As audiologists now have better access to training in delivering tinnitus-related CBT themselves, studies into the combination of hearing care and audiologist-delivered CBT versus single approaches may be of value, and can be compared to studies investigating psychologist-delivered CBT.

4.5. Conclusion

The current study was the first of its kind to compare singular audiological and psychological intervention approaches to a combined approach in the treatment of tinnitus within the same participants, reflecting on the changes in THI scores, TFI scores and psychoacoustic properties of tinnitus. The results indicated that both the singular approaches as well as the combined intervention approach lead to clinically relevant shifts in the THI and TFI scores. Although the study results support the evidence for audiological intervention (Searchfield et al., 2010; Hoare et al., 2011, McNeill et al., 2012) and for psychological intervention (Zachriat & Kröner-Herwig, 2004; Jun & Park, 2013), it was not successful in proving that a combination of audiological and psychological intervention was more successful than a singular approach. It did, however, still indicate that a combination approach yielded relevant reductions in THI and TFI scores and, therefore, that a combination approach is successful and effective.

Despite substantial changes in THI and TFI scores in response to intervention, the assessment results of the psychoacoustic properties of tinnitus did not yield any relevant results, and failed to identify any patterns or trends with regard to the effect of intervention on the psychoacoustic properties of tinnitus. The author agrees that the use of subjective tinnitus questionnaires are superior to the measurement of psychoacoustic properties in determining the effects of intervention and that it should remain the primary outcome measurement (Rabau et al., 2015).

The current study serves as another stepping stone in the direction of tinnitus intervention to be delivered as a conscious multidisciplinary effort where psychology and audiology complement each other. The combination of audiological service in the form of hearing care, tinnitus counselling and sound therapy with psychological care that includes CBT and relaxation is regarded as specialised care (Maes, Cima, Anteunis, Scheijen, Baguley & Refaie et al., 2014). As tinnitus may have long-lasting and devastating effects on quality of life (Henry et al., 2005; Newman et al., 2011), the implementation of specialised care for tinnitus is justified, especially since it has been shown to be more cost-effective than usual care in the long run (Maes et al., 2014). As we continue to push for better standardisation of tinnitus treatment protocols (Searchfield, 2011), in light of the evidence that the current study showed for both audiological and psychological interventions, the researcher believes that combining the two fields are a step in the right direction for quality tinnitus treatment.

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6. APPENDICES

Appendix A:

Ethical Clearance from the Research Ethics Committee of the Faculty of Humanities at the University of Pretoria

UNIVERSITEIT VAN PRETORIA
UNIVERSITY OF PRETORIA
YUNIBESITHI YA PRETORIA

Faculty of Humanities
Research Ethics Committee

29 August 2014

Dear Prof Vinck

Project:	**Collaborative audiological and psychological intervention where tinnitus, hearing loss and psychological factors co-exist**
Researcher:	**H Kroon**
Supervisor:	**Prof Bart Vinck**
Department:	**Speech-Language Pathology & Audiology**
Reference numbers:	**24037789**

Thank you for the application that was submitted for ethical consideration.

I am pleased to inform you that the above application was **approved** by the **Research Ethics Committee** on 28 August 2014. Data collection may therefore commence.

Please note that this approval is based on the assumption that the research will be carried out along the lines laid out in the proposal. Should the actual research depart significantly from the proposed research, it will be necessary to apply for a new research approval and ethical clearance.

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

We wish you success with the project.

Sincerely

Prof Karen Harris
Acting Chair:Research Ethics Committee
Faculty of Humanities
UNIVERSITY OF PRETORIA
e-mail:Karen.harris@up.ac.za

Appendix B:

Invitation letter to prospective study participants

UNIVERSITEIT VAN PRETORIA
UNIVERSITY OF PRETORIA
YUNIBESITHI YA PRETORIA

Faculty of Humanities
Department of Speech-Language Pathology and Audiology

17 June 2014

Dear Participant

INVITATION TO PARTICIPATE IN A RESEARCH PROJECT

We would like to invite you to participate in a research project from the Department of Speech-Language Pathology and Audiology. The purpose of this research project is to determine the effects of audiological and psychological intervention methods on tinnitus severity.
The research will take place at the Department of Speech-Language Pathology and Audiology and the Department of Psychology at the University of Pretoria, with the option to complete the audiological component in Centurion should it suit you better. Prior to the data collection, assessments to determine suitability for partaking must be performed. These assessments may be performed at different venues. The procedures that will be included in order to determine candidacy for the study are:

Tinnitus severity assessment:	Completion of the Tinnitus Handicap Inventory (THI) questionnaire.
Diagnostic hearing evaluation:	Otoscopy (visual inspection of the ear), Tympanometry (evaluation of middle ear functioning), Pure tone audiometry and Word recognition testing.
Psychoacoustic measures of tinnitus:	Pitch matching, loudness matching, minimum masking levels and residual inhibition.
Psychological Assessment:	Psychometric analysis.
Medical assessment:	A clinical examination performed by an Ear-, Nose- and Throat specialist.

Procedures involved for data collection involve the following:
Hearing aid fitting, audiological counselling about tinnitus and hearing loss, repeated completion of the THI and psychological intervention in the form of cognitive behavioural therapy. Three intervention periods of two months each, with rest periods of two months after each treatment period will apply. An intervention period will entail either audiological management, or psychological management, or a combination of both audiological and psychological treatment approaches to tinnitus. All three of these intervention periods must be completed for participation in the research project. The sequence of the intervention methods will be randomly assigned to you by the researcher.

The findings of the research project will be provided to you, should you wish to have insight into the findings. Participation in this research project is completely voluntary, therefore should you wish to withdraw, you may feel free to do so. Confidentiality will be ensured throughout the project as a code will be allocated to each participant. There are no risks involved for you to participate in the project and no discomfort will be experienced. The results will be archived for 15 years.

Should you require any further information regarding the study, please do not hesitate to contact the researcher, Hannelie Kroon at 071 681 2787. If you agree to participate in this study, please complete the consent form attached and bring with on the day of testing.

Thank you for showing interest in this research project.

Kind regards,

_____
Hannelie Kroon
Researcher

_____
Mrs Barbara Heinze
Supervisor/Lecturer

_____
Professor Bart Vinck
Supervisor and Head: Dept of Speech-Language Pathology and Audiology

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UNIVERSITEIT VAN PRETORIA
UNIVERSITY OF PRETORIA
YUNIBESITHI YA PRETORIA

17 Junie 2014

Beste deelnemer

Faculty of Humanities
Department of Speech-Language Pathology and Audiology

UITNODIGING VIR DEELNAME AAN 'N NAVORSINGSPROJEK

Ons wil u graag uitnooi om deel te neem aan 'n navorsingsprojek van die Departement Spraak-Taal Patologie en Oudiologie. Die doel van die studie is om die effekte van oudiologiese en sielkundinge intervensie metodes op die graad van tinnitus te bepaal.
Die navorsing sal plaasvind by die Departement van Spraak-Taal Patologie en Oudiologie en die Department van Sielkunde by die Universiteit van Pretoria, met die opsie om die oudiologiese gedeelte te voltooi in Centurion indien dit u beter sou pas. Voordat die data insameling aanvang kan neem moet evaluasies uitgevoer word om te bepaal of u 'n geskikte kandidaat is vir die studie. Hierdie evaluasies mag op verskillende plekke uitgevoer word. Die prosedures vir die bepaling van kandidaatskap sluit in:

Evaluering van die graad van tinnitus:	Die "Tinnitus Handicap Inventory" (THI) vraelys sal deur u voltooi word.
Diagnostiese gehoor evaluasie:	Otoskopie, (visuele inspeksie van die oor), Timpanometrie (evaluasie van middeloorfunksionering),Suiwertoon oudiometrie en woordherkenning toetsing.
Psigo-akoestiese evaluasie van tinnitus:	Toonhoogte- en luidheid passing, minimum maskeringsvlakke en residuele inhibisie.
Sielkundige evaluasie:	Psigometriese analise.
Mediese assessering:	'n Kliniese ondersoek deur 'n Oor-, Neus- en Keelarts.

Prosedures wat by die data insameling ingesluit word omvat die volgende:
Gehoorapparaat passing, oudiologiese berading oor tinnitus en gehoorverlies, herhaalde voltooiing van die THI en sielkundige intervensie in die vorm van kognitiewe gedragsterapie. Drie intervensie periodes van twee maande elk, met rusperiodes van twee maande ná elke intervensie tydperk, sal van toepassing wees. 'n Intervensie periode behels óf oudiologiese hantering, óf sielkundige hantering, óf 'n kombinasie van die twee benaderings tot tinnitus. Elkeen van hierdie drie benaderings moet deur die deelnemer voltooi word vir deelname aan die studie. Die volgorde van die intervensie benaderings sal op 'n toevallige basis deur die navorser aan u toegeken word.

Die bevindinge van die navorsingsprojek sal aan u beskikbaar gestel word, sou u verkies om inligting daaromtrent te ontvang. Deelname aan hierdie navorsingsprojek is totaal vrywillig. Sou u uself uit die studie wou onttrek, is u vry om dit te doen. Vertroulikheid sal verseker word regdeur die loop van die projek aangesien 'n kode gebruik sal word om elke deelnemer te verteenwoordig. Daar is geen risiko's aan u deelname aan die projek verbonde nie en geen ongemak word voorsien nie. Die resultate sal gestoor word vir 15 jaar vandat die studie afgehandel is.

Sou u enige verdere inligting rondom die studie benodig, is u welkom om die navorser, Hannelie Kroon, te kontak by 071 681 2787. Indien u instem om aan die studie deel te neem, voltooi asseblief die toestemmingsvorm wat aangeheg is en bring dit saam met u op u eerste afspraak.

Dankie vir u belangstelling in hierdie navorsingsprojek.

Vriendelike groete,

_____
Hannelie Kroon
Navorser

_____
Mev. Barbara Heinze
Opsigter/Dosent

_____
Professor Bart Vinck
Opsigter en Hoof: Departement van Spraak-Taal Patologie en Oudiologie

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Appendix C:

Informed consent

UNIVERSITEIT VAN PRETORIA
UNIVERSITY OF PRETORIA
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Faculty of Humanities
Department of Speech-Language Pathology and Audiology

INFORMED CONSENT FOR PARTICIPATION IN THE RESEARCH PROJECT

Researcher: Hannelie Kroon
Contact number: 071 681 2787
Email address: audiology@midrand-estates.co.za

Name of participant: _____

Title of the research project: Collaborative audiological and psychological intervention where tinnitus, hearing loss and psychological factors co-exist.
Purpose of the study: To determine the effects of audiological and psychological intervention methods on tinnitus severity.
Procedures: I understand that I will undergo audiological, psychological and tinnitus severity assessments to determine candidacy, and audiological and psychological intervention during the data collection stage.
Risks and discomforts: There are no known risks and discomforts associated with this study.
Benefits: I understand that I may benefit from the treatment provided for my tinnitus. There is no financial compensation for taking part in the study.
Participant's rights: I understand that I may withdraw from participating in the study at any time without any consequences.
Confidentiality: I understand that all information collected from me will be handled confidentially. However, I give permission that the information collected from me may be used for research and academic publications in South Africa and other countries, but that my identity will not be revealed unless required by law.
Data storage: I understand that all raw data will be stored for a period of 15 years in the Department of Speech-language Pathology and Audiology at the University of Pretoria for archival or further research purposes.

If I have any concerns about this study, or my participation, I am liberated to contact the researcher, Hannelie Kroon, whose contact details are provided above. I understand my rights as a research participant and I voluntarily
consent to participate in the study. I understand what the study is about, and how and why it is being conducted. I will receive a signed copy of this consent form.

_____ _____
Signature of researcher Date

_____ _____
Signature of Participant Date

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UNIVERSITEIT VAN PRETORIA
UNIVERSITY OF PRETORIA
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Faculty of Humanities
Department of Speech-Language Pathology and Audiology

INGELIGTE TOESTEMMING VIR DEELNAME AAN DIE NAVORSINGSPROJEK

Navorser: Hannelie Kroon
Kontak nommer: 071 681 2787
Epos adres: audiology@midrand-estates.co.za

Naam van deelnemer: _____

Titel van die navorsingsprojek: "Collaborative audiological and psychological intervention where tinnitus, hearing loss and psychological factors co-exist."
Doel van die studie: Om die effekte van oudiologiese en sielkundige intervensie metodes op die graad van tinnitus te bepaal.
Prosedures: Ek verstaan dat ek oudiologiese, sielkundige en tinnitus evaluasies sal ondergaan om kandidaatskap te bepaal, en oudiologiese en sielkundige intervensie gedurende die data insamelingsfase.
Risiko's en ongemak: Daar is geen bekende risiko's en ongemak geassosieer met hierdie studie nie.
Voordele: Ek verstaan dat ek kan voordeel trek uit die behandeling vir tinnitus wat voorsien gaan word. Daar is geen finansiële kompensasie vir deelname aan die studie nie.
Regte van die deelnemer: Ek verstaan dat ek ten enige tye myself mag onttrek uit hierdie studie, sonder enige nagevolge.
Vertroulikheid: Ek verstaan dat al die inligting wat van my af ingesamel word as vertroulik behandel sal word. Ek gee egter toestemming dat die inligting gebruik mag word vir navorsing en akademiese publikasies in Suid-Afrika en ander lande, en dat my identiteit nie bekend gemaak sal word nie tensy dit wetlik vereis word
Data bewaring: Ek verstaan dat alle rou data gestoor sal word vir 'n tydperk van 15 jaar in die Departement van Spraak-Taal Patologie en Oudiologie by die Universiteit van Pretoria vir argief of verdere navorsingsdoelwitte.

Indien ek enige bekommernisse oor hierdie studie of oor my deelname het, is ek vry om die navorser, Hannelie Kroon, te kontak by die kontakbesonderhede soos bo verskaf. Ek verstaan my regte as deelnemer en stem vrywilllig in om deel te neem aan die studie. Ek verstaan waaroor die studie handel en waarom dit uitgevoer word. Ek sal 'n getekende kopie van hierdie vorm ontvang.

_____ _____
Handtekening van die navorser Datum

_____ _____
Handtekening van die deelnemer Datum

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Appendix D:

Tinnitus Handicap Inventory

Tinnitus Handicap Inventory

(Newman, Jacobson and Spitzer, 1996)

Name:_____ Date:_____

INSTRUCTIONS: The purpose of this questionnaire is to identify difficulties you may be experiencing because of your tinnitus. Please answer every question by marking the appropriate answer. Do not skip any questions.

1. Because of your tinnitus, is it difficult for you to concentrate?	Yes	Sometimes	No
2. Does the loudness of your tinnitus make it difficult for you to hear people?	Yes	Sometimes	No
3. Does your tinnitus make you angry?	Yes	Sometimes	No
4. Does your tinnitus make you feel confused?	Yes	Sometimes	No
5. Because of your tinnitus, do you feel desperate?	Yes	Sometimes	No
6. Do you complain a great deal about your tinnitus?	Yes	Sometimes	No
7. Because of your tinnitus, do you have trouble falling asleep at night?	Yes	Sometimes	No
8. Do you feel as though you cannot escape your tinnitus?	Yes	Sometimes	No
9. Does your tinnitus interfere with your ability to enjoy your social activities (such as going out to dinner, to the movies)?	Yes	Sometimes	No
10. Because of your tinnitus, do you feel frustrated?	Yes	Sometimes	No
11. Do you feel that your tinnitus is a terrible disease?	Yes	Sometimes	No
12. Does your tinnitus make it difficult for you to enjoy life?	Yes	Sometimes	No
13. Does your tinnitus interfere with your job or household responsibilities?	Yes	Sometimes	No
14. Because of your tinnitus, do you find that you are often irritable?	Yes	Sometimes	No
15. Because of your tinnitus, is it difficult for you to read?	Yes	Sometimes	No
16. Does your tinnitus make you upset?	Yes	Sometimes	No
17. Do you feel that your tinnitus problem has placed stress on your relationships with members of your family and friends?	Yes	Sometimes	No
18. Do you find it difficult to focus your attention away from your tinnitus and on other things?	Yes	Sometimes	No
19. Do you feel that you have no control over your tinnitus?	Yes	Sometimes	No
20. Because of your tinnitus, do you often feel tired?	Yes	Sometimes	No
21. Because of your tinnitus, do you feel depressed?	Yes	Sometimes	No
22. Does your tinnitus make you feel anxious?	Yes	Sometimes	No
23. Do you feel that you can no longer cope with your tinnitus?	Yes	Sometimes	No
24. Does your tinnitus get worse when you are under stress?	Yes	Sometimes	No
25. Does your tinnitus make you feel insecure?	Yes	Sometimes	No

Official use only: Total			

Tinnitus Vraelys

(Newman, Jacobson and Spitzer, 1996)

Naam:_____ Datum:_____

INSTRUKSIES: Die doel van hierdie vrae is om probleme wat deur u tinnitus veroorsaak word, te identifiseer. Beantwoord asseblief die vrae deur óf "Ja", óf "Soms" óf "Nee" by elke vraag te merk. Moenie enige vrae oorslaan nie.

1. Is dit vir u moeilik om te konsentreer, as gevolg van die tinnitus?	Ja	Soms	Nee
2. Maak die luidheid van die tinnitus dit vir u moeilik om mense te hoor?	Ja	Soms	Nee
3. Maak die tinnitus u kwaad?	Ja	Soms	Nee
4. Laat die tinnitus u deurmekaar voel?	Ja	Soms	Nee
5. Voel u, as gevolg van die tinnitus, desperaat?	Ja	Soms	Nee
6. Kla u gereeld oor die tinnitus?	Ja	Soms	Nee
7. Sukkel u om snags aan die slaap te raak as gevolg van die tinnitus?	Ja	Soms	Nee
8. Voel dit vir u asof u die tinnitus nie kan ontsnap nie?	Ja	Soms	Nee
9. Meng die tinnitus in met u vermoë om sosiale geleenthede te geniet (soos om uit te gaan vir ete, gaan fliek)?	Ja	Soms	Nee
10. Voel u gefrustreerd as gevolg van die tinnitus?	Ja	Soms	Nee
11. Voel dit vir u asof u, as gevolg van die tinnitus, 'n ernstige siekte het?	Ja	Soms	Nee
12. Maak die tinnitus dit vir u moeilik om u lewe te geniet?	Ja	Soms	Nee
13. Meng die tinnitus in met u verantwoordelikhede by die werk of huishouding?	Ja	Soms	Nee
14. Voel u dat u gereeld geïrriteerd is as gevolg van die tinnitus?	Ja	Soms	Nee
15. Vind u dit moeilik om te lees as gevolg van die tinnitus?	Ja	Soms	Nee
16. Ontstel die tinnitus u?	Ja	Soms	Nee
17. Voel u dat die tinnitus spanning plaas op die verhoudings tussen u en u familie en vriende?	Ja	Soms	Nee
18. Vind u dit moeilik om u aandag weg van die tinnitus, en op ander dinge te fokus	Ja	Soms	Nee
19. Voel u asof u geen beheer oor die tinnitus het nie?	Ja	Soms	Nee
20. Voel u gereeld moeg as gevolg van die tinnitus?	Ja	Soms	Nee
21. Voel u depressief as gevolg van u tinnitus?	Ja	Soms	Nee
22. Laat u tinnitus u gereeld angstig voel?	Ja	Soms	Nee
23. Voel dit vir u asof u nie langer u tinnitus kan verdra nie?	Ja	Soms	Nee
24. Raak die tinnitus erger wanneer u gespanne is?	Ja	Soms	Nee
25. Laat die tinnitus u onseker oor uself voel?	Ja	Soms	Nee

Slegs vir offisiële gebruik: Totaal			

Appendix E:

Tinnitus Functional Index

Tinnitus Functional Index (TFI)

Today's date: _____ Your Name: _____

Please read each question below carefully. To answer a question, select ONE of the numbers that are listed for that question, and draw a CIRCLE around it like this: ⑩% or ①.

I. Over the PAST WEEK …

1. What percentage of your time awake were you consciously **aware of** your tinnitus?
   Never aware ▶ 0% 10% 20% 30% 40% 50% 60% 70% 80% 90% 100% ◀ Always aware
2. How **strong** or **loud** was your tinnitus?
   Not at all strong or loud ▶ 0 1 2 3 4 5 6 7 8 9 10 ◀ Extremely strong or loud
3. What percentage of your time awake were you **annoyed** by your tinnitus?
   None of the time ▶ 0% 10% 20% 30% 40% 50% 60% 70% 80% 90% 100% ◀ All of the time

SC. Over the PAST WEEK …

4. Did you feel **in control** with regard to your tinnitus?
   Very much in control ▶ 0 1 2 3 4 5 6 7 8 9 10 ◀ Never in control
5. How easy was it for you to **cope** with your tinnitus?
   Very easy to cope ▶ 0 1 2 3 4 5 6 7 8 9 10 ◀ Impossible to cope
6. How easy was it for you to **ignore** your tinnitus?
   Very easy to ignore ▶ 0 1 2 3 4 5 6 7 8 9 10 ◀ Impossible to ignore

C. Over the PAST WEEK, how much has your tinnitus interfered with…

7. Your ability to concentrate?
   Did not interfere ▶ 0 1 2 3 4 5 6 7 8 9 10 ◀ Completely interfered
8. Your ability to **think clearly**?
   Did not interfere ▶ 0 1 2 3 4 5 6 7 8 9 10 ◀ Completely interfered
9. Your ability to **focus attention** on other things besides your tinnitus?
   Did not interfere ▶ 0 1 2 3 4 5 6 7 8 9 10 ◀ Completely interfered

SL. Over the PAST WEEK …

10. How often did your tinnitus make it difficult **to fall asleep** or **stay asleep**?
    Never had difficulty ▶ 0 1 2 3 4 5 6 7 8 9 10 ◀ Always had difficulty
11. How often did your tinnitus cause you difficulty in getting **as much sleep** as you needed?
    Never had difficulty ▶ 0 1 2 3 4 5 6 7 8 9 10 ◀ Always had difficulty
12. How much of the time did your tinnitus keep you from **sleeping** as **deeply** or as **peacefully** as you would have liked?
    None of the time ▶ 0 1 2 3 4 5 6 7 8 9 10 ◀ All of the time

A. Over the PAST WEEK, how much has your tinnitus interfered with…

13. Your ability to **hear clearly**?
    Did not interfere ▶ 0 1 2 3 4 5 6 7 8 9 10 ◀ Completely interfered
14. Your ability to **understand people** who are talking?
    Did not interfere ▶ 0 1 2 3 4 5 6 7 8 9 10 ◀ Completely interfered
15. Your ability to **follow conversations** in a group or at meetings?
    Did not interfere ▶ 0 1 2 3 4 5 6 7 8 9 10 ◀ Completely interfered

R. Over the PAST WEEK, how much has your tinnitus interfered with …

16. Your **quiet resting activities**?
    Did not interfere ▶ 0 1 2 3 4 5 6 7 8 9 10 ◀ Completely interfered
17. Your ability to **relax**?
    Did not interfere ▶ 0 1 2 3 4 5 6 7 8 9 10 ◀ Completely interfered
18. Your ability to enjoy **"peace and quiet"**?
    Did not interfere ▶ 0 1 2 3 4 5 6 7 8 9 10 ◀ Completely interfered

Q. Over the PAST WEEK, how much has your tinnitus interfered with …

19. Your enjoyment of **social activities**?
    Did not interfere ▶ 0 1 2 3 4 5 6 7 8 9 10 ◀ Completely interfered
20. Your **enjoyment of life**?
    Did not interfere ▶ 0 1 2 3 4 5 6 7 8 9 10 ◀ Completely interfered
21. Your **relationships** with family, friends and other people?
    Did not interfere ▶ 0 1 2 3 4 5 6 7 8 9 10 ◀ Completely interfered
22. How often did your tinnitus cause you to have difficulty performing your **work or other tasks**, such as home maintenance, school work, or caring for children or others?
    Never had difficulty ▶ 0 1 2 3 4 5 6 7 8 9 10 ◀ Always had difficulty

E. Over the PAST WEEK …

23. How **anxious** or **worried** has your tinnitus made you feel?
    Not at all anxious or worried ▶ 0 1 2 3 4 5 6 7 8 9 10 ◀ Extremely anxious or worried
24. How **bothered** or **upset** have you been because of your tinnitus?
    Not at all bothered or upset ▶ 0 1 2 3 4 5 6 7 8 9 10 ◀ Extremely bothered or upset
25. How **depressed** were you because of your tinnitus?
    Not at all depressed ▶ 0 1 2 3 4 5 6 7 8 9 10 ◀ Extremely depressed

Tinnitus Funksionele Indeks (TFI)

Datum: _____ Naam: _____

Lees asseblief elke onderstaande vraag deeglik. Om te antwoord, kies EEN van die nommers wat gelys is vir die vraag en trek 'n SIRKEL rondom die antwoord soos volg: ⑩% of ①.

II. Gedurende die AFGELOPE WEEK …

1. Watter persentasie van die tyd wat u wakker was, was u **bewus van** u tinnitus?
   Nooit bewus ► 0% 10% 20% 30% 40% 50% 60% 70% 80% 90% 100% ◄ Altyd bewus
2. Hoe **sterk of hard** was u tinnitus?
   Glad nie sterk of hard nie ► 0 1 2 3 4 5 6 7 8 9 10 ◄ Uitermatig hard
3. Watter persentasie tyd wat u wakker is, was u **geïrriteerd** deur u tinnitus?
   Nooit nie ►0% 10% 20% 30% 40% 50% 60% 70% 80% 90% 100%◄ Heeltyd geïrriteerd

SC. Gedurende die AFGELOPE WEEK …

4. Het u **in beheer** gevoel van u tinnitus?
   Totaal in beheer ► 0 1 2 3 4 5 6 7 8 9 10 ◄ Nooit in beheer nie
5. Hoe maklik was dit om u tinnitus **te hanteer**?
   Baie maklik ► 0 1 2 3 4 5 6 7 8 9 10 ◄ Onmoontlik om te hanteer
6. Hoe maklik was dit om u tinnitus te **ignoreer**?
   Maklik om te ignoreer ► 0 1 2 3 4 5 6 7 8 9 10 ◄ Onmoontlik om te ignoreer

C. Gedurende die AFGELOPE WEEK, hoe het die tinnitus ingemeng met...

7. U vermoë om te **konsentreer**?
   Nie ingemeng nie ► 0 1 2 3 4 5 6 7 8 9 10 ◄ Totaal ingemeng
8. U vermoë om **helder te dink**?
   Nie ingemeng nie ► 0 1 2 3 4 5 6 7 8 9 10 ◄ Totaal ingemeng
9. U vermoë om u **aandag te fokus** op ander goed behalwe u tinnitus?
   Nie ingemeng nie► 0 1 2 3 4 5 6 7 8 9 10 ◄ Totaal ingemeng

SL. Gedurende die AFGELOPE WEEK …

10. Hoe gereeld het u tinnitus dit bemoeilik om **aan die slaap te raak** of **aan die slaap te bly**?
    Was nooit moeilik nie ► 0 1 2 3 4 5 6 7 8 9 10 ◄ Was altyd moeilik
11. Hoe gereeld het u tinnitus veroorsaak dat u gesukkel het om **soveel te slaap soos wat u benodig?**
    Nooit gesukkel nie ► 0 1 2 3 4 5 6 7 8 9 10 ◄ Altyd gesukkel

12. Hoe gereeld het u tinnitus verhoed dat u so **diep en rustig slaap** soos wat u graag wou?
Glad nie ▶ 0 1 2 3 4 5 6 7 8 9 10 ◀ Altyd verhoed

A. Gedurende die AFGELOPE WEEK, hoeveel het u tinnitus ingemeng met …

13. U vermoë om **duidelik te hoor**?
Glad nie ingemeng nie ▶ 0 1 2 3 4 5 6 7 8 9 10 ◀ Totaal ingemeng
14. U vermoë om mense **te verstaan** as hulle praat?
Glad nie ingemeng nie ▶ 0 1 2 3 4 5 6 7 8 9 10 ◀ Totaal ingemeng
15. U vermoë om **gesprekke te volg** in ‘n groep of in vergaderings?
Glad nie ingemeng nie ▶ 0 1 2 3 4 5 6 7 8 9 10 ◀ Totaal ingemeng

R. Gedurende die AFGELOPE WEEK, hoeveel het u tinnitus ingemeng met …

16. U **stil, rustende aktiwiteite**?
Glad nie ingemeng nie ▶ 0 1 2 3 4 5 6 7 8 9 10 ◀ Totaal ingemeng
17. U vermoë om te **ontspan**?
Glad nie ingemeng ▶ 0 1 2 3 4 5 6 7 8 9 10 ◀ Totaal ingemeng
18. U vermoë om “**rus en vrede**” te geniet?
Glad nie ingemeng nie ▶ 0 1 2 3 4 5 6 7 8 9 10 ◀ Totaal ingemeng

Q. Gedurende die AFGELOPE WEEK, hoeveel het u tinnitus ingemeng met …

19. U genot van **sosiale aktiwiteite**?
Glad nie ingemeng nie ▶ 0 1 2 3 4 5 6 7 8 9 10 ◀ Totaal ingemeng
20. U **lewensgenot**?
Glad nie ingemeng nie ▶ 0 1 2 3 4 5 6 7 8 9 10 ◀ Totaal ingemeng
21. U **verhoudings** met familie, vriende en ander mense?
Glad nie ingemeng nie ▶ 0 1 2 3 4 5 6 7 8 9 10 ◀ Totaal ingemeng
22. Hoe gereeld het u tinnitus veroorsaak dat dit moeilik was om u **werk en ander take uit te voer**, soos huishoudelike take, skoolwerk of versorging van kinders en ander mense?
Was nooit moeilik nie ▶ 0 1 2 3 4 5 6 7 8 9 10 ◀ Was altyd moeilik

E. Gedurende die AFGELOPE WEEK …

23. Hoe angstig of bekommerd het u tinnitus u laat voel?
Glad nie angstig of bekommerd ▶ 0 1 2 3 4 5 6 7 8 9 10 ◀ Baie angstig en bekommerd
24. Hoe **ontsteld en gepla** was u deur u tinnitus?
Glad nie ontsteld of gepla nie ▶ 0 1 2 3 4 5 6 7 8 9 10 ◀ Baie ontsteld en gepla
25. Hoe depressief was u as gevolg van u tinnitus?
Glad nie depressief ▶ 0 1 2 3 4 5 6 7 8 9 10 ◀ Baie depressief