# A Systematic Evaluation of the Cognitive Behavioural Model of Tinnitus Distress

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#### **Abstract**

#### **Introduction & Aims**

Tinnitus has long been known to be a much more distressing problem to some people than to others, and understanding the reasons for this is crucial to the development of tinnitus therapy. McKenna et al. (2014) developed a Cognitive Behavioural Model of Tinnitus Distress based on psychological theory- in particular, the Cognitive Model of Insomnia (Harvey, 2002a)- existing evidence, and clinical experience. It attempts to explain how tinnitus distress arises and is then maintained in certain individuals. It proposes that interaction between negative thoughts, arousal and distress, attention and monitoring, behaviour and underlying beliefs makes tinnitus a psychologically distressing experience. A strength of this model is that it consists of several testable hypotheses. It makes a series of predictions about what the individual components of tinnitus distress are and how they relate to one another. The primary aim of this project was to test all these predictions using questionnaire data gathered from people with tinnitus and thereby to evaluate whether and to what extent the Cognitive Behavioural Model is supported by evidence. In some contexts, the model is used as a therapeutic tool to help people understand their own experience of tinnitus. The secondary aim of this project was therefore to investigate whether and to

what extent people with tinnitus feel the model applies to them and whether they find it easy to understand.

#### Methods

Two studies were conducted in order to investigate the two project aims. In the first, volunteers with tinnitus were asked to fill in a survey online or on paper which consisted of a series of questionnaires (or parts of questionnaires) each of which was designed to assess an individual component of the Cognitive Behavioural Model. Questionnaire data were used first to conduct factor analysis of each questionnaire individually. The resulting factor scores were then used to evaluate the full model using path analysis. A series of models based on the original, theoretical model were created and tested and results were compared.

In the second study, tinnitus patients who had the Cognitive Behavioural Model explained to them in a therapy group were interviewed about their impressions of it. A focus group discussion about the model was also held with tinnitus therapists who were familiar with it. Interviews and the focus group were audio recorded, transcribed, and analysed using thematic analysis.

#### **Results**

Three hundred and forty-two adults with tinnitus completed the survey. Eleven tinnitus patients were interviewed and five therapists attended the focus group.

Examination of mean questionnaire scores indicated a strong correlation between each of the measures used and overall tinnitus distress, with the exception of a modified version of the illness perception questionnaire, which was used to measure tinnitus control beliefs. A robust factor structure was identified for all but one of the questionnaires used in the survey; the Fear of Tinnitus Questionnaire. This questionnaire was excluded from further analysis. Path analysis indicated that a number of configurations of the

Cognitive Behavioural Model were a fairly good fit to the data obtained. The two best fitting models differed principally in the placement of tinnitus magnitude, which was seen as a product of attention in the first and as an independent variable in the second. Key fit indices for the two best fitting models were RMSEA = 0.061, 90% CI = 0.047-0.076, CFI = 0.984 and RMSEA = 0.055, 90% CI = 0.035-0.075, CFI = 0.993.

Results of qualitative analysis indicated that people with tinnitus are able to understand the Cognitive Behavioural Model and for the most part feel it broadly reflects their experience, although some people did not identify with certain parts of it. There were differing opinions amongst both patients and therapists as to how useful a part of tinnitus therapy it might be.

#### Conclusion

The Cognitive Behavioural Model of Tinnitus Distress is empirically supported by data obtained from a sample of people with tinnitus. Questions remain as to whether beliefs are important and what kind of beliefs influence tinnitus experience. The fact that different configurations of the model fit the data equally well and that people with tinnitus do not necessarily think that the model is a perfect reflection of their experience, indicate that there may in fact not be one universal model of tinnitus distress but several, some of which apply more to certain sub-groups of people with tinnitus than others. Further investigation of this is needed. This notwithstanding, this project indicates that the Cognitive Behavioural Model is a firm, evidence-based foundation on which to build psychological tinnitus therapies.

#### **Declaration**

I certify that this thesis is my own work, except where indicated by referencing. No part of this thesis has been submitted elsewhere for any other degree or qualification.

Lucy Handscomb

#### Acknowledgements

I would like to thank my three supervisors, who made an excellent team; Prof Deborah Hall, Dr Derek Hoare and Dr Gillian Shorter. I am very grateful for their expert guidance, detailed and constructive feedback, and continuous eagerness to discuss ideas. I would also like to thank Dr Laurence McKenna and Dr Liz Marks for several illuminating discussions about the Cognitive Behavioural Model in some unusual locations.

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List of Abbrev	iations	
ACT	Acceptance and Commitment Therapy	
BDI	Beck Depression Inventory	
BRU	Biomedical Research Unit	
BTA	British Tinnitus Association	
CBT	Cognitive Behavioural Therapy	
CFA	Confirmatory Factor Analysis	
FOTQ	Fear of Tinnitus Questionnaire	
German TQ	German Tinnitus Questionnaire	
HADS	Hospital Anxiety and Depression Scale	
IPQ	Illness Perception Questionnaire	
PHQ-9	Patient Health Questionnaire (9-item version)	
PVAQ	Pain Vigilance and Awareness Questionnaire	
RNTNE	Royal National Throat. Nose and Ear	

Structured Clinical Interview

Structural Equation Modelling

Symptoms Checklist (25-item version)

Symptoms Checklist (90-item version)

SCID

SCL-25

SCL-90

SEM

SF36 Short Form 36

STAI State Trait Anxiety Inventory
TCQ Tinnitus Cognitions Questionnaire
TCS Tinnitus Catastrophising Scale
TFAS Tinnitus Fear Avoidance Scale
TFI Tinnitus Functional Index
THI Tinnitus Handicap Inventory
THQ Tinnitus Handicap Questionnaire

TMI Tinnitus Magnitude Index
 TQ Tinnitus Questionnaire
 TRI Tinnitus Research Initiative
 TRQ Tinnitus Reaction Questionnaire

TRSS Tinnitus-related Self-statements Scale

TVAQ Tinnitus Vigilance and Awareness Questionnaire

# Chapter 1. **Development of a Cognitive Behavioural Model of Tinnitus Distress**

#### 1.1 Introduction

The widely adopted definition of tinnitus is: "the conscious expression of a sound that originates in an involuntary manner in the head of its owner, or may appear to him to do so." (McFadden, 1982). Most of the population experience tinnitus temporarily after being in a very noisy place, and so for research purposes a person is normally considered to have tinnitus only if it lasts for more than five minutes at a time and does not only arise after noise exposure. This is sometimes referred to as "prolonged spontaneous tinnitus." However, this definition is not universal, and partly because of this, the prevalence of tinnitus is not easy to determine. McCormack et al. (2016) reviewed 39 studies from 16 different countries published since 1980 and found that while the majority used the definition above, others asked about 'permanent' tinnitus and others about 'recurrent' tinnitus. Overall, they found that reported prevalence rates ranged from around 5% to around 40% of the population. Prevalence estimates varied within the same geographical region and within the same decade, so it is not safe to assume that tinnitus is becoming steadily more common or is more common in some countries than others. The authors attribute the variability in findings to different ways of asking people whether they have tinnitus, different response options and different sampling methods. All that can be concluded with any degree of certainty is that tinnitus is a common condition in many parts of the world.

Most tinnitus surveys enquire about tinnitus severity as well as presence, and although there is- again-variability in findings depending on how questions are

asked (McCormack et al., 2016) a consistent finding is that a large proportion of people who have tinnitus do not rate it as particularly troublesome. Davis and El Refaie (2000) found that only half of respondents reporting tinnitus in a UK- based survey rated it as either moderately or severely annoying. Only a quarter of respondents in a more recent UK survey of people aged 40-69 (McCormack et al., 2014) said that they were moderately or severely upset by their tinnitus. Similar findings have been reported in Japan (Michikawa et al., 2010), Norway (Krog et al., 2010) and Poland (Fabijanska et al., 1999). Nevertheless, those who are troubled by their tinnitus may find it very distressing indeed (Andersson et al., 2005b, Pridmore et al., 2012).

A number of researchers have attempted to identify what factors might account for a perception of noise in the ears or head being an untroubling experience with no consequences to one person, and a catastrophe affecting every aspect of life to another (cf. McCombe et al., 2001). Although it might be assumed that the louder the noise is, the more distressed the person hearing it is likely to be, this assumption is not supported by studies which have shown only weak correlation between perceived tinnitus loudness and tinnitus-related distress (Cope et al., 2011, Degeest et al., 2016, Hoekstra et al., 2014). The psychological model hypothesised by Hallam et al. (1984) was the first to give central prominence to psychological reaction to tinnitus as a moderator of distress. Since then, other attempts have been made to explain the internal processes that may lead to tinnitus becoming persistently troublesome. Jastreboff (1990) developed a neurophysiological model which takes a behaviourist perspective, and proposes that conscious awareness of tinnitus is largely maintained by a subconscious, conditioned association between tinnitus and negative emotions (figure 1.1). McKenna (2004) takes a psychological perspective and, in keeping with Hallam (1984), argues that a conscious thought process triggers a chain of events that maintains tinnitus distress. This is congruent with current thinking about how psychological distress is maintained across a range of long-term health conditions by an

interaction between negative cognition, emotion, and behaviour. This interaction is commonly illustrated by the 'five areas' or 'five aspects' model (Padesky and Mooney, 1990) reproduced in figure 1.2. Specifically, McKenna (2010, McKenna et al., 2014) propose that thinking of tinnitus in a negative way leads to feelings of distress, which in turn draws the person's attention towards the tinnitus more and may cause the perception of it to be distorted. Increased attention fuels further negative thoughts, while underlying beliefs and changes in behaviour (e.g. avoiding previously enjoyed situations thought to make tinnitus worse) further enhance negative thinking, which increases distress, and so the cycle continues.

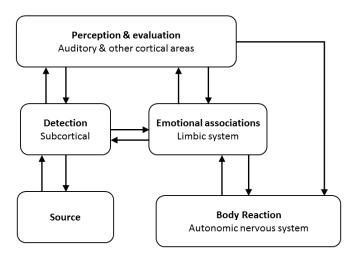


Figure 1.1: Jastreboff's neurophysiological model of tinnitus; redrawn

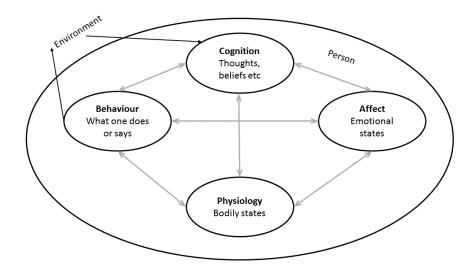


Figure 1.2: Padesky and Mooney's 'Five Areas' model; redrawn

McKenna based his cognitive behavioural model of tinnitus explicitly on the cognitive model of insomnia proposed by Harvey (2002a, see figure 1.3). There are a number of parallels between insomnia and tinnitus which make this an appropriate choice. Both are long-term conditions associated with significant psychological disturbance and in both, the trigger factors are (usually) different from the factors that maintain the condition as a persistent problem (Andersson et al., 2005b, Harvey, 2002a). Furthermore, Cognitive Behavioural Therapy, which aims to break negative cycles of emotion, cognition and behaviour has been shown to be effective for both conditions (Mitchell et al., 2012, Martinez-Devesa et al., 2010). One important distinction is that while Harvey's model seeks to explain the maintenance of insomnia per se, McKenna's model (figure 1.4) seeks to explain the maintenance not of tinnitus perception but of tinnitus-related emotional distress. While removal of tinnitus perception is currently rarely possible, reduction of tinnitus distress is both possible, highly desirable to sufferers, and the object of psychological intervention (McKenna and Andersson, 2008).

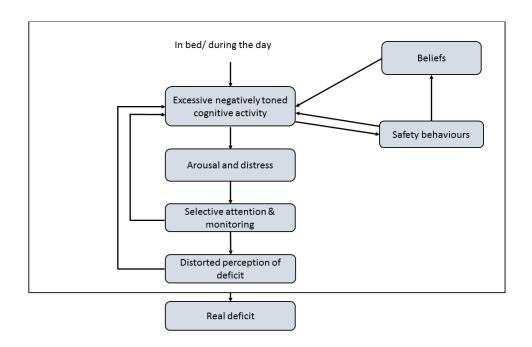


Figure 1.3: Harvey's cognitive model of insomnia; redrawn

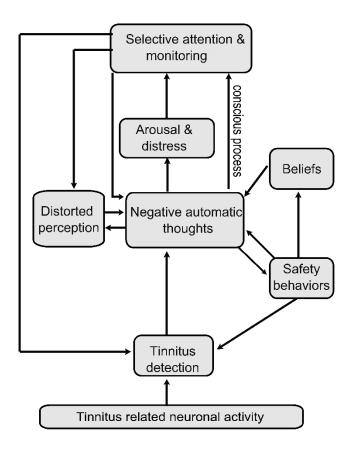


Figure 1.4: McKenna et al's cognitive behavioural model of tinnitus distress; reproduced from McKenna, et al. (2014).

A strength of the cognitive models of both insomnia and tinnitus is that they consist of a series of distinct, testable hypotheses. For example, one hypothesis in the Cognitive Behavioural Model of Tinnitus Distress is that negative automatic thoughts contribute to tinnitus distress. Another is that selective attention and monitoring contribute to tinnitus distress. A third (represented by an arrow) is that negative automatic thoughts lead to selective attention and monitoring. All of these hypotheses are testable, and refutable (if, for example, people who scored high on a measure of tinnitus distress scored low on a measure of attention). By contrast, the neurophysiological model hypothesises that subcortical detection of tinnitus triggers an automatic response in the limbic system. This is not testable, as it is presumed to be happening at a subconscious level. In a paper which precedes the development of the Cognitive Behavioural Model, McKenna (2004) highlights the need for a model firmly founded on empirical evidence rather than theory and intuition. This, he argues, is essential to the development of more effective treatment.

#### 1.2 Aims and overview of the research project

This project consists of two research studies which aim to evaluate the Cognitive Behavioural Model of Tinnitus Distress in two different ways. Study one is a large-scale, cross-sectional study which aims to systematically test all the hypotheses within the model. Results of study one will indicate whether and to what extent these hypotheses are consistent with data obtained from people with tinnitus. Study two is a qualitative study which aims to investigate how people with tinnitus respond to the model and to what extent they feel it reflects their own experience.

A synthesis of results of both studies will give an indication of whether the Cognitive Behavioural Model of Tinnitus Distress is a plausible and helpful way of viewing the development and maintenance of tinnitus-related distress.

# Chapter 2. **Investigating Tinnitus**-Related Distress; a Review of the Literature

The Cognitive Behavioural Model of Tinnitus Distress (McKenna et al., 2014) and the Cognitive Model of Insomnia from which it derives (Harvey, 2002a) are underpinned by a fairly large degree of existing evidence supporting the various hypotheses contained within them. In this chapter, a brief overview of literature which supports the Cognitive Model of Insomnia is presented, followed by a more in-depth discussion of literature pertaining to the various components of the Cognitive Behavioural Model of Tinnitus Distress.

#### 2.1 Definition of terms

Given that the development of both models was informed by the five-areas model (illustrated in figure 1.2) and the principles of cognitive behavioural therapy (CBT), the terms used within them are best understood in this context. This section provides a brief overview of the terms based on CBT-related literature. Fuller descriptions of each theoretical construct are given later in the thesis.

#### 2.1.1 Negative Automatic Thoughts

The theory behind cognitive behavioural therapy sees negative thoughts as essential to the development and maintenance of a negative emotional state, whether that state is depression, anxiety, or a more specific condition such as social phobia or health anxiety (Beck et al., 1979). The guiding principle behind CBT is that there is no direct link between events and emotions. Rather, an event may trigger different thoughts in different people and it is these thoughts that give rise to the subsequent emotional state. A creaking sound in the night may trigger the thought: "someone is trying to break in!" in one person, and lead to anxiety. The same creaking sound may, in someone

else, trigger the thought: "ah, here comes my lovely cat!" and lead to pleasure. Many psychological disorders are characterised by a tendency towards negative automatic thoughts, that is, thoughts which are negative in their content and which 'pop in' to the thinker's mind without a deliberate decision having been made to think them (Beck et al., 1979).

#### 2.1.2 Arousal and Distress

In common parlance, the term 'distress' can pertain to physical as well as emotional sensations but in CBT, emotional distress is normally implied. The term may be used to describe general dysphoria (a sense of unease or dissatisfaction) or more specific psychiatric disorders, particularly depression and anxiety (Ridner, 2004) . 'Arousal' is generally taken to mean the physical sensations that typically accompany emotional distress, such as muscle tension or increased heart rate. The term 'autonomic arousal' is sometimes used to emphasize that these sensations are not under voluntary control (Steimer, 2002).

#### 2.1.3 Selective Attention and Monitoring

Selective attention is defined by Harvey et al (2004) as: "a process by which specific stimuli, within the external and internal environment, are selected for further processing." (p. 26). They also specify it involves dominance of one stimulus over others. Selective attention to a stimulus which has personal significance is a natural phenomenon. For example, a person considering buying a particular breed of dog will find his attention drawn to every dog of that breed he sees, and most people will detect the sound of their own name clearly in a conversation in which they were previously uninvolved (Cherry, 1953). When people are psychologically distressed, selective attention is similarly directed towards stimuli associated with the cause or experience of that distress (Williams et al., 1996). Laboratory studies of selective attention usually involve consciously picking out relevant stimuli while ignoring irrelevant stimuli. Monitoring is related to selective attention, but implies a

more active and deliberate searching or checking process. In the context of pain, McCracken (1997) defines it as 'keeping track' of changes in pain sensations.

#### 2.1.4 Beliefs

While automatic thoughts are fleeting and change according to context, beliefs (in the context of CBT) are a more stable way of seeing the world (Padesky 1994). Dysfunctional beliefs underlie negative thoughts (Beck et al., 1979), and in therapy, core beliefs are accessed by first examining the content of automatic thoughts. As an example, the negative automatic thought: "I'll never be able to keep up with the conversation at university" might be underpinned by the belief: "I'm not clever enough."

#### 2.1.5 Safety Behaviour

In a psychological context, safety behaviour refers to things that people do in an attempt to avoid the feared consequences of a particular event (Salkovskis, 1991). Use of safety behaviour actually prevents beliefs about these feared consequences being disconfirmed. Salkovskis discusses the use of safety behaviour amongst people who have panic attacks. The person in panic may fear he is going to have a heart attack, and to prevent this he sits down and breathes deeply. When the attack has passed he tells himself he only avoided a heart attack by sitting down and breathing deeply. Thus, he continues to believe the feared consequence is likely. Similarly, a person with social phobia might worry that others will consider her boring and therefore speak as little as possible at a social function, thus denying herself the opportunity for expressions of interest from others (Wells et al., 1995).

#### 2.1.6 Distorted Perception

The term 'distorted perception' implies that a person's way of seeing a situation or interpreting a stimulus is different from what would be expected, or from some kind of norm. It is quite context-specific so, for example, in body

dysmorphia it might refer to viewing one's physical appearance differently from how most people view it (Auchus et al., 1993), while somebody with arachnophobia might estimate the size of a spider to be bigger than it actually is (Shiban et al., 2016). The different interpretations of distorted perception for insomnia and tinnitus are discussed in sections 2.2 and 2.3.6.

#### 2.1.7 Tinnitus-related Distress

Although the term tinnitus-related distress is not used in the model, it is the overall construct which the model seeks to explain. Most intervention studies seek to measure change in tinnitus-related distress as a primary outcome, but there is no universally agreed definition of this term. Many commonly used measures of 'tinnitus distress,' such as the Tinnitus Questionnaire (TQ; Hallam, 1996), the Tinnitus Handicap Questionnaire (THQ; Kuk et al., 1990) and the Tinnitus Handicap Inventory (THI; Newman et al., 1996) also include items about functioning, thoughts and behaviour. For the purposes of this study, emotional distress related to tinnitus is regarded as a separate construct from thoughts and behaviour.

There is considerable overlap between the constructs of tinnitus-related distress and emotional distress, but there is also a distinction, which is one of attribution. It is conceivable that somebody could answer 'always' to the question 'my tinnitus makes me depressed' but 'sometimes' to the question 'I feel depressed' because they only notice their tinnitus some of the time, but whenever they do, they feel depressed. The inverse could also be true. Some authors have noted that when questioned about emotional distress, patients often mention other difficulties in their lives apart from tinnitus (Halford and Anderson, 1991, Marciano et al., 2003, Zoger et al., 2001). Some people might describe themselves as depressed or anxious but not attribute this to their tinnitus. Support for this idea comes from validation studies which have reported on convergent validity between measures of tinnitus distress and of emotional distress. For example, Wilson et al. (1991) found moderate correlation between their Tinnitus Reaction Questionnaire (TRQ) and the

'state' and 'trait' subscales of the state- trait anxiety inventory (STAI; Spielberger et al., 1970). This strongly suggests that tinnitus-related distress is not the same thing as general emotional distress.

### 2.2 Summary of evidence supporting Harvey's Cognitive Model of Insomnia

Before developing her model, Harvey (2000) found that people with insomnia reported more worrying thoughts on a questionnaire than good sleepers and that thoughts often focused on the subject of sleep and the consequences of not sleeping. She also found that insomniacs were more likely to rate their thoughts as 'uninvited' (automatic) than good sleepers. Autonomic arousal in insomnia has been quite extensively researched. In a review (Akerstedt, 2006) a number of studies are discussed which have shown increased levels of cortisol and proinflammatory cytokines, increased heart rate and oxygen consumption and elevated body temperature amongst poor sleepers, all of which can be stress indicators. Although Harvey provides no definition of 'distress,' most work on distress related to insomnia has focused on symptoms of anxiety and/ or depression. One standard for diagnosis of a mental health condition is the Structured Clinical Interview (SCID; Spitzer et al., 1992) which is based on the diagnostic criteria contained within the Diagnostic and Statistical Manual of Mental Disorders produced and periodically revised by the American Psychiatric Association. A number of researchers (Schramm et al., 1995, Buysse et al., 1994, Ohayon and Roth, 2003) have used this type of interview with people who have insomnia and found anxiety and depression to be the most common diagnoses. The numbers with co-existing depression and/or anxiety range from 26% (in a random population sample) to 75% (in a sample from a specialist sleep clinic). Another large population survey in Norway (Sivertsen et al., 2009) used the Hospital Anxiety and Depression Scale (HADS; Zigmond and Snaith, 1983) to screen for generalised depression and anxiety and posed questions about sleep problems to 47 000 people. Using the HADS cut-off score of >8 for

'probable' depression/ anxiety, they found insomnia increased the odds for both probable anxiety (odds ratio = 2.42) and probable depression (odds ratio = 1.99). The overall picture, then, is that rates of anxiety and depression are high amongst people with insomnia, and highest amongst those troubled enough by insomnia to seek specialist help.

Selective attention and monitoring have been measured in a variety of ways. Investigating selective attention, Marchetti et al. (2006) found that insomniacs were able to detect sleep-related picture changes (e.g. removal of pillow or pyjamas) faster than other changes, and faster than controls. Taylor et al. (2003) investigated selective attention by using an emotional Stroop task. Typically, participants take longer to name the colour of words which hold an emotional significance to them than they do to colour name neutral words. Taylor et al. found that persistent insomniacs took significantly longer to respond to sleep-related words than neutral ones, which they interpret as an indicator of selective attention towards words associated with insomnia. Interestingly, the control group in this study were people suffering from acute insomnia which had not (yet) become chronic. Here perhaps is an indication that selective attention is one of the factors that distinguishes people with a persistent insomnia problem from those who sometimes have problems sleeping due to current, specific worries, which includes most of the population (Harvey, 2002a). Monitoring behaviour in insomnia can be measured by the Sleep Associated Monitoring Index (Semler and Harvey, 2004). When this questionnaire was completed by 400 volunteers, many types of monitoring behaviour such as clock-watching, checking for signs of falling asleep at night and checking for signs of sleepiness in the day were found to be present amongst insomniacs.

Harvey (2002b) investigated people's reported use of safety behaviour by asking questions and having the responses rated according to whether the self-reported behaviour was designed to prevent a feared outcome and would

be likely to make the person's insomnia or daytime functioning worse (and thus met the definition of safety behaviour). She found safety behaviour use to be common amongst (although not exclusive to) people with insomnia, to be frequent both at night and during the day and to be linked to dysfunctional beliefs about sleep. Following this she devised a sleep related behaviours questionnaire (Ree and Harvey, 2004) and using this measure, Woodley and Smith (2006) found that dysfunctional beliefs about sleep predicted use of safety behaviour amongst 40 students. Other than in this study, sleep-related beliefs have not been very much investigated, but Harvey (2002a) discusses the role that beliefs about sleep may have in maintaining insomnia by using examples from her extensive clinical experience. Beliefs about the minimum amount of sleep people require to function seem to be relatively common, and have the paradoxical effect of keeping people awake due to increased effort.

Harvey (2002a) defines distorted perception as a misperception of the amount of sleep obtained, and describes this as 'ubiquitous' amongst people with insomnia. In this paper and a later review (Harvey and Tang, 2012) she and her colleagues conclude from evidence from multiple studies comparing self-report with actigraphy (using bodily movement to measure sleep) or polysomnography (measuring sleep using brain waves, breathing and heart rate) that people frequently underestimate both the amount of time they have spent asleep and the amount of time it has taken to fall asleep, sometimes by quite large amounts. By contrast, good sleepers have been shown to be quite accurate in their estimates (Manconi et al., 2010).

The evidence above provides a reasonable degree of empirical support for Harvey's model and several successful psychological interventions have been based on it (Harvey et al., 2007). However, it has not yet been subject to systematic testing in its entirety, which perhaps limits the extent to which it has been adopted by other specialists in the area.

### 2.3 Empirical evidence supporting McKenna et al.'s Cognitive Behavioural Model of Tinnitus Distress

Systematic testing of the Cognitive Behavioural Model of Tinnitus Distress has been carried out and is described in chapters 3, 4, 5 and 6. What follows below is a summary of evidence which was gathered prior to this testing process which supports the various predictions made by the model about factors which contribute to tinnitus distress and the connections between them. Further discussion of this evidence can be found in a paper which describes the model's development (McKenna et al., 2014).

#### 2.3.1 Negative Automatic Thoughts

There is limited research into the thoughts and thought processes of tinnitus patients, which is surprising given the effectiveness of CBT- which addresses thoughts- as a treatment (Hoare et al., 2011, Cima et al., 2014). Wilson and Henry (1998) developed a Tinnitus Cognitions Questionnaire (TCQ), the psychometric properties of which are described in section 3.4.2. In their initial questionnaire evaluation using 200 Australians with tinnitus (a mixture of clinic patients and volunteers), the authors found the most commonly endorsed statements to be: "Why me? Why do I have to suffer this horrible noise?", "I can't enjoy what I'm doing because of the noise" and "The noise will drive me crazy." They also found that there was no correlation between the positive and negative subscales (r=0.09) suggesting that the absence of positive thoughts does not necessarily imply the presence of negative thoughts. Tendencies to think negatively and to have difficulty thinking positively may contribute independently to feelings of arousal or distress, or one tendency may be more important than the other. However, the TCQ has not been widely adopted by other researchers so it is unclear whether similar thoughts are common in different populations.

A few studies have used questionnaire tools to investigate the extent to which people catastrophise about their tinnitus; that is, think about it in an exaggeratedly negative way. Cima et al. (2011) developed a Tinnitus catastrophising scale, based on the pain catastrophising scale (Sullivan et al., 1995). This is a 13-item, single-factor questionnaire which asks patients to indicate how frequently they have certain thoughts on five-point Likert scale with the anchors 'not at all' and 'always'. A high score indicates a tendency to 'think the worst' about tinnitus most of the time. Items include: 'I worry all the time about whether the tinnitus will end' and 'I become afraid the tinnitus will get worse.' In a study involving 61 tinnitus patients in the Netherlands, the questionnaire showed very high internal consistency ( $\alpha$ =0.93.) The mean score was 25.1 (SD=13.7) out of 52, indicating that catastrophic thinking is frequent amongst tinnitus patients. The authors also found that higher scores on this scale correlated with lower scores on a quality of life measure, the Short Form 36 (SF36; Ware and Sherbourne, 1992), r= 0.32, p<0.05 and higher scores on the TQ (r=0.7, p<0.01) indicating that catastrophising is a distinct construct from tinnitus distress, but associated with it.

Weise et al. (2013) used a different measure to assess catastrophising, the 9-item 'catastrophising' subscale of the tinnitus-related self- statements scale (TRSS; Flor and Schwarz, 2003), which has a six-point Likert response scale using the anchors 'almost never' and 'almost always' to indicate frequency of thoughts. It includes statements such as 'I cannot stand this tinnitus any longer' and 'this will never end.' The mean score amongst 278 German participants (who were enrolled on a tinnitus intervention study in the same clinic) was fairly low, at 13.45 (SD= 8.88) out of 45. This may be due to the strong wording of negative statements and indicates that most people with tinnitus are not engaging in extremely negative thinking most of the time. The authors also found that high scores on this scale were strongly correlated with

high levels of tinnitus-related distress measured by overall scores on the German Tinnitus Questionnaire (Goebel and Hiller, 1994; r=0.74, p<0.01) and also with the number of medical visits participants had made in relation to their tinnitus ( $\beta=0.02$ , Z=2.5).

Some evidence of negatively toned cognitive activity amongst people with tinnitus emerges from Andersson et al.'s work on autobiographical memory (2003a). The authors note that people with depression have previously demonstrated a negative bias in thinking in that they are less able than controls to retrieve specific autobiographical memories in response to cue words, particularly positive ones. They found a similar pattern amongst tinnitus patients, even when controlling for depression. This is a small study and the only one of its kind, but it does lend some support to the idea that cognition amongst tinnitus patients tends to have a negative bias.

It seems that it is not only thoughts and thinking which influence people's experience of tinnitus but also the way in which thoughts are dealt with. Both Riedl et al. (2015) and Hesser et al. (2015) have investigated acceptance amongst tinnitus patients, which can be defined as openness to one's current situation and internal experiences, including thoughts. Both teams of researchers found that a high degree of tinnitus acceptance was associated with a lower level of tinnitus distress.

One study has investigated the use of thought suppression amongst tinnitus patients (Westin et al., 2008). Participants were instructed to focus on a pleasant mental image and to hold down a button for as long as their focus was maintained. Interestingly, this study found that instructions to suppress thoughts about tinnitus during the exercise were as successful as instructions to 'accept' tinnitus. This runs contrary to Harvey's (2000) finding that suppression actually results in more thoughts when people are trying to sleep.

However, Westin et al.'s experiment was carried out over a 5-minute period, and continued attempts at thought suppression may be less successful.

#### Effects of tinnitus intervention on negative thoughts

Although intervention based on CBT usually includes activities designed to modify negative thoughts, most intervention studies have used measures of tinnitus distress rather than measures of thoughts, so specific effects of intervention on thinking are not very clear. An exception is an investigation of 'cognitive skills training' (Henry and Wilson, 1996) which found that scores on a pre-publication version of the TCQ reduced significantly more in a cognitive skills group (who learned attention diversion and thought challenging techniques) than in either an education group (who were taught facts about tinnitus) or a waiting list group; F (1,57) = 9.89, p<0.05. This suggests that therapy can alter negative thoughts. A more recent and larger study by Cima et al. (2012) found that scores on their Tinnitus Catastrophising Scale (TCS) reduced for both groups of participants (group 1 received standard tinnitus care while group 2 received a specialised programme of CBT, which included cognitive restructuring exercises). Reductions were significantly greater for those in the specialised care group (at 8 months, group difference= -4.68, 95% CI = -6.94 - 2.43; p < 0.001, effect size = 0.6). Weise et al. (2008) measured catastrophic thinking in their investigation of biofeedback and CBT. They found that mean scores on the catastrophising subscale of their TRSS reduced significantly in their treatment group from 31.38 (SD= 7.26) to 21.41 (SD = 8.83) out of 45. Comparing the treatment group to the waiting list group, effect size was 0.97. They also reported a significant reduction in mean scores on the cognitive distress subscale of the German TQ, from 9.88 (SD = 2.85) to 5.45 (SD = 3.48) in the treatment group. All these studies showed significant reductions in overall tinnitus-related distress.

As both distress and catastrophic thinking can be reduced by successful intervention, it does seem that the two concepts are interlinked, as proposed by the model. In CBT, modifying negative thoughts is the key to disrupting the whole negative cycle that causes distress (Burns, 1999) while in other forms of psychological therapy such as Acceptance and Commitment Therapy (Hayes et al., 2011) distress is reduced by disengaging with thoughts. Hesser et al. (2009b) provide useful evidence that modifying thinking style may be important to the success of tinnitus therapy. A component of their Acceptance and Commitment Therapy (ACT) is teaching patients about cognitive diffusion; that is, distancing oneself from thoughts and observing them rather than engaging with them. They analysed video recordings of 19 ACT sessions and noted that the degree to which patients understood and used cognitive diffusion early in the therapeutic process correlated with greater decreases in tinnitus distress at the end of therapy (r=0.62, p=0.006). Further research is needed to establish how best to deal with negative thoughts around tinnitus, but their contribution to tinnitus distress is unequivocal.

#### Predicted links within the model

The Cognitive Behavioural Model proposes that negative automatic thoughts give rise to arousal and (emotional) distress. Some evidence for this is provided by Budd and Pugh (1996) who, as part of an investigation into coping styles, identified catastrophic thoughts such as 'my tinnitus will lead to a nervous breakdown' as important contributors to maladaptive coping, and found that maladaptive coping correlated with depression (r=0.62, p <0.001). However, as behavioural strategies (such as avoiding activities) were assessed by the same measure, it is difficult to judge the relative contributions of the various components of maladaptive coping to distress. Clearer evidence is provided by Weise et al. (2013), who found that scores on the Patient Health Questionnaire (PHQ-9; Spitzer et al., 1999), which is a measure of depression,

contributed significant unique variance (15%) to the prediction of catastrophising. In other words, people who frequently engaged in exaggeratedly negative thinking about their tinnitus were more likely to have symptoms of depression. Wilson and Henry (1998) also found a moderate correlation between the negative subscale of their TCQ and the Beck Depression Inventory (BDI; Beck et al., 1961); r=0.46, also indicating a possible link between negative thinking and depressed mood. There is no similar investigation of a potential link between negative thinking and anxiety, even though several items on tinnitus thought questionnaires reflect common worries.

#### 2.3.2 Arousal and Distress

#### **Autonomic arousal**

Tinnitus patients often complain of feeling tense or 'on edge', but the extent to which autonomic arousal contributes to a negative tinnitus experience is far from clear. Investigating physiological arousal in people with tinnitus, Heinecke et al. (2008) administered five stress inducing tasks including mental arithmetic and listening to unpleasant sounds to a sample of volunteers with tinnitus. Physiological measures (e.g. skin conductance, muscle tension) were correlated only marginally with subjective strain measures and were, for the most part, no different from controls. In contrast, Hebert and Lupien (2007) found a significant group effect of a stress-inducing task on level of cortisol measured 30 minutes after exposure (F(1, 34) = 11.2, p < .003). A delayed and blunted cortisol response in the tinnitus group indicated greater autonomic arousal. Hebert et al. (2004) calculated the median cortisol level for a group made up of nine people with bothersome tinnitus, nine people with non-bothersome tinnitus and eighteen people without tinnitus by taking samples at different times of day. They used this to investigate how much of the time members of each group had cortisol levels above the median. They found that cortisol samples taken from people with

bothersome tinnitus in everyday settings across one week exceeded the median level 64.4% of the time, which was significantly more of the time than samples from controls or from people with non-bothersome tinnitus (F(2,32) = 3.34, P<0.05). Similar conclusions can be drawn from a study by Weber et al. (2002). Using a different indicator of arousal (immunological response) they found higher levels of cytokine in tinnitus patients than controls without tinnitus prior to relaxation training (p=0.002). These preliminary findings indicate that arousal may be a factor that differs between people with bothersome tinnitus, non-bothersome tinnitus, and no tinnitus.

Self-reported stress is not always associated with physiological indicators. For example, Betz et al. (2017) asked their group of tinnitus clinic patients to wear earplugs and listen to their tinnitus. They found that self-rated stress was high during and immediately after this task, but this was not reflected in increased heart rate. Similarly, Heinecke et al. (2008) found comparable physiological measures for tinnitus and control groups despite the people with tinnitus reporting greater subjective 'strain' than controls following four of the five stress-inducing tasks. The authors suggest that patients may have overestimated the stress-inducing effects of tinnitus and it seems possible that some sort of cognitive distortion is taking place; people with tinnitus might be more likely to think negatively about fairly small changes in arousal. Some support for this idea comes from Hesser and Andersson (2009), who investigated anxiety and anxiety sensitivity (a fear of bodily sensations associated with anxious arousal which is common in individuals who have panic attacks, Reiss, 1991). Using broad questions about tinnitus distress and an anxiety sensitivity index, the authors conducted a multiple regression analysis and found that anxiety sensitivity was a significant predictor of tinnitus distress, even when anxiety itself was controlled for ( $\beta$  = 0.22, p=0.017). By contrast, in Weber et al.'s study (2002) self-reported stress (indicated on a Likert scale) was no greater in tinnitus patients than controls. However, the authors point out that controls were motivated to volunteer for

a relaxation study and were themselves more stressed than the general population. Hebert and Lupien (2007) also failed to find a difference in self-rated stress levels between tinnitus patients and controls after completing stress-inducing tasks. Nevertheless, within the Cognitive Behavioural Model of Tinnitus Distress, it is reasonable to consider that people's own perception of how aroused or stressed they feel is more important than the physiological indicators themselves.

#### Effects of intervention on arousal

A small number of randomised controlled trials (reviewed by Hoare et al., 2011) have assessed approaches to therapy based primarily on physiological relaxation and two recent studies have used relaxation classes as a comparison to mindful meditation classes (Arif et al., 2017, McKenna et al., 2017a). Improvements in general emotional distress and tinnitus-related distress following relaxation therapy have been reported, but it is difficult to determine how much benefit derives from reduction in physiological arousal and how much from other factors, such as engaging in discussions about tinnitus.

#### **Emotional Distress**

Although the term emotional distress may encompass a wide range of feelings (Masse, 2000), most tinnitus studies have limited their investigations to anxiety and depression. Several questions have been addressed in the literature. First, in the general population, are people with tinnitus more likely to report symptoms of anxiety and/ or depression than people without tinnitus? Second, what proportion of tinnitus clinic patients meet diagnostic or screening criteria for mental health conditions? Third, do people with tinnitus generally have high scores on emotional distress measures? Fourth,

are those with more severe tinnitus likely to be more emotionally distressed?

And fifth, do tinnitus interventions reduce emotional distress?

# Population characteristics of tinnitus and self-reported mental health problems

A population study of 51,000 Norwegian adults (Krog et al., 2010) found scores on a brief version of the Symptoms Checklist-25 (SCL-25; Hesbacher et al., 1980), a measure of anxiety and depression, to be significantly higher amongst people with tinnitus than people without, although effect sizes were small; partial n2 was between 0.01 and 0.03, depending on age group. Other population studies have found increased odds of depression (Gopinath et al., 2010, Michikawa et al., 2010, Loprinzi et al., 2013) and anxiety (Shargorodsky et al., 2010) amongst people with tinnitus compared to people without. A study by McCormack et al. (2014) investigated the association between tinnitus and neuroticism, which can be defined as 'the propensity to experience a variety of negative affects such as anxiety, depression, anger and embarrassment.' (McCrae and Costa, 1987, p.87). The researchers analysed responses from more than 172,000 members of the UK Biobank, which contains medical data from volunteers aged between 40 and 69. They found that having tinnitus increased the odds for neuroticism and that having tinnitus classed as 'bothersome' increased the odds further (odds ratio = 4.11, CI=3.69-4.58; P<0.001). They also found a particularly strong association between bothersome tinnitus and considering oneself to be a 'worrier' (odds ratio=1.17, CI=1.09-1.25, p<0.001) and a tendency to feel miserable (odds ratio=1.15, CI=1.07-1.24, p<0.001). Overall, the findings from these large-scale studies indicate that tinnitus often co-exists with anxiety and depression in the general population.

# Diagnosis of and screening for mental health conditions amongst tinnitus patients

Several studies have conducted more in-depth investigations of mental health conditions using tinnitus clinic patients. A systematic review of 16 studies by Pinto et al. (2014) concluded that psychiatric disorders, particularly anxiety and depression, are prevalent amongst tinnitus patients and are associated with greater tinnitus distress. Different methods have been used to assess psychiatric symptoms in clinics, with diagnostic interviews being the most robust. Marciano et al. (2003) used the SCID. They found that 77% (58/75) of new patients at an Italian tinnitus clinic were diagnosable with some form of lifetime psychiatric disorder. Anxiety and depression were the most common diagnoses, affecting 22 and 20 patients respectively. Comparable rates of lifetime anxiety and depression were also found by Zoger, Svedlund et al. (2001). These authors also report on disorders present at the time of the interview; 55% were found to have a current mental disorder (45% anxiety, 39% depression, some with both diagnoses). An alternative diagnostic interview schedule based on the World Health Organisation's International Classification of Disease (1992) was used by Goebel and Floetzinger (2008). They reported a 69% prevalence of current psychiatric disorder amongst 163 patients at a specialist tinnitus centre. Depression was the most common disorder, affecting 57%, with anxiety affecting 43.5%. Again, some had both.

Psychiatric diagnoses require specialist training and so perhaps for this reason many studies opt to use screening tools to investigate the possible prevalence or levels of symptomatology of mood disorders amongst tinnitus patients. Such questionnaires are not designed to diagnose these conditions but rather to flag up a need for more in-depth investigation when a problem is suspected. Only current, not lifetime, disorders are considered. One of the most widely used tools is the HADS. Using the originally recommended cut-off scores of 11 out of 21 for each subscale, Zoger et al. (2004) found the

prevalence of 'probable' anxiety to be 12% and 'probable' depression to be 18% in 98 tinnitus clinic patients. Using a more conservative cut-off score of 8 out of 21 (which was recommended in a review of the HADS by Bjelland et al., 2002), Bartels et al. (2008) found 49% with 'possible' anxiety, and 49% with 'possible' depression (of these, 39% had both) in 265 tinnitus clinic patients.

#### Overall scores on emotional distress measures

Although previous findings suggest that mental health problems are common amongst people with tinnitus, they are far from being an inevitable part of tinnitus experience. Both cohort studies which have questioned volunteers from the general public with tinnitus (Andersson et al., 2003b, Kleinstauber et al., 2013, Andersson et al., 2005c) and trials involving tinnitus clinic patients (Cima et al., 2012, Kaldo et al., 2008) have found relatively low mean scores on the HADS, ranging from 5.9 (SD = 3.9; Andersson et al., 2005c) to 7.9 (SD = 4.6; Andersson et al., 2003b); for anxiety and 5.0 (SD = 4.1; Andersson et al., 2005c); to 6.8 (SD = 3.7; Kaldo et al., 2008) for depression. These mean scores are all below the cut-off of 8 for a possible diagnosis of anxiety or depression and are not vastly different from norms for the general population. In a population survey of more than 4000 German people (Hinz and Brahler, 2011) mean scores for anxiety were 4.4 (SD=3.3) for men and 5.0 (SD3.6) for women respectively and for depression 4.8 (SD=4.0) and 4.7 (SD=3.9). Similarly, mean scores on the BDI have been found to be at or just below the lower end of the 'mild depression' range (between 10 and 15; Beck et al., 1988) in several investigations involving tinnitus clinic patients (Andersson et al., 2003a, Andersson and McKenna, 1998, Hebert and Lupien, 2007, Ooms et al., 2011). As significant numbers of people with tinnitus have sufficient symptoms to reach a diagnosis of depression and anxiety, mean scores must be lowered by a fair proportion of people (including tinnitus clinic patients) who experience no such symptoms.

# Association between tinnitus-related distress and measures of general emotional distress

If the predictions of the Cognitive Behavioural Model are correct and general emotional distress is part of a more negative tinnitus experience, it should be higher amongst those patients who are finding their tinnitus more troublesome. A few studies have found a positive association between measures of tinnitus-related distress (which invite participants to consider how they feel about their tinnitus) and general emotional distress (which invite participants to consider their overall mood). For example, Langenbach et al. (2005) administered a series of questionnaires to 34 patients who had developed tinnitus within the past four weeks, and then again 6 months later. They used the Symptoms Checklist 90 (SCL-90; Derogatis et al., 1973) to measure emotional distress and the TQ to measure tinnitus-related distress. They found that anxiety at tinnitus onset was a strong predictor of severe tinnitus-related distress at follow- up; β=0.319, p=0.02. Milerova et al. (2013) found evidence of a link between some forms of emotional distress and tinnitus-related distress measured on the TQ (Hallam, 1996) and the THI (Newman et al., 1996). Specifically, the depression subscale of the SCL- 90 influenced both THI and TQ scores (for THI,  $\beta$ =0.713, p=0.002 and for TQ,  $\beta$ =0.369, p=0.027). Interestingly, the anxiety subscale did not have a significant influence. Similar positive associations have been reported in a survey of 112 members of the British Tinnitus Association (BTA; Halford and Anderson, 1991) and in a survey of 4075 members of the German Tinnitus Association (Wallhausser-Franke et al., 2012).

Some studies have singled out a group of patients considered to be particularly severely affected by tinnitus and found symptoms of anxiety and depression to be especially common in these people. Zoger et al. (2006) assessed a group considered to be 'at high risk of developing chronic and disabling tinnitus', although the criteria for entering the 'high risk' group were not defined. Correlations between HADS score and tinnitus-related distress

were r=0.45 for anxiety and r=0.38 for depression; all statistically significant at p<0.01. Holgers, Zoger et al. (2005) focused on a group of 30 patients they classed as 'severe' who had been off work for a month or more due to tinnitus and had attended the tinnitus clinic more than three times in two years. They found that 90% of people in this group were diagnosed with a psychiatric disorder by a SCID interview, compared to a significantly smaller percentage of 73% in a less severe group. It is unclear, however, how many of the more general group just missed the 'severe tinnitus' definition, and how many patients were excluded altogether for not working at all.

The wide range of measures used in different studies and the somewhat arbitrary categorization of 'severe' patients makes it difficult to draw firm conclusions, but the weight of existing evidence does seem to support the idea that people who have symptoms of anxiety and depression are more likely to find their tinnitus highly distressing. The direction of causality has not been clearly established. There is some indication that anxiety may precede tinnitus distress (Langenbach et al., 2005) and some that tinnitus may precede depression (Michikawa et al., 2013), but most studies are cross- sectional.

A few studies have looked beyond anxiety and depression to milder forms of emotional disturbance such as stress. In tinnitus clinics, reports of tinnitus being more distressing during or after stressful life events are common. Handscomb (2006) reported a high mean score of 2.38 for the THI item "Does your tinnitus get worse when you are under stress?" amongst 274 tinnitus clinic patients. Recently, a mobile application called 'Track your Tinnitus' was developed by members of the Tinnitus Research Initiative (TRI). This application allows users to rate perceived tinnitus loudness and different types of emotions periodically through the day and upload their ratings to a website. Probst et al. (2016b) analysed data from 604 users drawn from the TRI volunteer database who had been sent random prompts over a period of

9 months to rate their current tinnitus loudness, tinnitus distress level and general stress level. They tested a mediation model with tinnitus distress as an outcome variable and tinnitus loudness and stress level as predictor variables. They found that stress level was a partial mediator between tinnitus loudness and tinnitus distress ( $\beta$ =0.297, SE=0.031, p<0.001), suggesting that feeling stressed could contribute to a negative tinnitus experience.

There is also some evidence to suggest that the variability of emotions plays a part in tinnitus-related distress. In another study using Track your Tinnitus, Probst et al. (2016a) asked 306 volunteers to rate the type of emotion they were feeling and its intensity at different time points and investigated how much these measures varied within users. They found that there was a weak positive correlation between tinnitus-related distress and variability in both emotion type ( $\rho$ =0.12;  $\rho$ <0.05) and emotion intensity ( $\rho$ =0.19;  $\rho$ <0.05). To obtain a true picture of how tinnitus is affected by emotions, it might be helpful to look at stress, emotional stability and wellbeing as well as measures of anxiety and depression.

# Effect of tinnitus interventions on general emotional distress

If general emotional distress and tinnitus-related distress are linked, it should be that interventions which influence one also influence the other. A Cochrane review of randomised controlled trials investigating CBT for tinnitus (Martinez-Devesa et al., 2010) found that depression (measured on a variety of validated scales) was reduced following therapy in the six trials that compared a CBT group to a no-intervention group (standardised mean difference=0.37; 95% CI 0.15 to 0.59; I<sup>2</sup> =0%). The authors note that these findings do not hold for studies which compared CBT to another active intervention, and so it is hard to determine what elements of intervention were specifically effective in reducing depression. Some high-level evidence

comes from a large randomised controlled trial of specialised CBT for tinnitus patients (Cima et al., 2012) that reported a significantly greater improvement in both TQ and global HADS scores for the treatment group compared to controls, who received usual audiological care (for HADS, group difference= -1.507, 95% CI= -2.67- 0.148; p<0.001, effect size=0.24) at 12 months post intervention. Since successful tinnitus-focussed therapy reduces general emotional distress, it must be that emotional distress is at least partially connected to the way people feel about tinnitus specifically.

Overall, existing evidence indicates that symptoms of anxiety and depression are common in people with tinnitus but not universally present, and more likely when tinnitus itself is more distressing. This partially supports the Cognitive Behavioural Model's prediction that emotional distress is part of tinnitus suffering although, as only anxiety and depression have been studied extensively, the picture is incomplete.

## Predicted links within the model

The Cognitive Behavioural Model makes the specific prediction that arousal and emotional distress lead to selective attention and monitoring of tinnitus. Andersson et al. (2000) found no correlation between anxiety and depression scores and a Stroop test of attention towards words associated with tinnitus, which fails to support the hypothesis that emotional distress leads to increased attention. However, whether a Stroop task is an adequate measure of selective attention is (as discussed by the authors) questionable (see also Mohamad et al., 2016). Otherwise, this potential link between general emotional distress and selective attention has not been investigated.

## 2.3.3 Selective Attention and Monitoring

Some studies have investigated the effects of tinnitus on attention in a laboratory setting. Selective attention has been the focus of only a few, while others have investigated executive attention (which involves the ability to control one's attention and switch it between tasks), alerting attention (involuntarily responding to an external cue such as a tone) and sustained attention (focusing attention on a single task for a period of time). Two recent reviews (Mohamad et al., 2016, Tegg-Quinn et al., 2016) both concluded that the evidence for an effect of tinnitus on executive attention is stronger than for any other type. Since these reviews were published, further support for the theory that tinnitus affects executive attention has been provided by Trevis et al. (2016a) who conducted an attention-switching task in which people with tinnitus did significantly worse than controls. Few researchers have compared results between tests of different types of attention. Heeren et al. (2014) used a visual task to investigate the effect of tinnitus on three different types of attention in the same study: executive, selective, and alerting. They found that their tinnitus group scored significantly worse than controls without tinnitus on the executive attention task, but not on the selective or alerting tasks.

Most laboratory studies have investigated whether the presence of tinnitus impairs one's ability to pay attention to other things. When results are positive, the implication is that it is because the individual is selectively attending to tinnitus that they attend less to other stimuli. Trevis et al. (2016a) propose that inwardly-focussed thinking about tinnitus diminishes external attention. However, attention towards tinnitus has rarely been measured directly. Andersson et al. (2000) did attempt to measure attention towards tinnitus by adapting a Stroop test to include a mixture of tinnitus-related, emotionally loaded and neutral words printed in different colours. They did not find an effect in 23 tinnitus clinic patients when conditions were

compared. The lack of effect may, they feel, be due to the tinnitus- related words not being personally relevant enough to the participants, who all had different tinnitus experiences from each other. They did find that tinnitus patients colour-named more slowly overall than controls, which may indicate that tinnitus patients struggle more than others to maintain focussed attention due to depletion of cognitive resources. In a later study, Andersson et al. (2005c) presented a similar task to a much larger number of participants over the internet using tinnitus-related words, neutral words and strings of XXXX as stimuli. This time, results of ANOVA revealed a main effect of stimulus type within the tinnitus group; F(1,102)=0.38.9, p<0.001 and within the control group; F(1,220)=7.94, p=0.0013. Reaction time to XXXX was faster in the control group while reaction time to tinnitus words was actually faster in the tinnitus group. The authors postulate that these different results may be due to the slower nature of doing the task over the internet. They suggest that, while the mouse is being moved, information may have time to move to a later stage of processing so that a vigilance-avoidance response is used ("I don't like this word, so I'll make it go away"). In any case, it does seem that there is a difference in the way that people with and without tinnitus respond to tinnitus-related stimuli. However, research to date does not provide clear evidence that selective attention towards tinnitus is a key component of tinnitus distress, as suggested by the Cognitive Behavioural Model. Those studies which have measured selective attention at all have only measured it under experimental conditions. There is plenty of anecdotal evidence to suggest that people who are not distressed by tinnitus and often unaware of it will notice it immediately when asked to attend to it (Jastreboff and Hazell, 2004). A question more pertinent to the Cognitive Behavioural Model is: how much do people attend to their tinnitus in their everyday lives? There has been very little investigation of this. A few studies have investigated tinnitus awareness, usually expressed as a percentage of waking hours. Sheldrake et al (1999) asked 483 patients seeking tinnitus treatment how much of the time they were aware of their tinnitus and found average pre-treatment awareness to be around 67% of waking hours. McKinney et al (1999) found a similar

mean awareness of 65% amongst patients prior to treatment at a different clinic. Wallhausser-Franke et al. (2012) surveyed 4700 members of the German tinnitus association and found that the majority (79%) reported being aware of tinnitus 'all the time', although the phrasing of their question about awareness and its response options are not specified. These authors also found that permanent awareness of tinnitus increased the odds of severe tinnitus distress (odds ratio=10.61; 95% CI =2.43-46.28, p<0.001) suggesting that people who are troubled by tinnitus do notice it more of the time. An association between the percentage of time one is aware of tinnitus and the degree of tinnitus distress has also been reported amongst clinic patients by Hoekstra et al. (2014) and Degeest et al. (2016). However, selective attention and awareness are not necessarily the same thing. Selective attention suggests dominance of one stimulus over others (Harvey et al., 2004) while a person might be equally aware of several things at the same time. Indeed, mindfulness meditation, which has shown some success as a tinnitus treatment (McKenna et al., 2017a) involves developing an ability to hold many things in awareness simultaneously (Williams et al., 2007).

Inability to ignore tinnitus perhaps comes closer to the concept of selective attention than awareness does. Hiller and Goebel (2007) conducted a large scale survey and divided respondents into high and low annoyance groups. They found a particularly high correlation between 'high annoyance' group membership and reported inability to ignore tinnitus (r=0.87), which lends some support to the idea that people who are bothered by their tinnitus struggle to shift their attention from it.

A study by Cima et al. (2011) adapted the Pain Vigilance and Awareness Questionnaire (McCracken, 1997) for use with tinnitus patients. The resulting Tinnitus Vigilance and Awareness Questionnaire (TVAQ) includes items which fit the definition of selective attention (inability to ignore tinnitus, focusing on tinnitus above other things) as well as monitoring behaviour,

measured with items such as: "when I do something that increases my tinnitus, the first thing I do is check to see how much my tinnitus was increased." Using a sample of 61 tinnitus clinic patients, the authors found a negative correlation between scores on this questionnaire and a quality of life measure (r = -0.31, p<0.05), indicating that selective attention and monitoring may indeed be part of a more negative tinnitus experience. No other studies to date have investigated monitoring behaviour amongst tinnitus patients, although a number of case studies (e.g. McKenna et al., 2010) have given examples of the kind of monitoring behaviour engaged in by patients, which may include checking tinnitus loudness in different environments or after different activities.

# Effect of tinnitus interventions on selective attention and monitoring

Several studies have included 'attention shifting' exercises as part of a tinnitus rehabilitation programme (Henry and Wilson, 1996, Cima et al., 2012, Eysel-Gosepath et al., 2004). Although all of these report reductions in tinnitus distress post treatment, none report specifically on whether ability to shift attention from tinnitus improved, and so it is unclear whether reduced attention is a key part of reduced distress.

#### Predicted links within the model

Cima et al. (2011) created three new scales for a clinical trial; the TVAQ, the Tinnitus Catastrophising Scale (TCS) and the Fear of Tinnitus Questionnaire (FOTQ). They report a positive correlation between scores on the TVAQ and the TCS (r=0.62, p<0.01) and between scores on the TVAQ and the FOTQ (r=0.42, p<0.01), suggesting a possible link between negative automatic thoughts, fearful beliefs and selective attention and monitoring. They did not, however, investigate whether arousal and distress mediate between these two constructs, as proposed in the Cognitive Behavioural Model.

## 2.3.4 Beliefs

Clinical experience suggests that beliefs about the origin of tinnitus ("it must be a brain tumour") its potential effect ("it will make me deaf") and its psychological impact ("it's impossible to cope with a continuous noise") are common. Such beliefs are likely to have the effect of increasing worry about and attention towards tinnitus, but tinnitus beliefs have not been extensively researched. In a Korean guestionnaire study (Lee et al., 2004) dysfunctional beliefs were found to correlate with increased tinnitus distress; r=0.563, p=0.01, but it is unclear precisely how beliefs were defined and measured. Sirois et al. (2006) investigated more general health-related beliefs amongst tinnitus patients in an internet survey. Using validated questionnaires developed in other fields, they found that holding positive beliefs about being able to control one's own health correlated with a greater sense of well-being (r=0.43, p<0.001), especially when tinnitus was rated as more severe. As part of an investigation of predictors of tinnitus distress, Unterrainer et al. (2003) used a German health locus of control measure with 149 tinnitus clinic patients and found that a strongly internal health locus of control (defined as a belief that one's state of health is largely one's own responsibility; Wallston et al., 1978) was a significant predictor of lower tinnitus distress ( $\beta = -0.084$ , p=0.01). These two studies suggest that having a sense of control over tinnitus may have a protective effect against it becoming distressing. Conversely, in an analysis of responses to the THI, Handscomb (2006) found that patients who had low global THI scores tended to answer 'yes' to the item: "Do you feel that you have no control over your tinnitus?" In a later analysis of responses to the THI, Zeman et al. (2014a) found that the same item was not significantly related to scores on depression or quality of life measures. Taken together, these findings suggest that it is possible to believe that one's tinnitus cannot be controlled without feeling particularly distressed by this.

Cima et al. (2011) proposed a Fear Avoidance Model of tinnitus which is based on the Pain Fear Avoidance Model (Vlaeyen and Linton, 2000). They use the term 'fear' to encompass a collection of negative beliefs, such as a belief that tinnitus is caused by a brain tumour, causes deafness or is impossible to cope with. Their Fear of Tinnitus Questionnaire enquires specifically about some of the beliefs about origins and effects of tinnitus mentioned above. They found a negative correlation between scores on the FOTQ and the SF-36, which measures quality of life (r= -0.43. p=0.01), and a positive correlation between the FOTQ and the TVAQ, which measures attention to tinnitus (r= 0.31, p= 0.05). This suggests that those with fearful beliefs tend to pay more attention to their tinnitus and be more negatively affected by it.

## Effects of tinnitus intervention on beliefs

Erroneous beliefs are sometimes relatively easy to change with clear, accurate information, and the fact that some people note an improvement in their tinnitus after reading an information booklet (Nyenhuis et al., 2013) may well be due to the fact that fears have been allayed, although few studies have reported on the effect of intervention on beliefs specifically. An exception is a study conducted by Henry and Wilson (1996) which found that scores on the irrational beliefs subscale of the TQ reduced significantly in treatment groups compared to waiting-list controls (F (1, 57) = 25.00, p<0.01). Beliefs changed to a comparable degree in both treatment groups (interactive cognitive behavioural training and didactic education) suggesting that education may be sufficient to alter beliefs. However, tinnitus-related distress, measured by the TRQ, reduced significantly more in the cognitive training group than either the education or control groups (F 91,57) = 16.19, p<0.01). This indicates that having more accurate beliefs about tinnitus does not necessarily lessen distress. These findings indicate that beliefs may play a part in distress but are not pivotal, just as the Cognitive Behavioural Model suggests.

## Predicted links within the model

Cima et al. (2011) predicted in their Fear Avoidance Model that tinnitus-related fear is a product of catastrophic thinking and leads directly to increased awareness, which in turn negatively affects quality of life. Some support for this is provided by the outcome of their regression analysis; they found that tinnitus-related fear fully mediates between catastrophic thinking and impaired quality of life. This is slightly at odds with the Cognitive Behavioural Model of Tinnitus Distress, which sees negative beliefs as a potential but not universal intensifier of negative thoughts.

Lee et al. (2004) report a positive correlation between their belief questions and the Anxious Thought and Tendencies scale (Uhlenhuth et al., 1999); r=0.441, p=0.01. This association provides some support for the notion that dysfunctional beliefs about tinnitus go hand in hand with a generally negative thinking style, although they do not provide details of the items they used to measure beliefs or how these were derived.

## 2.3.5 Safety Behaviour

Safety behaviour appears to be common amongst tinnitus patients (McKenna and Andersson, 2008), although it has been less thoroughly researched than in other conditions. Only avoidance behaviour (one type of safety behaviour) has been empirically investigated. An interview study (Andersson et al., 1999) found that 62% of 216 tinnitus clinic patients reported 'avoidance of situations' due to tinnitus. Examples were not given in this study, but McKenna and Irwin (2008) observe a common practice is avoidance of silence due to fear of being unable to cope if fully exposed to tinnitus for even a short while.

There is some indication that use of avoidance behaviour is linked to more distressing tinnitus. Hesser and Andersson (2009) asked 283 respondents to a survey to rate the statement: "I cannot expose myself to situations that may result in tinnitus or a deterioration of tinnitus" on a five point scale (0=entirely false, 4=entirely correct). They found strong endorsement of the statement to be a significant predictor of tinnitus distress ( $\beta$ =0.28, p<0.001). The small number of other studies which have investigated avoidance behaviour have not fully separated it from other constructs. Budd and Pugh (1996) constructed a questionnaire to investigate coping styles amongst tinnitus patients, which included items about avoiding situations but also behaviours like complaining to others and wishing tinnitus away. They found that maladaptive coping correlated with severity of tinnitus (r=0.68, p=0.001) but they did not examine avoidance as a distinct component of maladaptive coping. A Tinnitus Fear Avoidance Scale (TFAS) was developed by Kleinstauber et al. (2013) which measures fears about tinnitus and avoidance behaviour related to these. Using the THI, they divided their patients into five categories according to severity of tinnitus handicap and found a significant effect of category on TFAS scores; F(4, 368) = 65.63, p<0.01, suggesting that people who are more troubled by tinnitus are more likely to use avoidance behaviour and have fearful beliefs. However, the relative importance of beliefs and behaviour cannot be ascertained.

## Effect of tinnitus interventions on safety behaviour

People with tinnitus are often encouraged to abandon their safety behaviours by carrying out 'behavioural experiments' such as increasing or decreasing environmental noise levels and noticing the effect on tinnitus and how they feel (McKenna et al., 2010). Although behaviour change is described as an important component of successful CBT programmes (Cima et al., 2012) changes in behaviour have not yet been measured separately from thoughts and emotions in tinnitus intervention studies. As it is possible to support patients in conducting behavioural experiments outside the context of a full

CBT programme (Thompson et al., 2017), ascertaining the effectiveness of this kind of intervention seems particularly important.

## Predicted links within the model

A link between safety behaviour, negative thoughts and beliefs has been proposed by Cima et al. (2011) as well as McKenna et al. (2014) but there is no empirical evidence to fully support these ideas. However, both Kleinstauber et al. (2013) and Hesser and Andersson (2009) have measured anxiety sensitivity. Although this concept per se is not included in the Cognitive Behavioural Model, it does contain within it an element of negative thinking (e.g. "my heart is thumping so hard I'm going to collapse"). These researchers demonstrated that avoidance behaviour partially mediates between anxiety sensitivity and tinnitus distress (Hesser and Anderson, 2009) or tinnitus catastrophising (Kleinstauber et al., 2013) which suggests that avoidance behaviour may play a part in intensifying negative thought.

Hesser et al. (2009a) investigated a potential link between attention and safety behaviour. They divided tinnitus patients into two groups, both of whom completed a series of demanding cognitive function tests and after each one rated how much they felt their tinnitus had interfered with it. Both groups had to listen to a background sound while doing the tests, but one group had the type and volume of sound chosen for them while the other group was asked to choose a sound and given control of its volume throughout the test. For both groups, tinnitus interference increased as the tests progressed, but the rate of increase was significantly greater for the group which had control of the background sound. One interpretation of these findings is that attempts to prevent tinnitus interference by altering the level of background sound (safety behaviour) has the paradoxical effect of increasing attention towards tinnitus. The Cognitive Behavioural Model

postulates that this happens via increased negative thinking. This was not investigated by Hesser and colleagues, but they do propose that having control of background sound increases inward focus.

## 2.3.6 Distorted Perception

## **Interpretation of Distorted perception**

As discussed in section 2.1.6, distorted perception is quite straightforward to measure in insomnia, as reliable objective measures of sleep exist. The situation with tinnitus is far less clear cut. Several features of tinnitus perception could be subject to distortion; sound type (ringing, buzzing, whistling etc), pitch, or loudness. Although descriptions of tinnitus have been collected (Stouffer and Tyler, 1990, Moring et al., 2016) and tinnitus pitch has been measured in several studies (see Andersson et al., 2005b for a summary), the possibility that perception may be distorted has only been raised in the context of loudness. The idea that some people perceive tinnitus as louder than it actually is was first put forward in an early commentary entitled "the illusion of loudness of tinnitus" by Fowler (1942), who noted that tinnitus was often "not actually as loud as the patient stated" (p.278.) However, demonstrating this empirically is fraught with difficulty as, while there are objective measures of sleep duration, there is no objective measure of tinnitus loudness.

# **Measuring tinnitus loudness**

Loudness matching has been used for some 70 years as a kind of proxy for 'actual loudness', but it is far from perfect. Matching is usually done by asking patients to indicate when a pure tone played through headphones is as loud as their tinnitus. Some studies have used a tone of 1 kHz in pitch for all participants, some a tone that corresponds to the participant's best region of hearing, and others have first asked patients to pitch match their tinnitus and

then used the selected pitch for loudness matching. Of course, many people with tinnitus also have hearing loss, which inevitably affects loudness judgments and there is no reliable way of compensating for this (Andersson et al., 2005b). Also, most people's tinnitus sounds nothing like a pure tone (Ward and Baumann, 2009), making comparison difficult. Loudness matching is far from objective and personal judgements of how loud different tones are is bound to vary, particularly in people with hearing loss, who may experience recruitment. Some attempts have been made to compensate for this; for example Tyler and Conrad- Armes (1983) suggested measuring loudness in sones; a kind of personal loudness unit. However, this measurement scale has not been widely adopted.

Another difficulty with loudness matching is that estimates tend to vary within subjects. Hoare et al. (2014) asked volunteers (who were acting as notreatment controls in another study) to match their tinnitus loudness over a series of five visits. Participants were using an external sound they had selected as being like their tinnitus and had control of the volume themselves. Loudness estimates varied between visits, but tended to become more consistent over time, which led the authors to suggest that first attempts at loudness matching should be disregarded as 'practice runs.' Notably, most studies which have used loudness matching have performed the procedure only once (Attias et al., 1995, Newman et al., 1994, Savastano, 2004).

Even asking a person to rate how loud their tinnitus sounds to them is harder than asking how long they think they have been asleep. Different studies have used numerical scales, which ask people to select a number from 0-100 (Weise et al., 2013) or 0-10 (Wallhausser-Franke et al., 2012), and adjectival scales from which descriptors such as 'quiet' and 'extremely loud' are selected (Jakes et al., 1986). Others have used Klockhoff and Lindblom's (1967) grading system that classifies tinnitus according to whether it can only be heard in silence (grade 1), can be heard in 'ordinary acoustic environments' but is

masked by loud noise (grade 2) or is audible in all acoustic environments (grade 3) (Andersson et al., 1999, Hiller and Goebel, 2007). All of these instruments are measuring slightly different concepts, as they variously invite the patient to consider how loud their tinnitus is in quiet or in different surroundings, compared to some other sound or to how loud they think tinnitus is for others or to how loud they imagine it could possibly be.

Additionally, loudness ratings have been shown to vary considerably between visits (Hoare et al., 2014) and may be influenced by the current surroundings.

# Is loudness perception distorted?

If people's perception of tinnitus loudness is distorted, we might expect to find a mismatch between matched loudness and self-reported loudness. Since Fowler (1942) observed that many patients who say their tinnitus is loud match it to a tone of 5 or 10 decibels, it has often been noted that tinnitus is usually matched to very quiet tones (Savastano, 2004, Tyler and Stouffer, 1989, Degeest et al., 2016). There are two notable exceptions which suggest tinnitus may not be as 'soft' as sometimes suggested. Andersson (2003) found mean loudness measured at the frequency closest to tinnitus to be 40.3 dB HL (SD=22.1) and Cope et al. (2011), who allowed patients themselves to adjust the loudness of a tone played at their best hearing frequency, found the mean loudness of tinnitus to be 54.6 dB HL (SD=21.0). Both studies involved only small numbers of participants (18 in each) but do raise questions about the reliability of earlier findings. Unfortunately, none of the authors asked participants how loud they considered their tinnitus to be using a self-report measure. In fact, only a few studies have directly compared self-rated loudness to matched loudness. Jakes et al. (1986) tested various loudness measurement techniques and found only weak correlations between matched and self-reported loudness. In a study involving a series of more than a thousand patients, Savastano (2004) reported that 71% of those who had rated their tinnitus as being of 'medium intensity' matched it to tones quieter

than 10 dB. More recently, De Ridder et al. (2015) also found no correlation between loudness ratings on a numerical scale (0=no tinnitus, 10=as loud as imaginable) and loudness matching to tinnitus pitch amongst a sample of 136 tinnitus patients (r=0.04, p>0.05). These findings lend some support to the notion that people may have a distorted perception of how loud their tinnitus is, but considering the difficulties with measurement discussed above, no firm conclusions can be drawn.

## The relationship between loudness and distress

The Cognitive Behavioural Model proposes that distorted perception contributes to tinnitus distress. Although there is no reliable way of demonstrating distortion, contained within this prediction is the supposition that people who are distressed by tinnitus are likely to perceive it as loud. There has been some investigation of this idea, and findings are mixed.

Several studies have reported weak or no correlation between matched loudness and tinnitus distress (Andersson, 2003, Baskill and Coles, 1999, Ooms et al., 2012), although for reasons discussed above, loudness measures may not be reliable. It is notable that Cope et al. (2011), who reported greater average matched loudness than previous studies, also found no correlation between tinnitus-related distress (measured by the THI) and tinnitus loudness measured in dB HL at the best hearing frequency (r=-0.07, p>0.05). Attias et al. (1995) found that loudness levels matched to tinnitus pitch were actually significantly lower in tinnitus help-seekers than non-help-seekers (z=3.9; p=0.001). These findings indicate that people who perceive their tinnitus as distressing do not necessarily perceive it as loud. However, some degree of correlation has been found between self-reported loudness and tinnitus distress. For example, Wallhausser-Franke et al. (2012) asked more than 4000 members of the German tinnitus association to rate their tinnitus loudness on a scale of 0-10 (0=only audible in silence, 10=louder than all external sounds) and their tinnitus distress on the brief version of the German TQ, and found a

positive correlation between the two (r=0.52, p<0.05). In an earlier study of nearly 5000 members of the same association, Hiller and Goebel (2007) found that Klockhoff and Lindblom gradings and annoyance ratings (using the German TQ) were congruent (r=0.48, P<0.05). Weise et al (2013) found a strong, positive correlation between loudness rated on a numerical scale and tinnitus-related distress measured by the German TQ (r=0.60, p<0.01). Unterrainer et al. (2003) found loudness rated on a ten-point scale to be a significant predictor of high tinnitus distress measured using the THI ( $\beta$ =0.146, p<0.001). Just as people who are troubled by insomnia usually rate their sleep duration as short, people who are distressed by tinnitus usually rate it as loud.

Recently, a few studies have investigated the contribution of both self-rated and matched loudness to tinnitus distress. Collecting data from 81 tinnitus clinic patients, Degeest et al. (2016) asked patients to pitch match their tinnitus and then used that pitch for loudness matching. They also asked them to rate the loudness of their tinnitus on a 0-100 scale. They found a significant positive correlation between self-rated loudness and THI scores ( $\rho$ = 0.270,  $\rho$ =0.01) but no correlation between matched loudness and THI scores ( $\rho$ = 0.178,  $\rho$ = 0.113). Very similar findings are reported by Hoekstra et al. (2014) using both the THI and TQ as tinnitus distress measures.

However, there are people for whom self-rated loudness and distress are discrepant. Hiller and Goebel (2007) reported that 12% (n=587) of their participants rated tinnitus as Grade 3 on the Klockhoff and Lindblom system (audible in all acoustic environments) and yet had low scores on the German TQ. They also highlight a small group of participants (0.6%; n=28) who scored high on the TQ and yet rated their tinnitus as grade 1 (audible only in quiet). Similar findings are reported by Wallhausser-Franke et al. (2012), who report that 4.4% (n=209) of their participants rated their tinnitus as very loud (>8 on a 10-point scale) but had low scores on the TQ. For 0.3% (n=13), loudness was

<2 but TQ scores were high. It seems then that perceived loudness does not always contribute to a person's overall tinnitus distress.

#### **Effects of intervention on tinnitus loudness**

Many intervention studies illustrate that distress changes post therapy while self-rated loudness stays the same. If perceived loudness were a function of distorted perception in distressed individuals, we would expect to see it reduce along with the distress. In their review of CBT for tinnitus, Martinez-Devesa et al. (2010) conclude that subjective loudness (measured using a variety of rating scales) does not alter, while quality of life improves.

However, in a recent investigation of mindfulness-based CBT for tinnitus, McKenna et al. (2017a) found that there was a statistically significant reduction in mean loudness ratings on a 100-point VAS from 70.6 (SD=20.3) before treatment to 56.6 (SD=25.2) after. The question of whether and to what extent perceived loudness is influenced by attention therefore remains unresolved.

#### Predicted links within the model

The Cognitive Behavioural Model predicts more specifically that distorted perception leads to an increase in negative automatic thoughts. Some support for a connection between loudness and negative thinking is provided by Weise et al. (2013) who found a positive correlation between catastrophising and self-rated tinnitus loudness (r=0.41, P<0.01). Another study involving 362 tinnitus patients by Hesser et al. (2015) found that poor acceptance (which involves engaging with negative thoughts) partially mediated between self-rated loudness (measured on a 0-100 scale) and tinnitus distress (measured by the THI). This provides some support for the idea of a two-way relationship between negative thoughts and loudness perception, although directionality cannot be established with any certainty.

## 2.4 Conclusion

Although tinnitus is not a problem for everybody who has it, it can be very distressing, and understanding the nature of this distress is crucial to developing treatment. There is a fairly large body of evidence supporting the Cognitive Behavioural Model's prediction that general emotional distress is prevalent amongst people with tinnitus and contributes to a more distressing experience. There is also some empirical support for the idea that autonomic arousal and negative thinking are associated with tinnitus distress, while a very limited amount of evidence currently supports the notion that safety behaviour and negative beliefs are important contributors. Although there has been some investigation of selective attention, little is currently understood about how much this plays a part in the everyday lives of people with tinnitus and, although there have been various attempts to measure tinnitus loudness, the concept of distorted perception remains largely unexplored. Importantly, while some research supports the prediction of a link between thinking and distress and between avoidance behaviour and negative thoughts, the predicted interaction between the different components of the model has not, for the most part, been tested.

# Chapter 3. **Methods of Data Collection** and Analysis

# 3.1 Deciding on appropriate methodology

Several previous studies which have investigated the question of how tinnitus becomes a distressing problem have used multiple regression analysis to assess the degree to which a number of independent variables (such as depression, anxiety, and insomnia) explain the variance in a dependent variable, such as tinnitus distress or quality of life (Zeman et al., 2014a, Oishi et al., 2011, Langenbach et al., 2005). However, multiple regression analysis on its own is not sufficient for testing the Cognitive Behavioural Model of Tinnitus Distress. This model does not simply postulate that thoughts, behaviour, attention, and other factors all contribute to the experience of tinnitus distress. Rather, it predicts that all these components interact in a particular way, with tinnitus distress being the outcome. Specifically, it predicts that certain constructs mediate between others; for example, arousal and distress mediates between negative thoughts and attention. An appropriate methodology for testing a complex model such as this is structural equation modelling (Streiner, 2006).

Structural equation modelling (SEM) can perhaps best be seen as a family of statistical techniques which includes confirmatory factor analysis (CFA), path analysis and full structural equation modelling (Streiner, 2006). These techniques are confirmatory rather than exploratory in nature; that is, they are designed for testing existing hypotheses which are derived from empirical evidence and theory (Byrne, 2012). In all types of SEM, models are composed of a series of regression equations which represent the relationships between variables. SEM uses these equations to assess how well a hypothesised model

fits the data obtained from a population sample. It can be used to test measurement models, which typically assess the proposed factor structure of a questionnaire, and structural models, which make predictions about how a series of variables interrelate. One advantage of SEM is that measurement error is always taken into account in calculations. This is especially important when subjective measures such as self-report questionnaires need to be used.

A path model is a particular type of structural model consisting of a series of measured variables which are predicted to interrelate in certain ways (Streiner, 2005). A measured variable might be age, height, a physiological measure such as heart rate, a score on a questionnaire, or a score on an individual factor of a multifactorial questionnaire. Path models must include at least one exogenous variable, which predicts the value of other variables in the model but is not predicted by any of them, and an outcome variable, which is predicted by the value of other variables in the model but does not predict any of them (Streiner, 2005). Before constructing a path model using subjective measures, it is important to establish the factor structure of each measure that best fits the population to be tested. This is done through constructing a series of measurement models (one for each questionnaire to be used) and finding the best fit for each using factor analysis. Once a factor structure has been established for each measure, the estimated factor scores can be used in full path analysis. A detailed description of the process of factor analysis is given in chapter 5, and of path analysis in chapter 6.

Structural equation modelling has previously been used to test cognitive models of other problems such as smoking (Kouimtsidis et al., 2016), eating disorders (Dakanalis et al., 2015), and chronic pain (Vranceanu et al., 2010). It was selected as the most appropriate methodology for testing a Cognitive Behavioural Model of Tinnitus Distress in this cross-sectional, observational study. We aimed to identify and test at least one measure of each variable contained within the model and then build one or more structural models composed of these measured variables which we could test using path analysis.

# 3.2 Ethical Approval

This study was approved by the University of Nottingham Research Ethics Committee (Faculty of Medicine and Health Science) in February 2014.

Reference: G13022014 School of Medicine NIHR Nottingham Hearing

Biomedical Research Unit.

# 3.3 Participants

## 3.3.1 Inclusion criteria

The study sought to recruit a broad cross-section of people who have tinnitus. The primary inclusion criteria were having had tinnitus for more than 2 months (to exclude short-term tinnitus related to noise exposure, blocked ears and so on) and being over 18 years old. Exclusion criteria were being unable to understand written English and being unable to read text in print or on screen.

#### 3.3.2 Recruitment

In order to reach members of the public with tinnitus, around 500 volunteers on a research participant database held by the National Institute for Hearing Research (NIHR) Nottingham Hearing Biomedical Research Unit (BRU) were sent an invitation email with a participant information sheet attached. Emails were sent out to around 50 volunteers at a time, with one batch being sent every two to three weeks. The British Tinnitus Association advertised the study in its members' magazine ('Quiet'), on its website (which is accessible to members and non-members), and on social media (Facebook and Twitter). Reminders about the study were posted on the BTA Facebook page periodically. In addition, the study was advertised on a forum run by an organisation for people with hearing loss (Hearing Link) and some of my personal contacts (colleagues and relatives) were also approached.

#### 3.3.3 Stratification

In order to test a model that can account for the range of tinnitus experience, it is important to recruit participants who are affected by it to varying degrees. Otherwise we may only be able to demonstrate that the model is applicable (or not) to a subset of the population; for example, people who are very severely affected by tinnitus. Those who are more bothered by tinnitus may be more likely to volunteer to answer questions about it, so we were concerned that our sample might not be representative of the wider tinnitus population. To address this, we decided to set a target number to recruit into each of five problem categories. These categories were derived from a tinnitus problem scale developed by Meikle et al. (2012). Participants are asked to answer the question: "How much of a problem is your tinnitus?" by choosing one of five responses: not a problem, a small problem, a moderate problem, a big problem, or a very big problem. To decide on target numbers for each category, we referred to research by Zeman et al. (2012). They analysed questionnaire data from the TRI database, which holds standardised information about more than 4000 people with tinnitus from several different countries. Zeman et al. (2012) reported that a subset of 1318 people with tinnitus listed on the database proportionally fell into the categories shown on Table 3.1. They used scores on the THI to categorise people, but to reduce burden on participants we wanted to use a single question. Although the Tinnitus Problem Scale has never been directly compared to the THI, in a later study using the TRI database Zeman et al. (2014b) found that problem category explained 16% of the variance in psychological health measured by the WHO-Quality of Life Questionnaire (Skevington et al., 2004) and when Meikle et al. (2012) compared problem ratings to scores on the Tinnitus Functional Index – a measure of tinnitus distress- they found differences in mean scores on the TFI to be large and statistically significant between each of the problem categories. These authors all conclude that the problem scale is an adequate brief measure of the extent to which people are bothered by their tinnitus.

Table 3.1: percentage of sample in tinnitus categories in Zeman et al.'s study (2014b) and target percentage in our current study.

TRI Category (based on THI score)	Percentage of sample in this category	Equivalent Statement on Tinnitus Problem Scale	Percentage of whole sample to recruit in this problem category in current study
No handicap	10%	Not a problem	10%
Mild handicap	26%	Small problem	25%
Moderate handicap	28%	Moderate problem	30%
Severe Handicap	24%	Big problem	25%
Catastrophic handicap	12%	Very big problem	10%

## 3.4 Measures

## 3.4.1 The process of choosing appropriate measures

In order to test a model using SEM, at least one measure needs to be identified which is suitable for testing each variable (Byrne, 2012). Although a number of methods exist for measuring certain variables in the model (physiological arousal, for example, is sometimes measured using cortisol samples) in tinnitus research, thoughts, feelings and reactions to tinnitus are most commonly measured by self- report questionnaires (Hall et al., 2015). The use of questionnaires also facilitates the recruitment of a large number of people from a wide geographical area and eliminates the need for participants to travel, so we decided to test the model using questionnaires exclusively. A large number of questionnaires related to tinnitus exist (Hall et al., 2016) and it was important to select from these those that were most suitable for measuring the variables within the model. Once I had compiled a shortlist of possible questionnaires, a meeting was held which included tinnitus

researchers, a tinnitus clinician and a statistician, to make the final choices. Considerations which guided these choices were:

- 1. The measure's relevance to a particular component of the model
- 2. The extent to which the measure avoided overlap with others
- 3. The validity and reliability of the measure, and whether there was an established factor structure.
- 4. The length of the questionnaire and time needed to complete it.

These considerations made several general measures of tinnitus distress-such as the THI (Newman et al., 1996) unsuitable, as they measure several dimensions of tinnitus complaint and many do not have a clear factor structure that enables these different dimensions to be separated out into distinct subscales (Fackrell et al., 2014). Although ideally questionnaires used in a structural model should have been independently analysed, some questionnaires which had been tested only by their creators were included on the final list because they were the only instrument available to measure a certain construct. The questionnaires chosen are summarised in table 3.2.

## 3.4.2 Negative Automatic Thoughts

The Tinnitus Cognitions Questionnaire (TCQ, Wilson and Henry, 1998) was chosen to assess the content and frequency of thoughts participants have in relation to their tinnitus. This questionnaire is unique in that it enquires about many different types of thought, both positive and negative. Respondents are asked to indicate how often they have been aware of thinking a particular thought using a five-point Likert scale with the anchors: 'never' and 'very frequently.' The TCQ consists of two separate subscales comprising 13 items each dealing with positive and negative thoughts relating to tinnitus. All positive and all negative items are grouped together as an earlier prototype of the questionnaire, in which positive and negative items were mixed up, caused confusion amongst respondents (Wilson and Henry, 1998).

Initial testing of the TCQ used 200 Australian participants who were a mixture of tinnitus clinic patients and members of the public with tinnitus (the proportion of participants drawn from each group is unclear). The authors found very high internal consistency ( $\alpha$  = 0.91) and adequate test-retest reliability ( $\rho$ =0.80). Item-total correlations were between 0.43 and 0.66. Moderate correlations were shown with other tinnitus measures, such as the TRQ ( $\rho$ =0.55) and weaker correlations with mental health scales, such as the BDI ( $\rho$ =0.33). This suggests that the questionnaire is measuring a construct separate from overall tinnitus distress and from overall emotional disturbance, making it an appropriate tool for assessing the Negative Automatic Thoughts component of the model specifically.

#### 3.4.3 Arousal and Emotional Distress

The Cognitive Behavioural Model of Tinnitus Distress proposes that autonomic arousal and emotional distress form part of a negative tinnitus experience, but it does not make any predictions about what type of arousal or emotional distress might be felt, nor does it separate these two constructs out. It would therefore be inappropriate to use a questionnaire designed to measure symptoms of a particular form of distress such as the BDI (Beck et al., 1961) or the HADS (Zigmond and Snaith, 1983). Instead the questionnaire chosen to measure emotional distress was Clinical Outcomes in Routine Evaluation (CORE-OM, Evans et al., 2002). The creators of the CORE-OM specify on their website (www.coreims.co.uk) that this questionnaire was explicitly designed not to be linked to any single diagnosis (such as anxiety or depression) nor to any one school of psychological therapy. Rather, it is intended as a measure of global distress and it includes items that pertain both to mental processes (e.g. "unwanted images or memories have been distressing me") and to feelings of autonomic arousal (e.g. "I have felt tense, anxious or nervous"). A further advantage is that it includes a mix of high and low intensity items (e.g.:

"I have felt panic or terror" and "I have felt OK about myself") which enables it to measure all degrees of emotional distress, not just those which meet criteria for a clinical diagnosis of mental illness. This is important, as the Cognitive Behavioural Model suggests that any amount of emotional distress may be linked to increased attention towards tinnitus; it does not have to reach a certain diagnostic threshold.

The CORE-OM contains 34 items and is divided into four domains: well-being, symptoms, functioning, and risk. Respondents are invited to indicate how much each item has applied to them over the past week, using a 5-point Likert scale with the anchor points 'not at all' and 'most or all of the time.' Initial testing of the CORE-OM was carried out on both clinical samples (users of mental health services) and non-clinical samples (students and members of the public). Data from the non-clinical sample is reported in table 3.2 as this group, being made up of members of the public, is closest to the sample I am studying. Its authors report very high internal consistency for the full questionnaire ( $\alpha$ =0.94) and for each subscale (well-being;  $\alpha$ = 0.77, symptoms;  $\alpha$ =0.90, functioning;  $\alpha$ =0.86 and risk  $\alpha$ =0.79). They also report good testretest reliability ( $\rho$ =0.90) and high convergent validity with the BDI ( $\rho$ =0.85). The CORE-OM has been used across a wide range of healthcare settings internationally, although it has not been widely used in tinnitus research. A number of alternative factor structures have been proposed and tested which are discussed in detail in chapter 5. The alternative factor structures need to be tested in order to determine which measured variables to insert into the full Cognitive Behavioural Model for the dimension 'arousal and distress'.

## 3.4.4 Selective Attention and Monitoring

The Tinnitus Vigilance and Awareness Questionnaire (Cima et al., 2011) is the first instrument designed to measure the extent to which people attend to their tinnitus in everyday life. Its 18 items cover both selective attention and monitoring behaviour. Respondents are asked how often each statement applies to them using a 6-point Likert scale with the anchor points 'never' and 'always.' Its original authors presented it as a unifactorial measure, although factor analysis was not done.

The TVAQ is derived from the Pain Vigilance and Awareness Questionnaire (PVAQ, McCracken, 1997). The PVAQ has been translated into and validated in Dutch (Roelofs et al., 2003) and this Dutch version was used for development of the TVAQ. Ten items are common to both measures (with the word 'tinnitus' substituted directly for the word 'pain' in the TVAQ) while the remaining eight items on the TVAQ cover similar themes to the remaining six on the PVAQ, but are differently worded. It is not clear how these items were chosen or why two were added to the total. The Dutch TVAQ was first used in a study of 61 tinnitus clinic patients (Cima et al., 2011). It was found to have very good internal consistency  $\alpha$ =0.81) and only moderate convergent validity with the Tinnitus Questionnaire ( $\rho$ =0.57), which indicates that it is, as intended, measuring a construct related to but distinct from tinnitus distress. Further investigation of the TVAQ's properties has not been carried out and notably, the TVAQ has yet to be validated in English. The current project afforded an opportunity to test its structural validity.

## 3.4.5 Safety Behaviour

There is no existing measure of tinnitus-related safety behaviour. However, the Tinnitus Fear Avoidance Scale was developed and used in a study by Kleinstauber et al. (2013). It contains 15 items with which respondents are

asked to indicate their agreement on a six-point Likert scale with the anchor points: 'strongly disagree' and 'strongly agree.' Principal component analysis identified three factors: cognitions, tinnitus-related avoidance and ear-related avoidance. An example of an item pertaining to tinnitus-related avoidance is: "Due to my tinnitus I avoid quiet or silent environments". An ear-related avoidance item is: "Due to my tinnitus I try to avoid getting water into my ears when I have a shower, a bath or when I go swimming". Avoidance items were chosen by asking clinicians to give examples of the kind of behaviour their clients tend to avoid due to fear of tinnitus deterioration. It is not clear how the final item selection was reached, but these two factors have good face validity, and medium to large item-subscale correlations were found in the analysis (Kleinstauber et al., 2013). There is considerable overlap between the four items on the cognitions subscale of the TFAS and both the TCQ and the Fear of Tinnitus Questionnaire (discussed in section 3.4.6). For example, both the cognitions subscale of the TFAS and the TCQ deal with worries about the effects of tinnitus on one's mental health. It is therefore unlikely that the inclusion of the cognitions subscale would add to the data obtained in this study, and it was decided to use the two avoidance subscales only, as a more specific measure of safety behaviour. The properties of the TFAS were investigated using data from 373 German volunteers who were registered for a study investigating different forms of CBT for tinnitus. Although not specified, it is assumed that the questionnaire was validated in German. The current study provided an opportunity to assess the validity of the questionnaire in the English translation provided by its authors.

## 3.4.6 Beliefs

The measurement of beliefs in people with tinnitus poses some difficulty. No questionnaire has yet been developed to do this and it is not well established what kind of beliefs are commonly held by people who have tinnitus. It has been suggested that reactions to tinnitus may be influenced by beliefs about

tinnitus itself and by a wide range of personal beliefs about health and about oneself (McKenna, personal communication). This would be difficult to capture in a single measure. There is some indication in the literature that control beliefs play an important part in determining the level of tinnitus distress, with a belief that tinnitus is beyond one's control being linked to greater distress (Attias et al., 1995, Budd and Pugh, 1996, Sirois et al., 2006). Part of the Illness Perception Questionnaire (IPQ) is suitable for measuring such beliefs. This questionnaire was created by Weinman et al. (1996) and then substantially revised by Moss-Morris et al. (2002). It is a 38-item questionnaire with seven subscales designed to measure illness representations across a range of health conditions. Responses are given on a five-point Likert scale with the anchor points 'strongly disagree' and 'strongly agree' and higher scores indicate a more positive outlook. It was recently used in tinnitus research by Vollmann et al. (2014) in an investigation of illness representations amongst tinnitus patients. Two of the subscales included in the IPQ deal with control beliefs ('personal control' and 'treatment control'). These subscales were chosen to measure control beliefs amongst participants in the study described here. Both subscales have shown good internal consistency (personal control;  $\alpha$ =0.81, treatment control;  $\alpha$ =0.80). Lack of correlation ( $\rho$ =-0.07) with the negative affect subscale of the Positive and Negative Affect Schedule (Watson et al., 1988) suggests that control beliefs are not merely a reflection of mood.

It has been proposed that beliefs about the meaning of tinnitus also contribute to distress (Jastreboff and Hazell, 2004). My own clinical experience indicates that some patients believe that tinnitus relates to a serious health condition, causes deafness or indicates an impending emotional breakdown. While there is no tinnitus-related beliefs questionnaire, several items on the Fear of Tinnitus Questionnaire (Cima et al., 2011) assess whether misguided ideas about the causes and consequences of tinnitus are present. This questionnaire contains 17 items which

respondents are asked to rate true or false. It is based on two pain measures; the Tampa Scale for Kinesiophobia (Roelofs et al., 2007) and the Pain Anxiety Symptoms Scale (McCracken et al., 1992). Because the FOTQ was not designed expressly as a tinnitus beliefs questionnaire, it required some modification for use in this study. Therefore, a panel of seven people with clinical and research expertise in tinnitus were asked to select the items on the FOTQ which they felt best expressed commonly held erroneous beliefs about tinnitus. For inclusion in the survey, items had to be selected by at least five people. The panel reached agreement on eight out of the 17 items, which were then used to form a modified version of the questionnaire (FOTQ-M). The response scale was also changed from true/ false to a five-point Likert scale with the anchor points 'strongly disagree' and 'strongly agree' to allow for more sensitivity and more consistency with other measures in the survey. The study afforded an opportunity to test the structural validity of this new form of the FOTQ.

# 3.4.7 Distorted Perception

If it were possible to obtain an accurate measure of tinnitus loudness, one could compare this with the individual's subjective loudness rating. A mismatch would indicate that distorted perception is occurring. However, the 'actual loudness' of tinnitus cannot be measured, as it is perceived only by the individual experiencing it (see section 2.3.6 for a discussion of loudness measurement). The hypothesis that tinnitus perception is distorted in distressed individuals cannot therefore be tested in the same way as the other hypotheses contained within the model. However, the notion of distorted perception contains within it the prediction that people who are distressed by tinnitus will perceive it as loud, prominent or intrusive, and this can be tested.

Many studies have used a simple Visual Analogue or numerical rating scale to obtain loudness ratings from patients (for example, Hoekstra et al., 2014,

Weidt et al., 2016, Unterrainer et al., 2003). However, Schmidt et al. (2014) argue that this is inadequate, as single item scales are less reliable than multiitem scales and that measuring 'loudness' alone is over simplistic. They advocate measuring tinnitus magnitude instead and developed a Tinnitus Magnitude Index (TMI), which contains three items to be rated on a numerical scale of 0-10. The authors define magnitude as "a scaled, multivariate construct of tinnitus perception" (p.12) which is a combination of loudness, perceived severity, and amount of time aware of tinnitus. In much the same way as a person working on a busy street might rate the traffic noise as loud when she listens to it but be generally unaware of it, a person who rates tinnitus as loud might also be generally unaware of it. This person would score lower on the TMI than another who rates tinnitus as loud and awareness as constant. Similarly, a person might rate tinnitus as 'quiet' but 'severe', perhaps because the noise is continuous or has a timbre that is unpleasant. This person would score higher on the TMI than another with tinnitus which is rated as quiet and not severe. The authors of the TMI stress that they regard severity as a separate construct from distress, although the two terms are sometimes used interchangeably in the literature. It is plausible that, in the same way as one might have a 'bad' cold which is not upsetting, one might have 'severe' tinnitus which does not cause distress.

The TMI was tested on 347 tinnitus clinic patients in the USA, most of whom were male veterans, and high internal consistency was found ( $\alpha$ =0.86). The TMI has not so far been used by members of the public with tinnitus. Moderate correlation between the TMI and measures of global tinnitus-related difficulties such as the THI (r=0.62) supports the notion that, although there is an association between magnitude and handicap, the TMI is not measuring the same construct as other scales.

## 3.4.8 Tinnitus- related Distress

As the entire model seeks to explain tinnitus-related distress, it is particularly important that this should be measured robustly and thus two measures were chosen. There is no agreed standard for measuring tinnitus-related distress (Londero and Hall, 2017) and to use only one might be to omit important aspects of this construct. The TFI (Meikle et al., 2012a) was developed within a veterans' hospital in the USA and tested on some 300 participants who were mostly war veterans seeking help with tinnitus. It consists of 25 items divided up into eight subscales and asks the respondent to select a number between 0 and 10 or 0 and 100 for each item. It includes an emotional distress subscale which was found to have very high internal consistency ( $\alpha$ =0.94) with all three items loading only onto this factor, indicating that only emotional distress is measured by them. This subscale is referred to as the TFI-E.

The 26-item Tinnitus Reaction Questionnaire (Wilson et al., 1991) was designed explicitly to measure psychological distress related to tinnitus. It consists of 26 items to be answered on a five-point Likert scale with the anchor points 'not at all' and 'almost all of the time.' It was tested on 156 participants in Australia, who were a mixture of tinnitus clinic patients and members of the public with tinnitus and in this respect like the sample studied here. Although the authors propose a two-factor structure, they conclude from their principal components analysis that 'the full scale appears to be rather homogenous' (p.200). Subsequent analysis (Kennedy et al., 2004) found that >75% of items focus on the single domain of tinnitus distress, which supports the notion that the scale is suitable for measuring this as a single construct. The TRQ showed good test re-test reliability (p=0.88) and moderate correlation with measures of depression (BDI; p=0.63) and anxiety (STAI State; p=0.60, STAI trait; p=0.58), indicating that it is not simply a measure of mental health.

Table 3.2: Properties of questionnaires included in tinnitus survey

Component measured	Name (authors)	α	Items used	Factors used (α)	Response scale	Test- retest ρ	Convergent / divergent validity
Negative thoughts	Tinnitus Cognitions Questionnaire (Wilson & Henry, 1998)	0.91	26/ 26	Positive Negative (α NR.)	5- point Likert	0.8	TRQ; ρ = 0.55 BDI; ρ = 0.33.
Arousal & distress	Clinical Outcomes in Routine Evaluation (Evans et al, 2000.)	0.94	34/34	Well-being (0.77) Symp-toms (0.90) Function (0.86) Risk (0.79)	5- point Likert	0.9	BDI; ρ= 0.85
Selective attention & moni- toring	Tinnitus Vigilance & Awareness Questionnaire (Cima et al., 2011)	0.81	18/ 18	n/a	6- point Likert	NR	TQ; ρ = 0.57
Beliefs	Illness Perception Questionnaire Revised (Moss-Morris et al., 2002)	NR	12/ 38	Personal control (0.81) Treatment control (0.80)	5- point Likert	Pers. control = 0.57 Treat. control = 0.50	PANAS neg; For personal control, $\rho$ = -0.07 For treat- ment control, $\rho$ = -0.08
Beliefs	Fear of Tinnitus Questionnaire (Cima et al., 2011)	0.82	8/ 17	n/a	5- point Likert	NR	TQ; ρ = 0.7
Safety be- haviour	Tinnitus Fear Avoidance Scale (Kleinstauber et al., 2013)	0.85	11/ 15	Tinnitus- related behavior (0.80) Ear- related behavior (0.76)	6- point Likert	NR	THI; ρ = 0.69

Tinnitus magni- tude	Tinnitus Magnitude Index (Schmidt et al., 2014)	0.86	3/3	n/a	0-10	0.74	THI; ρ = 0.62
Tinnitus distress	Tinnitus Functional Index (Meikle et al., 2012)	0.86	3/ 25	Emotion- al (0.94)	0-10	0.78	THI; p= 0.86 (only whole TFI tested)
Tinnitus distress	Tinnitus Reaction Questionnaire (Wilson et al., 1991)	0.97	26/ 26	n/a	5- point Likert	0.88	BDI; ρ = 0.63 STAI State; ρ= 0.6, trait; ρ = 0.58.

Abbreviations:

NR = Not reported

PANAS Neg = Positive and Negative Affect Schedule (Watson et al., 1988): Negative affect subscale

STAI = State- trait anxiety inventory (Spielberger et al., 1970)

## 3.4.9 Sample size

A prototype path model was constructed using the original factors of the questionnaires detailed in table 3.2 as measured variables in order to calculate the sample size required. It consisted of 15 measured variables (factors). The power calculation was determined using methods recommended by MacCallum et al. (1996) and was based on 80% power, an anticipated effect size of 0.3, alpha 0.05 and conservative degrees of freedom of 38. It indicated that 320 individuals should be recruited to test the model using SEM techniques. This target number is also roughly in line with the rule of thumb in multivariate statistics that 20 participants should be recruited per variable measured (Schumacker and Lomax, 2004).

## 3.4.10 Creation of survey

The selected full questionnaires, modified questionnaires, and subscales discussed above were brought together into a single survey named "Tinnitus: thoughts, feelings and actions". An online version of this survey was created

using Bristol Online Surveys, a web-based survey tool, and a paper version was also printed for those participants who preferred this method or who did not have access to the internet. An initial page asked for demographic information and a brief tinnitus history; this is shown in appendix 1. Following this, participants were required to respond to questionnaire items by clicking on or ticking the appropriate response. All questionnaires used in the survey are shown in appendix 2. The online survey was designed so that a response to each item must be given before progressing to the next page. Two free text boxes were provided at the end of the survey, one for comments about the survey itself, and the other for any additional comments about the respondent's tinnitus.

# 3.5 Study procedure

People who had seen the study advertised and were interested in participating contacted the research team and were sent an initial package consisting of a participant information sheet, a consent form, and the single question: "how much of a problem is your tinnitus?" with the response categories described in section 3.3.3. This package was sent either electronically or by post, depending on the participants' preference. On receipt of a completed consent form and problem question, I either emailed the participant with a link to the full survey and an automatically generated password or posted a paper copy of the survey to them with a stamped, addressed envelope for return. In addition, I allocated each participant a unique number and instructed them to add this to their online or paper questionnaire. This unique number ensured that names were not shown on questionnaires but I was able to identify who had returned which questionnaire using a secure database of names and numbers, in case the participants' responses or comments indicated that they needed help. Entry to a £100 prize draw was offered to all participants as an incentive and the secure database was also used to identify the winner. Once the target number of participants in each problem category had been reached (see section 3.3.3)

any further potential participants in that category were thanked for their interest and told that their participation was not required. Participants who had completed a consent form but had not completed the full survey 4 to 6 weeks later were sent a reminder. This reminder also invited them, if they wished, to give reasons for not completing the survey if they had decided not to. The survey was available for completion online and on paper between 7<sup>th</sup> May 2014 and 16<sup>th</sup> December 2014.

# 3.6 Data Analysis

All scores were recoded prior to analysis with the minimum value being set to 0 to reflect the lowest value of any questionnaire. Mean scores were calculated for each questionnaire used and these were compared between problem categories using ANOVA. The correlation between overall tinnitus distress (measured by the TRQ) and each of the other questionnaires used was calculated, and multiple regression analysis was used to assess the amount of variance in tinnitus-related distress explained by each questionnaire. These analyses were carried out using SPSS version 22 (IBM).

The data obtained were further analysed using MPlus software version 7.2 (Muthen and Muthen, 2005-2014). There were two phases to data analysis; first a series of measurement models were tested and then a series of structural models.

#### 3.6.1 Measurement models

At least one measurement model was constructed and tested for each of the questionnaires/ questionnaire subscales detailed above, using the following procedure:

Confirmatory Factor Analysis (CFA) was carried out using a
measurement model derived from the original factor structure
proposed by the questionnaire's authors. Goodness of fit was judged

using two types of fit indices. Absolute fit indices compare the data to an estimated model, which is predicted by the MPlus program using the data, error calculations, and constraints indicated by the user. Comparative fit indices compare the data to a baseline or null model, in which there is no response pattern. The absolute fit index used was the Root Mean Square Error of Approximation (RMSEA; Steiger, 1990), reported with 90% confidence intervals. The comparative fit indices were the chi square, The Comparative Fit Index (CFI; Bentler, 1990) (CFI; Bentler, 1990) and the Tucker Lewis Index (TLI; Tucker and Lewis, 1973). The estimator used for CFA was robust weighted least squares (WLSMV), as this accounts for the categorical nature of the observed data in the model (Byrne, 2012, Brown, 2006). Details of criteria for good fit are given in section 5.2, in which results of factor analysis are reported.

- 2. If initial CFA did not result in a good fit, further CFA was carried out using any alternative factor structure which had been proposed in the literature.
- If this did not result in a good fit, or if no alternative factor structure
  had been proposed, very poorly fitting items were removed, and CFA
  was repeated.
- 4. If this did not result in a good fit, exploratory factor analysis was carried out and a new factor structure developed based on best fit.
- 5. Internal consistency and reliability of the best fitting measurement model was established.

Two of the scales used in the survey (the TFI-E and the TMI) contained only three items each and were thus not suitable for factor analysis (Brown, 2006). They were, however, assessed for internal consistency.

#### 3.6.2 Structural models

Once an adequate factor structure for each questionnaire had been established, estimated factor scores were calculated. The theoretical model then needed to be adapted in order to be testable using SEM techniques. This process resulted in a series of path models to be tested, with each measured variable contained within them being a factor score. All the variables contained within the models and the relationships between them were tested simultaneously to investigate how closely the data obtained fit the model proposed. The goodness of fit of the entire models was judged using the fit indices described in section 3.6.1. Inspection of factor scores indicated that they were not normally distributed for all factors used. Therefore, the estimator chosen for path analysis was Maximum Likelihood with Robust Standard errors and  $\chi^2$ , known as MLM, as its use of the Satorra-Bentler  $\chi^2$  statistic has been shown to perform well with non-normally distributed continuous data (Curran et al., 1996) and it is also appropriate for use with small to medium sample sizes (Asparouhov, 2005).

Modification Indices are also provided by MPlus. These indicate changes in parameters which, if implemented, would improve the fit of the model. The structure of the model may be amended according to the modification indices in order to produce a better fit, but only if such changes can be supported by theory (Schumacker and Lomax, 2004, Byrne, 2012).

# 3.6.3 Missing and spurious data

Missing data were identified prior to analysis and recoded. MPlus is able to accommodate missing data using full information maximum likelihood estimation, and thus imputes missing data (Muthen and Muthen, 2012).

There was limited missing data as the online survey required all items to be completed; only paper surveys contained missing items.<sup>1</sup>

Any outliers were investigated, initially by checking for mistakes in data entry. Unusual response patterns were discussed by the research team with a view to excluding data considered to be spurious from analysis. SEM is flexible to cope with a range of data types (e.g. categorical Likert data, or continuous scale data) and is robust to non-normality when the correct estimators are used. Once all data had been collected, its characteristics were explored, and the correct estimator chosen for each stage in collaboration with the statistician on the team.

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<sup>&</sup>lt;sup>1</sup> In total, 0.008% of data were missing. However, the pattern of distribution of missing values was not random as the online survey could not be submitted until all items were completed while the paper survey could be returned incomplete.

# Chapter 4. **Preliminary Results**

# 4.1 Participants

During the 7 months in which the survey was open, 534 people contacted the research team to express interest in participating. The sources from which these people came is shown in Figure 4.1.

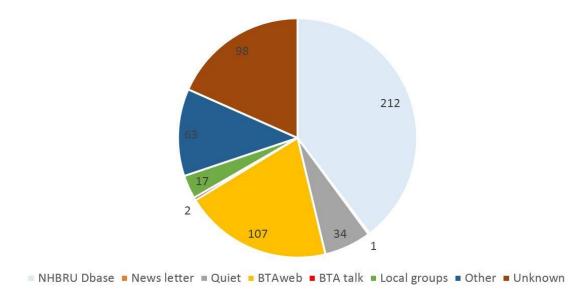


Figure 4.1: sources of people expressing interest in study.

Most participants were either research volunteers on the NHBRU database or people who had heard about the study via the BTA. Those in the 'unknown' category are people who made contact without saying where they had heard about the study; it is likely that most of these also came from the same two sources. The 'other' category includes my personal contacts and people who had heard about the study from another participant.

Of those who initially expressed interest, 438 (82%) went on to fill in a consent form. Of these, 342 (78%) went on to complete the full survey. The large majority of these completed the survey online (n=323, 95%). The

remaining 19 participants (5%) completed the survey on paper and returned it in the post. For a discussion of the merits and disadvantages of online data collection in this study, please see Handscomb et al. (2016b). Progress of participants through the study is illustrated in figure 4.2

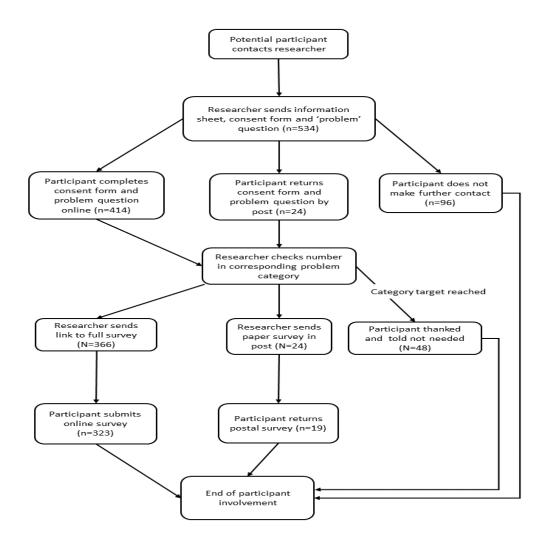


Figure 4.2: flowchart showing progress through the study

The median number of days between being sent a link to the survey and submitting it online was one. The range was 0 days to 70 days. Overall, 175

participants (54%) submitted their survey on the same day or the day after they were sent the link to it. No record was kept of how long it took participants to return postal surveys.

Twenty-six percent (n=5) of postal participants who were sent a survey failed to return it and 9.5% (n=38) of online participants who were emailed a link to the survey failed to submit it online. Only two people gave reasons for not going on to fill in the full survey; one re-read the information sheet and realised he was under age and the other felt she did not like answering questions about her tinnitus.

Forty-four email reminders were sent to people who had consented but failed to submit their survey within three weeks. Of these, 23 (52%) submitted their survey following a reminder.

## 4.1.1 Age, sex, and duration of tinnitus

There were 186 male respondents and 156 female respondents. The mean age was 55.0 (range = 21-87 years). The mean age of online respondents was 54.1 years (range = 21-83 years) while the mean age for postal respondents was 67.5 years (range = 43-87 years). The mean duration of tinnitus was 14 years (range = 3 months- 69 years) and the median was 10 years.

# **4.1.2** Number who were receiving or had received treatment for tinnitus

Most participants had never received treatment for their tinnitus. Fifty-six participants (16.4%) reported receiving some form of treatment for their tinnitus at the time of completing the survey. One hundred and twenty-four participants (36.3%) had received some form of treatment in the past.

## 4.1.3 Numbers of participants in each category

Table 4.1 shows the final number of respondents in each 'problem category.'

Table 4.1: number of respondents in each problem category

Category	Actual number	Target number
Not a problem	35	32
Small problem	85	80
Moderate problem	102	96
Big problem	83	80
Very big problem	37	32
Total	342	320

Forty-eight potential participants who had returned consent forms were emailed to say their participation was not required as enough people had already completed the survey in that category. Such emails were not sent out until the target number of completed surveys had been received. Target numbers were exceeded in all categories as some surveys were returned from participants who had consented some time ago after the target number had been reached.

The 'moderate' category was the first to reach its target, 23 weeks after the survey opened. The 'very big' category reached its target after 24 weeks, the 'small' category after 26 weeks, the 'big' category after 31 weeks and the 'not a problem' category after 32 weeks.

# 4.2 Mean Questionnaire Scores

Mean scores for each of the nine questionnaires in the survey were calculated for the whole sample and for each problem category. Results are shown in table 4.2.

Table 4.2: mean questionnaire scores

Questionnaire	Mean scor	Mean scores (SD)					
	Not a	Small	Moderate	Big	Very big	Overall	Score*
	problem	problem	problem	problem	problem		
TCQ	31.17	34.00	41.28	51.94	67.46	43.86	104
	(16.03)	(12.44)	(11.90)	(12.46)	(17.76)	(17.20)	
CORE-OM	21.97	22.17	29.29	41.89	59.14	32.96	136
	(17.06)	(15.61)	(16.70)	(22.27)	(25.94)	(22.33)	
TVAQ	14.17	24.96	40.42	52.99	64.62	39.56	90
	(10.25)	(12.48)	(13.85)	(12.79)	(11.76)	(19.77)	
IPQ-M	26.51	19.53	20.52	17.94	16.89	19.88	60
	(9.18)	(9.49)	(7.75)	(7.97)	(7.73)	(8.75)	
FOTQ-M	1.60	5.55	10.31	12.63	17.05	9.53	40
	(2.89)	(4.61)	(5.65)	(5.55)	(5.75)	(6.74)	
TFAS-M	4.40	9.25	16.96	21.69	26.81	15.98	66
	(6.74)	(7.94)	(9.58)	(11.29)	(11.24)	(11.72)	
TMI	8.26	11.99	18.43	23.61	26.5	17.92	30
	(5.82)	(6.41)	(5.41)	(5.04)	(3.23)	(7.98)	
TFI-E	0.46	2.15	7.69	13.71	21.97	8.58	30
	(1.24)	(3.76)	(6.43)	(7.78)	(6.91)	(8.87)	
TRQ	2.23	8.82	23.30	41.55	66.35	26.63	104
	(4.07)	(9.26)	(14.98)	(21.91)	(23.00)	(25.10)	

<sup>\*</sup>the maximum score possible on this questionnaire

# 4.2.1 Differences between mean scores

A series of one-way ANOVAs were carried out to investigate whether there were statistically significant differences in mean scores between problem groups for each questionnaire. For all questionnaires, statistically significant differences (p<0.001) between groups existed. For the TCQ, F (4,336)= 56.852, for the CORE-OM, F (4,335) = 31.973, for the TVAQ, F (4, 337) = 122.235, for the IPQ-M, F (4, 335) = 7.851, for the FOTQ-M, F (4, 337) = 60.815, for the TFAS-M, F (4, 337) = 42.445, for the TMI, F (4, 337) = 98.313, for the TFI-E, F (4, 337) = 102.436 and for the TRQ, F (4, 337) = 119.236. Differences in mean scores were statistically significant (p<0.05) between all problem categories for six of the questionnaires: FOTQ-M, TFI-E, TMI, TRQ, TFAS-M and TVAQ.

For the CORE-OM, there was no statistically significant difference in mean scores between the not a problem and small problem groups (mean

difference = 0.19, p = 1.00) or between the not a problem and moderate problem groups (mean difference = 7.32, p=0.28).

For the TCQ, there was no statistically significant difference in mean scores between the not a problem and small problem groups (mean difference = 2.83, p=0.99).

For the IPQ-M, there was no statistically significant difference in mean scores between the small problem and the moderate, big and very big problem groups (mean difference = 0.99, 1.60 and 3.63 respectively; p = 1.00 for all.) There was also no statistically significant difference in mean scores between the moderate problem and big problem groups (mean difference = 2.58, p=0.40), between the moderate problem and very big problem groups (mean difference = 3.63, p=0.27) or between the big problem and very big problem groups (mean difference = 1.05; p=1.00.)

# 4.3 Median Questionnaire scores

Although it is conventional for mean scores to be reported in tinnitus research using the questionnaires listed above (for example, Kleinstauber et al., 2013, Cima et al., 2011, Andersson et al., 2002), there is an argument for treating the data as ordinal rather than interval, and there are examples of studies in which this has been done (such as Meric et al., 1998, using the TRQ.) This is because questionnaires of this type use a five to seven point Likert scale for responses. For each item, respondents are invited to endorse statements like; 'some of the time' and 'a good deal of the time' or 'agree' and 'strongly agree.' Although each item is assigned a score and there is a clear hierarchy of responses, intervals between scores cannot be assumed to be equal (Gob et al., 2007, Jamieson, 2004). For this reason, median questionnaire scores were also calculated and compared. These are shown in table 4.3.

Table 4.3: median questionnaire scores

Question- naire	Median Score (range)						Max score
	Not a problem	Small problem	Moderate problem	Big problem	Very big problem	Overall	
TCQ	34	34	41	53	70	43	104
	(52)	(66)	(58)	(70)	(69)	(98)	
CORE-	19	19	26	37	55	27	136
ОМ	(71)	(76)	(69)	(111)	(101)	(117)	
TVAQ	14	23	38	54	64	38.5	90
	(58)	(60)	(68)	(68)	(43)	(90)	
IPQ-M	28	19	21	18	18	20	60
	(38)	(42)	(38)	(44)	(35)	(44)	
FOTQ-M	0	5	10	13	17	10	40
	(13)	(18)	(25)	(26)	(23)	(28)	
TFAS-M	2	8	17	20	24	15	66
	(34)	(37)	(47)	(47)	(51)	(52)	
TMI	8	12	19	25	28	19	30
	(24)	(27)	(22)	(27)	(12)	(30)	
TFI-E	0	1	6	15	24	5	30
	(6)	(26)	(26)	(30)	(25)	(30)	
TRQ	0	6	20.5	37	69	20	104
	(19)	(43)	(28)	(101)	(83)	(104)	

### 4.3.1 Differences between median scores

A Kruskal-Wallis test was carried out to investigate whether there were statistically significant differences in median scores between problem groups for each questionnaire. For all questionnaires, statistically significant differences (p<0.001) between groups existed. For the TCQ,  $\chi^2$  (4) = 125.868, for the CORE-OM,  $\chi^2$  (4) = 92.593, for the TVAQ,  $\chi^2$  (4) = 201.357, for the IPQ-M,  $\chi^2$  (4) = 31.565, for the FOTQ-M,  $\chi^2$  (4) = 145.971, for the TFAS,  $\chi^2$  (4) = 122.657, for the TMI,  $\chi^2$  (4) = 185.937, for the TFI-E  $\chi^2$  (4) = 189.659 and for the TRQ,  $\chi^2$  (4) = 212.427.

A series of Mann-Whitney U tests were then carried out to investigate which of the differences between similar medians were not statistically significant. For the CORE-OM, there was no statistically significant difference in median scores between the not a problem and small problem groups (U = 1438.500, Z = -0.283, p=0.77). For the TCQ, there was no statistically significant difference in median scores between the not a problem and small problem groups (U =

1384.000, Z = -0.598, p=0.550). For the IPQ-M, there was no statistically significant difference in median scores between the small problem and the moderate problem groups (U = 3921.500, Z= -1.015, p= 0.310), between the small problem and the big problem groups (U = 3180.500, Z=-1.102, p= 0.271) or between the small and very big problem groups (U = 1310.500, Z=-1.246, P=0.213). There was also no statistically significant difference in median scores between the big problem and very big problem groups (U = 1433.000, Z=-).353, p=0.724). Findings obtained from the analysis of median scores were very similar to those obtained from the analysis of mean scores.

# 4.4 Correlation between components of the model and tinnitus distress

The differences in scores between problem categories discussed above suggests that most of the constructs measured by the questionnaires used contribute to overall tinnitus distress. In general, the more problematic people consider tinnitus to be, the higher they are likely to score on measures of tinnitus-related thoughts, behaviour, and attention. This supports the model's predictions about the constructs which contribute to tinnitus distress. To further test these predictions, the correlation between the TRQ- a measure of tinnitus distress- and each measure of a specific construct was calculated. If all the components of the model contribute to overall tinnitus distress, we would expect this correlation to be strong. Results are shown in table 4.4 below.

Table 4.4: correlation between Tinnitus Reaction Questionnaire (TRQ) and each of the other measures.

	Pearson's r	Spearman's ρ	р
TCQ	0.697	0.626	<0.001
CORE-OM	0.788	0.732	<0.001
TVAQ	0.734	0.778	<0.001
TFAS-M	0.666	0.707	<0.001
IPQ-M	-0.271	-0.295	<0.001
FOTQ-M	0.756	0.777	<0.001
TMI	0.676	0.732	<0.001
TFI-E	0.882	0.863	<0.001

There was a positive, strong correlation between TRQ and seven of the eight other measures used within the survey. This suggests that emotional distress, negative thoughts, avoidance, perceived magnitude and attention all contribute to feelings of distress about tinnitus. The particularly strong correlation between TRQ and TFI-E is to be expected, as both are measuring the same construct; emotional distress related to tinnitus.

There was a weak, negative correlation between the TRQ and the IPQ-M. The IPQ is the only questionnaire on which a higher score indicates less difficulty, so the correlation between this and the TRQ would therefore be expected to be negative. However, the fact that this correlation is so much weaker than the others calls into question the extent to which control beliefs contribute to feelings of distress.

# Chapter 5. Factor Analysis of Questionnaires used in Tinnitus Survey

#### 5.1 Goodness-of-fit criteria

For all questionnaires which could be analysed using factor analysis, the following criteria were used to assess goodness-of-fit. For the RMSEA, a value of less than 0.05 was taken to represent good fit, errors of approximation of up to 0.08 were considered an acceptable absolute fit (Joreskog and Sorbom, 1993), and a RMSEA of between 0.08 and 0.1 was considered a mediocre fit (MacCallum et al., 1996). The chi-square should ideally be non-significant (i.e. p>0.05). This would indicate an equivalence between the predictions of the proposed model and what is shown by the data. However, on its own a significant chi-square value should not be taken to indicate a poorly fitting model (Streiner, 2006, Byrne, 2012) as, if the sample size if large, the chisquare value tends to be large and significant even when fit indices are otherwise good. Where the fit indices for two models were similar and one model was nested in another (that is, they shared the same variables but differed in the number of constrained parameters) a chi-square difference test was used to assess the statistical significance of the difference between them. For both The Comparative Fit Index (CFI; Bentler, 1990) and Tucker Lewis Index (TLI; Tucker & Lewis, 1973) a value of >0.95 indicates a good fit (Hu and Bentler, 1999).

An introduction to all the questionnaires selected for the survey is given in section 3.4 along with information about their development. The results of factor analysis for each questionnaire are presented here. Two of the factor analyses described in this chapter have also been published in peer reviewed journals.

Handscomb, L. E., Hall, D. A., Shorter, G. W., & Hoare, D. J. (2017). Positive and Negative Thinking in Tinnitus: Factor Structure of the Tinnitus Cognitions Questionnaire. *Ear and Hearing*, *38*(1), 126-132.

Handscomb, L., Hall, D. A., Hoare, D. J., & Shorter, G. W. (2016). Confirmatory factor analysis of Clinical Outcomes in Routine Evaluation (CORE-OM) used as a measure of emotional distress in people with tinnitus. *Health Qual Life Outcomes*, 14(1), 124.

# **5.2** The Tinnitus Cognitions Questionnaire

The expected two-factor structure of the TCQ was tested in the current study using CFA. Initial testing resulted in a poor fit (table 5.1). However, original validation of this questionnaire found the two subscales to be uncorrelated ( $\rho$ =0.09, Wilson and Henry, 1998). Analysis of the data collected for this study also found the two factors to be uncorrelated ( $\rho$ =-0.03). Therefore, CFA was repeated, specifying an expected lack of correlation between the two factors by fixing the correlation between factors 1 and 2 at 0. This resulted in a much better fit (table 5.1).

Table 5.1: Fit indices for Tinnitus Cognitions Questionnaire (TCQ)

Fit Indices	2 factor CFA	2 factor CFA:
		factors
		uncorrelated
RMSEA	0.115	0.064
(90% CI)	(0.110-0.121)	(0.058-0.070)
CFI	0.935	0.980
TLI	0.929	0.979
Chi-square	1657.007	711.918
	Df=298	Df=299
	P<0.001	P<0.001
WRMR	2.105	2.112

RMSEA=root mean square error of approximation.CI=confidence interval. CFI=comparative fit index.TLI= Tucker Lewis Index. WRMR = weighted root mean square residual.

All factor loadings were found to be moderately to very high. Standardised factor loadings and standard errors for the two uncorrelated factor model are shown in table 5.2.

Table 5.2: Factor loadings (with standard errors) for Tinnitus Cognitions Questionnaire (TCQ)

		sed factor score dard error)
Item	Factor 1: Negative	Factor 2: Positive
1. I think "if only the noise would go away"	0.837 (0.020)	
2. I think "why me? Why do I have to suffer this horrible noise?"	0.881 (0.014)	
3. I think "What did I do to deserve this?"	0.877 (0.016)	
4. I think "The noise makes my life unbearable."	0.912 (0.011)	
5. I think "Nobody understands how bad the noise is"	0.852 (0.017)	
6. I think "If only I could get some peace and quiet"	" 0.898 (0.015)	
7. I think "I can't enjoy what I'm doing because of the noise"	0.872 (0.0140	
8. I think "How can I go on putting up with this noise?"	0.920 (0.010)	
9. I think "The noise will drive me crazy"	0.925 (0.009)	
10. I think "Why can't anyone help me?"	0.824 (0.019)	
11. I think "My tinnitus is never going to get better"	0.731 (0.029)	
12. I think "The noise will overwhelm me"	0.927 (0.009)	
13. I think "With this noise, life is not worth living"	0.851 (0.022)	
14. I think "no matter how unpleasant the noise gets, I can cope"		0.661 (0.031)

15. I think "The noise might be unpleasant, but it won't drive me crazy"	0.760 (0.025)
16. I think "I'll be able to enjoy things if I keep my attention off the noise."	0.759 (0.023)
17. I think "I'm not the only person with tinnitus"	0.568 (0.037)
18. I think "There are things in life worse than tinnitus"	0.703 (0.028)
19. I think "The noise will eventually get less annoying if I try to distract myself from it"	0.822 (0.020)
20. I think "I have coped with the noise before, so I can cope again this time."	0.817 (0.018)
21. I say to myself "It will help if I try to think of something pleasant."	0.678 (0.027)
22. I tell myself "I can learn to live with it."	0.839 (0.016)
23. I think "The noise might be there, but I can still enjoy things"	0.827 (0.018)
24. I tell myself "Think of something else other than the noise"	0.830 (0.017)
25. I tell myself "I won't think about the noise"	0.804 (0.018)
26. I think "The noise is a nuisance, but I just won't let it bother me"	0.800 (0.021)

Reliability analysis found that the full questionnaire had very high internal consistency ( $\alpha$ = 0.901). Internal consistency was also very high for both negative and positive subscales ( $\alpha$ = 0.959 and 0.929 respectively).

Further discussion of these results and recommendations for use of the TCQ are given in Handscomb et al. (2017).

# **5.3 Clinical Outcomes in Routine Evaluation (CORE-OM)**

The CORE-OM is widely used in mental health settings and has been subject to more analysis than any of the tinnitus-specific measures used in this study. It was originally constructed as a four-factor questionnaire, these factors being Well-being, Functioning, Problems, and Risk (Barkham et al., 2001). However, subsequent factor analyses in different settings have not supported this four-factor structure, with the exception of one Japanese study. Uji et al. (2012) found the four-factor structure to be a reasonable fit (RMSEA=0.062, GFI=0.867).

Alternative factor structures have been explored in a number of studies. Evans et al. (2002) used exploratory principal components analysis to analyse scores from 890 mental health clinic patients from several sites across the UK and 1106 students without diagnosed mental health problems. For both groups, a three-factor solution best fit the data. The three factors were: positively worded items (n=8), negatively worded items (n=19) and items indicating risk to oneself or others (n=6). Barkham et al. (2005) also reported a three-factor solution to their data from two samples of adults aged 65-97 of which 118 were attending mental health services and 214 were not. However, the items were differently distributed across the factors compared with Evans et al. (2002) and five items were excluded as they had low factor loadings (<0.4). Bedford et al. (2010) also conducted principal components analysis using data from 543 people referred to a British psychological therapy service. They found a two-factor solution to be optimal, composed of 23 'psychological distress' items and five 'risk' items. The remaining six of the 34 original items were excluded due to having insufficient factor loadings. These authors conducted Mokken scaling of the CORE-OM and suggested the number of items in both factors could be further reduced without loss of sensitivity. Murray et al. (2014) also carried out Mokken scaling using data from 360 students who had been referred to a university counselling service. This resulted in a ten-item, single-factor measure.

Two studies have examined more complex structures. A study involving CORE-OM data from 2140 patients referred to psychotherapy and counselling services across the UK was conducted by Lyne et al. (2006). They used CFA to test alternate models, which they then compared. The four-factor model proposed by the original authors did not meet good fit criteria (RMSEA= 0.074, CFI=0.84). In addition, two risk items (involving risk to others) were found to be poorly related to the rest of the risk factor and were excluded from the analyses that followed. The three-factor model supported by the work of Evans et al. (2002) was also a less-than-optimal fit (RMSEA=0.070, CFI=0.87). The best-fitting model (RMSEA= 0.051, CFI=0.93) comprised one first-order 'general psychological distress' factor with four subordinate factors (the four domains originally proposed) and an additional two subordinate method factors (positive and negative). However, the authors note that there is a high degree of correlation between the three non-risk domains (ρ=0.75-0.79) and suggest that for clinical use, treating the CORE-OM as a two-factor measure (general psychological distress and risk to self) is sensible.

The psychometric properties of a Norwegian translation of the CORE-OM were investigated using data from 527 mental health clinic patients and 464 members of the general population (Skre et al., 2013). Using confirmatory factor analysis, these researchers found the original four-factor structure to be only a mediocre fit (RMSEA=0.080, CFI=0.94) and they also note a moderate to high correlation between the three non-risk factors (p=0.62-0.74), suggesting they may not be conceptually distinct. Similarly to Lyne et al. (2006), they found a higher-order factor model to be the best fit (RMSEA=0.057, CFI=0.97) with a general psychological distress factor and subordinate factors consisting of the four original domains. Adding positive and negative items to their model did not improve fit, but they did not test a three-factor model consisting of positive, negative and risk factors only. They

conclude by recommending that CORE-OM be treated as a two-factor measure (general psychological distress and risk) because this makes it a straightforward way to identify those at risk and measure the benefits of therapy.

In the current analysis, each of the first-order models described above was retested using the data collected from people with tinnitus. Model I was a four factor model with items 4, 14, 17 and 31 loading on factor one: 'well-being', items 1, 3, 7, 10, 12, 19, 21, 25, 26, 29, 32 and 33 loading on factor two: 'functioning', items 2, 5, 8, 11, 13, 15, 18, 20, 23, 27, 28 and 30 loading on factor three: 'problems/ symptoms' and items 6, 9, 16, 22, 24 and 34 loading on factor four: 'risk'.

Model II was the three-factor model identified by Evans et al. (2002) with items 1, 2, 5, 8, 10, 11, 13-15, 17, 18, 20, 23, 25-30 and 33 loading onto factor one: 'negatively worded', items 3, 4, 7, 12, 19, 21, 31 and 32 loading onto factor two: 'positively worded' and items 6, 9, 16, 22, 24 and 34 loading onto factor three: 'risk'.

Model III was the model specified by Lyne et al. (2006). It was same as model II except that items 6 and 22 were omitted from the risk factor.

Model IV was the three-factor model specified by Barkham et al. (2005) for their clinical population with items 1, 2, 5, 11, 13, 14, 15, 17, 20, 23 and 27 loading onto factor one: 'negatively worded,' items 3, 4, 7, 12, 19, 21, 31, 32 loading onto factor 2: 'positively worded', and items 6, 9, 16, 22, 24, 25, 26, 29, 33 and 34 loading onto factor 3: 'risk'.

Model V was the two-factor model which Skre et al. (2013) recommend for clinical use, with items 1-5, 7-21, 23, and 25-33 loading on factor one: 'general psychological distress' and items 6, 9, 16, 22, 24 and 34 loading on factor two: 'risk.' Model VI was the same as model V but excluded items 6 and 22 in accordance with Lyne et al. (2006). Model VII was also a two factor model

similar to model V, but excluding items 8, 24, 25, 28, 29 and 33 in accordance with Bedford et al. (2010).

Model VIII was a single-factor model containing all 34 items. This model has not been found to be optimal in any previous studies (Skre et al., 2013, Bedford et al., 2010), but it was tested for the sake of completeness. Model IX was the 6-item Mokken scale recommended by Bedford et al. (2010) and model X was the 10-item Mokken scale recommended by Murray et al. (2014). The complex, higher-order models proposed by Lyne et al. (2006) and Skre et al. (2013) were not tested. Although they were both shown to be a good fit, these models do not allow individual factor scores to be calculated. Calculation of factor scores is essential for the next step in this study; path analysis of the full Cognitive Behavioural Model of tinnitus distress.

Examination of the correlation matrices indicated that for item 3 ("I have felt I have someone to turn to for support when needed") correlation coefficients were very low, and mostly negative in relation to other items (as positively worded items are reverse-scored, a positive correlation should be expected). Factor analyses were run on datasets with and without item 3 and as this item did not load onto any factor in any of the two, three or four factor solutions, all the results are given without item 3. Fit indices for all 10 models tested are shown in table 5.3.

Table 5.3: Fit indices for Clinical Outcomes in Routine Evaluation (CORE-OM) models I-X.

Fit Indices	Model I	Model II	Model III	Model IV	Model V	Model VI	Model VII	Model VIII	Model IX	Model X
RMSEA	0.071	0.057	0.061	0.058	0.072	0.078	0.079	0.075	0.092	0.076
90% CI	0.067-	0.052-	0.056-	0.052-	0.068-	0.074-	0.074-	0.071-	0.061-0.125	0.060-
	0.076	0.062	0.067	0.064	0.077	0.083	0.085	0.080		0.093
Chi Sq	1340.495	1041.814	987.639	746.699	1371.46	1344.077	1015.401	1449.241	35.072	104.33
Df	489	492	431	347	494	433	323	495	9	35
P	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001
CFI	0.951	0.968	0.968	0.974	0.949	0.947	0.952	0.945	0.976	0.985
TLI	0.947	0.966	0.965	0.972	0.946	0.943	0.948	0.941	0.961	0.981
WRMR	1.349	1.144	1.149	1.100	1.374	1.401	1.363	1.426	0.702	0.892

RMSEA=root mean square error of approximation.CI=confidence interval. CFI=comparative fit index.TLI= Tucker Lewis Index. WRMR = weighted root mean square residual.

For the original four-factor structure, although absolute fit indices were adequate (RMSEA = 0.071), the correlation between factors 1 and 3 was greater than 1 ( $\rho$ = 1.007). This out of bounds estimate suggests this model does not represent the relationships in the data.

Model II comprising negative, positive and risk factors was a fairly good fit. Model III, in which items 6 and 22 had been deleted from the risk factor, was a slightly poorer fit. Model IV, in which five items were deleted and four moved from the negative factor to the risk factor was a comparable fit to Model II. Model V, the two-factor structure recommended by Skre et al. (2013) was a reasonable fit. Model VI, the same two-factor model but with items 6 and 22 deleted from the risk factor was a poorer fit than Model V. Model VII, the 28-item, two-factor model, was also a worse fit than Model V. Model VIII, the single-factor model including all items, met adequate fit criteria. Model IX, the shortened six-item scale, was a mediocre fit, while model X, the 10-item scale, was an acceptable fit to the data.

Chi- square difference testing was carried out for those models which were nested within each other (i.e. those which contained the same items but different numbers of factors). Between models VIII (one-factor) and V (two-factor), TRd=77.781, df=1, p<0.001, with model V being the better fit.

Between models V (two-factor) and II (three-factor), TRd=329.646, df=2, p<0.001, with model II being the better fit. Between models II (three-factor) and I (four-factor), TRd=325.681, df=3, p<0.001, with model II again being the better fit.

Model II was chosen as the optimal model as it was a fairly good fit to the data and closer to the original questionnaire than Model IV. For all items in Model II, factor loadings were positive, moderately to very high and statistically significant. There was a high degree of positive correlation between all three factors.

Standardised factor loadings for each of the three factors in the optimal model (Model II) are shown in table 5.4.

Table 5.4: Factor loadings (with standard errors) for Clinical Outcomes in Routine Evaluation, model II and correlation between factors

Item	Factor loading				
	(standard error)				
	Negative	Positive	Risk		
1. I have felt terribly alone and isolated	0.834				
	(0.023)				
2. I have felt tense, anxious or nervous	0.833				
	(0.019)				
4. I have felt OK about myself		0.568			
		(0.040)			
5 I have felt totally lacking in energy and	0.753				
enthusiasm	(0.028)				
6. I have been physically violent to others			0.604		
			(0.118)		
7. I have felt able to cope when things go		0.551			
wrong		(0.038)			
8. I have been troubled by aches, pains or	0.413				
other physical problems	(0.047)				
9. I have thought of hurting myself			0.930		
- ,			(0.030)		
10. Talking to people has felt too much for	0.704				
me	(0.035)				
11. Tension and anxiety have prevented	0.857				
me doing important things	(0.022)				
12. I have been happy with the things I	,	0.854			
have done		(0.027)			
13. I have been disturbed by unwanted	0.765				
thoughts and feelings	(0.026)				
14. I have felt like crying	0.815				
	(0.023)				
15. I have felt panic or terror	0.880				
·	(0.021)				
16. I made plans to end my life			0.894		
·			(0.030)		
17. I have felt overwhelmed by my	0.927				
problems	(0.011)				
18. I have had difficulty getting to sleep or	0.578				
staying asleep	(0.039)				
19. I have felt warmth or affection for	<u> </u>	0.454			
someone		(0.052)			
20. My problems have been impossible to	0.825	<u> </u>			
put to one side	(0.021)				
21. I have been able to do most things I	<u> </u>	0.757			
needed to		(0.035)			
22. I have threatened or intimidated			0.694		
another person			(0.079)		
- r	+	+	, ,		
23. I have felt despairing or hopeless	0.927				

24. I have thought it would be better if I			0.968
were dead			(0.023)
25. I have felt criticised by other people	0.750		
	(0.030)		
26. I have thought I have no friends	0.774		
	(0.032)		
27. I have felt unhappy	0.907		
	(0.013)		
28. Unwanted images or memories have	0.720		
been distressing me	(0.034)		
29. I have been irritable when with other	0.719		
people	(0.028)		
30. I have thought I am to blame for my	0.712		
problems and difficulties	(0.034)		
31. I have felt optimistic about my future		0.786	
		(0.032)	
32. I have achieved the things I wanted to		0.855	
		(0.023)	
33. I have felt humiliated or shamed by	0.778		
other people	(0.037)		
34. I have hurt myself physically or taken			0.815
dangerous risks with my health			(0.065)
Correlation			
F1		0.786	0.865
		(0.023)	(0.024)
F2			0.758
			(0.037)

For path analysis, the CORE-OM was regarded as a three-factor questionnaire made up of 33 items.

Internal consistency for this 33-item version of the CORE-OM was found to be very high ( $\alpha$ = 0.95). It was also very high for each of the three subscales; for the negative scale  $\alpha$ = 0.95, for the positive scale  $\alpha$ = 0.83 and for the risk scale  $\alpha$  = 0.80.

A separate account of this confirmatory factor analysis and a discussion of the potential use of the CORE-OM in tinnitus clinics can be found in Handscomb et al. (2016a).

# 5.4 The Tinnitus Vigilance and Awareness Questionnaire

The authors of the TVAQ (Cima et al., 2011) treat it as a one-factor questionnaire, although exploratory factor analysis does not appear to have been carried out. The Pain Vigilance and Awareness Questionnaire (Roelofs et al., 2003) from which it is derived, is also treated as such. Therefore, confirmatory factor analysis was initially carried out assuming that all items made up a single factor. Fit statistics and standardised factor loadings are shown in tables 5.5 and 5.6.

Table 5.5: Fit indices for Tinnitus Vigilance and Awareness Questionnaire (TVAQ)

Fit Indices	
RMSEA (90% CI)	0.195
	(0.187-0.203)
CFI	0.904
TLI	0.892
Chi Square	1889.497
	df=135
	p<0.001
WRMR	3.041

RMSEA=root mean square error of approximation.CI=confidence interval. CFI=comparative fit index.TLI= Tucker Lewis Index. WRMR = weighted root mean square residual.

Table 5.6: factor loadings with standard errors for 1-factor Tinnitus Vigilance and Awareness Questionnaire.

Item	Factor loading
	(standard
	error)
1. I am very aware of changes in my tinnitus.	0.912
	(0.009)
2. I am quick to notice changes in intensity of tinnitus.	0.961
	(0.007)
3. I am quick to notice effects of medication on tinnitus.	0.501
	(0.048)
4. I am quick to notice changes in the sound of my tinnitus.	0.865
	(0.013)
5. My tinnitus keeps me constantly occupied.	0.829
	(0.017)
6. I notice my tinnitus even if busy with another activity	0.717
	(0.023)
7. I find it easy to ignore my tinnitus	0.572
	(0.034)

	,
8. I know immediately when my tinnitus starts or increases.	0.717
	(0.024)
9. When I do something that increases my tinnitus, check to	0.617
see how much tinnitus was increased.	(0.034)
10. I know immediately when my tinnitus decreases	0.489
	(0.036)
11. I must attend to tinnitus a lot	0.784
	(0.021)
12. I carefully monitor how intense tinnitus is	0.791
	(0.023)
13. I become preoccupied with my tinnitus.	0.760
	(0.022)
14. I do not dwell on tinnitus	0.520
	(0.036)
15. I am able to ignore the tinnitus, even if it is present	0.638
	(0.030)
16. I am aware of my tinnitus from the moment I get up till the	0.768
moment I go to sleep	(0.021)
17. My tinnitus distracts me, no matter what I do	0.895
	(0.011)
18. My tinnitus is so bad that I cannot ignore it.	0.911
	(0.011)

Although all items were found to have moderately to very high factor loadings, the fit statistics indicate a poor fit for the one-factor model. Therefore, exploratory factor analysis was carried out specifying a maximum of six factors (so that it would be possible to have at least three items per factor). Oblique rotation was used as the whole questionnaire is designed to measure a single construct, so correlation between factors is to be expected. SRMR (standardised root mean square residual) is reported instead of WRMR as Maximum Likelihood is a more appropriate estimator when using exploratory factor analysis (Brown, 2006).

The five-factor model failed to find a solution (using 1000 iterations) and is not reported. Fit indices for 1, 2, 3, 4, and 6 factor models are shown in table 5.7.

Table 5.7: fit indices for Tinnitus Vigilance and Awareness Questionnaire (TVAQ) using exploratory factor analysis

Fit Indices	1-factor	2-factor	3-factor	4-factor	6-factor
RMSEA	0.195	0.134	0.085	0.056	0.043
(90% CI)	(0.187-	(0.126-	(0.075-	(0.044-	(0.027-
	0.203)	0.143)	0.095)	0.067)	0.058)
CFI	0.904	0.960	0.986	0.995	0.998
TLI	0.892	0.949	0.979	0.991	0.995
Chi-Square	1889.497	845.747	354.308	178.894	97.793
	Df=135	Df=118	Df=102	Df=87	Df=60
	P<0.001	P<0.001	P<0.001	P<0.001	P<0.001
SRMR	0.138		0.031	0.022	0.014

RMSEA=root mean square error of approximation.Cl=confidence interval. CFI=comparative fit index.TLI= Tucker Lewis Index. SRMR = standardised root mean square residual.

Although the six-factor solution appears to be the best fit, there are multiple cross-loadings which make this an unsatisfactory solution. Both three-and four-factor solutions show a much clearer pattern of factor loadings. These are shown in table 5.8.

Table 5.8: factor loadings (standard errors) for 3 and 4 factor models of Tinnitus Vigilance and Awareness Questionnaire using EFA with oblique rotation, and correlation between factors.

Item	3-Factor		3-Factor		4-Factor		
	F1	F2	F3	F1	F2	F3	F4
1. I am very	0.944			0.898			
aware of	(0.029)			(0.031)			
changes in							
my tinnitus.							
2. I am quick	0.969			0.929			
to notice	(0.018)			(0.034)			
changes in							
intensity of							
tinnitus.							
3. I am quick	0.328			0.316			
to notice	(0.093)			(0.089)			
effects of							
medication							
on tinnitus.							

	1	1	1	1	1	_
(0.023)			(0.027)			
	0.795			0.719		
	(0.031)			(0.047)		
	0.700			0.047		
	(0.037)			(0.052)		
	0.707					0.486
	(0.035)					(0.063)
	, ,					`
0.730			0.690			
(0.038)			(0.040)			
		(0.050)			(0.057)	
0.507			0.499			
(0.001)			(0.030)			
		0.624			0.661	
		(0.046)			(0.042)	
		(0.058)			(0.061)	
	0.844 (0.023)	(0.023)    0.795	(0.023)	(0.023)       (0.027)         (0.023)       (0.031)         (0.031)       (0.031)         (0.037)       (0.037)         (0.707       (0.035)         (0.038)       (0.035)         (0.038)       (0.624         (0.050)       (0.040)         (0.050)       (0.056)         (0.064)       (0.046)         (0.046)       (0.046)	(0.023)       0.795 (0.031)       0.719 (0.047)         0.703 (0.037)       0.817 (0.052)         0.730 (0.038)       0.690 (0.040)         0.507 (0.064)       0.624 (0.050)         0.507 (0.064)       0.634 (0.046)         0.634 (0.046)       0.499 (0.056)         0.634 (0.046)       0.634 (0.046)         0.825       0.825	(0.023)       (0.027)       (0.022)       (0.022)       (0.022)       (0.027)

13. I		0.639			0.447		
become		(0.046)			(0.059)		
preoccupied		(0.040)			(0.039)		
with my							
tinnitus.							
14. I do not		0.500					0.500
		0.598					0.568
dwell on		(0.046)					(0.057)
tinnitus		0.702					0.770
15. I am able		0.782					0.779
to ignore		(0.033)					(0.094)
the tinnitus,							
even if it is							
present							
16. I am		0.747			0.914		
aware of my		(0.030)			(0.054)		
tinnitus							
from the							
moment I							
get up till							
the moment							
I go to sleep							
17. My		0.901			0.906		
tinnitus		(0.025)			(0.038)		
distracts							
me, no							
matter what							
I do							
18. My		0.881			0.837		
tinnitus is so		(0.023)			(0.040)		
bad that I							
cannot							
ignore it.							
Correlation							
F1	1.000			1.000			
F2	0.531	1.000		0.461	1.000		
F3	0.438	0.290	1.000	0.476	0.466	1.000	
F4				0.185	0.694	0.249	1.000

Examining the three-factor solution, a clear pattern emerges. Factor 1 (items 1,2,3,4, 8, and 10) deals with noticing changes in tinnitus, while factor 2 (items 5, 6, 7, 13, 14, 15, 16, 17, and 18) deals with inability to ignore tinnitus (regardless of whether it is changing). Factor 3 (items 9, 11, and 12) concerns active monitoring or checking behaviour.

A similar set of factors emerge when examining the four-factor solution. The fourth factor emerges which comprises only the three positively worded items

on the questionnaire (previously located in factor 2, inability to ignore tinnitus). A chi-square difference test revealed a statistically significant difference between three- and four-factors solutions, with a four-factor solution being a better fit (TRd=175.414, df=15, P<0.001). Given the good fit statistics and the logical grouping of items in line with theory, a four-factor solution (shown in table 5.9) is preferred.

Table 5.9: Final factor structure for Tinnitus Vigilance and Awareness Questionnaire (TVAQ)

Factor	Items
Factor 1: awareness of changes in	1,2,3,4,8,10
tinnitus	
Factor 2: preoccupation with	5,6,13,16,17,18
tinnitus	
Factor 3: monitoring behaviour	9,11,12
Factor 4: positive items (ability to	7,14,15
ignore)	

There was a statistically significant correlation between each factor and each other factor (p<0.05) as one would expect. It is notable that the correlation between factors 1 and 4 is low, indicating that awareness of changes in tinnitus and lack of positive coping ability may be quite separate concepts. A possible reason for this is that people who do not cope well with their tinnitus report that it does not change at all, and so these items may not have been applicable to all participants.

# **5.5** The Illness Perception Questionnaire

For the purposes of this study, two subscales of the Illness perception Questionnaire (Moss-Morris et al., 2002) were selected to measure control beliefs about tinnitus. All the items included in these two subscales collectively are referred to as IPQ (control).

Confirmatory factor analysis was conducted with items organised under the two factors 'personal control' and 'treatment control' following the structure

identified by Moss-Morris et al. (2002). Factor loadings were moderately to very high for all items ( $\lambda$ = 0.525-0.907) and there was a moderate correlation between the two factors ( $\rho$ = 0.672). However, overall model fit was poor. Fit indices are shown in table 5.10.

Table 5.10: Fit indices for 2-factor Illness Perception Questionnaire (control)

Fit indices	
RMSEA	0.173
(90% CI)	(0.160-0.185)
CFI	0.911
TLI	0.889
Chi-square	592.466
	df= 53
	P<0.001
WRMR	1.966

RMSEA=root mean square error of approximation.CI=confidence interval. CFI=comparative fit index.TLI= Tucker Lewis Index. WRMR = weighted root mean square residual.

Because of the poor fit statistics, exploratory factor analysis was then carried out testing one, two, three, and four factor models. As shown in table 5.11, the only model to result in a reasonably good fit (RMSEA<0.1) was a four-factor model (RMSEA=0.079). Examination of factor loadings indicated that items grouped together under 'personal control' and 'treatment control' as originally proposed, but that negatively worded items pertaining to each of these concepts formed two separate factors. Each of the 'negative' factors contained only two items, which is not adequate for modelling purposes (Brown, 2006).

Table 5.11: Fit indices for IPQ Illness Perception Questionnaire (control) following EFA

Fit Indices	1-factor	2-factor	3-factor	4-factor
RMSEA	0.242	0.162	0.135	0.079
(90% CI)	(0.230- 0.254))	(0.148- 0.176)	(0.119-0.151)	(0.060-0.100)
CFI	0.829	0.939	0.968	0.992
TLI	0.791	0.906	0.035	0.977
Chi-square	1133.570	429.829	237.292	75.671
	df=54	df=43	df=33	df=24
	P<0.001	P<0.001	P<0.001	P<0.001
SRMR	0.131	0.058	0.043	0.021

RMSEA=root mean square error of approximation.CI=confidence interval.

CFI=comparative fit index.TLI= Tucker Lewis Index. SRMR = standardised root mean square residual.

Negatively worded items on the IPQ were not intended to form separate factors, but it appears that participants responded to them differently than they responded to positively worded items. Literature pertaining to the IPQ was searched for any previous investigation of this issue. A 'think aloud' study in which diabetic patients were asked for their thoughts while completing the IPQ (McCorry et al., 2013) indicated some confusion over negatively worded items and in particular with the task of disagreeing with a negative statement. In the field of education, Roszkowski and Soven (2010) examined the effect of including two negatively worded items in an otherwise positively worded questionnaire and found that these had low item-total correlations and also formed a separate factor, even though they dealt with the same topic as other items on their intended factor. These authors conclude that including a few negatively worded items on a predominantly positively worded questionnaire confuses the interpretation of the items. Owing to these difficulties, CFA was repeated including the positively worded items of the IPQ (control) only. This yielded better although still rather poor fit statistics.

Further examination of EFA results indicated a tendency for item 7 ('my tinnitus will improve in time') to cross-load onto more than one factor, regardless of how many factors were in the final solution. Interestingly, McCorry et al. (2013) also observe that item 7 (in this case, 'my diabetes will

improve in time') was variously interpreted as pertaining to the natural course of the disease over time and to the effects of treatment over time, which supports the idea that it does not clearly pertain to one factor or the other. Perhaps in the case of tinnitus there is also ambiguity over the meaning of 'improve.' Some participants may have interpreted it as 'become quieter' while others may have interpreted it as 'bother me less.' Investigation of individual questionnaire responses indicated that many participants who considered their tinnitus to be 'not a problem' disagreed with or were neutral about the statement 'my tinnitus will improve in time' while overall IPQ scores were fairly high (good) for this group. Believing that tinnitus will improve over time may be quite different from believing one can control it day-to-day. Due to these issues, CFA was repeated using the positive items of the IPQ subscales but omitting item 7. This yielded a much better fit. Fit statistics are shown in table 5.12.

Table 5.12: Fit indices for 2-factor Illness Perception Questionnaire (control) including/excluding item 7.

Fit Indices	Positive	Positive
	items inc #7	items exc #7
RMSEA	0.119	0.079
(90% CI)	(0.098-0.141)	(0.052-0.107)
CFI	0.983	0.995
TLI	0.974	0.991
Chi-square	11.452	40.788
	df = 19	df=13
	P<0.001	P<0.001
WRMR	1.040	0.643

RMSEA=root mean square error of approximation.CI=confidence interval. CFI=comparative fit index.TLI= Tucker Lewis Index. WRMR = weighted root mean square residual.

Exclusion of all negatively worded items and the positively worded item 7 resulted in a seven-item, two-factor questionnaire. This modified questionnaire was named IPQ-M. Standardised factor loadings for the seven items retained are shown in table 5.13.

Table 5.13: Factor loadings (with standard errors) for IPQ- M.

Item	Factor 1	Factor 2
	Personal	Treatment
	Control	Control
1. There is a lot which I can do to	0.832	
control my symptoms	(0.020)	
2. What I do can determine whether	0.848	
my tinnitus gets better or worse	(0.017)	
3. The course of my tinnitus depends	0.840	
on me	(0.023)	
4. I have the power to influence my	0.805	
tinnitus	(0.023)	
5. My treatment will be effective in		0.593
curing my tinnitus		(0.027)
6. The negative effects of my tinnitus		0.908
can be prevented (avoided) by my		(0.021)
treatment		
7. My treatment can control my		0.942
tinnitus		(0.021)

Factors 1 and 2 correlated moderately with each other ( $\rho$ =0.513) suggesting that they represent separate but related constructs.

Mean scores were calculated for the IPQ-M. The overall mean and mean scores for each problem category are shown in table 5.14.

Table 5.14: Mean scores (with standard deviation) for IPQ-M

	Not a problem	Small problem	Moderate Problem	Big problem	V big Problem	Overall
IPQ-M	15.371	11.412	11.960	9.795	9.528	11.388
mean	(5.673)	(5.571)	(4.887)	(5.058)	(4.638)	(5.394)

A one-way ANOVA was conducted to analyse difference between means. This showed that there was a statistically significant difference in mean IPQ-M scores between the five problem categories [F(4, 335) = 8.654, p < 0.001]. Post hoc comparison using Bonferroni correction showed a statistically significant difference (p < 0.01) between the 'not a problem' category and all other categories and a borderline significant difference between 'moderate' and 'big problem' categories (p = 0.049). Otherwise, differences in means were not significant between groups.

# 5.6 The Fear of Tinnitus Questionnaire

As discussed in section 3.4.6, a subset of eight items from the FOTQ (Cima et al., 2011) were selected for the current study which were felt to capture commonly held erroneous beliefs about tinnitus and a 5-point Likert response scale was introduced.

The eight-item modified FOTQ (FOTQ-M) was subject to CFA specifying a single-factor structure, as the original version of the questionnaire was unifactorial. This resulted in a very poor fit (table 5.15). No modifications were suggested by the program that would make a significant difference to Chi-Square values.

Table 5.15: Fit indices for modified Fear of Tinnitus Questionnaire with 1 factor

Fit Indices	
RMSEA	0.271
(90% CI)	(0.252-0.292)
CFI	0.903
TLI	0.864
Chi square	523.730
	Df=20
	P<0.001
WRMR	2.720

RMSEA=root mean square error of approximation.CI=confidence interval.

CFI=comparative fit index.TLI= Tucker Lewis Index. WRMR = weighted root mean square residual.

Exploratory factor analysis was then carried out to see if an alternative factor structure would produce a better fit. A maximum of two factors was specified as this is an eight-item questionnaire so more than two factors would result in factors with fewer than three items. Both the one- and two-factor solutions also showed a very poor fit (table 5.16).

Table 5.16: Fit indices for 1 and 2 factor versions of modified Fear of Tinnitus Questionnaire

Fit Indices	1-factor	2-factor
RMSEA	0.271	0.230
(90% CI)	(0.252-0.292)	(0.206-0.256)
CFI	0.903	0.954
TLI	0.864	0.904
Chi square	523.730	248.449
	Df=20	Df=13
	P<0.001	P<0.001
SRMR	0.149	0.104

RMSEA=root mean square error of approximation.CI=confidence interval. CFI=comparative fit index.TLI= Tucker Lewis Index. SRMR = standardised root mean square residual.

In the two-factor solution, four of the eight items cross-loaded onto both factors, indicating that this is not a valid structure. In the one-factor solution, however, all factor loadings were moderately to very high, so low factor loadings is not the reason for poor fit. Internal consistency for the scale was good ( $\alpha$ =0.856) and all item-total correlations were adequate (all >0.36).

The possibility was considered that too large a range of response choices might be the reason for poor fit, especially as the full range of choices was not used for two items. For example, only one of 342 participants 'strongly agreed' with item 8. Therefore, responses were recoded into two categories, with 'neither agree nor disagree,' 'disagree' and 'strongly disagree' being recategorized as 0, and 'agree' and 'strongly agree' as 1. This resulted in a somewhat better fit (table 5.17), but is still failed to reach even the 'mediocre' threshold (MacCallum et al., 1996).

Table 5.17: Fit indices for modified Fear of Tinnitus Questionnaire with modified scoring.

Fit Indices	
RMSEA	0.188
(90% CI)	(0.169-0.209)
CFI	0.885
TLI	0.839
Chi square	262.983
	df=20
	P<0.001
WRMR	2.373

RMSEA=root mean square error of approximation.CI=confidence interval.

CFI=comparative fit index.TLI= Tucker Lewis Index. WRMR = weighted root mean square residual.

Owing to the very poor fit of this questionnaire, it was decided to exclude it from analysis of the full model as it cannot be regarded as a reliable measure of tinnitus-related beliefs. Unreliable measures can compromise the results of path analysis (Schumacker and Lomax, 2004). This highlights the need to develop a tinnitus beliefs questionnaire in a systematic way and subject it to thorough evaluation.

For the purposes of testing the full Cognitive Behavioural Model, only the IPQ-M was used as a measure of beliefs. This limits the scope of the model to control beliefs, which may or may not be the most important type of beliefs influencing thoughts and behaviour. This question is discussed further in section 8.1.5.

### 5.7 The Tinnitus Fear Avoidance Scale

The TFAS (Kleinstauber et al., 2013) was designed to measure both cognitions and avoidance behaviour related to tinnitus. The original principal components analysis identified three factors, which the authors named cognitions, tinnitus-related avoidance and ear-related avoidance. For the purposes of this study, only the two avoidance subscales were used, as

discussed in section 3.4.5. This modified two-factor version of the questionnaire is referred to as TFAS-M.

Confirmatory factor analysis of the resulting two-factor questionnaire showed a very poor fit (table 5.18).

Table 5.18: Fit indices for modified Tinnitus Fear Avoidance Scale (TFAS-M)

Fit Indices	
RMSEA	0.152
(90% CI)	(0.138-0.166)
CFI	0.936
TLI	0.918
Chi-square	383.265
	df=43
	P<0.001
WRMR	1.501

RMSEA=root mean square error of approximation.CI=confidence interval. CFI=comparative fit index.TLI= Tucker Lewis Index. WRMR = weighted root mean square residual.

The TFAS has not been subject to any further analysis since its development. Therefore, EFA was carried out on the TFAS-M to see whether an alternative factor structure produced a better fit. An upper limit of three factors was specified as the modified questionnaire only has eleven items and no factor should be composed of fewer than three items (Brown, 2006). Neither a one-, two- or three-factor solution resulted in a good fit. Fit indices are shown in table 5.19.

Table 5.19: Fit indices for 1, 2 and 3-factor models of modified Tinnitus Fear Avoidance Scale

Fit Indices	1-factor	2-factor	3-factor
RMSEA	0.180	0.133	0.110
(90% CI)	(0.166-	(0.118-	(0.091-
	0.194)	0.149)	0.129)
CFI	0.908	0.961	0.981
TLI	0.886	0.937	0.957
Chi-square	531.161	239.979	127.996
	df=44	df=34	df= 25
	P<0.001	P<0.001	P<0.001
SRMR	0.098	0.051	0.034

RMSEA=root mean square error of approximation.CI=confidence interval.

CFI=comparative fit index.TLI= Tucker Lewis Index. SRMR = standardised root mean square residual.

The questionnaire was re-examined to consider possible reasons for poor fit in the study population. It was noted that the response choices offered could have been ambiguous. Participants were asked to respond on a six-point Likert scale with rather unclear distinctions between categories concerning strength of agreement or disagreement ('strongly agree/ agree/ somewhat agree'). All the items used concerned behaviour, with participants being asked to say whether or not they avoid certain activities or situations. To 'somewhat agree' rather than 'agree' that one avoids noisy environments, say, could mean different things to different people ('I only avoid them sometimes' or 'I avoid them only if they're very noisy', or 'I might avoid them but don't think it is very important'). The original questionnaire was in German and it is possible that the language was clearer to German speakers. A more meaningful distinction might be simply: 'do you (ever) avoid this situation because of your tinnitus?'

Owing to the concerns discussed above, all the responses to the TFAS-M were recoded, with 'strongly disagree' to 'somewhat disagree' considered to mean 'I do not avoid this' and categorised as 0, and 'somewhat agree' to 'strongly agree' taken to mean 'I avoid this' and categorised as 1. Means for this recoded version of the questionnaire, overall and split by problem category, are shown in table 5.20.

Table 5.20: mean scores (with standard deviation) on modified Tinnitus Fear Avoidance Scale according to problem category

Not a problem	Small Problem	Moderate Problem	Big problem	Very Big Problem	Overall	Total max score
0.771	1.718	3.167	4.386	5.378	3.096	11
(1.285)	(1.829)	(2.321)	(2.917)	(2.498)	(2.700)	

One-way ANOVA showed that there was a statistically significant difference in mean TFAS-M scores between the five problem categories [F (4, 337) =

31.847, p<0.001]. Post hoc comparison using the Tamhane T2 test indicated that the differences in means between each problem category were statistically significant except between the 'big problem' (M = 4.386, SD = 2.917) and 'very big problem' groups (M = 5.387, SD = 2.498, p=0.462).

CFA was then repeated using the re-categorised data. This resulted in a better fit (table 5.21). Examination of the modification indices suggested that item 8 ('Due to my tinnitus I avoid flying or other situations where it is necessary to equalise air pressure') may cross-load onto factor 1 as well as factor 2, and that specifying this would result in a better fit. Conceptually this makes sense; flying is sometimes avoided due to ear sensations (which fits with the 'ear-related behaviour' category) but also sometimes due to the feared effects of aircraft noise (which fits with the 'tinnitus-related behaviour' category).

CFA was therefore repeated specifying this cross-loading. As predicted, this resulted in a better fit. Factor loadings were moderately to very high for all items in the originally specified two-factor model. However, when item 8 was allowed to cross-load, it was found to have a much higher loading on factor 1 than factor 2, and its loading on factor 2 failed to reach statistical significance (p=0.063). CFA was repeated with item 8 loading onto factor 1 only. The item's loading on factor 1 was high and the overall fit was good. Fit indices for both the re-categorised two-factor models (with and without cross-loading) are shown in table 5.21.

Table 5.21: Fit indices for final versions of modified Tinnitus Fear Avoidance Scale (TFAS-M)

Fit Indices	2-factor Original structure no cross- loading	2-factor #8 cross- loading	2-factor #8 on F1
RMSEA	0.078	0.055	0.056
(90% CI)	(0.063-0.093)	(0.039-0.072)	(0.040-0.073)
CFI	0.945	0.973	0.971
TLI	0.930	0.964	0.963
Chi-square	131.698	86.180	89.312
	df=43	df=42	df=43
	P<0.001	P<0.001	P<0.001
WRMR	1.256	0.982	1.012

RMSEA=root mean square error of approximation.CI=confidence interval. CFI=comparative fit index.TLI= Tucker Lewis Index. WRMR = weighted root mean square residual.

Loadings for all three models along with correlations between factors are shown in table 5.22.

Table 5.22: Factor loadings (with standard errors) and correlations for final versions of modified Tinnitus Fear Avoidance Scale (TFAS-M)

	Model 1		Model 2 loading)	(Cross-	Model 3	-
Item	F1	F2	F1	F2	F1	F2
Due to my tinnitus I avoid noisy	0.790		0.791		0.787	
environments	(0.046)		(0.045)		(0.045)	
Due to my tinnitus I     avoid conversations	0.762		0.764		0.759	
with more than one person.	(0.043)		(0.043)		(0.044)	
Due to my tinnitus I avoid sporting	0.862		0.861		0.858	
activities.	(0.044)		(0.044)		(0.044)	

	1	ı	ı	ı	ı	1
4. Due to my tinnitus I avoid exhausting	0.904		0.899		0.894	
activities and jobs.	(0.037)		(0.037)		(0.037)	
5. Due to my tinnitus I avoid activities that	0.708		0.710		0.706	
demand high levels of concentration.	(0.053)		(0.053)		(0.053)	
6. Due to my tinnitus I avoid quiet or silent	0.535		0.526		0.524	
environments.	(0.068)		(0.068)		(0.068)	
7. Due to my tinnitus I avoid using electronic	0.657		0.657		0.653	
devices that emit electromagnetic radiation	(0.086)		(0.085)		(0.085)	
8. Due to my tinnitus I		0.849	0.621	0.210	0.778	
avoid flying or other situations where it is necessary to equalize air pressure.		(0.059)	(0.100)	(0.113)	(0.053)	
Due to my tinnitus I     try to avoid getting		0.822		0.865		0.866
water into my ears when I have a shower, a bath or when I go swimming.		(0.059)		(0.047)		(0.047)
10.Due to my tinnitus I		0.703		0.750		0.749
try to protect my ears whenever it is possible		(0.054)		(0.055)		(0.055)
11.Due to my tinnitus I		0.859		0.909		0.909
do everything to avoid getting a cold or an ear problem.		(0.043)		(0.043)		(0.044)
Correlation						
F1.	1.00		1.00		1.00	
F2.	0.692	1.00	0.581	1.00	0.605	1.00

The whole scale was found to have adequate internal consistency ( $\alpha$ = 0.796). Internal consistency for the alternative factor structures is show in table 5.23.

Table 5.23: Internal consistency of modified Tinnitus Fear Avoidance Scale (TFAS-M)

	F1 items 1-7	F1 items 1-8	F2 items 8-11	F2 items 9-11
α	0.730	0.759	0.709	0.727

The modified version of the TFAS (TFAS-M) described above was used in all subsequent data analysis. It is a two--factor questionnaire with binary response categories and with factor 1 (tinnitus-related avoidance) composed of items 1-8 and factor 2 (ear-related avoidance) composed of items 9-11.

### **5.8** The Tinnitus Magnitude Index

Factor loadings for all three items on the TMI were high (table 5.24) and it was shown to have very high internal consistency;  $\alpha$ = 0.921.

Table 5.24: Factor loadings (standard errors) for Tinnitus Magnitude Index (TMI)

TMI Item	Factor
	loading
1. How strong or loud was your tinnitus?	0.906
	(0.016)
2. What percentage of your time awake were	0.803
you consciously aware of your tinnitus?	(0.023)
3. How severe has your tinnitus been?	0.996
	(0.011)

## 5.9 The Tinnitus Reaction Questionnaire

In their paper describing the development of the TRQ, Wilson et al. (1991) propose both one, two- and four-factor solutions. All of these structures were therefore tested in the current study using confirmatory factor analysis. Table 5.25 shows fit indices for one- and two-factor solutions using CFA.

Table 5.25: Fit indices for 1 and 2 factor versions of Tinnitus Reaction Questionnaire (TRQ)

Fit Indices	1-factor	2- factor
RMSEA	0.093	0.087
	(90% CI: 0.088-0.099)	(90%CI: 0.081-0.093)
CFI	0.980	0.982
TLI	0.978	0.981
Chi square	1190.634	1070.538
	df = 299	df = 298
	p<0.001	p<0.001
WRMR	1.439	1.337

RMSEA=root mean square error of approximation.CI=confidence interval.

CFI=comparative fit index.TLI= Tucker Lewis Index. WRMR = weighted root mean square residual.

The four-factor solution was also tested. This factor model failed to converge using 1000 iterations. The number of iterations was increased to 10,000 and then 100,000, but the model still failed to converge, suggesting that a four-factor solution is not appropriate. Wilson et al (1991) reached a four-factor solution using principal components analysis and orthogonal rotation.

Applying those methods here yielded a solution in which several items loaded onto more than one factor. This is likely to influence non-convergence, such that the model may be suited to the data used to derive the factor structure, but is not replicable using factor analysis. Table 5.26 shows standardised factor loadings for a one- and two-factor solution.

Table 5.26: factor loadings (standard errors) for 1 and 2 factor versions of Tinnitus Reaction Questionnaire (TRQ)

Question	Model 1 Model 2		
"My tinnitus has"	F1	F1	F2
TR1: made me unhappy	0.919	0.922	
	(0.010)	(0.010)	
TR2: made me feel tense	0.917	0.920	
	(0.010)	(0.010)	
TR3: made me feel irritable	0.891	0.893	
	(0.013)	(0.012)	
TR4: made me feel angry	0.918	0.919	
	(0.012)	(0.012)	
TR5: led me to cry	0.809	0.812	
	(0.029)	(0.029)	
TR6: led me to avoid quiet situations	0.656	0.660	
	(0.035)	(0.035)	

TR7: made me feel less interested in going out	0.854		0.884
and the second s	(0.020)		(0.018)
TR8: made me feel depressed	0.931	0.933	( /
	(0.009)	(0.009)	
TR9: made me feel annoyed	0.883	0.885	
,	(0.014)	(0.014)	
TR10: made me feel confused	0.891	0.893	
	(0.017)	(0.017)	
TR11: 'driven me crazy'	0.857	0.860	
·	(0.019)	(0.019)	
TR12: interfered with my enjoyment of life	0.915		0.953
	(0.011)		(0.010)
TR13: made it hard for me to concentrate	0.884		0.910
	(0.014)		(0.013)
TR14: made it hard for me to relax	0.911		0.941
	(0.012)		(0.011)
TR15: made me feel distressed	0.947	0.948	
	(0.008)	(0.008)	
TR16: made me feel helpless	0.927	0.928	
	(0.013)	(0.013)	
TR17: made me feel frustrated with things	0.930	0.934	
	(0.009)	(0.009)	
TR18: interfered with my ability to work	0.838	0.844	
	(0.020)	(0.019)	
TR19: led me to despair	0.959	0.961	
	(0.009)	(0.009)	
TR20: led me to avoid noisy situations	0.676		0.697
	(0.033)		(0.033)
TR21: led me to avoid social situations.	0.807		0.832
	(0.024)		(0.023)
TR22: made me feel hopeless about the future	0.924	0.926	
	(0.014)	(0.014)	
TR23: interfered with my sleep	0.725	0.728	
	(0.030)	(0.030)	
TR24: led me to think about suicide	0.814	0.817	
TD 25, made made feel madel	(0.036)	(0.036)	
TR 25: made me feel panicky	0.877	0.879	
TD2C: made me feet to me and d	(0.020)	(0.020)	
TR26: made me feel tormented	0.890	0.892	
Correlation between F4 and F3	(0.017)	(0.016)	
Correlation between F1 and F2	0.939	P<0.001	

There was a very high correlation between factors 1 and 2. This calls into question the usefulness of dividing the questionnaire into two factors.

Although the authors suggest factor 2 represents 'activity avoidance', it relates so strongly to the first factor (which the authors do not name) that to

treat this as a separate construct seems meaningless. Those items which make up factor 2 also had high loadings on factor 1.

Because CFA did not produce an optimal fit, exploratory factor analysis was carried out using both orthogonal rotation and oblique rotation. When the TRQ was developed, its authors used orthogonal rotation to investigate its factorial structure. They do not explain why they chose orthogonal over oblique rotation. Oblique rotation would seem a more appropriate method as it assumes the factors are correlated with each other. Given that the whole scale was designed specifically as a measure of psychological distress related to tinnitus, one would expect there to be at least a degree or correlation between factors.

EFA was carried out specifying up to eight factors (to allow at least three items per factor). Results showed a better fit as the number of factors increased. This is shown in table 5.27.

Table 5.27: Fit indices for Tinnitus Reaction Questionnaire (TRQ) using exploratory factor analysis, 1-8 factors

Fit Indices	1-factor	2-factor	3-factor	4-factor	5-factor	6-factor	7-factor	8-factor
RMSEA	0.093	0.075	0.061	0.049	0.042	0.039	0.031	0.024
90%	0.088-	0.069-	0.055-	0.041-	0.033-	0.029-	0.019-	0.000-
CI	0.099	0.081	0.068	0.056	0.050	0.048	0.042	0.037
CFI	0.980	0.988	0.993	0.996	0.997	0.998	0.999	0.999
TLI	0.978	0.986	0.990	0.994	0.996	0.996	0.997	0.999
Chi	1190.364	806.424	572.289	412.364	329.051	278.851	219.545	173.801
square	p<0.001	p<0.001	p<0.001	p<0.001	p<0.01	p<0.01	p<0.01	p=0.05
	df=299	df=274	df=250	df=227	df=205	df=184	df=164	df=145
SRMR	0.049	0.037	0.028	0.022	0.018	0.016	0.013	0.011

RMSEA=root mean square error of approximation.CI=confidence interval. CFI=comparative fit index.TLI= Tucker Lewis Index. SRMR = standardised root mean square residual.

However, further examination of the results show that these fit indices are misleading due to a large amount of cross-loading and to redundant factors.

Although the eight-factor solution appears to be a well-fitting model, examination of the factor loadings indicate that all items load onto more than one factor, with the majority having moderate to high loadings on five or six factors. Factor loadings are low on factors 7 and 8 for all but four of the 26 items and none of the items have their highest loading on factors 7 or 8, suggesting that these factors are redundant.

The seven- factor structure shows low or negative loadings for all items on factor 6 and for all but 3 items on factor 7. All 3 items have much higher loading on other factors. Similarly, in the six- factor structure, factor 6 contains only low or negative factor loadings. In the five-, four- and three-factor solutions, there are no redundant factors, but there is a high degree of cross- loading. Likewise, in the two- factor solution, items 20 and 21 have higher loadings on factor 2 than factor 1, but both also have high loadings on factor 1. All other items load more highly on factor 1, with again many cross-loadings. Orthogonal rotation did not reveal a more satisfactory factor solution, with a similar pattern emerging of multiple cross- loadings and redundant factors for the higher factor solutions.

Overall, examination of the TRQ data suggests that it is best regarded as a single-factor questionnaire. In the original development paper, the authors note that the scale 'appears to be rather homogenous' (Wilson et al., 1991, p.200). This conclusion is supported by Fackrell et al. (2014) in their evaluation of multiple tinnitus questionnaires.

Confirmatory factor analysis of the one-factor TRQ shows high to very high factor loadings for all items (table 5.26) and a moderate to very high degree of correlation between all items ( $\rho$ = 0.512- 0.924). However, the overall fit of the one-factor model is only mediocre. One possible reason why the fit was not better is that some items correlate too highly with each other. This finding suggests that there is a large degree of conceptual and semantic overlap between items and hence more parameters in the model than there need to be. A smaller number of parameters could result in a lower (better) RMSEA statistic. For example, items 16 and 19, which correlate very highly, are worded "my tinnitus makes me feel helpless" and "my tinnitus has led me to despair", respectively. Items 3 and 9 are also highly correlated and these are worded "my tinnitus has made me feel irritable" and "my tinnitus has made me feel annoyed", respectively. These similar pairs would perhaps be better combined into single items concerning hopelessness and irritability. While the terms are not exactly synonymous, it is hard to conceive of a clinical treatment which would target despair but not helplessness, or irritability but not annoyance, so there is little clinical value in separating out these concepts.

Floor effects can also result in less good fit, and there were 33 individuals who scored 0 on the TRQ (9.6% of the sample). However, the WLSMV estimator performs better for samples with floor or ceiling effects than other estimators (Brown, 2006). To investigate whether floor effects were influencing model fit, the model was retested excluding all participants who scored 0. This resulted in a higher RMSEA (0.098, 90% CI 0.092-0.103), which suggests the absolute fit of the model has not been compromised by floor effects.

# **5.10 The Tinnitus Functional Index (emotional subscale)**

The emotional subscale of the TFI used in this study was labelled the TFI-E. Factor loadings for all three items it contains were high (table 5.28) and it was found to have very high internal consistency;  $\alpha$ =0.946.

Table 5.28: Factor loadings (standard errors) for Tinnitus Functional Index emotional subscale (TFI-E)

TFI-E Item	Factor
	Loading
1. How anxious or worried has your tinnitus	0.946
made you feel?	(0.014)
2. How bothered or upset have you been	0.944
because of your tinnitus?	(0.011)
3. How depressed were you because of your	0.884
tinnitus?	(0.021)

# Chapter 6. Testing the Cognitive Behavioural Model: how do the variables relate to predict tinnitus distress?

# 6.1 Regression analysis

Prior to path analysis of the full model, multiple regression analysis was conducted on the questionnaire data to assess the relative contribution to tinnitus distress of all the predictors in the model. As both the TRQ and the emotional scale of the TFI (TFI-E) were used as measures of tinnitus distress, both were used in turn as separate dependent variables. Two standard multiple regressions were performed with tinnitus distress (first using TRQ score and then using TFI-E score) as the dependent variable and negative thoughts (measured by the TCQ), emotional distress (CORE-OM), avoidance behaviour (TFAS-M), magnitude (TMI), attention and monitoring (TVAQ), and control beliefs (IPQ-M) as the six independent variables. Analysis was performed using IBM SPSS. Assumptions relating to normality, linearity and multicollinearity were assessed prior to analysis and were met.

Using the TRQ as the dependent variable, there was a statistically significant correlation (p<0.05) between it and all independent variables (r = -0.271-r=0.788) and between all independent variables (r = -0.138 - 0.745). Scores on the TCQ, CORE-OM, TFAS-M, TMI and TVAQ were positively correlated with higher TRQ scores, such that high scores on these measures were associated with high scores on the TRQ. Scores on the IPQ-M were negatively correlated with the TRQ.  $R^2$  for the full model was 0.813, indicating that 81% of the variance in tinnitus distress (measured by TRQ) was predicted by scores on the six independent variables in combination.

Using the TFI-E as the dependent variable, there was also a statistically significant correlation (p<0.05) between it and all independent variables (r = -0.246-0.730) and between all independent variables (r = -0.319-0.45) with positive and negative correlations as described above.  $R^2$  for the full model was 0.734, indicating that 73% of the variance in tinnitus distress (measured by the TFI-E) was predicted by scores on the independent variables in combination. Results of both regression analyses are shown in table 6.1.

Table 6.1: results of multiple regression analysis

	Dependent variable = TRQ			Dependent variable = TFI-E		
Indep- endent variable	Zero-order correlation	β (p value)	Semi- partial correlation	Zero-order Correlation	β	Semi- partial correlation
CORE- OM	0.788	0.421 (p<0.001)	0.315	0.726	0.358 (p<0.001)	0.268
TCQ	0.697	0.186 (p<0.001)	0.133	0.668	0.184 (p<0.001)	0.131
TFAS-M	0.666	0.187 (p<0.001)	0.143	0.600	0.102 (p<0.001)	0.077
TMI	0.676	0.162 (p<0.001)	0.103	0.677	0.203 (p<0.001)	0.129
TVAQ	0.734	0.163 (p<0.001)	0.094	0.730	0.221 (p<0.001)	0.128
IPQ-M	-0.271	0.009 (p=0.726)	0.008	-0.246	0.031 0.322	0.028

TRQ=tinnitus reaction questionnaire, TFI-E= tinnitus functional index, emotional subscale, CORE-OM=clinical outcomes in routine evaluation, TCQ=tinnitus cognitions questionnaire, TFAS-M= modified tinnitus fear avoidance scale, TMI= tinnitus magnitude index, TVAQ= tinnitus vigilance and awareness questionnaire, IPQ-M= modified illness perception questionnaire.  $\theta$ = standardised beta estimate.

The standardised beta values demonstrate that the greatest unique contribution to variance in both TRQ and TFI-E scores was made by CORE-OM, a measure of emotional distress. A statistically significant contribution to variance in TRQ and TFI-E scores was made by all the other independent variables except for IPQ-M.

There is some overlap in the content of the CORE-OM and the content of the TRQ and the TFI-E, as all of them focus on the experience of negative emotions. It is therefore not surprising that the CORE-OM explains more of the variance in both TRQ and TFI-E scores than any other measure. The

amount of variance explained by TCQ, TFAS-M, TMI and TVAQ is similar, suggesting that negative thoughts, avoidance behaviour, tinnitus magnitude and selective attention all contribute to tinnitus distress to a similar degree. The fact that none of the variance in tinnitus distress can be explained by control beliefs (measured by the IPQ-M) independently of other factors raises further questions about the relevance of this component of the model.

The correlation between the two measures of tinnitus distress was very high;  $\rho = 0.863$ ; p<0.001. There are some theoretical grounds for using the TRQ as the measure of the main outcome variable (tinnitus distress) rather than the TFI-E subscale. One is that the TRQ was designed for use as complete measure of tinnitus-related distress, while the TFI emotional subscale is part of a larger questionnaire and was not intended for use as a stand-alone measure. Test-retest reliability of the individual subscales of the TFI has been shown to be poor (Fackrell et al., 2016). Moreover, the TRQ has 26 items to the TFI subscale's three. Although some of the TRQ items may be redundant (see section 5.9), it is nevertheless likely to be measuring tinnitus distress in a broader and more comprehensive way.

### 6.2 Path analysis

### 6.2.1 Constructing testable structural models

In order to test the hypotheses contained within the theoretical Cognitive Behavioural Model of Tinnitus Distress (McKenna et al., 2014) it was first necessary to adapt it to fit a structural equation modelling framework. The original, theoretical model is shown in figure 1.4. An issue in interpreting this as a structural equation model is the assumption that all aspects relate to each other in a cyclical way. As such, the theoretical model illustrates a circular process with no distinct beginning or end. However, in structural equation modelling, we are more concerned with what predicts variability on a single outcome variable mapping both direct and indirect influences on this

outcome. Therefore, the model needed to be reconfigured with a single endpoint- an outcome variable- and one or more starting points, or exogenous variables. Exogenous variables are independent and assumed to influence other elements within the model but not be influenced by them.

The theoretical model describes the processes involved in the development and maintenance of tinnitus-related distress, as discussed in section 1.1. Therefore, tinnitus-related distress is the logical outcome variable. Despite the high degree of correlation between the TFI-E and the TRQ discussed in section 6.1, it was decided to test each model constructed first with the TFI-E and then with the TRQ as endpoints. If model results were significantly different depending on which outcome variable were used, this would suggest that the measures of tinnitus-related distress were not equivalent.

The appropriate starting point is less clear. The original, theoretical model 'begins' with tinnitus related neuronal activity and tinnitus detection. These constructs were not measured in the study described here because tinnitusrelated neuronal activity cannot be precisely measured (Baguley et al., 2013) and people had to be able to detect tinnitus in order to take part. These constructs therefore cannot act as exogenous variables. Of the constructs which were measured in the tinnitus survey, each one is assumed in the original model to be influenced by at least one other construct, so none of them are exogenous. However, 'beliefs' could reasonably be considered to be more independent than other variables in the model. Although the original model shows an arrow running from safety behaviours to beliefs, the proposal is that beliefs may be re-enforced by safety behaviours, they are not likely to be caused by them in the same way that, for example, emotional distress may be caused by negative thoughts (Burns, 1999). Psychological theory suggests that beliefs are relatively stable and deep-rooted (Beck et al., 1979) and can therefore logically be seen as the 'driver' for a cognitive and behavioural sequence of events. Beliefs was therefore selected as an exogenous variable.

Nevertheless, my findings raise questions over whether control beliefs, as measured by the IPQ-M, should be included in the structural model at all. The correlation between control beliefs and tinnitus distress was found to be very weak and the IPQ-M was the only measure not to make any independent contribution to tinnitus distress in the regression analysis (see sections 4.4 and 6.1). Nevertheless, beliefs are a component of the original model and a satisfactory factor structure for the IPQ-M was found in this study, so there are no good theoretical or statistical grounds for ignoring them altogether. A decision was made to test versions of the model both with and without control beliefs and to observe whether omission of this construct improves or worsens model fit. Without beliefs as the driver, negative thoughts (measured using the TCQ) become an exogenous variable. In cognitive behavioural therapy, negative thoughts are seen as a trigger for emotional distress and safety behaviour (Beck et al., 1979) and so their position as an independent variable seems logical.

Another potential exogenous variable is tinnitus magnitude, which may be influenced by factors outside the model, such as the nature or extent of damage to the ear. Tinnitus magnitude does not appear in the original, theoretical model; this refers to 'distorted perception' rather than 'magnitude' but, as discussed in section 2.3.6, we cannot measure whether loudness perception is distorted as we cannot measure the actual loudness of tinnitus; we can only measure subjectively how loud people perceive it to be. Nevertheless, in a structural model, placing magnitude in an equivalent position to 'distorted perception' in the original model, with an arrow running from selective attention and monitoring to it, maintains the supposition contained within the idea of 'distorted perception'; that perceived magnitude is chiefly a product of attention. However, the fact that a number of studies (reviewed by Martinez-Devesa et al., 2010) have reported no change in perceived tinnitus loudness even when tinnitus distress has been reduced by therapy indicates that magnitude may to some extent be independent of other components in the model. Placing it in a new position, as an exogenous

variable which influences attention and monitoring, would see magnitude as the 'driver' of the ensuing psychological process. Such a configuration is further removed from the original, theoretical model, but theoretically equally plausible.

Given that there is no strong empirical reason to favour one configuration over the other, it was decided to test two sets of structural models (both of which had tinnitus distress as the outcome variable). The first set broadly followed the configuration of the original, theoretical model, with magnitude being predicted by attention and monitoring. The second set departed further from the configuration of the original, theoretical model, having magnitude as an exogenous variable and attention and monitoring being predicted by magnitude.

### 6.2.2 First set of path models

The six path models in the first set are summarised in table 6.2 and the rationale for each discussed.

Table 6.2: description of models tested in first set

Model	Measure of tinnitus distress	Key features
1A	TFI-E	Exogenous variable is IPQ-M. Includes a path between CORE-OM and TVAQ
1B	TRQ	Exogenous variable is IPQ-M. Includes a path between CORE-OM and TVAQ
2A	TFI-E	Exogenous variable is IPQ-M. Omits path between CORE-OM and TVAQ
2B	TRQ	Exogenous variable is IPQ-M. Omits path between CORE-OM and TVAQ
3A	TFI-E	Exogenous variable is TCQ. Omits IPQ-M.
3B	TRQ	Exogenous variable is TCQ. Omits IPQ-M.

TFI-E= tinnitus function index, emotional subscale. TRQ= tinnitus reaction questionnaire. CORE-OM= clinical outcome sin routine evaluation. IPQ-M= modified illness perception questionnaire. TVAQ= tinnitus vigilance and avoidance questionnaire.

In all the models, subscales were assumed to covary with each other subscale which formed part of the same questionnaire except for the two subscales of

the TCQ, which had previously been shown to be uncorrelated (see section 5.2). All models ending in 'A' use the TFI-E as the measure of tinnitus distress while all models ending in 'B' use the TRQ.

Models 1A and 1B adhered as closely as possible to the Cognitive Behavioural Model of Tinnitus Distress (McKenna et al., 2014), within the confines of structural equation modelling. The exogenous variables in these models are the two subscales of the IPQ-M; personal control beliefs and treatment control beliefs. Models 1A and 1B assume that attention and monitoring (measured by the TVAQ) predict magnitude (measured by the TMI) because the original model predicts that attention and monitoring may cause perception of tinnitus to be distorted (i.e. its apparent magnitude may be affected by the amount of attention which is directed towards it). They also assume that attention and monitoring mediate between general emotional distress and overall tinnitus-related distress. Again, this is an assumption of the original Cognitive Behavioural Model.

Models 2A and 2B differ from models 1A and 1B only in that the path between the CORE-OM and the TVAQ has been omitted. This is because, despite the Cognitive Behavioural Model's prediction, there is no empirical evidence in the literature that emotional distress influences tinnitus distress by means of increasing attention and/ or monitoring. All other assumptions are the same and the two IPQ-M subscales remain the exogenous variables.

Models 3A and 3B differ from models 2A and 2B in that the IPQ-M (IPQF1 and IPQF2) has been omitted altogether. The exogenous variables are the two subscales of the TCQ (TCQF1 and TCQF2.) All the models in the first set are illustrated figures 6.1, 6.2 and 6.3.

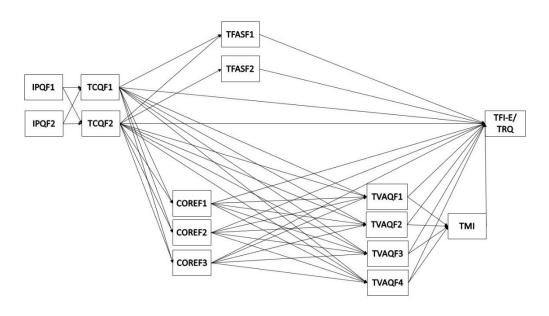


Figure 6.1: models 1A and 1B, showing all paths tested

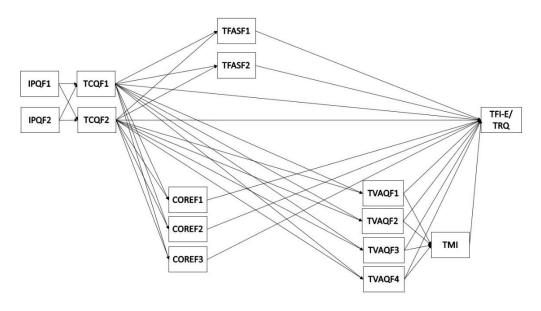


Figure 6.2: models 2A and 2B, showing all paths tested

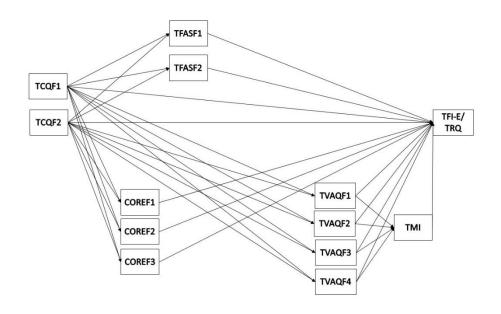


Figure 6.3: models 3A and 3B, showing all paths tested

# 6.2.3 Second set of path models

The six path models in the second set are summarised in table 6.3 and the rationale for each is discussed.

Table 6.3: description of second set of models

Model	Measure of tinnitus distress	Key features
4A	TFI-E	Exogenous variable is TMI
4B	TRQ	Exogenous variable is TMI
5A	TFI-E	Exogenous variables are TMI and IPQ-M
5B	TRQ	Exogenous variables are TMI and IPQ-M
6A	TFI-E	Exogenous variable is TMI. Omits IPQ-M
6B	TRQ	Exogenous variable is TMI. Omits IPQ-M

TFI-E= tinnitus function index, emotional subscale. TRQ= tinnitus reaction questionnaire. TMI=tinnitus magnitude index. IPQ-M= modified illness perception questionnaire.

Models 4A and 4B have TMI (magnitude) as the exogenous variable and a path between TFAS (avoidance behaviour) and IPQ-M (beliefs) for consistency

with the original Cognitive Behavioural Model, which proposes that behaviour influences beliefs. This path had been omitted from models 1A-3B to maintain the IPQ-M's status as an exogenous variable.

An alternative version of the model described above was also tested which removes the path between IPQ-M and TFAS-M (control beliefs and behaviour) as the relationship between beliefs and behaviour has been little investigated in tinnitus research. Currently there is no evidence to suggest that avoiding certain activities or situations influences beliefs about whether tinnitus can be controlled, even though it is theoretically plausible that failed attempts to control tinnitus through avoidance might reinforce beliefs that it is not controllable. Models 5A and 5B are the same as models 4A and 4B except that the path between the IPQ-M (used to measure beliefs) and the TFAS-M (used to measure avoidance behaviour) has been removed. A consequence of this is that both factors of the IPQ-M become exogenous variables along with the TMI.

Models 6A and 6B differ from models 5A and 5B in that the IPQ-M has been omitted altogether. Without the IPQ-M there is only one exogenous variable; the TMI. All models in the second set are illustrated in figures 6.4, 6.5 and 6.6.

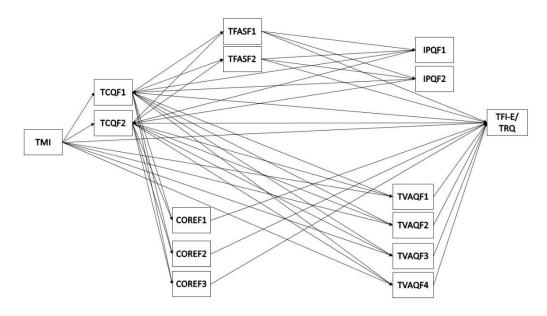


Figure 6.4: models 4A and 4B, showing all paths tested

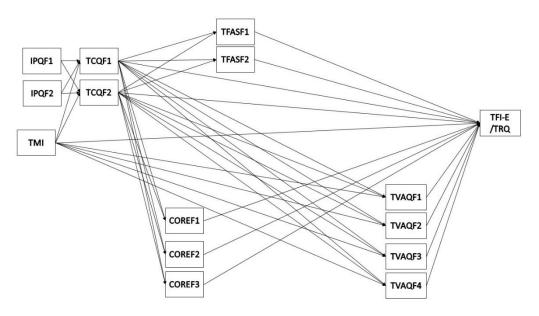


Figure 6.5: models 5A and 5B, showing all paths tested

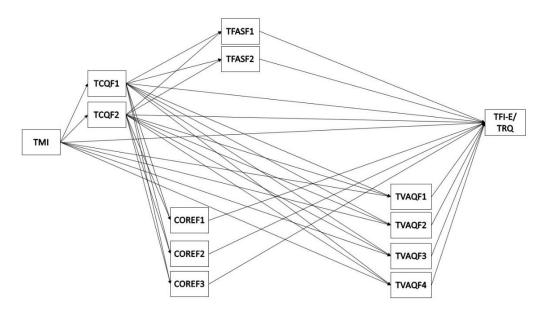


Figure 6.6: models 6A and 6B, showing all paths tested

# 6.3 Results of Path Analysis

### 6.3.1 Fit Indices

A comparison of fit indices for both sets of models is shown in tables 6.4 and 6.5. Those meeting the criteria for an acceptable fit are shown in bold.

Table 6.4: Fit indices for first set of models

Fit	1A	1B	2A	2B	3A	3B
Index						
RMSEA	0.073	0.074	0.070	0.071	0.081	0.081
90% CI	0.058-	0.059-	0.057-	0.057-	0.064-	0.064-
	0.088	0.089	0.084	0.084	0.098	0.098
Chi Sq.	124.548	126.531	149.947	151.924	106.641	106.641
df	44	44	56	56	33	33
Р	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001
CFI	0.981	0.981	0.978	0.978	0.983	0.984
TLI	0.955	0.956	0.959	0.960	0.960	0.962
SRMR*	0.050	0.050	0.053	0.054	0.050	0.050
AIC	8443.989	7426.812	8445.708	7428.531	5779.025	4761.848
BIC	8792.957	7775.780	8748.658	7480.876	6032.123	5014.946

RMSEA=root mean square error of approximation.CI=confidence interval.

CFI=comparative fit index.TLI= Tucker Lewis index. SRMR = standardised root mean square residual. AIC = Akaike's information criterion. BIC = Bayesian information criterion.

Table 6.5: Fit indices for second set of models

Fit	4A	4B	5A	5B	6A	6B
Index						
RMSEA	0.078	0.079	0.076	0.077	0.072	0.072
90% CI	0.064-	0.065-	0.063-	0.064-	0.055-	0.055-
	0.092	0.093	0.090	0.091	0.090	0.090
Chi Sq.	154.393	156.518	161.491	163.738	89.198	89.198
df	50	50	54	54	32	32
р	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001
CFI	0.976	0.977	0.975	0.975	0.986	0.987
TLI	0.950	0.951	0.952	0.953	0.967	0.968
SRMR	0.073	0.074	0.086	0.087	0.046	0.046
AIC	6886.424	5869.247	6885.099	5867.922	5695.180	4678.003
BIC	7204.713	6187.536	7188.049	6170.872	5963.617	4946.384

RMSEA=root mean square error of approximation.Cl=confidence interval.

CFI=comparative fit index.TLI= Tucker Lewis index. SRMR = standardised root mean square residual. AIC = Akaike's information criterion. BIC = Bayesian information criterion.

### 6.3.2 Selecting models for further evaluation

Differences in fit indices between A and B versions of all the models were minimal. Considering this, a decision was made to retain only one version of each model for further analysis. For the reasons given in the section on regression analysis above, the B versions of all models, in which tinnitus distress is measured by the TRQ, were retained for further evaluation.

The differences in fit indices between all models tested were small. There is notably little difference between models belonging to the first and second set, therefore structural models which are close to and further away from the theoretical model are equally well supported by the data. Statistics for model 3B just exceeded the values required for an acceptable fit, therefore this model was rejected. Models 1B, 2B, 4B, 5B and 6B all had acceptable fit criteria. Considering the first set of models, 2B is a slightly better fit than model 1B and is more parsimonious as there is no path between CORE-OM

and TVAQ. Where there is little difference between fit indices, more parsimonious models are preferred to more complex ones (Byrne, 2012). There are no empirical grounds for maintaining this path even though it appears in the original theoretical model. Additionally, a chi-square difference test showed the difference between models 1B and 2B to be statistically significant (TRd=32.555, df=2, p<0.001), with 2B being a better fit. Considering the second set, 5B is a slightly better fit than 4B and again there are no empirical grounds for maintaining the path between behaviour and control beliefs. Therefore, the more complex model 4B was also excluded from further analysis, even though the difference between models was not shown to be statistically significant (TRd=6.885, df=4, p=0.142). Model 6B (IPQ-M excluded and the TMI as the exogenous variable) was a better fit than model 5B (which had two exogenous variables; TMI and IPQ-M). Nevertheless, the differences in fit statistics were not large enough to provide a clear case for excluding a variable. Therefore, models 2B, 5B and 6B were all retained for further analysis.

### 6.3.3 Modifications

The modification indices for models 2B, 5B and 6B were examined. Any modifications which involved simply reversing the direction of a path between one variable and another were not considered for testing. Modifications which involved changing the status of either the exogenous or the end variable were also rejected. For all models, the only modifications that were theoretically plausible were the addition of a path from COREF1 (negative emotions) and TFASF1 (tinnitus-related avoidance) and the addition of a path from TMI (perceived magnitude) to TFASF1 (tinnitus-related avoidance). Although these connections have not been investigated in tinnitus research, it is plausible that a negative emotional state increases the likelihood of avoiding certain situations and that louder tinnitus also leads to avoidance; particularly as some of the situations to be avoided involve noise exposure and people may worry about noise making their tinnitus even louder

(Erlandsson, 2008). The models were re-tested with the addition of a path from COREF1 to TFASF1 first (the new models were named 2.1B, 5.1B and 6.1B) and then with the addition of both this path and another from TMI to TFASF1. These models were named 2.2B, 5.2B and 6.2B.

Addition of the new parameters slightly improved the fit of all the models tested (table 6.6). Chi-square difference testing confirmed that these differences were statistically significant. Between models 2B and 2.1B, TRd=14.057, df=1, p<0.001. Between models 2.1B and 2.2B, TRd=12.318, df=1, p<0.001. Between models 5B and 5.1B, TRd=17.356, df=1, p<0.001. Between models 5.1B and 5.2B, TRd=11.439, df=1, p=0.001. Between models 6B and 6.1B, TRd=17.589, df=1, p<0.001. Between models 6.1B and 6.2B, TRd=11.649, df=1, p=0.001. As the models which included both modifications fit better than those which included only one, these (models 2.2B, 5.2B and 6.2B) were retained for further examination.

Table 6.6: Fit indices for models including modifications

Fit	2.1B	2.2B	5.1B	5.2B	6.1B	6.2B
Index						
RMSEA	0.066	0.061	0.073	0.068	0.064	0.055
90% CI	0.052-	0.047-	0.059-	0.054-	0.045-	0.035-
	0.080	0.076	0.087	0.083	0.082	0.075
Chi Sq	136.765	123.507	148.475	135.438	74.021	60.902
df	55	54	53	52	31	30
р	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001
CFI	0.982	0.984	0.978	0.981	0.990	0.993
TLI	0.965	0.970	0.958	0.963	0.975	0.982
SRMR	0.050	0.049	0.084	0.083	0.040	0.038
AIC	7415.206	7403.226	5854.597	5842.616	4664.678	4652.698
BIC	7721.991	7713.845	6161.382	6153.236	4936.950	4928.804

RMSEA=root mean square error of approximation.CI=confidence interval.

CFI=comparative fit index.TLI= Tucker Lewis index. SRMR = standardised root mean square residual. AIC = Akaike's information criterion. BIC = Bayesian information criterion.

Standardised parameter estimates (with standard errors) for all three retained models are shown in tables 6.7, 6.8 and 6.9.

Table 6.7: standardised parameter estimates for model 2.2B

Outcome	Predictors	Beta	Standard	Р
(R <sup>2</sup> )		Estimate	Error	value
TRQ on	TMI	0.137	0.033	<0.001
(R <sup>2</sup> =0.853)	TFASF1	0.170	0.038	<0.001
	TFASF2	-0.041	0.031	0.186
	TCQF1	0.396	0.050	<0.001
	TCQF2	-0.012	0.024	0.620
	COREF1	0.296	0.073	<0.001
	COREF2	-0.007	0.045	0.875
	COREF3	0.004	0.081	0.960
	TVAQF1	-0.028	0.035	0.426
	TVAQF2	0.010	0.071	0.892
	TVAQF3	0.106	0.037	0.004
	TVAQF4	0.071	0.050	0.152
TCQF1 on	IPQF1	-0.270	0.068	<0.001
$(R^2=0.098)$	IPQF2	-0.067	0.063	0.286
TCQF2 on	IPQF1	-0.137	0.083	0.099
$(R^2=0.025)$	IPQF2	-0.032	0.070	0.644
TFASF1 on	TCQF1	0.354	0.050	<0.001
(R <sup>2</sup> =0.359)	TCQF2	0.004	0.040	0.923
	COREF1	0.164	0.040	<0.001
	TMI	0.173	0.042	<0.001
TFASF2 on	TCQF1	0.448	0.040	<0.001
(R <sup>2</sup> =0.201)	TCQF2	-0.056	0.045	0.215
COREF1 on	TCQF1	0.633	0.035	<0.001
(R <sup>2</sup> =0.423)	TCQF2	0.122	0.048	0.011
COREF2 on	TCQF1	0.556	0.039	<0.001
(R <sup>2</sup> =0.376)	TCQF2	0.233	0.049	<0.001
COREF3 on	TCQF1	0.596	0.037	<0.001
(R <sup>2</sup> =0.386)	TCQF2	0.147	0.050	0.003
TVAQF1 on	TCQF1	0.520	0.045	<0.001
(R <sup>2</sup> =0.271)	TCQF2	-0.057	0.045	0.203
TVAQF2 on	TCQF1	0.842	0.015	<0.001
(R <sup>2</sup> =0.716)	TCQF2	0.051	0.032	0.107
TVAQF3 on	TCQF1	0.618	0.035	<0.001
(R <sup>2</sup> =381)	TCQF2	-0.007	0.040	0.870
TVAQF4 on	TCQF1	0.788	0.022	<0.001
(R <sup>2</sup> =0.628)	TCQF2	0.056	0.040	0.159
TMI on	TVAQF1	0.143	0.055	0.009
(R <sup>2</sup> =0.612)	TVAQF2	0.790	0.124	<0.001
	TVAQF3	-0.238	0.051	<0.001
	TVAQF4	0.062	0.104	0.549

Table 6.8: standardised parameter estimates for model 5.2B

Outcome	Predictors	Beta	Standard	P value
(R <sup>2</sup> )		Estimate	Error	
TRQ on	TMI	0.138	0.033	<0.001
(R <sup>2</sup> =0.850)	TFASF1	0.171	0.038	<0.001
	TFASF2	-0.042	0.032	0.187
	TCQF1	0.393	0.051	<0.001
	TCQF2	-0.012	0.024	0.616
	COREF1	0.294	0.073	<0.001
	COREF2	-0.007	0.044	0.875
	COREF3	0.004	0.081	0.960
	TVAQF1	-0.028	0.036	0.427
	TVAQF2	0.010	0.067	0.887
	TVAQF3	0.107	0.038	0.004
	TVAQF4	0.071	0.049	0.151
TVAQF1 on	TMI	0.249	0.057	<0.001
$(R^2=0.301)$	TCQF1	0.338	0.062	<0.001
	TCQF2	-0.055	0.044	0.215
TVAQF2 on	TMI	0.347	0.037	<0.001
$(R^2=0.765)$	TCQF1	0.601	0.035	< 0.001
	TCQF2	0.056	0.029	0.050
TVAQF3 on	TMI	0.045	0.055	0.408
(R <sup>2</sup> =0.374)	TCQF1	0.579	0.054	<0.001
	TCQF2	-0.006	0.040	0.876
TVAQF4 on	TMI	0.308	0.045	< 0.001
$(R^2=0.662)$	TCQF1	0.573	0.045	<0.001
	TCQF2	0.061	0.038	0.113
TCQF1 on	TMI	0.694	0.030	< 0.001
$(R^2=0.488)$	IPQF1	-0.060	0.044	0.169
	IPQF2	-0.027	0.045	0.543
TCQF2 on	TMI	-0.121	0.061	0.047
$(R^2=0.054)$	IPQF1	-0.173	0.083	0.037
	IPQF2	-0.039	0.069	0.571
TFASF1 on	TCQF1	0.349	0.055	<0.001
$(R^2=0.355)$	TCQF2	0.004	0.043	0.926
	COREF1	0.161	0.039	<0.001
	TMI	0.173	0.049	<0.001
TFASF2 on	TCQF1	0.440	0.041	<0.001
$(R^2=2.00)$	TCQF2	-0.056	0.046	0.217
COREF1 on	TCQF1	0.632	0.038	<0.001
(R <sup>2</sup> =0.404)	TCQF2	0.125	0.048	0.009
COREF2 on	TCQF1	0.557	0.041	<0.001
(R <sup>2</sup> =0.349)	TCQF2	0.240	0.050	<0.001
COREF3 on	TCQF1	0.595	0.040	<0.001
(R <sup>2</sup> =0.365)	TCQF2	0.151	0.050	0.002

Table 6.9: standardised parameter estimates for model 6.2B

Outcome	Predictors	Beta	Standard	Р
(R <sup>2</sup> )		Estimate	Error	value
TRQ	TMI	0.136	0.034	<0.001
$(R^2=0.855)$	TFASF1	0.170	0.038	<0.001
	TFASF2	-0.041	0.031	0.191
	TCQF1	0.395	0.052	<0.001
	TCQF2	-0.012	0.024	0.620
	COREF1	0.293	0.074	<0.001
	COREF2	-0.007	0.044	0.876
	COREF3	0.004	0.082	0.961
	TVAQF1	-0.028	0.035	0.416
	TVAQF2	0.010	0.067	0.887
	TVAQF3	0.106	0.037	0.005
	TVAQF4	0.071	0.049	0.153
TVAQF1 on	TMI	0.248	0.059	<0.001
$(R^2=0.306)$	TCQF1	0.343	0.063	<0.001
	TCQF2	-0.054	0.044	0.212
TVAQF2 on	TMI	0.342	0.038	<0.001
$(R^2=0.772)$	TCQF1	0.604	0.035	<0.001
	TCQF2	0.055	0.028	0.051
TVAQF3 on	TMI	0.045	0.057	0.433
$(R^2=0.383)$	TCQF1	0.586	0.055	<0.001
	TCQF2	-0.006	0.039	0.876
TVAQF4 on	TMI	0.304	0.046	<0.001
$(R^2=0.671)$	TCQF1	0.576	0.045	<0.001
	TCQF2	0.059	0.037	0.113
TCQF1 on	TMI	0.708	0.029	<0.001
$(R^2=0.501)$				
TCQF2 on	TMI	-0.053	0.063	0.403
$(R^2=0.003)$				
TFASF1 on	TCQF1	0.353	0.056	<0.001
$(R^2=0.363)$	TCQF2	0.004	0.042	0.926
	COREF1	0.162	0.040	<0.001
	TMI	0.172	0.051	0.001
TFASF2 on	TCQF1	0.447	0.041	<0.001
$(R^2=0.204)$	TCQF2	-0.056	0.046	0.222
COREF1 on	TCQF1	0.637	0.037	<0.001
$(R^2 = 0.415)$	TCQF2	0.123	0.048	0.011
COREF2 on	TCQF1	0.562	0.041	<0.001
(R <sup>2</sup> =0.361)	TCQF2	0.235	0.049	<0.001
COREF3 on	TCQF1	0.601	0.040	<0.001
$(R^2=0.377)$	TCQF2	0.149	0.050	0.003

### **6.3.4** Direct and indirect effects

Further investigation of models 2.2B, 5.2B and 6.2B was carried out to identify which variables (if any) act as mediators between the exogenous and the outcome variable. To do this, direct and indirect effects were examined. A statistically significant direct effect with a statistically non-significant indirect effect indicates that there are no mediators between the exogenous and the outcome variable. A statistically non-significant direct effect with a statistically significant indirect effect indicates that the relationship between the exogenous and the outcome variable is fully mediated by one or more other variables and would not exist without them. A statistically significant direct and indirect effect indicate that the relationship is partially mediated by other variables, but it continues to exist without them (Sobel, 1987).

In model 2.2B, no direct path between the exogenous variables (IPQF1 and IPQF2) and the outcome variable (TRQ) is specified, therefore only indirect effects were tested. The overall indirect effect was statistically significant; estimate = -0.238 (SE = 0.058), p<0.001. This indicates that there is a mediated relationship between control beliefs and tinnitus distress.

Statistically significant mediators were negative thoughts (TCQF1); negative thoughts and tinnitus avoidance behaviour (TCQF1 and TFASF1); negative thoughts and negative emotions (TCQF1 and COREF1); negative thoughts and monitoring (TCQF1 and TVAQF3); negative thoughts, negative emotions, and avoidance (TCF1, COREF1 and TFASF1); negative thoughts, preoccupation, and magnitude (TCQF1, TVAQF2 and TMI); and negative thoughts, monitoring and magnitude (TCQF1, TVAQF3 and TMI). There were no statistically significant indirect effects between the second exogenous variable (treatment control beliefs; IPQF2) and tinnitus distress. A diagram showing all statistically significant mediators in model 2.2B is shown in figure 6.7. Estimates for all direct and indirect effects are shown in table 6.10.

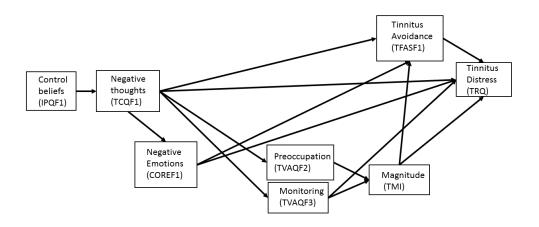


Figure 6.7:Statistically significant mediators in model 2.2B

Table 6.10: indirect effects in model 2.2B. Statistically significant mediators are shown in bold.

Model 2.2B effects between IPQF1 &TRQ				2.2B effects between IPQF2 & TRQ		
Mediator(s)	Estimate	SE	р	Estimate	SE	р
TCQF1	-0.107	0.031	0.001	-0.027	0.025	0.290
TCQF2	0.002	0.003	0.636	0.000	0.001	0.712
TCQF1/TFASF1	-0.016	0.005	0.003	-0.004	0.004	0.312
TCQF2/TFASF1	0.000	0.001	0.923	0.000	0.000	0.925
TCQF1/TFASF2	0.005	0.004	0.207	0.001	0.002	0.415
TCQF2/TFASF2	0.000	0.000	0.442	0.000	0.000	0.690
TCQF1/COREF1	-0.050	0.017	0.004	-0.013	0.012	0.305
TCQF2/COREF1	-0.005	0.004	0.229	-0.001	0.002	0.643
TCQF1/COREF2	0.001	0.007	0.875	0.000	0.002	0.877
TCQF2/COREF2	0.000	0.001	0.875	0.000	0.000	0.881
TCQF1/COREF3	-0.001	0.013	0.960	0.000	0.003	0.960
TCQF2/COREF3	0.000	0.002	0.960	0.000	0.000	0.961
TCQF1/TVAQF1	0.004	0.005	0.432	0.001	0.002	0.533
TCQF2/TVAQF1	0.000	0.000	0.550	0.000	0.000	0.681
TCQF1/TVAQF2	-0.002	0.016	0.892	-0.001	0.005	0.892
TCQF2/TVAQF2	0.000	0.000	0.892	0.000	0.000	0.895
TCQF1/TVAQF3	-0.018	0.007	0.013	-0.004	0.004	0.328
TCQF2/TVAQF3	0.000	0.001	0.871	0.000	0.000	0.879
TCQF1/TVAQF4	-0.015	0.011	0.166	-0.004	0.005	0.405
TCQF2/TVAQF4	-0.001	0.001	0.424	0.000	0.000	0.662
TCQF1/COREF1/ TFASF1	-0.005	0.002	0.020	-0.001	0.001	0.327

TCQF2/COREF1/ TFASF1	0.000	0.000	0.234	0.000	0.000	0.652
TCQF1/TVAQF1/TMI	-0.003	0.001	0.053	-0.001	0.001	0.349
TCQF2/TVAQF1/TMI	0.000	0.000	0.376	0.000	0.000	0.663
TCQF1/TVAQF2/TMI	-0.025	0.010	0.010	-0.006	0.006	0.306
TCQF2/TVAQF2/TMI	-0.001	0.001	0.288	0.000	0.000	0.658
TCQF1/TVAQF3/TMI	0.005	0.002	0.018	0.001	0.001	0.308
TCQF2/TVAQF3/TMI	0.000	0.000	0.870	0.000	0.000	0.879
TCQF1/TVAQF4/TMI	-0.002	0.003	0.556	0.000	0.001	0.610
TCQF2/TVAQF4/TMI	0.000	0.000	0.607	0.000	0.000	0.716
TCQF1/TVAQF1/TMI/ TFASF1	-0.001	0.000	0.064	0.000	0.000	0.367
TCQF2/TVAQF1/TMI/ TFASF1	0.000	0.000	0.386	0.000	0.000	0.659
TCQF1/TVAQF2/TMI/ TFASF1	-0.005	0.002	0.018	-0.001	0.001	0.328
TCQF2/TVAQF2/TMI/ TFASF1	0.000	0.000	0.295	0.000	0.000	0.652
TCQF1/TVAQF3/TMI/	0.001	0.001	0.031	0.000	0.000	0.331
TFASF1						
TCQF2/TVAQF3/TMI/	0.000	0.000	0.871	0.000	0.000	0.879
TFASF1						
TCQF1/TVAQF4/TMI/ TFASF1	0.000	0.001	0.562	0.000	0.000	0.617
TCQF2/TVAQF4/TMI/ TFASF1	0.000	0.000	0.610	0.000	0.000	0.713

Because model 5.2B has three exogenous variables, three indirect paths were tested; i) from TMI to TRQ, ii) from IPQF1 to TRQ and iii) from IPQF2 to TRQ.

The direct and indirect effects from TMI to TRQ were both statistically significant. Total direct effect = 0.246 (SE = 0.013), p<0.001, total indirect effect = 0.197 (SE = 0.015), p<0.001. This indicates that the path between perceived magnitude and tinnitus distress is partially mediated by other factors. No direct path between IPQ-M and TRQ was specified. Neither the total indirect effect from IPQF1 to TRQ nor from IPQF2 to TRQ was statistically significant. From IPQF1, total effect = -0.056 (SE = 0.037), p=0.130. From

IPQF2, total effect = -0.034 (SE=0.053), p=0.516. This indicates that there is no mediated path between control beliefs and tinnitus distress.

In model 6.2B, the direct and indirect effects from TMI to TRQ were both statistically significant. Total direct effect = 0.708 (SE = 0.026), p<0.001, total indirect effect = 0.572 (SE = 0.034), p<0.001. Statistically significant mediators were tinnitus-related avoidance (TFASF1); negative thoughts (TCQF1); negative thoughts and tinnitus avoidance (TCQF1 and TFASF1); negative thoughts and negative emotions (TCQF1 and COREF1); negative thoughts and monitoring (TCQF1 and TVAQF3); and negative thoughts, negative emotions and tinnitus avoidance (TCQF1, COREF1 and TFASF1).

The lack of any mediated path between control beliefs (IPQ-M) and tinnitus distress and the lack of any significant regression path between control beliefs and negative thoughts (TCQ) calls into question the role of control beliefs in this configuration of the model. Given that the data fit model 6.2B (from which IPQ-M is omitted) somewhat better than model 5.2B and that model 6.2B is theoretically simpler, the latter model is to be preferred. A diagram showing all statistically significant mediators in model 6.2B is shown in figure 6.8. Estimates for all direct and indirect effects are shown in table 6.11.

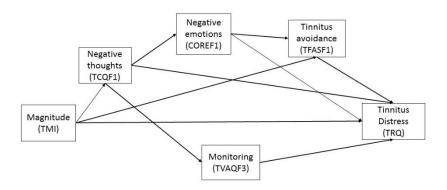


Figure 6.8: Statistically significant mediators in model 6.2B

Table 6.11: indirect effects for model 6.2B. Statistically significant mediators are shown in bold.

	Estimate	SE	р
TFASF1	0.029	0.011	0.006
TCQF1	0.279	0.039	<0.001
TCQF2	0.001	0.002	0.682
TVAQF1	-0.007	0.009	0.423
TVAQF2	0.003	0.023	0.887
TVAQF3	0.005	0.006	0.449
TVAQF4	0.021	0.015	0.158
TCQF1/TFASF1	0.042	0.012	<0.001
TCQF2/TFASF1	0.000	0.000	0.926
TCQF1/TFASF2	-0.013	0.010	0.193
TCQF2/TFASF2	0.000	0.000	0.534
TCQF1/ COREF1	0.132	0.035	<0.001
TCQF2/COREF1	-0.002	0.002	0.422
TCQF1/COREF2	-0.003	0.018	0.876
TCQF2/COREF2	0.000	0.001	0.874
TCQF1/COREF3	0.002	0.035	0.961
TCQF2/COREF3	0.000	0.001	0.961
TCQF1/TVAQF1	-0.007	0.009	0.426
TCQF2/TVAQF1	0.000	0.000	0.606
TCQF1/TVAQF2	0.004	0.029	0.887
TCQF2/TVAQF2	0.000	0.000	0.889
TCQF1/TVAQF3	0.044	0.016	0.007
TCQF2/TVAQF3	0.000	0.000	0.880
TCQF1/TVAQF4	0.029	0.020	0.157
25TCQF2/TVAQF4	0.000	0.000	0.488
TCQF1/COREF1/TFASF1	0.012	0.005	0.007
TCQF2/COREF1/TFASF1	0.000	0.000	0.440

TRQ=tinnitus reaction questionnaire, CORE-OM=clinical outcomes in routine evaluation, TCQ=tinnitus cognitions questionnaire, TFAS-M= modified tinnitus fear avoidance scale, TMI= tinnitus magnitude index, TVAQ= tinnitus vigilance and awareness questionnaire, IPQ-M= modified illness perception questionnaire. F= factor.

# 6.4 Comparison of models 2.2B and 6.2B

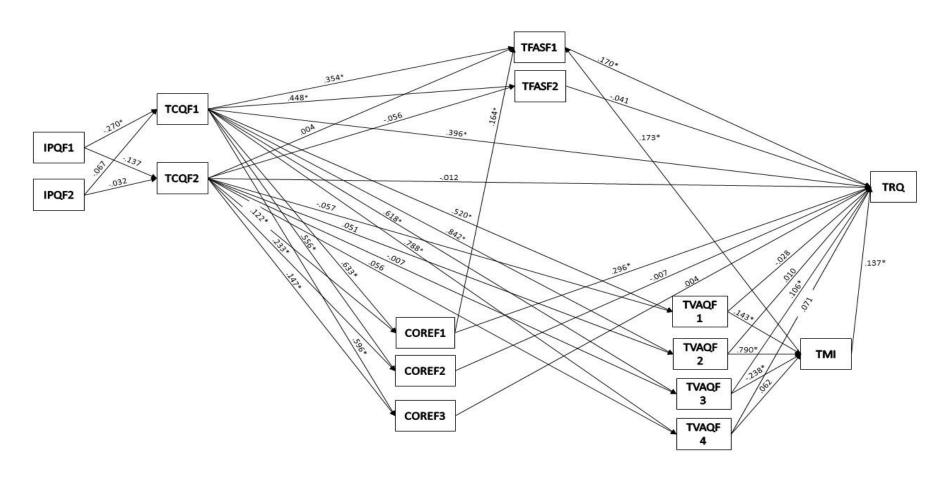
For ease of reference, fit indices for the two models retained (models 2.2B and 6.2B) are shown again in table 6.12. Diagrams of each model showing standardised estimates are shown in figures 6.9 and 6.10.

Table 6.12: fit indices for models 2.2B and 6.2B

Fit Index	2.2B	6.2B
RMSEA	0.061	0.055
90% CI	0.047-	0.035-
	0.076	0.075
Chi Sq	123.507	60.902
df	54	30
р	<0.001	<0.001
CFI	0.984	0.993
TLI	0.970	0.982
SRMR	0.049	0.038
AIC	7403.226	4652.698
BIC	7713.845	4928.804

RMSEA=root mean square error of approximation.CI=confidence interval.

CFI=comparative fit index.TLI= Tucker Lewis index. SRMR = standardised root mean square residual. AIC = Akaike's information criterion. BIC = Bayesian information criterion.



 $\textit{Figure 6.9: Model 2.2B showing all standardised estimates. Statistically significant paths are \textit{marked with *}.}$ 

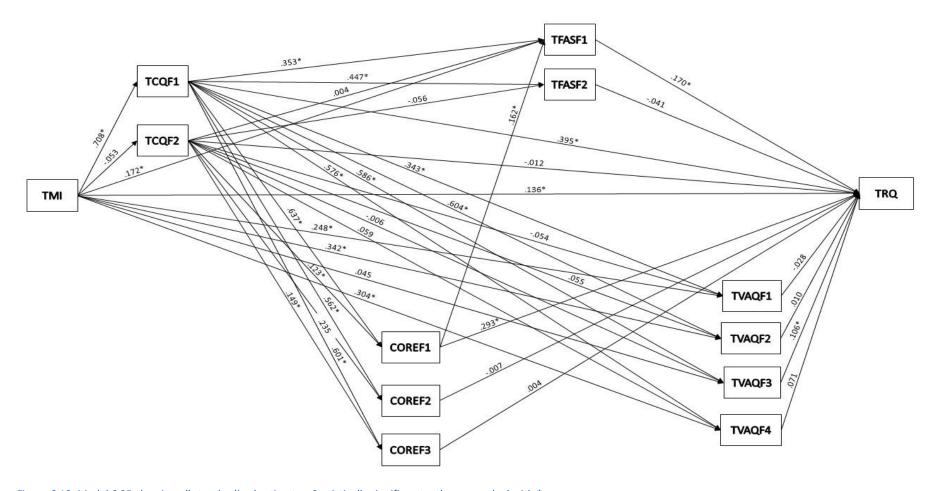


Figure 6.10: Model 6.2B showing all standardised estimates. Statistically significant paths are marked with \*

In conclusion, questionnaire data obtained from people with tinnitus provided empirical support for different configurations of a Cognitive Behavioural Model of Tinnitus Distress. In both of the best-fitting configurations, the comparative fit indices (CFI and TLI) indicate a good fit compared to a null model and in both the RMSEA indicates an acceptable fit compared to a perfect model, which approaches the threshold for a good fit. While the fit of model 6.2B is slightly better across all indices than that of model 2.2B, the differences are not large enough to favour model 6.2B on statistical grounds. Theoretical arguments in support of both models will be returned to in chapter 8.

# Chapter 7. Qualitative investigation of patients' and therapists' perceptions of the Cognitive Behavioural Model of Tinnitus Distress

# 7.1 Background and Aims

A guiding principal of CBT is its transparency. Therapists are trained to be open about the methods they use and to discuss these with their patients in therapeutic partnerships (Burns, 1999). More specifically, they are encouraged to talk through with patients theoretical models on which therapeutic intervention is based. Padesky and Mooney (1990) for example, describe how their five-areas model (see section 1.1) can be explained to clients early on in therapy to help them better understand their difficulty and how psychological therapy can help them with it.

In a similar way, it may be useful to explain the Cognitive Behavioural Model of Tinnitus Distress early on in tinnitus therapy, so that patients can understand the psychological processes that influence their experience of tinnitus. This is likely to be an important first step in learning how to alter these processes. A number of researchers (Myers et al., 2014, Kroner-Herwig et al., 2003) list information or education about tinnitus as a key component of an initial tinnitus therapy session, although it is not always clear whether this involves explanation of a tinnitus model. Explaining the neurophysiological model of tinnitus to patients is stipulated as a fundamental part of Tinnitus Retraining Therapy (Jastreboff and Hazell, 2004). In their paper comparing different approaches to tinnitus therapy, Cima et al. (2012) also state that they explain specific models of tinnitus to patients at the start

of treatment. In this case, the models are the neurophysiological and fear avoidance models.

The Cognitive Behavioural Model of Tinnitus Distress is routinely explained to participants who attend mindfulness-based CBT groups for tinnitus (McKenna et al., 2017b). However, while it is often used in the training of clinicians who wish to work with tinnitus patients, my impression from talking to colleagues is that clinicians rarely share it with patients. The aim of this qualitative study was to find out how patients respond to the model when it is explained to them; especially whether they find it easy to understand and whether they feel they relate to it. The second aim was to explore the views of tinnitus therapists who are familiar with the model but may not necessarily use it in their clinics.

#### 7.2 Methods

The qualitative study had two parts. The first involved a series of interviews with tinnitus patients. Ethical approval was granted by South Central-Hampshire B Research Ethics committee; ref 16/SC/0243. The second involved a focus group with tinnitus therapists. I acted as the interviewer and the focus group facilitator. I am a hearing therapist with many years' experience of working one-to-one with tinnitus patients and have also spent several years studying the Cognitive Behavioural Model of Tinnitus Distress as part of this PhD project.

#### 7.2.1 Participants: interviews

Interviewees were all patients who were attending or had recently attended the Mindfulness-based Cognitive Behavioural Therapy for Tinnitus course at the Royal National Throat Nose and Ear Hospital (RNTNE) in London. This 8 week course is run by the clinical psychology team and involves weekly sessions lasting 2 hours each in which group members learn mindful meditation and discuss how to use this to live better with tinnitus. Patients

can be referred to the group by a psychologist, ENT doctor, hearing therapist or audiologist. In order to participate, they must have had tinnitus for at least three months, but many have had it a great deal longer. They must also have sufficient hearing and English language ability to be able to participate in group discussions and be willing to commit to attending at least 6 sessions. Most group members have had at least one individual tinnitus therapy appointment with a hearing therapist or psychologist prior to attending, although this is not a requirement. There are 6-14 members in each group and a new course starts about every two months. During week 4, one of the psychologists running the group shows a diagram of the Cognitive-Behavioural Model of Tinnitus Distress on a screen (see fig 1.4) and talks through its meaning. The model is presented as an explanation of how tinnitus becomes a problem, with the arrows indicating how one thing leads to another (for example, "the more distressed you feel, the more attention you pay to your tinnitus"). Members are invited to ask questions about it if they wish. A printed copy of the diagram and other course materials are given to them to keep.

I attended one of these 8- week courses myself and took part in all exercises. I invited other members of that group to attend an interview with me if they wished and handed out participant information sheets. I also visited two other groups on week 4, told them about this study and handed out participant information sheets. Anyone interested in participating could contact me using the details on the sheet. Group leaders were asked to mention the study to members during other sessions and they also had a supply of information sheets to hand out. Participants were offered a £30 gift voucher as an incentive for taking part.

In all, 11 participants were recruited from four of the mindfulness groups. Everyone who volunteered was accepted for interview. Demographic

information such as age and occupation was obtained during interviews, but any missing details were supplied afterwards by one of the clinical psychologists who led the groups. Early in each interview, participants were asked to rate their tinnitus on the problem scale described in section 3.3.3. Participant details are shown in table 7.1. All names are pseudonyms. Julie and Jay were members of the same mindfulness group as me while other interviewees had met me only briefly, when I came to talk about the study in week 4 of their course.

Table 7.1: participants in interview study

	Pseudonym	Age	Occupation	Tinnitus duration	Tinnitus problem rating
1	Graham	70	Retired engineer	Approx. 10 months	Moderate
2	Julie	63	Retired business manager	5 years	Small- moderate
3	Jay	58	Teaching assistant	4 years	moderate
4	Emma	29	Hospital administrator	20 years	Big
5	Jessica	52	Communications manager	Approx 14 months	small
6	Frank	66	Retired engineer	Approx 14 months	Big
7	Pat	66	Retired	Since childhood	Very big
8	Suzannah	52	Teacher	3.5 years	varies
9	Bridget	53	Business development consultant	2 years	Big
10	Rachel	57	Telesales worker	6.5yrs	Very big
11	Mick	36	Unemployed	1.5 years	Very big

#### 7.2.2 Procedure: interviews

Participants either approached me at the end of the group meeting or contacted me by telephone or email if they were interested in taking part. In most cases, interviews were arranged to take place either immediately before or immediately after the group session, so there was no need for participants to make extra journeys. All interviews took place in a room at the Ear Institute, University College, London, which is my usual place of work. This building is next door to the RNTNE Hospital. Interviews lasted between 30 and 45 minutes. A consent form was filled in by each participant just before the start of the interview and at this stage participants were invited to ask any questions they had about the study. All participants attended by themselves.

Interviews started with some general questions about the interviewees' experience of tinnitus and they were asked to rate their tinnitus on the problem scale. A diagram of the Cognitive Behavioural Model of Tinnitus Distress was then placed on a table in front of the interviewee so they could refer to it. The same interview schedule was used for each participant (appendix 3). All participants were asked to talk through the model in their own words while looking at the diagram. They were then asked questions about how much they felt it applied to them, whether they could relate to certain parts of it particularly, whether aspects of their experience of tinnitus were missing from the model, whether it was easy or difficult to understand and whether they felt it was helpful for people with tinnitus to know about it. I deviated from the schedule where appropriate to explore ideas and opinions as they came up. However, the main topics from the schedule were covered with all participants.

#### 7.2.3 Participants: focus group

Participants in the focus group were six trained tinnitus therapists with at least 10 years' experience of seeing tinnitus patients within an NHS audiology and hearing therapy service. All of them were currently actively involved in delivering tinnitus therapy. All group participants knew each other and all of them had known me for several years. They had all seen the Cognitive Behavioural Model of Tinnitus Distress before, either in a journal article or on a training course, or both. They were not offered any remuneration but were given lunch after the group.

#### 7.2.4 Procedure: focus group

The group took place in a room at UCL Ear Institute with all participants sitting round a table. A diagram of the Cognitive Behavioural Model of Tinnitus Distress was displayed on a screen at one end of the room throughout the discussion. I posed questions to the group about their interpretation of the model, how much they felt it applies to their patients and whether it informs the therapy they offer in any way. The focus group schedule was devised after having conducted the individual interviews and addressed some of the same topic areas; in particular ease or difficulty understanding the model and whether it reflects people's experience with tinnitus. Group participants were also invited to talk about whether they ever show the model to patients and their reasons for doing so, or not doing so. The schedule can be found in appendix 4. The group discussion lasted just over one hour.

#### 7.2.5 Data recording and analysis

Both the interviews and the focus group were audio recorded using a digital audio recorder. Recordings were checked for clarity and completeness and then transferred securely to a professional transcription company where they

were transcribed verbatim. All transcripts were checked against the audio files.

Transcripts were analysed using thematic analysis (Braun and Clarke, 2006). Because the research set out to find answers to specific questions, a theoretical or 'top down' approach was taken and only material which was related in some way to the Cognitive Behavioural Model of Tinnitus Distress was coded. Two broad themes were identified in advance for the interview study ('understanding the model' and 'relating to it personally'). Pre-identified broad themes for the focus group discussion considered whether the model was applicable to most tinnitus patients and its clinical usefulness. Further themes and sub-themes were derived from the data. Transcripts were coded using Nvivo software version 11 (QSR International) and a coding manual was created which included a description of all themes and subthemes and example quotations. All transcripts were then examined by a second coder using the coding manual.

#### 7.3 Results and Discussion

#### 7.3.1 Overview of themes

A large amount of data gathered in the interview study was found to relate to the two broad pre-defined themes. These were 'ease or difficulty understanding the model' and 'how well the model reflects personal experience with tinnitus'. Broadly, the first of these themes concerned whether the model makes sense, regardless of whether one agrees with its ideas or not. The second concerned whether people see their experience with tinnitus reflected in the model as a whole or in its various component parts. It included examples people give about different aspects of their tinnitus experience, such as negative thoughts they have about it or things they do to avoid it. One additional theme was identified from the interviews, which was

'what the model tells patients.' This theme was about the perceived message of the model and how this is interpreted.

Analysis of the focus group transcript identified a substantial amount of data which related to the three themes derived from the interviews, but from a therapist's perspective. Therefore, theme 1 was called 'ease or difficulty understanding the model' and is mostly about how well therapists think patients understand the model but also contains comments about how well therapists understand the model themselves. Theme 2 was called 'how well the model reflects patients' experience with tinnitus' and is about therapists' views about whether the ideas in the model reflect what their patients tell them about their tinnitus experience. Theme 3 was called 'what the model is saying' and includes therapists' ideas about what the model's message is and their views on whether this message is acceptable to patients. Two further themes identified in the focus group data only were 'how therapy addresses different components of the model' (theme 4) and 'whether the model is clinically useful' (theme 5). The former referred to therapists' thoughts about how what they do in therapy relates to the different components of the model, even though they do not use the model explicitly. The latter included opinions about whether explaining the model to patients could be a useful part of therapy. Each theme was divided into between one and nineteen subthemes.

## 7.3.2 Theme 1: ease or difficulty understanding the model

Examination of interview data indicated that patients' comments could be grouped together into four sub-themes:

- 1. understanding the full model
- 2. understanding individual components
- 3. how the model looks on paper
- 4. reviewing the model to help understanding after presentation

All of the clinicians' comments on understanding fit under sub-themes 1 and 3.

#### 1. <u>Understanding the full model</u>

Most of the interviewees felt that they had understood the model well when it was presented to them in the group.

"So, I do think that, yes. It's easy to understand" (Jay)

"I think first of all just to see it mapped out like this it was so helpful because it was like, "Okay, I get it" (Jessica).

"I know, as soon as we looked at this last week I mean I knew exactly what [group leader] was saying. I followed it step for step." (Frank)

Some commented specifically on the helpfulness of having somebody talk through the model with them.

"Although I was aware of it, when [group leader] went through it, it was the first time anyone had ever gone through it with me. And I just was nodding. Yes, makes sense." (Julie)

"It did rely on [group leader] just taking us through, so it needs commentary." (Jessica)

Some interviewees commented on the fact that the model looked quite complicated, but they did not find this to be a problem. For example:

"I found it- Well, I don't know, it's a bit of a mixed answer. I found it complicated but logical at the same time" (Mick)

"But I think it is as simple as, given the complexity of what is going on I think it is as simple and as clear as it can be" (Jessica).

Several interviewees expressed the view that the model might be difficult to understand for some people, but was made easier for them personally because of some kind of previous experience, in one case the study of Psychology (Emma), and in others the use of engineering models (Frank and Graham):

"I used to study psychology so you know I kind of, I've seen similar kinds of models, not related to tinnitus, more to do with behaviours and everything like that." (Emma)

"Well I, all my life I have seen these sort of things." (Frank)

The experience of CBT also provided a useful context to understand the model. Suzannah felt she had a version of the model in her mind before attending the tinnitus group, because she had been learning about CBT after a stressful event in her life. This made the model easy to understand.

"Erm, I've talked, and looked, and thought about how one functions as a human being so much over the last three and a half years, that no, I think it makes sense." (Suzannah)

Jessica had undergone CBT in the past for a different problem and felt that aided her understanding:

"I have sort of seen similar and I have done some cognitive therapy in the past around various things. I understand the interrelatedness just through some other experiences, so this makes perfect sense." (Jessica)

None of the clinicians in the focus group had ever explained the Cognitive Behavioural Model to a patient, but the consensus amongst them was that patients would find it difficult to understand.

"It's quite clinical language, isn't it? It's not exactly in layman terms, so I'm not sure how helpful it would be for the vast majority of the people we see, I think." (clinician 2)

There was also a view that distressed patients might find it hard to focus on the kind of explanation the model requires:

"If it's someone that's very highly distressed, they're just not able to take on board something like that I think." (clinician 4).

One clinician expressed some difficulty with understanding the model herself, despite knowing a lot about tinnitus:

"The whole thing is really quite confusing. I've been working with tinnitus for a while." (clinician 2).

#### 2. Understanding Individual Components

The potential for confusion referred to by the clinicians, whilst not widely supported in patients' comments about understanding the model as a whole, was reflected in some comments about understanding some of the individual elements. Two particularly problematic aspects were uncertainty about what the 'safety behaviour' and 'beliefs' boxes referred to.

"I wasn't automatically clear about what safety behaviours meant." (Julie)

"because you read say 'beliefs' and I instantly thought about heavy, well they're not heavy beliefs, but beliefs to me means things like religion and so forth and so forth." (Graham)

Jay said she had only understood some aspects of the model at first: "it was such a huge, "Oh! Is this what it's about?" when it happened, I just went away with snippets of it."

Clinicians did not comment on understanding individual components.

#### 3. Thoughts about how the model looks on paper

All patients had seen the model projected onto a screen and then been given a paper copy of it to take home along with other information relating to group sessions. Some commented that the way in which the ideas behind the model were represented, as a series of boxes connected with arrows, was appealing or helpful.

"Erm, but no, as best as I can understand it, I think it's quite an elegant model of it." (Mick)

"I like models because instead of holding it all in your head, if you can plot it out..." (Graham)

"I think first of all just to see it mapped out like this it was so helpful because it was like, "Okay, I get it." You could see very clearly what you have experienced, but set out very, very clearly. This kind of analysis of the different stages and what happens and how it is reinforced and how you can get trapped it was so reassuring. It was like, yes exactly that is exactly what I experience, but I couldn't see it in these different stages and I couldn't see a way out. If you see it mapped out like that you can see at what point you can influence things. So, it's a very, very helpful diagram." (Jessica).

Some patients felt that, based on their experience, there could be more arrows between components than are shown, but there was also a sense that the diagram should not be made to look more complicated.

"And listening for it more does definitely make more distress, which definitely makes more negative... So this whole thing really. But then you'd end up with arrows going everywhere." (Julie)

"but then you don't want this to be any more crowded than it is, do you?" (Graham).

A similar view was expressed by clinicians; there was a sense that there might be additional pathways that were not shown, but that to illustrate all possibilities would be over-complicated.

"Yes. And also the beliefs in the safety behaviour, so safety behaviours lead to beliefs, but would beliefs not lead to safety behaviours? (clinician 5)

Yes. I think there needs to be more two-way arrows (clinician 1).

Which would make it even more over complicated." (clinician 5). (Laughter)

#### 4. Reviewing the model after presentation

Most of the interviewees had looked at the model diagram that they had taken home with them and given it some thought. In some cases, this was because they knew they were going to be interviewed about it:

"I've obviously thought about last week's session, and the model that you wanted to, to talk about....and thought about it quite a bit (Jay)."

In other cases, it was to check their own understanding. For both Emma and Suzannah, it was when they thought about the model at home that they began to question whether it fully reflected their own experience:

"I agreed to a point and then I went home and I thought about it and actually, I understand this bit with the reinforcement and the whole safety behaviours, but I just don't agree with the perception of tinnitus, that distorted particularly, sort of" (Emma)

"And I made the point of sitting down, thinking about it, and drawing my own." (Suzannah)

Bridget commented that although she could understand the model when it was presented, she found the information difficult to retain: "and then, by the time I got back to it, I was thinking, "What was he saying about this?" She attributed this to difficulties with thinking due to tinnitus and chronic lack of sleep. When he looked at the model on his own, Graham found that he had forgotten parts of the explanation given:

"well I.....yes, she explained it very well at the time. Like a lot of things, you get back on the train.....and you think, so and so, and I got home and I looked at it and it took me a while to get it, and I got quite cross with myself cos I thought, well, perhaps you weren't concentrating hard enough."

#### <u>Discussion of theme 1</u>

Although clinicians expressed doubts as to whether patients would be able to understand the model, all the patients interviewed reported that they had found it quite easy to understand, even though some had struggled with one or two elements of it. Moreover, it was clear to me during the interviews that interviewees were not confused by the diagram in front of them. Clinician 4 had a concern about distressed patients being unable to focus on a model, born out to some degree by Bridget, who felt that having tinnitus made it

harder to retain information. However, she showed no difficulty understanding the model once we began to discuss it. The fact that most of the interviewees had revisited the model after its presentation indicates that they felt it was important to understand it, although the fact that they were due to be interviewed about the model may well have influenced this behaviour.

#### 7.3.3 Theme 2: how model reflects patients' experience with tinnitus

More interview data were coded under this theme than any other. In each interview, I asked patients whether they felt the model as a whole applied to them and we discussed each of its components (boxes) in turn. Similarly, I invited clinicians in the focus group to talk about whether the model reflected their conversations with patients during tinnitus appointments.

Comments relating to this theme could be broadly grouped together according to whether they were about the model as a whole, one of its boxes, or the connections between boxes (arrows). In the interview data, for each component of the model there was more than one sub-theme. There was also an additional sub-theme which encompassed comments about which elements of tinnitus experience were missing from the model. In the focus group data, there were no comments relating to some of the sub-themes derived from the interviews, but all comments about how the model reflects patients' experience of tinnitus could be mapped onto one of the interview sub-themes. There were no additional sub-themes under theme 2 for the focus group. A full list of sub-themes is shown in table 7.2. It is notable that, for most of the model components, there seemed to be little ambiguity about how to interpret them and their meaning was not even discussed. However, 'beliefs' and 'distorted perception' were interpreted differently by different patients and there was also some uncertainty about the meaning of these two terms amongst therapists.

Table 7.2: list of sub-themes under theme 2: how model reflects patients' experience of tinnitus.

Interview sub-theme	Equivalent focus group sub-
	theme
Full model reflects personal experience	Full model reflects patients' experience
Negative Automatic Thoughts are part of personal experience of tinnitus	
Experience of managing Negative Automatic Thoughts	
Experience: tinnitus influences or is influenced by thinking process	
Arousal and emotional distress are part of personal experience of tinnitus  Experience of interaction between	Arousal and emotional distress are part of patients' experience
tinnitus and non-tinnitus related distress	
Experience of tinnitus as an emotional barrier	
Experience of indirect effects of tinnitus on emotions	
Selective attention and/ or monitoring are part of personal experience of tinnitus	Selective attention & monitoring are part of patients' experience
Experience of situation or activity affect attention	
Safety behaviour is part of personal experience of tinnitus	Patients use safety behaviour
Experience of making own attempts to cure or control tinnitus	Safety behaviour versus coping
Own interpretation of the term beliefs	Therapists' interpretation of term 'beliefs'
Beliefs influence experience of tinnitus	Beliefs patients have

Interpretation of the term	Therapists' interpretation of
-	
distorted perception	the term distorted perception
Own perception of whether	Whether patients feel their
tinnitus loudness may be distorted	loudness perception may be
	distorted
Connections (arrows) within the	
model reflect own experience of	
tinnitus	
Some components are missing	Some components are missing
from model	from model

# Full model reflects personal/ patients' experience

Several patients were quite emphatic about the fact that the full model seemed to reflect their experience accurately.

"it just mirrors exactly my experience" (Jessica)

"I think it's spot on" (Julie)

"I do think that's a very good- but I thought that straight away. I didn't look at that and think, [tuts]. I did look at that and think, "My goodness, that really does actually sum it up." (Rachel)

Others did not feel the model reflected their experience so well. For one person, this was because he felt his tinnitus was less severe than that of most other members of his mindfulness group. When asked whether he felt the model applied to his experience of tinnitus, he said:

"Yes, yes I think it does. Not perhaps to the same extent as other people, I don't know" (Graham)

Similarly, Suzannah did not feel the model reflected her experience very accurately. She explained this is because she regards tinnitus as a symptom of stress rather than as a problem in itself.

"for me, it doesn't quite say the picture. Because most of the time, I'm not, erm, massively focused on my tinnitus." (Suzannah)

For Julie and Jay, the way in which tinnitus experience changes over time affected the relevance of the model to their experience. Julie felt that the full model applied to her less now than it did when her tinnitus first started because her thoughts and feelings had become less negative over time:

"Well, they've certainly, certainly modified over time. So when I first got it, this was much stronger in terms of negative automatic thoughts, arousal and distress". (Julie)

Jay felt that the model reflected her experience sometimes more than others, depending on the severity of her tinnitus. She noted that her tinnitus varied in volume depending on her sinuses, and at quieter times she did not see herself as being in the cycle depicted in the model.

Bridget felt that the model was too general, and did not account for different types of tinnitus.

"Whatever noise you've got, nobody's really interested in the type of noise, or why that type of noise, or what's the difference between your experience and somebody else's experience. It's just like, well, it's all just one big thing called 'tinnitus', and we've got to learn to ignore it." (Bridget)

In the focus group, mixed opinions were expressed. Clinician 1 felt that the model was quite an accurate reflection of what happens for patients:

"well, from my experience, that is the process that occurs"

However, some clinicians did not feel that the model fully took into account individual differences between patients. They felt the model was suggesting that everyone who has problems with tinnitus engages in a high degree of negative thinking, safety behaviour, monitoring and so on, and they disliked this suggestion.

"I think it's variable actually. I think things emerge with different patients, and you might hone in on one element of that because it comes from the patient." (Clinician 3)

"And all of those elements don't necessarily apply to somebody with tinnitus. So somebody might- they might

maybe have certain negative beliefs about tinnitus or maybe distorted perception, but not everybody resorts to safety behaviours and the level of arousal and distress is quite variable. So, yes, that model doesn't apply to everybody who has tinnitus." (Clinician 5)

Clinician 4 saw the model as a somewhat artificial simplification of the way things are for patients:

"that person isn't coming in with things in little boxes. They're coming in with possibly a whole muddle of thoughts and feelings and anxieties."

# Negative Autonomic Thoughts are part of personal experience of tinnitus

All patients thought that 'negative automatic thoughts' was a component of the model which definitely applied to them, and some saw it as a central element.

Interviewer: "Now are there any part of this model here that you think kind of apply to you particularly or that you know sort of stand out for you as being..?

Frank: This one, 'Negative automatic thoughts'.

*Interviewer: The thoughts?* 

Frank: Yes."

Graham: "and to me, although it might change a little bit, that's all important [pointing to 'thoughts' on diagram]

Interviewer: the negative thoughts. That's sort of the central

part for you

*Graham: it is for me".* 

All patients gave examples of negative thoughts they had about tinnitus. Mick had written these onto his model diagram and he talked through them during the interview.

"well I put things like, 'I can't relax', erm, I'm sure those are quite typical. Erm, 'Tinnitus will affect my mental health', erm, 'Life will never be the same again' I could add, erm,

and, 'I can't enjoy music'......and, sort of, rather depressingly, I've put 'I will never be happy' at the end because, erm, well, music for me was part, a big part of what kept me sane and happy, relatively."

Some patients described negative thoughts they had at tinnitus onset, which tended to involve regret about something they had done. Both Julie and Emma's tinnitus started after listening to loud music.

"And in the middle of the night, when I woke up, and it was even louder then I literally just burst into tears, because I just thought, "I have done something seriously wrong to my ears now." (Julie)

"like 'I should have, could have, would have'. (Laughter) That kind of thing. Definitely." (Emma)

Rachel's tinnitus started after ear syringing. She described frequent thoughts about wishing she had never had this done.

"So, I keep thinking.... "If only I'd have cancelled. I would have possibly..."

Jessica described having suicidal thoughts at tinnitus onset, after being told her tinnitus could not be cured.

"Very quickly I had suicidal thoughts because I just thought, 'How can I possibly live with this?'"

Others described negative thoughts they had habitually. These tended to be about the unpleasantness of tinnitus and the fact that it is always there.

There were also worries about tinnitus getting worse in future.

"Well, the negative thought patterns, clearly, you know, you get this ringing and you start to have, 'Oh my god, it's never going to go away. It's going to get into my life, it's going to be there'" (Jay)

"this is never going to go away, this is just awful and why can't I be like everybody else?" (Emma)

Rachel described struggling with a recurring negative thought about the future when she was caring for a relative with dementia. She had started to worry about how she would cope with tinnitus if she developed dementia herself in older age.

"And I used to think, "What am I going to be like, if God forbid, I get dementia and- but I've got this whistling in my noise?......Everything will be worse, because I won't only have to cope with the confusion of dementia. I won't be able to know where I am and explain to anybody, "I've got this loud noise in my head." and I think I got really very depressed at that time."

Some participants also described recurring thoughts about it being unfair that they should have tinnitus:

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"I keep thinking: 'why should I get tinnitus as well?'......I
mean, I haven't done anything to deserve it." (Graham)
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"yes, I do think why me? Why my heart? Why my back? Why my tinnitus? That kind of thing" (Emma)

Bridget also talked about blaming herself for not being able to cope with tinnitus better:

"it's like, 'Why can't I cope? I'm a good person at coping....and I should be able to deal with this.'"(Bridget)

#### **Experience of managing Negative Automatic Thoughts**

As well as describing the negative thoughts they had, some participants talked about things they did to try and manage their thoughts. Graham and Frank both tried to compare themselves to other people, for whom things could be worse, but they only found this partially successful.

"yes, but then life isn't fair, is it? But then you have a look at other people and stop telling yourself to be such a..whatever...... I can do that sometimes, but I've got to admit that I, I can't do that all the time." (Graham)

"But you can never reassure yourself with other people's problems. You never really make, it, it can give you a little bit, look up and see life as it really is. But then okay you still come back to yourself and feel a little bit sorry for yourself no matter what." (Frank)

In Julie's case, comparing herself to other people with tinnitus had actually intensified her negative thinking:

"And if you read in [tinnitus magazine] someone's written an article that says something along the lines of, "I didn't think it could get worse than this, but it did," that makes you think, "Oh my God, it can get worse."

Frank had tried talking to other (non-professional) people about tinnitus, but had found this made his negative thinking worse rather than better:

"people say when they speak to you and they find you have got tinnitus, the first thing they do is they sort of touch you on the hand and they say, "You know it's incurable don't you?" And you go, "Yes. Thank you". So that adds to the negative automatic thoughts."

Frank and Pat also described making deliberate efforts to stop themselves following a negative train of thought. Both felt this was difficult to do.

And I have to force myself to think about something else......Because I can feel the panic. I can feel panic symptoms, I can feel all these kind of things and I can feel fear....and therefore I think, "Well, okay then, I'm going to try and divert from these thoughts." (Pat)

"And, er, I sit there and think, 'Oh'. Then when I do that I got to stop myself going on to the real furthest out, like outreaches of it, like of, 'What's the point?' You know? I think, 'Well don't go down that road'"(Frank)

Jessica was the only participant who talked specifically about techniques she had learned on the mindfulness course and how she used these to help manage her negative thoughts:

"One of the other things I found really helpful is when you have got all of these negative automatic thoughts is the labelling. I found that really helpful because I just go off on this stream of consciousness. If I can say that is fixing, that is worrying, that is planning and that is that to bring myself

back into the present, keep bringing myself back. All of those things which are little things in a way, but they just give you a sense of control." (Jessica)

#### Experience: tinnitus influences or is influenced by thinking process

Some of the interviewees talked about their thinking style as well as the content of their thoughts. Graham, Rachel, Frank and Pat all noted that they tend to ruminate. They had been taught on the course that this can exacerbate tinnitus distress.

"I do sit in the garden a lot and I do ruminate a lot and yeah it [tinnitus] seems to grow when I'm doing that" (Graham)

"Erm, I found it very hard to shut my mind up in any circumstances, really. I overthink everything". (Pat)

Suzannah made the observation that, for her, having negative thoughts about things other than tinnitus was making tinnitus worse:

"The sort of, erm, injustice, and, and, erm, upset over some of the things that have happened in the last few years...Is what I focus on...... even though it then exacerbates and makes this [tinnitus] worse." (Suzannah.)

Bridget described how, for her, the noise of tinnitus interfered with her ability to think about other things:

"And that you're thinking with a big noise around you. You know, it's like, how do you think with a big noise around you?" (Bridget)

# <u>Arousal and emotional distress are part of personal/ patients' experience of tinnitus</u>

None of the patients discussed arousal as a separate entity from distress. There was little discussion of muscle tension or other signs of physiological arousal. However, all patients described negative feelings related to their tinnitus. Some of these were feelings that occurred often or even most of the time.

"it is another problem, and it does get me down, it does get me down" (Graham).

"it's always a problem. I'm always upset about it. I'm always on a heightened kind of state of like, 'Ahh, this thing is always here.'" (Emma)

"It is just, it is just something that is so, so annoying you know" (Frank)

"So it, it does tend to make you feel angry all the time" (Bridget)

Other negative emotions had occurred at a particular time. For example, Rachel recalled visiting her elderly mother on Mother's Day. It was supposed to be a special occasion, but her tinnitus was particularly bad and putting her into a bad mood.

"I remember feeling so guilty that I'm sitting there with my mum in her late eighties, in a foul mood. Because the tinnitus had come back so badly."

Jessica described very intense emotional distress when she first experienced tinnitus:

"I had such a strong emotional reaction to the sounds in my head and in my ears that I was in a state of high anxiety and panic. I have never experienced anything like it in my life, it was, I found it absolutely terrifying."

For Mick, it was not the onset of tinnitus but being told that it was permanent which caused severe distress:

"It was annoying but then it became absolutely, overnight........ thought I'd had a nervous breakdown, but an acute stress response, I think or something like that it was, it was called by a psychologist."

In the focus group, it was acknowledged that many tinnitus patients are emotionally distressed when they come for appointments. There was agreement around the table with this statement:

"I'd say that most of the people that we see with tinnitus come to us and they're distressed by their tinnitus. And so in terms of elements of the model, I think arousal and distress is quite a common theme of people with tinnitus" (Clinician 5).

#### Experience of interaction between tinnitus and non-tinnitus related distress

Several of the patients felt that their tinnitus was made worse by a preexisting mental illness. Graham and Emma both suffered from depression while Frank and Mick had both experienced depression and anxiety disorders. All of them felt that these conditions intensified the emotional distress they felt in relation to their tinnitus. Frank described himself as being "tailor made for tinnitus" because of the history of mental illness in his family.

Some interviewees also felt that stress arising from particular life events influenced how they felt about their tinnitus. Suzannah believed that a series of stressful experiences-mostly related to her work- had caused her tinnitus to start. She had drawn her own version of the model, with arousal and distress as a starting point, at the very bottom of the page. She explained it like this:

"I would say, for me, it feels like it's arousal or stress, or distress, here.....But it's that, erm, you know, there's been a number of traumatic things that I've had to deal with in these last three years that I just talked about......and that, to me, is what affects...... it feels like that's the start" (Suzannah)

#### Experience of tinnitus as an emotional barrier

Several interviewees expressed the opinion that, as well as causing negative emotions, their tinnitus acted as a kind of barrier to experiencing positive emotions such as relaxation or pleasure. This was both during everyday activities such as watching television, and during special events.

"when it's very bad, and this is what I find very distressing. If I'm watching television in the evening and it's interfering with that. Because that should be your downtime....when you're relaxing time for evening." (Rachel)

Emma described attending a friend's wedding but not really enjoying it because of her tinnitus. She added to this:

"I think, so when it comes to maybe one day my own wedding, I know for a fact that I probably won't enjoy it." (Emma)

Bridget described attending her daughter's school Christmas concert and feeling her enjoyment of that was spoiled by her tinnitus, which is aggravated by music.

"Well, that's supposed to be one of the highlights of my year as a mother.....It was the opposite." (Bridget)

Mick talked about how tinnitus, coupled with a mild hearing loss, had interfered with his enjoyment of playing the guitar:

"I can't get very much enjoyment from making it [music] anymore, not at the moment I should say." (Mick)

Jay felt that tinnitus could also act as a barrier to confronting negative emotions about other things. She described avoiding conversations after the funeral of a close family member

"I used the tinnitus to say, 'It's because I can't cope with these kind of conversations and those crowds, that I avoided them,' but what was that all about? Is that really me just making an excuse because.....I was finding it hard to process my own emotions at the time?" (Jay)

Both Jessica and Suzannah also expressed the idea that tinnitus can sometimes act as an emotional barometer, giving you a warning that stress levels are too high.

"When I am stressed it is much more obvious, but I am learning to recognise that and actually see it as indicating to me what my state of mind is. It is almost a positive thing" (Jessica)

"For me, it's sort of, "Ah, oh God, it's a lot worse. Why? Oh, okay, 'cause I'm so tired, or I've overdone it, or I've not been doing my yoga, or..." (Suzannah)

## Experience of indirect effects of tinnitus on emotions

A further theme which emerged from the interview data was that sometimes it is not so much the tinnitus per se that triggers negative emotions, but something else about the experience of having tinnitus. For Mick, it was not hearing the tinnitus, but being told by a doctor that it was unlikely to get better.

"That was when it became very distressing, yeah, following the, sort of, prognosis." (Mick)

Both Bridget and Rachel talked about trying different remedies to relieve their tinnitus. They both felt that the failure of these remedies caused negative feelings:

"But then, once they, you have realised it, you are gonna take steps yourself....erm, and it's the failure of those steps....that feed into the negativity, or the panic." (Bridget)

"When I first went to this person, she said to me cranial was the only thing that helps tinnitus. And when it didn't help me- and she has also said to me that I'm the only person she knows, that it's never really helped.....I felt really, well, more despondent." (Rachel).

Rachel had tried quite a lot of alternative therapies, some of which seemed to make her tinnitus better for a day or two. However, she described then feeling intensely distressed when the tinnitus returned to its previous level.

"But then when that time comes, and, and maybe you've got three days clear and then it comes back with a vengeance.....That is really, really distressing."

Bridget talked about how missing out on social events caused her emotional distress. She had stopped going to the cinema because she found it too noisy, and described this as "very sad, really." She also described how the lack of sleep caused by her tinnitus made her feel lethargic and low during the day.

Some of the participants also felt that other people's lack of understanding or support had increased their distress.

"Years ago I remember being at an appointment......They just said, "Oh, it's er, you do know it's not like an actual thing, don't you? It's your mind." Which impacts how you feel about it, which makes you feel a bit like 'well, maybe I am going a little bit mad.'" (Emma)

"And relationships are, who- which I previously trusted don't wanna know about it. Where are they, you know, where's the help?" (Bridget)

# Attention and/ or monitoring are part of personal/ patients' experience of tinnitus

There were different opinions amongst patients about whether they found themselves selectively attending to or monitoring their tinnitus. Pat and Graham recognised monitoring as part of their experience.

"Selective attention and monitoring, oh yeah, I mean, that's me, I'm watching for it. Yeah." (Pat)

"I do listen, and I do monitor it as in, is it getting any worse?" (Graham)

Others felt that monitoring varied. Mick noted his monitoring increased when he was told his prognosis; however, Julie, Frank, and Jessica observed that they monitored less as time went on. Mick felt this part of the model must apply to him particularly, because when he first had tinnitus it did not bother him very much. The fact that he only became upset by it when he was told it was incurable he put down to listening for it much more.

"So yeah, the idea of the selective attention and monitoring side of it I find particularly interesting from, from the point of view of living with it and trying not to selectively monitor it and being aware that that is something you do if you're checking all the time that it's there, or how bad it is" (Mick)

Both Julie and Jessica were aware of monitoring their tinnitus a great deal when they first got it, but felt they did this less now.

"you definitely do start to monitor. So when I first got it, literally every second of the day I didn't switch off. I was like, 'Is that noise air conditioning or is that noise my tinnitus? 'I'm in a meeting room, can I hear what they're saying or is it being...' You know." (Julie)

"I have experienced how dominating it can be even amidst other sounds, even if you are watching television or whatever. The danger you can get into this thing about seeing which is loudest, which is so unhelpful." (Jessica)

Frank also felt that he used to monitor his tinnitus but now made deliberate efforts to avoid doing so.

"Erm, and I try not to monitor it really. I don't monitor it because I know, I try to sort of like throw these things off"

Rachel described how trying different alternative therapies caused her to monitor her tinnitus, so she could judge whether the treatment had worked.

"someone told me about a very good acupuncturist that cured someone's pain, and their pain had gone. And I thought well- I gave them a.....ring, I spoke to him and he said he would know within three times if it would work, and when I did that, when I went to him, I woke up every day listening to hear for it."

Emma, on the other hand, disliked the term 'selective attention' because she felt it implied she had a choice about whether to attend to her tinnitus or not.

"I don't selectively pay attention to my tinnitus. It's always there, it's always asking for attention. ......I can always hear it. Yeah. For me there's nothing selective about my attention to my tinnitus."

In the focus group, clinician 3 also disliked the implication that paying attention to tinnitus was a deliberate action:

"I'm not that comfortable with the selective attention of monitoring. I mean, lots of people will notice their tinnitus, but I don't feel it's a conscious process. They often describe it as, "Well, I'm not doing it deliberately," and that [indicating model diagram] implies that there is a conscious effort involved." (clinician 3)

#### Experience of situation or activity affecting attention

Most patients felt that whether they paid attention to their tinnitus or not depended at least partly on the circumstances they were in. They felt their attention was drawn towards tinnitus in particular environments. Several people found themselves noticing their tinnitus in quiet surroundings:

"you find you notice that during the day, you're walking around, traffic etc. there's no tinnitus. It's, kind of gone, but the moment you sit here in a quiet room, its back." (Jay)

"I wouldn't say that it's worse at night time, I would say that my awareness of it, because it's quiet, is more at night time." (Julie)

"it's there all the time but it's when you lie down and you try to relax and, um, I notice it then" (Graham)

Rachel said that one of the reasons she was finding mindful meditation difficult was that the quiet made her notice her tinnitus.

"Now, I, I must admit, with this mindfulness and that- the only thing I do find, when I sit down and do the meditation, because although you're sitting yourself in a quiet environment, I do notice it a lot more." (Rachel)

Both Jay and Frank talked about how a blocked nose or sinuses had brought their attention to their tinnitus.

"...because of the sinuses. Because I'm in so much pain with that, I am monitoring the tinnitus as actually being really loud at the moment. Really, really intrusive at the moment" (Jay)

"I probably had it before but I was unaware of it. Erm, and then I had a severe cold and I took some really heavy duty anti, decongestants......Then all of a sudden I had a buzzing noise in my ears." (Frank)

Mick felt that trying to make music drew his attention towards his tinnitus.

"I guess, when you're trying to do music, you're deliberately paying more attention to the sounds around you and I find that the tinnitus is really almost crippling at that time. I play a note on the keyboard or, you know, play the guitar, I can hear it above anything...." (Mick)

Some participants also talked about times when they found themselves paying much less attention to their tinnitus because they were fully absorbed in something else.

"I mean the tinnitus could do what it liked. I mean I was so concentrating on getting this work [redecorating his house] done." (Frank)

"When you are absorbed in daily life and good things tinnitus does become a background thing and I hardly know it is there." (Jessica)

"I can actually sit quietly and do quiet things. It doesn't bother me. It's there, I know, but I can still get absorbed in my books and, you know, watch something, or listen to the radio. I can do things like that, yes." (Jay)

While sometimes circumstances were seen as being outside one's control, some interviewees described making deliberate efforts to shift their attention away from tinnitus and towards other things. Jessica found that learning meditation had helped her with this.

"what is interesting is if you, and this is some of the work we have done is being aware of not just the sound of your tinnitus but all the other sounds that you are hearing then that is very interesting because actually it takes the focus away." (Jessica)

Jessica felt that diverting her attention away from tinnitus had become quite easy to do. For Pat and Bridget, however, it was more of an effort.

"When you become aware of your tinnitus, for me, is most of the time unless I do some kind of diversionary thing." (Pat)

Pat went on to describe how she might read or listen to music, but she would find her attention drifting back to the tinnitus until she pulled it away again.

Bridget described the following situation as difficult:

"You've got to... You have to sort of focus on, on what you're, on things, on the things that you're doing, and you can't do the sort of splatter take on everything, because that lets the noise be everywhere as well." (Bridget).

#### Safety behaviour is part of personal/ patients' experience of tinnitus

All patients talked about behaviour they had adopted since developing tinnitus. For some, the first thing that sprang to mind when I asked about 'safety behaviour' was a physical rather than a psychological type of safety behaviour. Graham, Julie and Rachel spoke of things they did to keep their ears safe from further damage; either avoiding loud noise or using ear protectors.

"I suppose, trying to have a protective bubble a little bit....round that. No one claps by your ear, you know, trying not to sit near a loud speaker." (Rachel)

When we discussed it further, most participants recalled the explanation given in the group; that the term 'safety behaviour' includes the idea that the behaviour you are using to protect yourself from a feared consequence (such as being unable to cope with worse tinnitus) can have the adverse effect of fuelling your fear. Bridget explained it this way:

"once they, you have realised it [that you have tinnitus], you are gonna take steps yourself.....Erm, and it's the failure of those steps....That feed into the negativity, or the panic." (Bridget)

Some reported having made deliberate efforts to stop resorting to safety behaviour. For example, Frank said of his bedside sound generator:

"I was told to, to mask it is, er, is not a good thing because basically it is like a crutch......You need, you need to be walking unaided." (Frank)

Jay felt that she had come to understand that you need to confront tinnitus rather than blocking it out, and was now trying to do so.

"I listened to the radio at night, I had the television on, every time I would wake up I'd put the television on low......I coped by blocking it out every time I heard it.....I'd never heard about actually confronting it.... that was only when I came on the course" (Jay) Jessica was also making deliberate efforts not to avoid certain situations that might make her tinnitus worse. She had stopped attending her choir for a while but, with the group leader's encouragement, had gone back again.

"I was so depressed at the thought that I couldn't go to choir. I emailed [group leader] about it and he said, "Don't stop going, so many people with tinnitus..." I am so pleased he said that because I have been going back and fully participating and even if I have a bit of a problem it soon passes." (Jessica)

Several participants did not entirely agree with the suggestion that their 'safety behaviour' was wholly unhelpful. Mick described being invited in the mindfulness group to talk about tinnitus-related behaviour.

"A lot of people came up with things that were both helpful and unhelpful, but I had...almost everything on my list, which quite a few of them were probably labelled 'safety behaviours', seemed to me to be both helpful and unhelpful, and I know that paints quite a murky picture but...." (Mick)

Mick described using electric fans, alcohol and sometimes drugs as his safety behaviours. He felt these were a welcome source of relief to him; "Sometimes the safety behaviours feel like the only sanctity." Similarly, Bridget sometimes used cannabis to help her sleep, and noted that when she had slept better, she coped better with tinnitus the next day.

Pat talked about listening to music and reading as a distraction from tinnitus. She felt that doing this prevented negative thoughts sometimes.

"they are safety behaviours and they are safe....so, they stop you thinking silly things, you know. Sort of like, "Is it worth going on," and all this kind of thing. ....So, I'm not sure that they particularly reinforce the situation." (Pat)

Several participants talked about avoiding noise that could potentially make their tinnitus worse. Julie felt strongly that this was a positive coping strategy that helped give her a sense of control:

> "for me, I am protecting myself, I think, from it getting worse. So that's like a coping- that's a positive thing. Because I'm being sensible." (Julie)

Jessica also felt that declining an invitation to a concert had been a positive coping strategy.

"I think that was a rational response saying, "No, I don't think that is quite right for me at the moment." .....I felt that wasn't a negative response, that was a caring response." (Jessica)

The clinicians in the focus group all agreed they had seen examples of behaviour which they considered to be safety behaviour; mostly using masking or keeping busy.

Clinician 1: "Avoidance of silence, and I think it's that just of anxiety about being in environments where there isn't sound that's masking and, yes, it's that-.

Clinician 2: Noise on all the time.

Clinician 1: Noise on all the time, exactly

Clinician 3: And maybe keeping busy all the time is a big distraction, so from that way- and never allowing just to be quiet or with the tinnitus.

Clinician 4: Yes, that's quite- that's a relatively common thing, isn't it? That people just keep- they're fine when they're busy so they keep on being more and more busy, and actually that then becomes a self-perpetuating thing, doesn't it? And then they get tireder. They're more stressed. They can't stop".

However, the clinicians also expressed the view that some actions that might be classed as 'safety behaviour' are in fact helpful coping strategies.

"Yes, because I think the psychologists view sound enrichment or a lot of them do as safety behaviours, whereas I suppose we maybe look at it slightly differently in that it may facilitate habituation. So it's not considered something that somebody would use forever, but it's a step towards habituation. So in that sense, not a safety behaviour, although some patients still use in that way" (clinician 5)

"Almost everyone is trying to distract themselves as a- which might not actually be a safety behaviour. It depends how much they're doing it and to what extent that stops them living the life they want to live, I guess" (clinician 2).

### Patients/ therapists interpretation of the term 'beliefs'

Although none of the patients picked out 'beliefs' as an element of the model which was difficult to understand, in conversation it became clear that interpretations of the word were varied. Both Graham and Bridget first talked about religious beliefs:

"because you read say 'beliefs' and I instantly thought about heavy, well they're not heavy beliefs, but beliefs to me means things like religion and so forth and so forth" (Graham)

"So I wondered if people had Christianity, or, or, or Muslim beliefs, or those kind of deities....that, that they were turning to for help, or a reason for it being in their heads" (Bridget).

Pat thought this section might refer to beliefs about why tinnitus started. Some participants referred back to negative thoughts they had already discussed when I asked them to talk about the 'beliefs' section, suggesting that they did not see a distinction between 'thoughts' and 'beliefs'. Julie was an exception, and explained the distinction like this:

"That's an interesting one actually, because I had assumed that it was my beliefs that were influencing the negative thoughts. So I did see them as separate. But if you ask me to explain why I see them as separate, okay, I- maybe it goes back to what we were discussing about if your personality or whatever leads you to a set of beliefs in life, then those beliefs in life could possibly be influencing how you think about it. So that's how I distinguish the two." (Julie)

Clinicians also felt that the distinction between thoughts and beliefs was not very clear, but agreed with each other that thoughts are fleeting while beliefs are more stable. Clinician 1 put it this way:

"Thoughts are very fleeting. We have millions of them, whereas a belief is something that is founded on a range of both thoughts and external influences. So a belief is something more solid."

## Beliefs influence experience of tinnitus

Two fundamentally different types of beliefs were identified by participants as influencing their experience of tinnitus; beliefs about oneself and beliefs about tinnitus. Both Jay and Julie described themselves as people who believe they need to be in control. Julie discussed this at some length, describing how she always wanted to plan and prepare for "every eventuality under the sun." She recognised that this had caused her particular difficulty with tinnitus, over which she has no control. She felt this was a problem for others too.

"But the more I've met people with tinnitus, who have had problems with it, the more I believe that actually it does tend to come back to people who like to be in control." (Julie)

Mick had suffered from mental health problems and described himself as having low self-esteem. He felt that this, which could be interpreted as a belief about not being good enough, made him 'predisposed' to have problems with tinnitus.

Rachel, Julie and Jessica talked about pre-existing beliefs they had about tinnitus before developing it themselves. Julie recalled reading about tinnitus as a child.

"I used to think, "Oh my God, poor people who have got that. That must just be an absolute disaster." (Julie)

Both Rachel and Jessica had known people through work who had tinnitus.

"I remember....actually thinking, "Oh, that must be so awful." .... You know, thank goodness that's not me, type of thing." (Rachel)

"I think it was very odd that in a job I had about 10 years ago I remember someone I worked with said his wife had tinnitus, and that she was on sleeping tablets and she had to go to bed with the radio on. Then he talked about someone else and said some people commit suicide with this thing and I just remember being so horrified by that. Also as someone

who loves peace and quiet I had such empathy for his wife thinking just imagine having to go to sleep with a radio stuck to your head. That obviously was just deeply in my psyche." (Jessica)

Jessica had also heard a radio programme which mentioned a suicide related to tinnitus. She felt that this strengthened her belief that tinnitus is a dreadful thing to have and increased her sense of panic when she developed it herself.

Clinicians in the focus group also felt beliefs about tinnitus and what it means were important.

"I think a lot of people have very distorted beliefs about tinnitus. The classic one is that it's going to get worse over time. The other very classic one is that it's heralding hearing loss. It's going to make you go mad." (clinician 1)

## Interpretation of the term distorted perception

When the Cognitive Behavioural Model of Tinnitus Distress is explained in the mindfulness group, distorted perception is described in terms of loudness, and the suggestion is made that tinnitus might be made to appear louder (distorted) by the amount of attention directed towards it. A brief description is given of studies which have shown tinnitus to be of low intensity when matched to pure tones. During the interviews, however, it was clear that some participants thought the term 'distorted perception' applied to thoughts.

Several participants had undergone CBT and it seems likely that they had the term 'cognitive distortions' in mind. For example, Bridget described it in terms of catastrophising:

"Well... I think, at night, you can just think it's not worth going on, you know. You, you can start to feel it's, it's overwhelming."

Clinician 5 also thought 'distorted perception' referred to thinking:

"So, "I think I'm going to go mad," or, "I'm not sleeping well. I can't bear silence," or, "I'm robbed of silence," and all those sorts of things that people say when they're highly distressed."

Clinician 1 countered this with her interpretation:

"but just picking out what it actually means, we're talking about perception, so actually how we pick up the sound that then becomes distorted. So that-I'm assuming it means it becomes louder than it actually is."

#### Own/ patients' perception of whether tinnitus loudness may be distorted

During the interviews I explained to patients who were not clear about it that 'distorted perception' refers to tinnitus loudness. There were differing opinions about whether one could be perceiving tinnitus as louder than it actually is. Jay, Pat and Julie all accepted the idea.

"Yes, [it] seems much more than what it is." (Jay)

"Well, erm, because I start becoming aware of the tinnitus and then because I'm aware of it, it gets worse.....But it can't be, you know, it simply can't be getting worse it's not logical.....Its, it's a process of the nerves, therefore, I know I'm distorting what I'm hearing." (Pat)

"I do notice this still now, that if I selectively monitor it then I hear it's definitely louder." (Julie)

Frank felt that knowing that tinnitus is often matched to low intensity tones had made him question how loud his tinnitus really was.

"Er, one of the great things is when it, it is explained to me about the actual decibel value of it you know.....and you know that basically, erm, that if you focus on it and you concentrate on it, it does get distorted and it goes into the scenario of, "It's raging".....But is it? You know?" (Frank)

Mick described feeling surprised when his group was told about experiments matching tinnitus to low intensity tones. However, because his tinnitus seemed to become much louder after he was told it was permanent, he accepted that perceived loudness may be related to attention.

"I guess only the fact that I've had that period and it seems like a long time ago, it feels like it will never come back but I've had the time where, measurably, my hearing was no different to how it is now but I wasn't so fixated on the tinnitus problems. It makes me reluctantly accept that it's a distortion of my perception of how loud it is and, to whatever extent they're able to offer scientific measuring of it, then I can accept that." (Mick)

Rachel felt that the concept of distorted perception was rather missing the point. Her tinnitus was bound to be loud to her, she reasoned, because it was right inside her ear.

"So being told it's only however many deciBels, something- if you were to shout at the other end of the building, I wouldn't hear that loudly. But you shouting next to my ear....It would be an unbearable sound......So, anything that close to- within your head and your ears, is- maybe it is distorted perception because it is so loud to you." (Rachel)

The only participant who spoke about having had a tinnitus matching test herself was Pat. She recalled being told that her tinnitus was particularly loud:

"I was tested many years ago, erm, and I remember the technician at the time. They did that test, you know, where they play a sound and you say when it equals your tinnitus?......And I remember her saying, er, when they did it, "Oh, that is loud," which really was no comfort at all to me, you know, because I knew that this was only for the benefit of research...." (Pat)

Emma was very clear that she disagreed with the suggestion that her perception of tinnitus might be distorted:

"I immediately disagreed with distorted perception in the very first instance." (Emma)

She found that her tinnitus was sometimes partially masked by other sounds but she saw tinnitus loudness as being independent of everything else.

"for me personally, it's just saying well, the tinnitus is always going to be there and it is always very loud and just because there's something going on in the background doesn't mean that the tinnitus isn't loud. I can still hear it at the same level anywhere." (Emma)

Clinician 2 felt that most patients would not consider their perception of tinnitus loudness to be distorted:

"I'm not sure patients would particularly buy into the fact that that [distorted perception] maybe is what's happening. I think they would say, "My tinnitus is this loud. It's not that I'm paying attention to it. It's this loud."

#### Connections (arrows) within the model reflect own experience of tinnitus

As well as talking about how individual components of the model reflected their own experience with tinnitus, most of the participants also talked about the connections between components. Several of the participants felt that they were caught up in a circle or a loop, and felt that the model illustrated this quite well.

"we go round and round in this crazy circle" (Frank)

"I understand how it flows like one to the other and then it comes back and it's like a circle really but just more arrows." (Emma)

"It is definitely all very interconnected." (Julie)

"I do tend to think, I do listen, and I do monitor it as in, is it getting any worse? Is it getting any worse.....And then I notice sometimes that it is getting worse. And then that again will bring back the negative thoughts. It's all a loop.......life is a loop, you know, you just go round and round." (Graham)

Several interviewees gave examples of how one component of the model led to another in their lives. Rachel was aware of monitoring leading to negative thoughts about the tinnitus not being any better and these negative thoughts leading to depression. Julie and Jessica were both aware of how negative thoughts about tinnitus getting worse had led to feelings of anxiety. Frank had noticed that when he used a safety behaviour such as avoiding sounds, this increased his negative thinking, his anxiety, and the amount of attention he paid towards his tinnitus.

"And you go to sort of like trying to do behaviours of, erm, avoiding sounds ...Then I have negative thoughts ....tremendous negative thoughts about how long am I going to put up with this and am I going to live? How long, er, will I be able to cope? And, erm, and then, erm....you start to sort of, er, concentrate on the tinnitus.......And the tinnitus becomes, takes over. And, erm, and then you get anxious." (Frank)

Jay also felt that avoiding social activities because of her tinnitus might make her feel more negative about it. Julie gave an example of selective attention leading to distorted perception, which then led to negative thoughts.

"I do notice this still now, that if I selectively monitor it then I hear it's definitely louder. And I can hear different pitches and then I start worrying about, "Oh my God, is it higher?" or "Oh my God, is it modulating?" (Julie)

Some of the interviewees felt that the relationships in the model were important, but that the arrows did not necessarily point in the right direction. Graham felt that the arrow between negative thoughts and arousal and distress should go both ways. Emma gave an example of emotional distress (panic, in this case) intensifying negative thoughts:

"I tend to panic, which then leads to me believing that this is never going to go away, this is just awful and why can't I be like everybody else?" (Emma)

Bridget also expressed the view that sometimes emotional distress triggers negative thoughts, rather than visa-versa. Suzannah felt quite strongly that, for her, arousal and distress had been the starting point. She had drawn her own version of the model, with arousal and distress (at the bottom of the page) leading to negative thoughts and negative thoughts leading to attention. Her experience had been that prolonged distress caused by difficult life events had caused her to think more negatively in general, and this had made her pay attention to her tinnitus.

The clinicians in the focus group also felt that connections between components existed which were not depicted by arrows in the model. However, they did not feel that the model should be made to look more complicated.

Clinician 2: "Well, the beliefs lead to negative automatic thoughts, but do negative automatic thoughts not lead to beliefs as well? Can you see the safety behaviours and the NATs go back and forth? The whole thing is really quite confusing. I've been working with tinnitus for a while.

Clinician 5: Yes. And also the beliefs in the safety behaviour, so safety behaviours lead to beliefs, but would beliefs not lead to safety behaviours?"

#### Missing Components

I asked all patients and clinicians whether they felt anything was missing from the model. While some felt it was complete, others felt that there were important aspects of their tinnitus experience not shown in the model. Bridget felt that the things people do to try and manage their own tinnitus, such as changing their diet, should be reflected in some way. She saw these as different from safety behaviours.

"So you know, it missed the trying, and it missed the, erm, the things that you're giving up, you know, that, that that has a, a sad- you know, it brings an effect on you." (Bridget)

Mick felt the model was missing what he called 'predisposition.' In his own case, he felt that a predisposition towards low self-esteem affected his experience of tinnitus. He was unsure whether this kind of thing was adequately reflected in the term 'beliefs.'

"I do accept that I was predisposed to struggle with this because of what I, I've put, because of my history. I mean that, kind of, historical aspect of it doesn't seem, doesn't seem adequately, erm, highlighted in that just under this 'Beliefs' heading for me, perhaps." (Mick)

Several interviewees talked about their tinnitus being influenced by external factors which are not mentioned in the model. Rachel, Julie, Emma and Bridget all talked about their tinnitus being exacerbated by noise. Rachel, Jay and Frank all said that their tinnitus became more audible and therefore more annoying when their ears were blocked by a cold or sinus problems. Graham, Rachel, Mick, Jay, Emma and Bridget all talked about being bothered by hearing problems as well as tinnitus. All of them felt that, to some degree, frustration or distress caused by not hearing well or straining to hear also had an influence on how they felt about tinnitus. Mick put it this way:

"I think for, like, the hearing loss, even if I'm not massively bothered about the tinnitus on a particular day I will listen to a piece of music on the headphones and a certain piece of music where they've panned elements of the mix to one side and it's just on one side will really make me- Erm, certainly very distressed, almost bordering on tearful, I have to skip the track. And undoubtedly that has raised my distress levels that- and I take my headphones off after that but I'm probably going to have worse sensations with the tinnitus."

Clinician 5 also felt that hearing problems should be part of the model:

"A lot of people have tinnitus and have got hearing related issues, so there's no audiology in this [model]. And I think sometimes to tie people's actual hearing difficulties in with their problems with tinnitus can be helpful."

Other things which participants linked to changes in their tinnitus were hormones (Jessica and Suzannah), medication (Graham and Pat), vigorous exercise (Suzannah) jaw clenching and touching the head (Rachel). Graham and Rachel also said that their tinnitus sometimes changed to a different tone spontaneously, and this could make it more irritating.

### Discussion of theme 2

All patients felt that the Cognitive Behavioural Model reflected their experience of tinnitus at least to some degree. Some saw it as a very accurate summing up of what was going on for them, while others felt that a modified version of the model might better reflect their experience. All of the patients were aware of having negative thoughts about their tinnitus and could readily give examples of these. There were also many examples of different types of emotional distress caused by tinnitus along with much discussion of the interaction between tinnitus and emotional distress about other things, which is perhaps not fully reflected in the model. While most of the patients talked about using tinnitus avoidance behaviours, both patients and clinicians raised some interesting questions about the usefulness of behaviour related to tinnitus and whether it could sometimes be seen in a more positive light as a helpful coping strategy. There were some differing and quite strong opinions about attention, monitoring and distorted perception with perhaps some

tension between two opposing ideas; that perceived tinnitus loudness is primarily a function of attention and that loudness is simply an inherent property of tinnitus. As a former clinician, I was surprised that most interviewees appeared to accept that loudness perception could be distorted, as I have often heard people talk about tinnitus loudness as something totally beyond their control. However, even those who felt that attention influenced loudness also felt that loudness could be affected by external factors not acknowledged by the model, such as blocked ears or noise exposure. The interpretation of the term 'beliefs' varied considerably between participants and this seemed to be the component of the model which people were least inclined to discuss. Finally, there were quite a lot of comments made about connections between components and especially the circularity of the model, with there being no distinct start or end point.

## 7.3.4 Theme 3: What the model tells patients

The third broad theme identified from both the interviews and the focus group was around the 'messages' people feel they are getting from the model. For the interviews, it was found that this theme could be further divided into three sub-themes:

- 1. Interpretation and acceptability of the overall message of the model
- 2. What the model says to do about tinnitus
- 3. What the model says about research/ professional interest in tinnitus

Clinicians in the focus group talked about the first two of these sub-themes, but sub-theme 3 did not come up in the discussion.

## Interpretation and acceptability of the overall message of the model

This sub-theme includes patients' and clinicians' ideas about what the model, taken a whole, seems to be saying about tinnitus and whether this is

acceptable. I did not ask people directly how they interpreted the model's message and not all patients commented on this. Of those who did, most of them felt that the model implied that they were in some way responsible for tinnitus being a problem. It appeared that tinnitus being represented as a psychological rather than medical problem apportioned blame. Julie felt that this might be difficult for some people with tinnitus.

"Are they going to then start beating themselves up, because they recognise that they're having negative thoughts, which causes arousal and distress?

And so therefore it's their fault."

Suzannah described her initial reaction to the model like this:

"Oh, have we got to feel bad?" It's like we've all- it's almost our fault, our prob- not our fault, our, erm, we've almost brought it on ourselves, sort of thing."

However, she quickly went on to explain that she did not really believe that the group leader who presented the model was trying to blame the group members for having problems with tinnitus, and that she agreed with the idea that "pushing yourself too much" could lead to problems coping with tinnitus as well as other things.

Jay described feeling quite taken aback when the model was presented, because she had never thought about tinnitus in these terms before. She described her first reaction like this:

"But having heard this, I actually thought, 'It's me, I'm mad.'"

However, rather than making her feel bad, this gave her some hope that she could do something about it:

"I felt as though, "It's in my mind. I've got a psychological problem and it's about overcoming this."

However, Jay did not feel that the model's message would be acceptable to everyone:

"I know two people who have tinnitus..... both of them would throw this [model diagram] out the window."

She explained this was because the people she knows see tinnitus as an entirely medical problem, as she once did herself:

"I was definitely of the medical model in my head, which is, 'Tinnitus means medicine, it means operation, don't be silly.'"

Pat expressed similar ideas to Jay. She felt that the implication that tinnitus becomes a problem because of your attitude towards it gave her some hope.

"I view myself as a fairly intelligent woman so any rational or scientific approach to this would tick boxes with me. And I could see that this is probably exactly what's going on, that, er, tinnitus is not life-threatening unless you decide it is. Erm, so therefore, there must be some degree of coming down from that. Of being able to cope with it."

She expanded on this later in the interview, explaining that she had heard many "crazy things" about tinnitus over the years:

"this is the first one that's convinced me that there's any, any kind of possibility of dealing with it." (Pat)

Bridget felt that the model implied that she- and other people with tinnituswere getting things wrong in the way they were dealing with it. Again, she found this helpful rather than off-putting.

"I found the fact that they were... I found that useful, that, that in fact.....you are wrong a lot of the time. You get things wrong,"

Emma thought that the message that problems with tinnitus are partially linked to one's attitude towards it might be hard for some people to accept, but that she could cope with this information:

"Well, I think [group leader], he didn't pull any punches. He just said, "You're not going to like this, but..." Whereas I think for me that's a good approach because it's just facts. As a person I can deal with facts a lot better if you just say it straight. Other people might feel a bit more sensitive about it and they might need to be softly spoken to, a soft

approach, whereas I'm fine with the hard approach. It depends who you are."

Clinician 1 described the message of the model by comparing it to Jastreboff's neurophysiological model.

"this is basically just an enhanced vicious cycle model, isn't it?"

"And the thing I like about this model is that it evolves on from the Jastreboff model, which is very much operating at a sub-cortical level, that conditioned response, and it's looking at a much more cortical human- based response, which is I think how Laurence [Mckenna] developed it is to extend that much more conditioned response that Jastreboff worked with." (Clinician 1).

Like the patients, the clinicians thought that some of the terms used in the model- 'distorted perception' in particular- implied that people with tinnitus were wrong or at fault in some way. They were concerned about this and felt it was important not to give patients this message.

"This isn't your fault because this is what we do. It's what animals do. This is what we do, and you can't undo the way we respond to threatening sounds. We make them louder for our survival," which is I guess a way of saying, "Our perception gets distorted," but not using that language that you're saying, "Your perception is wrong." (Clinician 2)

Clinician 3: "I don't think I'd ever use the phrase 'distorted'.

Clinician 1: I wouldn't use that phrase, no.

Facilitator: Okay. What puts you off using 'distorted'?

Clinician 3: I think it almost implies a little bit of judgement that they're getting it wrong or- I've quite often had people who are quite defensive about this and said, "It might be like that for other people, but mine is this loud." And so I feel a little bit sensitive about using that. It doesn't feel comfortable to me.

Clinician 5: I wouldn't use the word distorted either".

The clinicians felt they would prefer the model to use different terms such as "hearing it more" or "increased noticing" rather than "distorted perception."

Clinicians 1 and 2 also felt that the term 'safety behaviour' was slightly judgemental.

"Even safety behaviours is slightly.... you're doing something to keep you safe rather than doing what would be helpful. I don't know. It's a slight judgement." (Clinician 2)

There was also some discussion within the focus group about whether certain patients might find the model's message- that psychological processes play a part in tinnitus distress – less acceptable than others. There was general agreement with clinician 5's comment:

"If somebody comes seeking a cure and that's all they want, they're not going to even want to engage in the idea of managing something. They want it to go, so there are a number of patients who fit into that category. But I would say by and large people can come round to the idea that actually they can learn to pay less attention to it, and that's within their control." (Clinician 5)

There was also a wariness of imposing a certain view of tinnitus on patients who might have a different way of thinking:

"And who are we to insist they have to go along with a particular model of understanding?" (Clinician 5).

# What the model says to do about tinnitus

While all the patients felt that, to at least some degree, the Cognitive Behavioural Model accurately explained what was going on for them, there were differing opinions about whether understanding this helped them to deal with their tinnitus in any way. Frank and Jessica both felt quite strongly that understanding the model helped them to get out of some of the negative cycles they found themselves in.

"it puts up on the notice board like a safety sign that you see down the road.....it gives you a warning and tells you where you are going and what's happening. It suddenly starts for me, it starts to show you behaviour patterns to which you can then say, 'Oh look I am doing that so that will lead to that....So I will stop doing that and that won't lead to that. Then I won't have a bad day'". (Frank)

"If you see if mapped out like that you can see at what point you can influence things. So, it's a very, very helpful diagram...... In your mind you are kind of decoupling things because you have seen it in this way" (Jessica)

Jay and Pat also felt that understanding the model told them what to do about their tinnitus, but that learning to respond differently was not going to be easy.

"That's how I saw the model. I just saw it as about thinking about your mind and trying to get your mind to process things in a different way...... I did think, 'Oh gosh, but I can't do that because how can I control my mind?" It's like a solution but, wow, what a big ask'" (Jay)

"For me it was a, a revelation actually....and I did find it immediately, you know... particularly when [group leader] said the idea was to try and break that and if you can break that then the tinnitus, everything else becomes irrelevant. So if you could actually stop these negative automatic thoughts- well not stop them just recognise that they are negative thoughts....and so I thought it was brilliant, erm, I thought it was very clear, and very interesting. I've yet to see it happen but..." (Pat)

On the other hand, Julie, Emma, Mick, and Bridget all saw the model as just an explanation without any indication of a solution.

"I agree with, with what it sets out but I don't know that there's that much usable information for me, suffering from it" (Mick)

"For me, I get the model but I don't know how it's going to help me. I think that's one of my problems.....you know, there's a model that's, without being rude, that's nice but what's that going to do for me?" (Emma)

"This isn't a way out. It's not like a map." (Bridget)

Bridget, Mick and Julie also suggested that the model might be more useful to researchers and clinicians than to patients.

"And the diagram itself is, is... I would, I just sort of classed it as your, as, as a working route from the practitioners."
(Bridget)

"it is good from an academic's perspective and it's absolutely spot on. But so what?" (Julie)

"Intellectually it's stimulating- You know, I would find it interesting, erm, but I still- Yeah, I still think it's more than just a, a- maybe it's more for the health professionals than for the patients" (Mick)

Jessica, Emma and Suzannah all suggested that it might be helpful to have a companion diagram which indicates ways in which you can get out of some of the negative cycles indicated in the model. Suzannah had drawn a 'sunny side' on her own diagram which indicated an exit point from negative thoughts and emotions and included things like 'rest' and 'yoga'.

Clinicians felt that looking at the model gave some kind of indication of what to do to help patients.

"it points to the areas where you can affect change" (Clinician 2)

"My very simple interpretation of the model is that one of the factors that will affect how somebody manages their tinnitus is going to be affected by the thoughts that surround the tinnitus and the beliefs surrounding the tinnitus. And so one of the jobs of us as therapists is to allow people to see maybe what are distorted beliefs, distorted cognitions, and look to maybe shift those and reframe tinnitus in a more non-threatening way". (Clinician 1)

## What the model says about research or professional interest in tinnitus

Although some of the interviewees felt that the model was more useful to professionals than patients, a view expressed by several of them was that the very existence of the model- the fact that it had been thought about and drawn up- was an indication that there are clinicians and researchers who are interested in how tinnitus makes people feel. This was reassuring and encouraging to some patients.

"I do like knowing that someone is working on this....and that someone is understanding it". (Rachel)

"it's positive knowing that actually you've got some researchers in the background and they're trying to figure out a way to...." (Emma)

"The fact that you [researchers] recognise there's distress, that's good, because nobody, you know, that seems to be a part that's, that's left out." (Bridget)

Emma, however, also felt it was disappointing that the model did not have more exposure.

"I've never seen this before so for me as someone who has tinnitus, why isn't this more widely known? Why is it not at the forefront while other things are?"

### Discussion of theme 3

It is interesting to observe that both patients and clinicians felt that one of the messages conveyed by the model is that, to some extent, people bring problems with tinnitus upon themselves because of the way they think and behave when they experience it. It has been well established that people tend to apportion blame to disorders considered to be 'psychological' rather than 'physical' in nature (Corrigan et al., 2000) and the model's psychological explanation of tinnitus distress seemed to carry with it an implication that it is your fault if you have problems with tinnitus. Contrary to what I might have expected, it was the clinicians who seemed offended by this suggestion on behalf of their patients. The patients who were interviewed seemed to accept this idea and even find it quite helpful, because it implied the possibility of change. Therapists' ideas about the use of language within the model needing to be more sensitive were not particularly supported by things patients said. Some of the patients used terms that were stronger and more judgemental than any terms used in the model, such as "tinnitus is in my mind" and "you are wrong".

Opinions were quite divided about whether just understanding the model helps you to manage your tinnitus better or whether it is simply an explanation of the way things are. This is interesting to consider in the light of different approaches to tinnitus therapy. A large part of Tinnitus Retraining Therapy hinges on the assumption that simply understanding the neurophysiological model enables people to see their tinnitus in a completely different light and therefore to habituate to it. In fact, Jastreboff and Hazell (2004) state that a good explanation of the neurophysiological model is all that is required by many patients. No such claim has ever been made about the Cognitive Behavioural Model and indeed all the patients interviewed had only had it explained in the context of a mindfulness-based CBT course.

Nevertheless, there is an indication here that, for some patients, the model itself could act as a therapeutic tool.

## Additional themes from focus group

Two themes were identified from the focus group analysis which were not discussed during the interviews. Both were about the process of tinnitus therapy rather than the experience of having tinnitus. The themes were called 'how therapy addresses different model components' and 'whether the model is clinically useful.'

## 7.3.5 Theme 4: How therapy addresses different model components

While none of the therapists in the focus group said they used the model explicitly during therapy, either to show patients or refer to themselves, they did talk about how what they did during tinnitus therapy appointments related to the ideas contained within the model.

"I would never stick that down, that actual model down, in front of a patient and talk through it. But just in the process of counselling, those themes would come up." (Clinician 1)

Some members of the group talked about how they helped patients to think about tinnitus in a less negative way.

"And some patients, especially if they're quite self-aware, will come to see it as a signal of some sort from their body, so a, "What do I need? What's going on with me that I need?

Do I need more rest? A bit more fun? Do I need to be eating better? Am I burning the candle at both ends?" So if it was a messenger from your body, if people are that way inclined, what would it be? And I guess that's reframing it." (Clinician 2)

"I'd do the thoughts not facts thing. It's the thing about just noticing the thoughts that you have about your tinnitus is then creating the narrative or the story around the tinnitus. And so then you're not just responding to the tinnitus per se. You're then responding to the story surrounding the tinnitus that your thoughts are creating. So if you just can see those thoughts and notice that they're thoughts not facts, that's when you start to introduce a mindful approach, isn't it?" (Clinician 1)

There was also some discussion about helping patients to reduce their arousal and distress.

"I think that's quite a good way in sometimes as kind of a broad brushstroke to look at the relaxation and stress management as a way of modifying that high arousal and high level of distress." (Clinician 5)

As far as beliefs are concerned, the therapists felt it was important to correct any erroneous beliefs patients might have about their tinnitus.

"..and I think for me often in the initial counselling and explanation of the tinnitus model, looking at their beliefs and maybe correcting those is fundamental. And often, not very often but sometimes, that in itself is enough to just allow the person to then reframe the tinnitus and allow it to be there." (Clinician 1)

Clinicians 1 and 2 thought it was often helpful to explain to patients the concept of distorted perception- that their tinnitus may seem louder than it actually is- but that it was important to word this explanation carefully.

"we'll be talking about how our primitive brain responds to sound and threats and how our brain makes it louder, so you're almost depersonalising it a bit. You're kind of saying, "This isn't your fault because this is what we do. It's what animals do. This is what we do, and you can't undo the way we respond to threatening sounds. We make them louder for

our survival," which is I guess a way of saying, 'Our perception gets distorted,' but not using that language that you're saying: 'Your perception is wrong.'" (Clinician 2)

The therapists did not specifically discuss whether and how they addressed other elements of the model (safety behaviour and attention and monitoring) in therapy. They did talk about including elements of therapy which fall outside the model, particularly sound enrichment and helping people with hearing.

"And we do use sound enrichments in hearing therapy, and that's not really included in that [model]" (Clinician 3)

There was an implication that the model is perhaps more suited to psychological therapy than to tinnitus therapy within an audiology department.

"I think we probably tend to be a bit more eclectic than maybe the psychologists." (Clinician 1)

## 7.3.6 Theme 5: Whether the model is clinically useful

This fifth theme was about whether therapists thought it might be useful to refer to the model during tinnitus appointments and included comments about why they chose not to do this, and how they preferred to explain tinnitus. This theme contained three sub-themes:

- 1. Keeping the model in mind
- 2. Model does not fit with therapeutic approach
- 3. Alternative ways of explaining tinnitus

## Keeping the model in mind

Although none of the clinicians had ever referred to the model during an appointment, they did feel that the ideas contained within it might be in their minds as they talked to patients.

"But I think we hold this model in mind as a patient is presenting to us. I think that's what we're saying. We hold this model in mind and maybe witness what's going on as we are talking to our patients" (Clinician 1)

Clinician 4 felt she used the ideas within the model as a kind of starting point

"and for me it would be- with a lot of people it's absolutely just where you start. That's my baseline, if you like" (Clinician 4)

However, she went on to say:

"But not like that, if you see what I mean. It's certainly putting in all the different bits, but perhaps not in quite that way." (Clinician 4)

Clinician 2 agreed that she used the ideas within the model, but not in the same form.

#### Model does not fit with therapeutic approach

There was some concern expressed amongst the clinicians that talking patients through the Cognitive Behavioural Model might interfere with the process of counselling and listening to the patient's story, which they viewed as the most important aspect of therapy.

"People tend to be quite distressed, as we said earlier, and they want their story heard. They want to tell you how awful their tinnitus is, and that needs to be heard in order for me as a therapist to decide where to go next, but also in order for that therapeutic relationship to be established where that person feels heard. And I don't think that complex model of that nature is appropriate, at least in the very initial stages of being in a therapeutic relationship with a patient." (Clinician 5)

There was also a feeling that the point of therapy should be to support patients in finding their own way of coping, whereas talking about the model felt too much like telling patients what they should do.

"Further along the place is the notion that actually I'm, yes, maybe I'm looking at this through the wrong label or whatever would- it's like I think rather than me telling this to a patient it's something that the patient discovers for themselves through that therapeutic process." (Clinician 5)

"what I quite enjoy doing is teasing out that notion of acceptance so that the patient will say, 'Well, really you're saying it's about acceptance.' And then I could say, 'Well, yes, it kind of is', but it's allowing the patient-, it's allowing the process to... rather than being prescriptive." (Clinician 1)

#### Alternative ways of explaining tinnitus

Some clinicians said that they found it helpful to talk through a diagram with patients to help them explain how thoughts or emotions can affect the experience of tinnitus. However, they preferred simpler diagrams.

"I will draw models on bits of paper that look similar to that [Cognitive Behavioural Model]....I do have external factors, so pre-existing stress, which I will list and how- so my model is simpler in that increased vigilance or increased attention leads to increased loudness, so we get more- the vicious cycle of tinnitus I would tend to, you know?" (Clinician 1)

"I use that vicious cycle, and using examples that patients themselves have given within that cycle in order for people to understand their experience." (Clinician 5)

"And I've got a model that I use. In fact, when I was a student, I still use, but it's got a picture of the brain and a picture of the ear and it's got little boxes on top of it and I try and fit patients' experiences into that. And it's got the vicious cycle in it, so it's got a few more tangents than- it goes off in different directions a bit more. It's got the essence of that [Cognitive Behavioural Model] probably there." (Clinician 3)

As well as seeing patients individually, some clinicians were involved in delivering group tinnitus information sessions. They reported using a series of simple diagrams on slides during these sessions.

"we do something similar but it's more broken down, isn't it, sort of, "This is what happens and then your brain responds

like and these are the chemicals that your body produces when it's under threat," and that's how neuroscience maybe comes into it a bit, doesn't it, on the slides. And this is what habituation is. That's more how it's described in the series of processes rather than one model." (Clinician 2)

With individual patients, clinician 2 preferred not to use a diagram at all.

"I don't think I've used a model for ages. I think I use metaphors a lot more now rather than models. I'm not sure why. It might just be what feels a bit more comfortable to work with." (Clinician 2)

However, both she and clinician 4 felt that the process of discussing models in the focus group might encourage them to think about using one more.

> "Yes, I think I did have one, again like you, that I'd had from when I was a student- I don't think I use it very often now, but thinking about it. (Clinician 4)

I might do. I might do now. I might go and find out. (Clinician 2)

At least to refer to, yes." (Clinician 4)

#### Discussion of additional focus group themes

All of the clinicians had several years of experience working with tinnitus patients and it was clear from the discussion that they had developed their own ways of explaining tinnitus with which they felt comfortable. There was not any sense that they needed to be doing something different or additional. Although they broadly agreed with the theory behind the model, there was a certain amount of resistance to the idea of talking it through with patients in diagram format. However, it was apparent that the focus group was the first occasion on which they had been invited to consider this; they had not discussed using the model between themselves before. It is also notable that therapists' views were based around how they thought patients would react. No actual examples were given of attempts to explain a 'complex' tinnitus model to which patients did not respond well.

## 7.3.7 Discussion of qualitative study

Both the patients and clinicians accepted most of the theoretical constructs contained within the model. Patients felt the whole model broadly reflected their own experience, although perhaps with some variations, and clinicians felt it broadly reflected the experience of most of their patients. Interestingly, none of the patients objected to tinnitus-related distress being explained in psychological terms. This is somewhat at odds with previous research findings outside the field of tinnitus (reviewed by Sharpe and Carson, 2001) which suggest that patients dislike being given a 'psychological' explanation for physical symptoms. A qualitative interview study involving patients with a range of medically unexplained symptoms found that patients objected to doctors' suggestions that their symptoms might have a psychological basis (Salmon et al., 1999). There has also been vocal opposition amongst patient groups to recommendations that people with chronic fatigue should be treated with psychological therapy (Shepherd, 2016) as this is seen to imply that the condition is 'all in the mind'. However, the Cognitive Behavioural Model of Tinnitus Distress does not suggest that the symptom of tinnitus is psychological, indeed the theoretical model begins with the words 'tinnitusrelated neuronal activity', which suggests a physiological basis for the noise. The suggestion is that tinnitus is a physiological symptom which becomes distressing for psychological reasons, and this perhaps improves the model's acceptability. Unfortunately, there has been little exploration of patients' attitudes towards cognitive behavioural models of other conditions, such as chronic pain, which convey similar ideas, even though the importance of explaining to patients how psychosocial factors influence pain perception has been emphasised (Hadjistavrooulos, 2017). Patients have, however, been found to consider CBT an acceptable approach to managing long-term health conditions such as chronic pain (Tang et al., 2012) and diabetes (McCrae et al., 2015) which implies some acceptance of the notion that psychological reactions play a part in symptom-related distress. It should, of course, be born in mind that people who opt into a CBT-based programme are likely to

be more open to the idea that their experience may be influenced by psychological processes than some other patients.

Both patients and clinicians seemed to feel that negative thoughts and emotional distress were particularly relevant concepts. Both groups had similar difficulties with the concept of 'safety behaviour,' with the concern that referring to behaviour *only* in this way denies the fact that many people are taking positive action to help themselves cope with their tinnitus. Clinicians seemed to be very uncomfortable with the term 'distorted perception', while only one of the patients had a strong objection to this and some found the idea somewhat helpful. In a similar vein, therapists were concerned about the message conveyed by the model that it was the patients' fault if tinnitus had become a problem. Interestingly, several patients also saw this message in the model but did not object to it and, in some cases, they felt it gave them hope that they could change things for themselves. It is already known that people with an internal locus of control tend to feel less distressed by tinnitus than those with an external locus (Budd and Pugh, 1995) and it may be that the model is effective in conveying the idea to patients that they can determine how much tinnitus affects them. However, as discussed, some patients felt the model lacked any indication of how to go about this. It is interesting that patients and clinicians talked about 'fault' and being 'wrong', even though these terms were never used in the explanation of the model. This may be reflective of persisting societal attitudes that individuals are to blame for problems with their mental health (Wood et al., 2014).

A view shared by all of the clinicians was that the Cognitive Behavioural Model would be difficult for most patients to understand, either because of its complexity or because being in a distressed state impedes patients' ability to take in new ideas. None of the patients, on the other hand, reported much difficulty with understanding the model at all. A few patients had struggled with some aspects of it, but they felt that the model as whole made sense.

They did not express concern that that the model was complicated. It should be noted, however, that the patients interviewed had the model explained to them in a particular context; during week 4 of a mindfulness course. During the previous three weeks, some of the key ideas behind the model, such as negative thoughts leading to negative emotions, are gradually introduced, so there is some preparation. Moreover, in most cases the model had been explained by its creator, who is likely to be able to present it with more confidence and clarity that anybody else.

None of the therapists had ever used the model with patients and they gave several reasons why they felt it was not appropriate to do so. However, most of the patients felt they had gained something positive from having the model explained to them, whether that was a sense of their experience being shared by others or some hope that researchers are trying to understand tinnitus better. Some patients felt that the model was a useful tool in itself; something they could refer to in order to help them manage their tinnitus better. Others felt that simply understanding the model did not help them with selfmanagement. Understanding of one's health condition from both a physiological and psychological perspective is seen as a key starting point of self-management interventions (Eldar et al., 2017) but how much guidance patients want or need in applying this knowledge to a process of problemsolving has been observed to vary between individuals (Lorig and Holman, 2003), as it did here.

Comparing the interview data with the focus group data highlights some important differences in opinion, and raises the possibility that some assumptions made about patients may not in fact be true. It should be born in mind, however, that the patients interviewed were from a group who had been referred to a specialist psychology service and opted in to an intensive 8-week course which is only recommended to people who have a sufficient level of motivation, can hear relatively well, and speak good English. Clinicians, on the other hand, were considering the much wider population of patients

referred to their clinics. It would be very interesting to evaluate perceptions of the model in a more diverse group of tinnitus patients.

All interview studies are subject to bias (Silverman, 2013) and this was no exception. Most of the patients knew that I am a colleague of the mindfulness course leaders and had seen me interact with them at the course. This may have made them reluctant to be critical of the course or of the model. Similarly, all the focus group members were aware that I had been studying the Cognitive Behavioural Model of Tinnitus Distress for some time and written a paper on it, and they may have been concerned about causing offence by being over-critical of it. Furthermore, my own desire for the model I have been studying to be considered worthwhile and useful is likely to have influenced the questions I asked about it and the manner in which I asked them.

# Chapter 8. Does the Cognitive Behavioural Model reflect the experience of people with tinnitus? Synthesis of quantitative and qualitative results

In this chapter, the findings of both quantitative and qualitative studies are considered in combination with each other. Mixing results of quantitative and qualitative studies at the interpretation stage is an increasingly popular approach in healthcare research, and allows for a deeper understanding of multi-faceted topics than considering results of one methodology in isolation from the other (Tariq and Woodman, 2013).

To synthesise data from quantitative and qualitative studies, O'Cathain et al. (2010) recommend examining each question investigated in turn and establishing for each where there is agreement, partial agreement, silence or dissonance. This process can inform recommendations for clinical practice and highlight areas in which further study is needed (O'Cathain et al., 2014). The Cognitive Behavioural Model of Tinnitus Distress proposes that negative automatic thoughts, arousal and distress, selective attention and monitoring, safety behaviour, beliefs, and distorted perception are all components of overall tinnitus distress, and that all components are inter-related. Support for and areas of disagreement about each of these ideas, considering both quantitative and qualitative data, is discussed below.

## **8.1.1** Negative Automatic Thoughts

Clear evidence is provided by survey data that negative automatic thoughtsas measured by the negative subscale of the TCQ- are a component of tinnitus-relate distress. Those who rate their tinnitus as a bigger problem score significantly higher on this subscale and it correlates strongly with TRQ score (a measure of overall tinnitus distress). In the interview study, most participants agreed that they had negative thoughts about tinnitus and that these contributed to their distress. They were readily able to provide examples. In agreement with the authors of the TCQ (Wilson and Henry, 1998), the questionnaire study found the positive subscale of the TCQ was uncorrelated with the negative subscale. In addition, scores on it were not found to be significantly different between tinnitus problem categories, with all but one member of the 'big' and 'very big' problem categories endorsing at least some positive items, indicating that people who are very troubled by tinnitus sometimes attempt to think positively. One positive item on the TCQ is: "there are things in life worse than tinnitus" and some interviewees talked about making attempts to stop their negative thoughts by trying to remind themselves that things could be worse. These attempts were, however, deemed unsuccessful. In the survey, the similarity in scores on the positive subscale across problem categories also indicates that those who do not consider their tinnitus to be a problem do not think positively about it, they just do not think about it very much at all. This idea is supported by some of the comments written at the end of surveys by people in the 'not a problem' category, such as: "the...[TCQ] questionnaire I found quite difficult as I just don't think about these things, I felt that my responses might come over as negative when actually I just do not have these thoughts about tinnitus at all." None of the interviewees put themselves in the 'not a problem' category and so this idea was not explored qualitatively. Several interviewees recognised in themselves a tendency to ruminate, and it seems likely that both specific negative thoughts themselves and a negatively toned thinking style can contribute to a more distressing experience of tinnitus, but this is not adequately captured in a questionnaire.

These findings are broadly in keeping with those of other researchers such as Weise et al. (2013), who found that catastrophising (overly-negative thinking) was a significant predictor of tinnitus-related distress. Recent studies (for

example, Weise et al., 2013, Cima et al., 2011) have focused on catastrophising, which is clearly important to address, but is not necessarily the only target of therapy. Given that people who are not bothered by tinnitus tend not to think about it much at all, therapy should also aim to reduce the frequency of less extreme thoughts (such as: 'if only the noise would go away'; the first TCQ item). Further analysis of the TCQ in clinical populations would help to establish whether it is a suitable measure of the extent to which psychological therapy influences all kinds of thinking related to tinnitus (Handscomb et al., 2017).

#### 8.1.2 Arousal and Distress

The CORE-OM was found to explain more of the variance in overall tinnitus distress (measured by the TRQ) than any other measure used in the survey. In agreement with this, most interviewees also spoke about a range of negative emotions being part of their experience of tinnitus. Nevertheless, the relationship between negative emotions and tinnitus distress is not straightforward. It is particularly notable that there was no significant difference in overall CORE-OM scores between 'not a problem' and 'moderate problem' groups. There were some very low (<20) CORE-OM scores in the 'moderate' group suggesting that bothersome tinnitus does not always greatly affect overall well-being. All interviewees who rated their tinnitus as a 'moderate problem' or above did describe emotional difficulties, however. There were also some relatively high scores on the CORE-OM within the 'not a problem' survey group, indicating that some people who do not find their tinnitus to be a problem are emotionally troubled by other things. Several interviewees described experiencing mental health problems, which they saw as somewhat distinct from their tinnitus, although all those people considered their tinnitus to be a problem. Both studies indicate that people do not tend to attribute all their negative feelings to tinnitus alone.

In line with previous research (Kaldo et al., 2008, Cima et al., 2012), these findings demonstrate that a wide range of emotional distress, from very low to very high, is experienced by people with tinnitus. They also add to the growing amount of evidence that high emotional distress often goes hand-inhand with the most bothersome tinnitus (Langenbach et al., 2005, Zoger et al., 2006, Unterrainer et al., 2003, Weidt et al., 2016, Trevis et al., 2016b). Previous work (Marciano et al., 2003, Zoger et al., 2001) has highlighted that people with tinnitus may attribute emotional distress to several causes rather than considering it to be solely or even principally tinnitus-related, and similar findings are indicated here.

Physiological arousal and emotional distress are grouped together as a single construct in the Cognitive Behavioural Model of Tinnitus Distress, indicating that they are not regarded as separate entities and that emotional distress is inevitably accompanied by physiological sensations. The standpoint taken by many psychologists is that bodily sensations are an integral part of how we experience emotions (McKenna et al., 2017b). In keeping with this viewpoint, the items of the CORE-OM which enquire about physical sensations do not form a distinct factor. Several interviewees described not being able to sleep because of tinnitus, but otherwise they tended to describe emotions (fear, depression, annoyance) rather than physical sensations such as muscle tension, shallow breathing and so on, which suggests that they either regarded physical sensations as less important or did not see them as separable from emotional distress. The mindfulness-based CBT group the patients were all attending aimed to address both arousal and distress in combination, which may have influenced their thinking. Nevertheless, there may be an argument for separating out these constructs when planning therapy. Weise et al. (2008), who combined CBT with biofeedback, suggest that there may be groups of tinnitus patients for whom physiological arousal is particularly important and who perhaps feel more comfortable targeting physical sensations (such as muscle tension) through relaxation exercises than emotional distress through talking therapy. They also suggest that use of biofeedback may help patients who find it hard to accept a psychological explanation of tinnitus distress to understand the relationship between bodily sensations and state of mind, which in turn is likely to increase the acceptability of CBT. Measurable markers such as cortisol (Hebert and Lupien, 2007) and heart rate (Datzov et al., 1999) have been shown to be different in tinnitus patients compared to controls and there is some empirical support for the use of physical relaxation therapies for tinnitus (Hoare et al., 2011, McKenna et al., 2017a, Arif et al., 2017). Currently there is growing interest in Shared Decision Making in medicine in general (Elwyn et al., 2012) and in tinnitus therapy in particular (Pryce et al., 2017). Part of this is establishing patient preferences, and it may be that through using Shared Decision Making in clinic it is possible to identify patients for whom a physiological approach to managing arousal is preferable, at least as a starting point, to a purely psychological one.

A few of the interviewees talked about tinnitus being a barrier to positive emotions as well as a trigger for negative ones. This was not reflected in the survey analysis, which indicates that low scores on the positive emotion subscale of the CORE-OM (indicating lack of good feelings) do not predict tinnitus distress. Interviewees tended to talk about their enjoyment of certain activities being marred by tinnitus; this was not captured by the CORE-OM. There is some existing evidence that people tend to avoid certain activities because of tinnitus (Andersson et al., 1999), but less work has been done on how tinnitus affects the enjoyment of activities that people choose to participate in regardless. European Tinnitus Guidelines, in draft form at the time of writing, recommend that 'patients should be encouraged to keep doing the things they enjoy' (p.63) and resumption of activities is taken as one indicator of success in Tinnitus Retraining Therapy (Jastreboff and Hazell, 2004). However, comments from interviewees indicated that it is possible to participate in activities with tinnitus while feeling miserable, and indeed that

distress may increase when a previously enjoyed activity stops being enjoyable. A pertinent question to ask is whether encouraging people to continue or resume their usual activities is enough, or whether support may need to be given in finding new sources of pleasure.

# 8.1.3 Selective Attention and Monitoring

There was a statistically significant difference in scores on the TVAQ between each tinnitus problem category, suggesting that people with more problematic tinnitus do pay more attention to it and monitor it more. Of the four TVAQ subscales, Monitoring may be particularly important as it was shown to mediate between negative thoughts and tinnitus distress in both final versions of the model. It seems logical that having negative thoughts about tinnitus may cause a person to check up on it more and this in turn may prevent it from receding into the background. This is borne out by some of the comments in the interviews about how listening out for tinnitus fuels a negative cycle of thoughts and emotions. It is interesting to note that the regression path between monitoring and magnitude was found to be statistically significant and negative in version 2.2B of the model. There are two possible interpretations of this. A low monitoring score may be predicting a high magnitude score, suggesting that people with loud tinnitus do not monitor it as it is obvious all the time. It is also possible that a high monitoring score may predict a low magnitude score, suggesting that monitoring may be a way in which quiet tinnitus becomes distressing. Examination of raw scores indicated that the former is more likely to be the case, as many people with high scores on the TMI had low scores on the monitoring subscale of the TVAQ. A view expressed by some interviewees and some therapists was that people with tinnitus have no choice about whether they pay attention to it; it simply demands attention by being loud. An item such as "I carefully monitor how intense my tinnitus is" (item 12 on the TVAQ) implies that a choice is being made.

A topic brought up by several interviewees was the extent to which the environment influences attention to tinnitus; particularly that being in quiet surroundings led them to notice it more. The TVAQ does not allow respondents to indicate whether changes in awareness or monitoring happen only in certain environments, and may therefore be missing certain determinants of attention.

It has been well documented that people affected by a range of conditions (including chronic pain and phobias) direct increased attention towards stimuli associated with that condition (Harvey et al., 2004). Previous research has also suggested that people who are more troubled by tinnitus find themselves unable to ignore it (Hiller and Goebel, 2007). Monitoring behaviour has received less attention from researchers in tinnitus. Monitoring, particularly clock-watching, has been shown to increase problems with insomnia (Tang et al., 2007) and a key part of therapy for insomnia is discouraging monitoring behaviour, by for example taking clocks out of the bedroom (Espie, 2002). A question arises as to whether reducing monitoring behaviour should be equally important in tinnitus therapy. 'Checking up' on tinnitus is already discouraged in tinnitus therapy (McKenna et al., 2010) and yet a number of research studies (for example, Probst et al., 2016a, Kaldo et al., 2008) require participants to monitor their tinnitus regularly by using apps or diaries, which could have adverse effects. Understanding more about monitoring behaviour amongst tinnitus patients would help to determine whether this aspect of therapy needs more emphasis and whether the use of monitoring should be discouraged in research.

Environment is a factor external to the model but none the less important to consider when trying to address attention in therapy. Echoing comments from interviewees, a survey of 258 American tinnitus patients found that 'being in a quiet place' was identified by 48% as making tinnitus worse (Pan et al., 2015). However, the advice to 'avoid silence', which is strongly emphasised in Tinnitus Retraining Therapy (Jastreboff and Hazell, 2004), has been questioned by McKenna and Irwin (2008) who contest that continuous

avoidance of quiet can exacerbate anxious thinking. As part of CBT, patients are sometimes challenged to spend a few minutes with a therapist in a sound proof room, to demonstrate to themselves that the anxiety they feel in this situation will, after a time, begin to subside (McKenna et al., 2010). It would be interesting to assess whether patients treated in this way experience more rapid improvements in tinnitus-related distress than those who are advised to 'avoid silence.'

### 8.1.4 Safety Behaviour

Quantitative analysis suggested that people who rate their tinnitus as a problem use avoidance behaviour and that tinnitus-related avoidance mediates between negative emotions and tinnitus distress. Most interviewees also felt they had altered their behaviour in some way because of having tinnitus. Often this involved avoidance (avoiding silence at night, keeping out of noise, not letting people touch your ears). However, some other behaviours were mentioned by interviewees which might be classed as 'safety behaviour', such as using drugs and alcohol to escape tinnitus. These were not included in survey questions and indeed there has been very little investigation of their use amongst tinnitus patients (Vanneste and De Ridder, 2012).

Some interviewees talked about recognising a need to confront tinnitus rather than 'block it out' and this implies a recognition that their avoidance behaviour might be unhelpful. Others, however, did not see a negative consequence of their avoidance and therapists indicated that psychologists were sometimes too quick to label as 'safety behaviour' a strategy used to minimise the impact of tinnitus. The TFAS does not include any measure of how people view the avoidance behaviour in question.

The findings from this study are congruent with those of Kleinstauber et al. (2013), who used the full version of the TFAS (including the cognitions subscale) and found a significant positive correlation between this and the

HADS, which they used to measure emotional distress. They also found, as did the current study, that both emotional distress and tinnitus-related avoidance behaviour were significant predictors of tinnitus-related distress.

However, the measurement of safety behaviour related to tinnitus poses some difficulty and there is no instrument designed specifically to measure it. Avoidance is the most common type of safety behaviour across conditions (Westbrook et al., 2011) and the two 'avoidance' subscales of the TFAS which were used in the survey (tinnitus-related avoidance and ear-related avoidance) do enquire about some of the more common avoidance behaviours reported by both patients and therapists in the qualitative study, in particular avoiding noise and avoiding silence, but there are other possible behaviours it does not enquire about. Furthermore, the very definition of safety behaviour is problematic. The term implies that the behaviour has a paradoxical effect- the intention is to protect oneself from bad feelings- but in the longer term, negative feelings are increased (Westbrook et al., 2011). However, sometimes avoiding a situation may bring about lasting relief. The same behaviour may be classed as 'safety behaviour' or not depending on how the person feels afterwards (Rachman, 2012). In her development of a safety behaviour measure for insomnia, Harvey (2002b) tried to take this into account by asking a group of psychologists to rate behaviours listed by patients in terms of whether or not they were likely to increase negative feelings before including them in her measure. In tinnitus research, more investigation is needed of behaviour to help distinguish between helpful, protective behaviour and safety behaviour with negative consequences. The frequency of the behaviour and how the person thinks about it is likely to be as important as the behaviour itself.

#### 8.1.5 Beliefs

Not all interviewees spoke about beliefs, but those who did spoke predominantly about pre-existing beliefs about tinnitus making their experience worse, and about beliefs to do with control affecting how they

viewed their tinnitus. Tinnitus-related beliefs were measured in the survey using part of the Fear of Tinnitus Questionnaire and scores indicated that people who rated their tinnitus as more of a problem were more likely to believe it might be caused by a brain tumour, would make them go deaf, or become impossible to cope with. Although these specific fears were not named by interviewees, some patients felt that having a longstanding belief that tinnitus is a dreadful thing had negatively influenced their thoughts about it. However, because the FOTQ-M did not have a clear factor structure it was excluded from further analysis and so the place of tinnitus-related beliefs in the model is unclear. Control beliefs were measured in the survey by a modified version of two factors of the Illness Perception Questionnaire. The 'treatment control' factor was very weakly correlated with tinnitus distress in this study and was not a significant predictor of negative thoughts. This is perhaps not surprising as many respondents to the survey had never had any treatment for tinnitus and therefore considered this to be irrelevant (some respondents wrote notes to this effect). By contrast, all interviewees were undergoing treatment for tinnitus. Only one of them expressed the belief that their treatment had given them a sense of control, but the focus of the interviews was not on the benefits of treatment. The symptom control subscale of the IPQ-M was also only weakly related to tinnitus distress. Although it was a weak, significant predictor of negative thoughts, some of the path models constructed were a better fit when control dimensions were excluded. Some interviewees talked about being upset by the idea that tinnitus is something you cannot control, but there were far fewer comments about control than there were about negative thoughts and emotions. Considering the results of both studies, the role of beliefs in tinnitus distress remains equivocal. A likely reason for this is that the measures available were inadequate. Not only is there no specific measure of beliefs related to tinnitus, there is a lack of knowledge as to what kind of beliefs are relevant to people's tinnitus experience. Beliefs about the meaning of tinnitus have sometimes been highlighted in tinnitus textbooks as important in determining how people react when tinnitus starts (Jastreboff and Hazell, 2004) and

therapists in the focus group considered these kinds of beliefs to be significant. The FOTQ-M was used in this study in an attempt to measure such beliefs, but the full FOTQ was not designed for this purpose and was derived from a pain measure (Cima et al., 2011). A questionnaire based on specifically tinnitus-related beliefs expressed by tinnitus patients would be helpful in future investigations, to determine how much of a role these kind of beliefs play in the development of tinnitus distress and to measure whether they can be changed through education. An initial, qualitative investigation in which people are asked for their views on the causes and consequences of their tinnitus would help to establish what kind of tinnitus-related beliefs exist.

It is interesting that some participants who rated their tinnitus as 'not a problem' or 'a small problem' had low scores on the IPQ-M and did not even partially agree with statements such as "there is a lot which I can do to control my tinnitus." This suggests that there may be people who do not believe they can control their tinnitus but for whom this does not matter. An earlier study of a clinical population (Handscomb, 2006) reached a similar conclusion. Many patients answered 'Yes' to the question "Do you feel that you have no control of your tinnitus?" while answering 'no' to most other items on the Tinnitus Handicap Inventory, suggesting that it is possible to feel you have no control over tinnitus without feeling angry, irritated, or depressed. Perhaps a more pertinent question to ask, rather than 'do you feel you can control your tinnitus' is 'does feeling in control matter to you?' Some interviewees in the current study described themselves as people who need to be in control and felt that this was part of the reason for their struggles with tinnitus, which they perceived as uncontrollable. Work by Andersson et al. (2005a) has indicated that certain dimensions of perfectionism are related to tinnitus distress and the authors suggest this may be because the uncontrollability of tinnitus may be particularly unsettling for people to whom neatness and order are very important. Beliefs such as "if I'm not in control of my life I can't cope" may be more important than specific beliefs about tinnitus. In CBT such beliefs are known as conditional beliefs (Williams and Chellingsworth, 2010)

and are difficult to change directly, but may be influenced by changing negative thoughts. An investigation of beliefs about control in general amongst tinnitus patients, rather than beliefs about the controllability of tinnitus, would perhaps be better able to inform therapeutic intervention.

Some recent research (Handley et al., 2015) offered group CBT for perfectionism (an element of which is a need to be in control) to patients with a range of diagnoses, including eating disorders, social anxiety and depression. They found that therapy not only reduced perfectionism but also reduced other symptoms associated with the diagnosed disorders. This raises the interesting possibility that addressing perfectionism in certain tinnitus patients may have a positive effect on tinnitus-related distress.

### 8.1.6 Tinnitus Magnitude and Distorted Perception

In this study, tinnitus magnitude was measured using the TMI, which enquires about loudness, severity, and awareness. In the survey, magnitude scores were clearly higher amongst people who regarded their tinnitus as a greater problem and there was a strong correlation between magnitude and tinnitus-related distress. In the interviews, people tended to describe their tinnitus as a loud sound and saw this as a reason for it being problematic. In line with the survey data described, the developers of the TMI (Schmidt et al., 2014) also reported a strong correlation between it and tinnitus-related distress, measured by the emotional subscale of the TFI. Further studies have reported a positive correlation between perceived tinnitus loudness and tinnitus-related distress measured in different ways (Wallhausser-Franke et al., 2012, Weidt et al., 2016, Unterrainer et al., 2003).

The use of the term 'distorted perception' in the theoretical Cognitive
Behavioural Model implies that the amount of attention paid to tinnitus
influences how loud it appears to be. Not all interviewees understood the
term 'distorted perception' to refer to perceived loudness; some (and one of
the clinicians) interpreted it as a way of referring to catastrophising. This is

perhaps not surprising as the term 'cognitive distortions' is used in CBT. A somewhat surprising finding from the qualitative study is that only one interviewee objected to the idea that tinnitus loudness perception might be distorted. Clinicians in the focus group anticipated that patients would object to the suggestion that their tinnitus may not be as loud as it seems and the mindfulness group leader clearly anticipated objections too, as he routinely preceded explanation of the concept with "you're not going to like this, but..." One interviewee felt he accepted the idea 'reluctantly' that his loudness perception may be distorted while others seemed to find it quite hopeful. If loudness is distorted by psychological processes, there is some hope that it can also be reduced.

The idea of distorted perception is not unique to tinnitus. It has been welldocumented that people suffering from eating disorders have a distorted perception of their own body size (Molbert et al., 2017) and people suffering from insomnia have a distorted perception of the amount of time they have spent awake at night (Harvey, 2002a). Unlike distorted perception of tinnitus loudness, distorted perception of body size and sleep duration can be demonstrated by the use of objective measurements. Nevertheless, in these conditions, simply showing people that their perception is distorted is rarely sufficient to change it. Rather, people learn to re-evaluate their perception through a process of structured therapy (Caddy and Richardson, 2012, Harvey and Tang, 2012). Clinical guidelines for tinnitus sometimes recommend 'reassuring' patients that, based on results of loudness matching, tinnitus is often not as loud as it seems (Henry, 2016, Jastreboff and Hazell, 2004) but there has been little investigation of whether patients actually do feel reassured by such information, and it may well be that simple re-assurance is not helpful. Further exploration of patients' attitudes towards the concept of distorted perception through interviews or focus groups would be helpful in determining how best to address this issue in therapy.

Taken together, results of both studies clearly indicate that perceived magnitude of tinnitus contributes to distress and qualitative results indicate

that magnitude may be influenced by attention. Survey data could not answer the question of whether magnitude predicts attention or is predicted by attention, but the results of model testing shed some light on this subject, which is discussed in section 8.2.

#### 8.1.7 Connections

A number of previous studies have shown that the experience of tinnitus distress is multi-dimensional (for example, Bruggemann et al., 2016, Andersson et al., 1999, Holgers et al., 2005) and the current study confirmed this idea by demonstrating that scores on measures of negative thinking, emotional distress, attention and monitoring, safety behaviour and magnitude are all high amongst people who are troubled by tinnitus. The aim of this project, however, was to go beyond establishing the contribution of various factors to tinnitus distress by exploring the proposed connections between them (represented by arrows on the model diagram). In a theoretical paper, Andersson and Westin (2008) called for investigation of mediators of tinnitus distress to inform the development of psychological therapies. Since then, a number of studies have looked at individual mediators; for example, Kleinstauber et al. (2013) showed that tinnitus-related avoidance partially mediates between anxiety sensitivity and catastrophic thinking about tinnitus, Cima et al. (2011) demonstrated that tinnitus-related fear fully mediates between catastrophising and quality of life and Trevis et al. (2016b) found that depressive mood fully mediates between tinnitus handicap and anxiety. However, the current study is the first to test a full structural model of tinnitus involving multiple mediators. The hypothesis that the various components of the model are inter-related is supported by the fact that reasonably well-fitting models were identified. It would have been possible to identify a group of components which all contribute to tinnitus distress, but which are unrelated to each other; this would have resulted in a poorly fitting model. Results of path analysis raised questions about the most appropriate configuration of the model, which are discussed in section 8.2, but in both of

the best fitting models, negative thoughts, negative emotions, monitoring and avoidance behaviour were all established as partial mediators between the exogenous variable and tinnitus-related distress. Interestingly, both attention (which may include monitoring) and avoidance were also proposed as possible mediators by Andersson and Westin (2008).

Comments from interviewees and focus group participants also indicated that people can relate to the way in which one component of the model may lead to another; for example, they are aware of having negative thoughts and these making them feel anxious. It is interesting to note that several comments were made about circularity, with people feeling they were caught up in a complex feedback loop rather than following a linear process, but at the same time there were concerns about the model diagram becoming too complicated with the addition of more two-way arrows. For therapeutic purposes it is perhaps sensible to use a simple diagram, but to acknowledge the fact that relationships between components may exist in both directions.

# 8.2 Comparing the two best fitting structural models

The two best-fitting structural models were identified and described in chapter 6. Results for both fall well within the criteria for 'acceptable' model fit and fit indices are similar, indicating that both are plausible and neither should be rejected. It is important to note at this stage that other configurations of the model could potentially prove to be an equally good or better fit and if new evidence is gathered which supports an alternative structural model, this should also be tested. Evidence and theory supporting each of the two best fitting models is discussed.

Model 2.2B assumes that the amount of attention directed towards tinnitus largely determines how loud and severe tinnitus is perceived to be. It also sees the process of tinnitus distress as being 'driven' by beliefs about control. On the other hand, model 6.2B sees perceived magnitude to be the 'driver' of

ensuing psychological processes, including attention, and control beliefs are omitted.

Model 2.2B is more similar to the original Cognitive Behavioural Model of Tinnitus Distress proposed by McKenna et al. (2014) and therefore also to the cognitive model of insomnia (Harvey, 2002a). It reflects one of the core principles of CBT; that beliefs are deep-rooted and give rise to thoughts and emotions, which are more transient. Bearing these principles in mind, beliefs seem to be a logical starting point. Going against this idea however is that the type of control beliefs measured in this study appeared to be only very weakly related to tinnitus distress. The fit indices for model 2.2B were not much worse, and are better for model 6.2B, when beliefs were excluded. It would be interesting to investigate whether a 'beliefs-driven' model would fit better if a different type of belief were measured using a different instrument, such as a measure of perceived need for control.

Although the phenomenon of distorted perception could not be tested in any structural model, model 2.2B, by including an arrow from attention to magnitude, does include the supposition contained within it; that perceived loudness is chiefly a product of attention. Existing studies which show a lack of correlation between matched and self-rated loudness (for example, De Ridder et al., 2015) lend some support to the idea that perceived loudness may be influenced by psychological processes. Some interviewees in the qualitative study reported here accepted the suggestion that their perception of tinnitus loudness may be inaccurate, and some described their tinnitus seeming louder at times when they paid it more attention. On the other hand, some interviewees and therapists disagreed with this idea and did not feel that thoughts or actions influenced loudness perception. In the survey, there were a small number of people who categorised their tinnitus as 'not a problem' who also rated it as loud. Thirteen out of the thirty-five people in the 'not a problem' group gave their tinnitus a loudness rating of more than 5 out of 10, and of these, one gave it a 7 and one a 10. Similar findings were reported by Hiller and Goebel (2007). There is an indication here that there is a (small)

number of people who are not troubled by loud tinnitus which perhaps lends some support to the idea that external factors determine tinnitus loudness. Clinically, patients often describe loudness increasing with worse hearing, blocked ears or infections and similar comments were made by some of the interviewees.

If loudness perception can be reduced by psychological therapy, this would indicate that psychological processes influence it to at least some degree. A number of studies (some of which are reviewed by Martinez-Devesa et al., 2010) have found that loudness perception stays the same even when distress decreases, which supports the idea that loudness is to some degree external to the tinnitus-distress cycle. A recent exception, however, is an investigation of mindfulness based CBT by McKenna et al. (2017a). In this study, patients who benefitted from mindfulness reported significant reductions in their loudness ratings, indicating that breaking the cycle of negative thoughts, emotional distress and selective attention may remove a person's distorted perception.

Given their statistical similarity and the theoretical arguments in favour of both, there are no grounds for regarding one model as superior to the other. Rather, different people with tinnitus may see their experience reflected more in one model or the other. It has often been proposed in tinnitus literature that tinnitus should not be regarded as a uniform condition (Van de Heyning et al., 2015, Hall et al., 2015) and a number of proposals have been made for identifying tinnitus sub-types (van den Berge et al., 2017, Landgrebe et al., 2010). There may well be a sub-group of people with tinnitus for whom loudness perception is largely determined by physiological factors such as hearing damage or sinus problems, and another for whom loudness perception is determined more by attention and monitoring. Of course, the two possibilities are not mutually exclusive; it may be that increasing deafness triggers louder tinnitus and by paying attention to that louder tinnitus the person perceives it as louder still. Nevertheless, being able to distinguish different 'loudness perception' sub-groups (perhaps by comparing how

individuals score on matched and self-rated loudness measures) could be helpful in planning therapy, with more emphasis on reducing monitoring behaviour, for example, for people whose loudness perception is largely driven by attention.

# 8.3 Study limitations

Limitations associated with the survey method of data collection applied to the first study in this project. A survey answered at a single time point can only ever be a 'snapshot' of a person's situation and, with a condition that fluctuates like tinnitus, this means it may not reflect how things are most of the time. One participant noted he had been on holiday just before completing the survey, so it had not been a 'typical' week. The same may have applied to other respondents. Another common problem with surveys is that there is often a disparity between what people think they do and what they actually do. This may be particularly true for questions about thoughts. Part of the definition of automatic thoughts is that they are transient and fleeting and people may hardly be aware of having them (Williams and Chellingsworth, 2010). Reporting on how often one has had different thoughts over the past week is likely to be inaccurate. However, recording thoughts in other ways, such as keeping a thought diary, is much more demanding for participants.

Another drawback of the survey method is that respondents may not be typical of the population. Although many respondents had not received professional help with their tinnitus, most were either involved in a tinnitus organisation or had previously put their names forward as volunteers to participate in research. People who have tinnitus and have not even accessed information about it are much harder to reach and may have quite different experiences. The large majority were also resident in the UK, so results cannot be generalised to other populations.

Only once the survey had been completed did it become apparent that the most appropriate measures of beliefs may not have been chosen. The adapted Fear of Tinnitus Questionnaire, which was intended to measure

beliefs about the meaning of tinnitus, was not robust enough to be used and the modified control subscales of the IPQ were only weakly related to tinnitus distress. Comments in interviews suggested that beliefs about the importance of feeling in control might have been more relevant. Re-testing the model using a more general measure of control beliefs could potentially result in a better fit.

There is a broader question as to whether any of the questionnaires used, or the factors they contain, were measuring precisely and exclusively what they purported to measure. The business of questionnaire naming- and the naming of factors contained within them- is a largely subjective one, and a collection of items may be regarded as representing different constructs by different adjudicators (Streiner, 2013). As an example, Wilson and Henry (1998) called the two subscales of their Tinnitus Cognitions Questionnaire 'negative thinking' and 'positive thinking' while another researcher might see the terms 'catastrophising' and 'self-encouragement' as a more accurate description of the items contained within them. Psychometric comparison of tinnitus-related measures with measures of similar constructs from other fields (catastrophising and self-encouragement in pain, for example) would help to determine the best descriptors to use.

Furthermore, although most of the questionnaires selected had demonstrated divergent validity with more general measures of tinnitus distress (see chapter 3) there is bound to be a degree of overlap between them as they all measure difficulties related to having tinnitus. An interesting question to contemplate is whether, if the same items were used to measure tinnitus-related distress without being separated into the instruments or factors to which they 'belong,' the same constructs would emerge as are depicted in the Cognitive Behavioural Model of Tinnitus Distress. In the field of eating disorders, Thompson et al. (1994) included all the items from seven widely used measures of body image disturbance in a single exploratory factor

analysis. Although all of the questionnaires treated body image as a multifaceted construct, only two factors emerged from the EFA, which led the authors to question the notion that body image disturbance comprises as many distinct components as supposed, and to recommend a reduction in the number of scales used to measure it. In a similar way, it would be possible to include all the 133 items used in the tinnitus survey described here in a single, large EFA. Examination of the optimum factor structure and factor loadings would help to determine whether tinnitus-related distress is best conceptualised as comprising the components included in the Cognitive Behavioural Model or whether the grouping together of items indicates that different components exist, such as 'hopelessness' or 'sense of isolation'. It may be that certain components of the model could be collapsed into one if insufficient evidence exists for their separateness, which would result in a simpler model. Such an exercise may also result in the rejection of a number of items which overlap strongly with others. The elimination of redundant items and subsequent reduction of burden on patients has important implications for the use of questionnaires in future research and clinical practice and for a clearer, simpler understanding of the psychological impact of tinnitus.

A limitation of the qualitative study is that all the participants were attending the same type of mindfulness based CBT course. While this meant that they all received the same explanation of the Cognitive Behavioural Model, it also meant that they were all people who had been referred to a (rare) specialist clinical psychology service for tinnitus and all people who had committed to an intensive, 8-week course accompanied by course notes which they were expected to read between each session. People who have had the model explained to them more briefly in a routine tinnitus clinic, in which there are typically more time pressures and longer periods between appointments, may not engage with it in the same way.

### 8.4 Recommendations for further study

It is generally good practice to cross-validate models using different data (Schumacker and Lomax, 2004). Unfortunately, no existing studies have investigated even a section of the models tested in this project using the same questionnaires or near equivalents. Furthermore, some of the questionnaires used in this study were found to have shortcomings. Prior to re-testing the models, it would be sensible to reconsider the measures used for certain variables, in particular beliefs. It would also be valuable to re-test the models using different samples, perhaps in particular a clinical sample, to see whether one configuration fits a group of help-seekers better than the other. Testing the models in populations outside the UK would also help to establish how cross-cultural the findings of this project are.

Given that there is little to choose between the two best fitting models, the possibility that different sub-types of people exist whose experience of tinnitus is reflected more in one model than the other would be interesting to investigate further. In recent years there has been increasing interest in stratified medicine, which involves the identification of sub-types of patients with a wide range of medical disorders in order to make better informed and more personalised treatment choices (Medical Research Council, 2013). While the focus was originally on targeting drug treatment, the scope of the stratified medicine agenda now extends to mental health and psychological therapies (Schumann et al., 2014). In the field of tinnitus, there have been several calls over the past decade for the identification of tinnitus sub-types (Landgrebe et al., 2010, Hall et al., 2015) in order to improve the outcomes of existing treatments and to inform the development of new ones. One approach to the investigation of sub-types is latent class analysis. This statistical technique enables the identification of groups which share characteristics which have not been pre-determined by the researcher (Schumacker and Lomax, 2004). A recent latent class analysis involving 2828

tinnitus patients (Langguth et al., 2017) identified eight distinct groups of tinnitus patients with different hearing characteristics (high frequency hearing loss, unilateral hearing loss, normal hearing, etc.) who were also found to differ in certain characteristics of tinnitus, such as sudden or gradual onset, and constant or intermittent perception. Similar methodology could be used to further investigate components of the Cognitive Behavioural Model of Tinnitus Distress. Latent class analysis may reveal a 'beliefs-driven' group of people who tend to score low on magnitude but high on distress and high on beliefs, for example, or a 'loudness driven' group who score high on magnitude and high on distress but low on monitoring. A large sample size would be needed for such an analysis and a variety of sources of participants would need to be exploited.

An essential addition to this investigation of possible subtypes would be to ask people with tinnitus specifically in a qualitative study about their views on tinnitus loudness- do they see the loudness of their tinnitus as something which 'just is', or do they feel it is strongly influenced by attention? This topic was touched upon in the interviews for this project, but would be worth exploring more explicitly. It would also be interesting to show people with tinnitus the two best fitting versions of the model and ask them to comment on which they feel is more applicable to them. It may be that one version is more effective in helping patients understand their experience of tinnitus than the other.

In addition to further investigation of the full model, it would be worthwhile validating some of the individual questionnaires used in the survey using different samples. None of the tinnitus- specific questionnaires used in this project had undergone a great deal of prior analysis, and yet they are potentially very useful in measuring change in the different aspects of tinnitus distress (such as negative thoughts and avoidance behaviour) which are targeted during therapy.

As discussed in section 2.3.4, a particular area in which further research is required is the nature of beliefs in tinnitus. Not only do beliefs about control and about the meaning of tinnitus need investigating further (see section 8.1.5), it is also important to find out about other, as yet unidentified, beliefs which are common in people with tinnitus. Beck (1976) saw three types of core belief as being important in the development of emotional disorders; beliefs about oneself, the world, and the future. It is conceivable that such beliefs may contribute to the development and maintenance of tinnitusrelated distress. For example, believing that other people cannot be trusted might give rise to a negative thought such as "if I tell people about my tinnitus they won't take me seriously", and this could increase feelings of emotional distress. Such beliefs have never been investigated in people with tinnitus. One approach to doing this is to conduct qualitative analysis of open-ended interviews, although this may present some difficulties as people are not necessary aware of what their core beliefs are prior to undergoing therapy (Padesky 1994). An alternative approach is that taken by Millings and Carnelley (2015) who analysed data from 1813 people who had been completing an online mental health program. One of the online exercises involved beginning with an automatic thought and repeatedly answering the question "what does that mean for me?" until a core belief was eventually uncovered. These core beliefs were recorded, collected and then grouped into themes. With the development of online CBT programs for tinnitus (Kaldo et al., 2008, Beukes et al., 2017) similar opportunities for analysing data from people with tinnitus now exist.

# 8.5 Implications for Clinical Practice

Writing in the field of disability research, Sullivan and Cen (2011) call for more attention to be paid to structural equation models when considering knowledge translation, that is, the use of evidence-based knowledge in clinical practice. They argue that, if summarised clearly, empirically supported

models provide clinicians with an evidence-based, accessible guide to areas that need targeting in therapy for complex conditions. The overriding aim of this project was to contribute towards improving therapeutic intervention for people who are struggling with tinnitus. The relevance of all components of the original Cognitive Behavioural Model to tinnitus distress- with the possible exception of beliefs- was established using both SEM and qualitative techniques, indicating that they should all be targeted in tinnitus therapy. Typically, CBT, ACT and mindfulness programmes for tinnitus do address thoughts, emotions, attention and behaviour (Kroner-Herwig et al., 2003, Hesser et al., 2012, McKenna et al., 2017b) and all of these elements seem to be important. Moreover, their inter-relatedness has been confirmed. This is important, as it indicates that targeting one component of the model is also likely to influence others. If, for example, learning mindfulness reduces negative thinking, this in turn is likely to reduce the amount of attention paid towards tinnitus. A negative cycle of thoughts, behaviour and attention may be broken by addressing any one of these components, and which to address first should be decided through careful discussion with the patient (McKenna and Andersson, 2008).

In more general terms, empirical support for a cognitive behavioural model re-enforces the argument for making CBT-based treatment more readily available. In their path analysis of a cognitive behavioural model of chronic pain, Vranceanu et al. (2010) make the point that, because they showed health anxiety predicted somatic symptoms and perceived disability, it would be preferable to move away from traditional clinical procedures consisting of multiple tests and monitoring (which enhance health anxiety) towards helping people manage their pain using CBT. In a similar way, once any treatable pathology has been excluded, it might be more helpful to move tinnitus services away from the Ear, Nose and Throat clinic and towards settings in which CBT can be provided.

A recent Delphi survey collected tinnitus patients' and clinicians' views about which elements of psychological therapy should be included in routine tinnitus intervention delivered in audiology departments (Thompson et al., 2017). There was a very high level of agreement that it is essential for clinicians to give patients information about how tinnitus becomes a problem and how it is maintained as such, and to provide information on psychological models of tinnitus and mental health. Discussion of a cognitive therapy model of some kind with patients who have bothersome tinnitus is also recommended in tinnitus treatment guidelines produced by the American Academy of Otolaryngology (Tunkel et al., 2014). This project has provided support to the idea of using the Cognitive Behavioural Model of Tinnitus Distress as a therapeutic tool; showing it to patients as a way of helping them gain a better understanding. Other models of tinnitus- the neurophysiological model in particular- have been strongly recommended for clinical use (Jastreboff and Hazell, 2004) and some studies have included explanation of the neurophysiological model as part of therapeutic intervention (Hiller and Haerkotter, 2005, Cima et al., 2012), but there has been no formal investigation of how either patients or clinicians respond to it, or of whether having such an explanation is considered helpful. Possibly, an adapted version or versions of the original model could be created for clinical use based on the findings of both quantitative and qualitative studies. A suggested patient model is shown in figure 8.1. It is evidence-based, as all the constructs and paths shown have been supported by evidence gathered in this study. It is also relatively simple. The dotted arrows acknowledge the possible influence of factors external to the model and, in particular, allow for the possibility that perceived loudness might not only be a product of attention (as discussed in section 8.2). Such a model could be easily explained in individual appointments or group therapy and could lead on to a discussion of how different areas can be addressed.

One of the interviewees spoke about an alternative, positive model, in which looking after oneself leads to feelings of calm and a shifting of attention away

from tinnitus. Creation of such a Cognitive Behavioural Model of Tinnitus Acceptance could also be very helpful to therapy. In other fields of healthcare, some successful self-management programmes have been developed which have shifted away from the problem-solving ethos of conventional CBT towards an approach based on positive psychology (Seligman et al., 2006) to include work on gratitude, fostering hope and finding personal meaning (Turner and Martin, 2017). This could be an interesting future direction for tinnitus therapy.

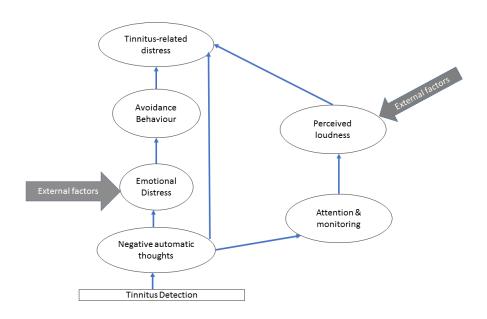


Figure 8.1: proposed patient model

#### 8.6 Conclusions

This study has provided empirical support for two structural models derived from the theoretical Cognitive Behavioural Model of Tinnitus Distress.

Elements of these models require further investigation, but predictions contained within the original, theoretical model about the contribution of negative thoughts, emotional distress, attention and monitoring, safety behaviour and perceived magnitude to tinnitus-related distress and about the existence of interrelationships between these concepts have been supported by data collected from people with tinnitus. McKenna (2004) highlighted the

need for tinnitus therapy to be based on empirically supported rather than purely theoretical models, and this study affords an opportunity to do this in future. Moreover, it has demonstrated that a Cognitive Behavioural Model of Tinnitus Distress is regarded as understandable by people with tinnitus and largely reflective of their own experience. Its use as a therapeutic tool should be explored.

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# Appendix 1. Initial page of survey: 'Tinnitus thoughts, feeling and actions'.

INSTRUCTIONS: Please answer the questions as accurately as possible as this is very important to the outcome of this research. Please answer every question.

The information you provide in this questionnaire will be treated confidentially.

1. How old are you?
2. Are you
Male
Female
(Please tick the applicable box)
3. Roughly how long have you had tinnitus?
4. Are you having any treatment for your tinnitus now?
Yes
No
5. If you are receiving treatment what kind?

6. Have yo	ou had any treatment for your tinnitus in the past?
Yes	
No	

7. If you have received any treatment in the past, what kind?

# **Appendix 2: Questionnaires included in survey**

### **Tinnitus Cognitions Questionnaire**

	Never	Rarely	Occasionally	Frequently	Very frequently
1. I think "if only the noise would go away"	0	1	2	3	4
2. I think "why me? Why do I have to suffer this horrible noise?"	0	1	2	3	4
3. I think "What did I do to deserve this?"	0	1	2	3	4
4. I think "The noise makes my life unbearable."	0	1	2	3	4
5. I think "Nobody understands how bad the noise is"	0	1	2	3	4
6. I think "If only I could get some peace and quiet"	0	1	2	3	4
7. I think "I can't enjoy what I'm doing because of the noise"	0	1	2	3	4
8. I think "How can I go on putting up with this noise?"	0	1	2	3	4
9. I think "The noise will drive me crazy"	0	1	2	3	4
10. I think "Why can't anyone help me?"	0	1	2	3	4
11. I think "My tinnitus is never going to get better"	0	1	2	3	4
12. I think "The noise will overwhelm me"	0	1	2	3	4
13. I think "With this noise, life is not worth living"	0	1	2	3	4
14. I think "no matter how unpleasant the noise gets, I can cope"	0	1	2	3	4
15. I think "The noise might be unpleasant, but it won't drive me crazy"	0	1	2	3	4

16. I think "I'll be able to enjoy things if I keep my attention off the noise."	0	1	2	3	4
17. I think "I'm not the only person with tinnitus"	0	1	2	3	4
18. I think "There are things in life worse than tinnitus"	0	1	2	3	4
19. I think "The noise will eventually get less annoying if I try to distract myself from it"	0	1	2	3	4
20. I think "I have coped with the noise before, so I can cope again this time."	0	1	2	3	4
21. I say to myself "It will help if I try to think of something pleasant."	0	1	2	3	4
22. I tell myself "I can learn to live with it."	0	1	2	3	4
23. I think "The noise might be there, but I can still enjoy things"	0	1	2	3	4
24. I tell myself "Think of something else other than the noise"	0	1	2	3	4
25. I tell myself "I won't think about the noise"	0	1	2	3	4
26. I think "The noise is a nuisance but I just won't let it bother me"	0	1	2	3	4

#### **Clinical Outcomes in Routine Evaluation**

Over the last week	Not at all	Only Occasionally	Sometimes	Often	Most or all the time
1. I have felt terribly alone and isolated					
2. I have felt tense, anxious or nervous					
3. I have felt I have someone to turn to for support when needed					
4. I have felt O.K about myself					
<ol><li>I have felt totally lacking in energy and enthusiasm</li></ol>					
6. I have been physically violent to others					
7. I have felt able to cope when things go wrong					
<ol><li>I have been troubled by aches, pains or other physical problems</li></ol>					
9. I have thought of hurting myself					

10. Talking to people has felt too much for me		
11. Tension and anxiety have prevented me doing important things		
12. I have been happy with the things I have done		
13. I have been disturbed by unwanted thoughts and feelings		
14. I have felt like crying		
15. I have felt panic or terror		
16. I made plans to end my life		
17. I have felt overwhelmed by my problems		
18. I have had difficulty getting to sleep or staying asleep		
19. I have felt warmth or affection for someone		
20. My problems have been impossible to put to one side		
21. I have been able to do most things I needed to		
22. I have threatened or intimidated another person		
23. I have felt despairing or hopeless		
24. I have thought it would be better if I were dead		
25. I have felt criticised by other people		
26. I have thought I have no friends		
27. I have felt unhappy		
28. Unwanted images or memories have been distressing me		
29. I have been irritable when with other people		
30. I have thought I am to blame for my problems and difficulties		
31. I have felt optimistic about my future		
32. I have achieved the things I wanted to		

33. I have felt humiliated or shamed by other people			
34. I have hurt myself physically or taken dangerous risks with my health			

# **Tinnitus Vigilance and Awareness Questionnaire**

	Never					Always
I am very aware of changes in my tinnitus.	0	1	2	3	4	5
I am quick to notice changes in the intensity of my tinnitus.	0	1	2	3	4	5
3. I am quick to notice the effects of medication on my tinnitus.	0	1	2	3	4	5
4. I am quick to notice changes in the sound of my tinnitus.	0	1	2	3	4	5
5. The tinnitus keeps me constantly occupied.	0	1	2	3	4	5
6. I notice the tinnitus even if I am busy with another activity	0	1	2	3	4	5
7. I find it easy to ignore my tinnitus.	0	1	2	3	4	5
8. I know immediately when my tinnitus starts or increases.	0	1	2	3	4	5
9. When I do something that increases my tinnitus, the first thing I do is check to see how much my tinnitus was increased.	0	1	2	3	4	5
10. I know immediately when my tinnitus decreases.	0	1	2	3	4	5
11. I must attend to my tinnitus a lot.	0	1	2	3	4	5
12. I carefully monitor how intense my tinnitus is.	0	1	2	3	4	5
13. I become preoccupied with my tinnitus.	0	1	2	3	4	5
14. I do not dwell on my tinnitus.	0	1	2	3	4	5
15. I'm able to ignore the tinnitus, even if it is present	0	1	2	3	4	5
16. I am aware of my tinnitus from the moment I get up till the moment I go to sleep	0	1	2	3	4	5
17. The tinnitus distracts me, no matter what I do.	0	1	2	3	4	5
18. My tinnitus is so bad that I cannot ignore it.	0	1	2	3	4	5

# Illness perception questionnaire (control subscales)

		1		I	I	
		Strongly disagree	Disagree	Neither agree nor disagree	Agree	Strongly agree
1.	There is a lot which I can do to control my symptoms	1	2	3	4	5
2.	What I do can determine whether my tinnitus gets better or worse	1	2	3	4	5
3.	The course of my tinnitus depends on me	1	2	3	4	5
4.	Nothing I do will affect my tinnitus	1	2	3	4	5
5.	I have the power to influence my tinnitus	1	2	3	4	5
6.	My actions will have no effect on the outcome of my tinnitus	1	2	3	4	5
7.	My tinnitus will improve in time	1	2	3	4	5
8.	There is very little that can be done to improve my tinnitus	1	2	3	4	5
9.	My treatment will be effective in curing my tinnitus	1	2	3	4	5
10.	The negative effects of my tinnitus can be prevented (avoided) by my treatment	1	2	3	4	5
11.	My treatment can control my tinnitus	1	2	3	4	5
12.	There is nothing which can help my tinnitus	1	2	3	4	5

## **Modified Fear of Tinnitus Questionnaire**

		Strongly disagree	Disagree	Neither agree nor disagree	Agree	Strongly agree
1.	I am afraid that my tinnitus will deteriorate my hearing	1	2	3	4	5
2.	I fear that my tinnitus is the result of a tumour	1	2	3	4	5
3.	I am afraid my tinnitus will leave me deaf	1	2	3	4	5
4.	I am afraid the moment will come that my head cannot withstand tinnitus anymore	1	2	3	4	5
5.	My mental condition will become severely affected by my tinnitus	1	2	3	4	5
6.	I am afraid that tinnitus will stop me from ever having a normal life again	1	2	3	4	5
7.	I am afraid I will not be able to do anything anymore because of my tinnitus	1	2	3	4	5
8.	I am afraid that tinnitus may be a preliminary sign of brain haemorrhage or similar	1	2	3	4	5

#### **Tinnitus Fear Avoidance Scale**

	Strongly disagree	Disagree	Somewhat disagree	Somewhat agree	Agree	Strongly agree
Due to my tinnitus I avoid noisy environments (e.g. concerts, cinema, theatre, parties, restaurants, pubs, discos, listening to loud music at home).	1	2	3	4	5	6
Due to my tinnitus I avoid conversations with more than one person.	1	2	3	4	5	6
Due to my tinnitus I avoid sporting activities.	1	2	3	4	5	6
Due to my tinnitus I avoid exhausting activities and jobs.	1	2	3	4	5	6
Due to my tinnitus I avoid activities that demand high levels of concentration.	1	2	3	4	5	6
Due to my tinnitus I avoid quiet or silent environments.	1	2	3	4	5	6
Due to my tinnitus I avoid using electronic devices that emit electromagnetic radiation (e.g., mobile phone, computer, electric	1	2	3	4	5	6
Due to my tinnitus I avoid flying or other situations where it is necessary to equalize air pressure.	1	2	3	4	5	6
Due to my tinnitus I try to avoid getting water into my ears when I have a shower, a bath o when I go swimming.	1	2	3	4	5	6
Due to my tinnitus I try to protect my ears whenever it is possible (e.g., wearing ear plugs, a cap, or by blocking my ears).	1	2	3	4	5	6
Due to my tinnitus I do everything to avoid getting a cold or an ear problem.	1	2	3	4	5	6

## **Tinnitus Magnitude Index**

1.	Over	the p	oast v	veek,	how	stroi	ng or	loud v	was yo	our tinnitus?		
0 Not at		2	3	4	5	6	7	8	9	10 Extremely		
strong	Over	the p				-		_	your t	strong or loud ime awake were you		
0% 10							nitus? 70%		90%	100%		
Never										Always		
3.	How	seve	re ha:	s you	r tinr	nitus	been	over t	the pa	st week?		
0	1	2	3	4	5	6	7	8	9	10		
No tinn presen										worst tinnitus you can imagine		
Tinnitus Functional Index (emotional subscale)												
1.	Ove feel?		e past	wee	k, ho	w an	xious	or wo	orried	has your tinnitus made you		
0	1	2	3	4	5	6	7	8	9	10		
Not at a		orrie	d							Extremely anxious or worried		
2.	Over tinni	-	oast v	veek,	how	both	ered	or up	set ha	ve you been because of your		
0	1	2	3	4	5	6	7	8	9	10		
Not at a		upset	ī							Extremely bothered or upset		

3. Over the past week, how depressed were you because of your tinnitus?

0 1 2 3 4 5 6 7 8 9 10

Not at all Extremely depressed depressed

### **Tinnitus Reaction Questionnaire**

		Not at all	A little of the time	Some of the time	A good deal of the time	Almost all the time
1.	My tinnitus has made me unhappy.	0	1	2	3	4
2.	My tinnitus has made me feel tense.	0	1	2	3	4
3.	My tinnitus has made me feel irritable.	0	1	2	3	4
4.	My tinnitus has made me feel angry.	0	1	2	3	4
5.	My tinnitus has led me to cry.	0	1	2	3	4
6.	My tinnitus has led me to avoid quiet situations.	0	1	2	3	4
7.	My tinnitus has made me feel less interested in going out.	0	1	2	3	4
8.	My tinnitus has made me feel depressed.	0	1	2	3	4
9.	My tinnitus has made me feel annoyed.	0	1	2	3	4
10.	My tinnitus has made me feel confused.	0	1	2	3	4
11.	My tinnitus has "driven me crazy".	0	1	2	3	4
12.	My tinnitus has interfered with my enjoyment of life.	0	1	2	3	4
13.	My tinnitus has made it hard for me to concentrate.	0	1	2	3	4
14.	My tinnitus has made it hard for me to relax.	0	1	2	3	4
15.	My tinnitus has made me feel distressed.	0	1	2	3	4
16.	My tinnitus has made me feel helpless.	0	1	2	3	4
17.	My tinnitus has made me feel frustrated with things.	0	1	2	3	4

18. My tinnitus has interfered with my ability to work.	0	1	2	3	4
19. My tinnitus has led me to despair.	0	1	2	3	4
20. My tinnitus has led me to avoid noisy situations.	0	1	2	3	4
21. My tinnitus has led me to avoid social situations.	0	1	2	3	4
<ol><li>22. My tinnitus has made me feel hopeless about the future.</li></ol>	0	1	2	3	4
23. My tinnitus has interfered with my sleep.	0	1	2	3	4
24. My tinnitus has led me to think about suicide.	0	1	2	3	4
25. My tinnitus has made me feel panicky.	0	1	2	3	4
26. My tinnitus has made me feel tormented.	0	1	2	3	4

# **Appendix 3: Interview schedule**

Note: this is a qualitative study, the aim of which is to explore individual's views and perspectives. As such, interview questions will not be identical for each participant. Rather, follow-up questions will depend on responses to preceding questions and areas which the participant identifies as important.

#### Possible questions include:

- Do you remember Laurence Mckenna/ Liz Marks explaining the cognitive model of tinnitus distress to you at a group meeting? (show diagram as a reminder.) Can you tell me in your own words what it means?
- Do you think this model applies to you and your experience of tinnitus in any way? Are there parts of it that you relate to particularly? Why do you think that is?
- Are there parts of the model which don't feel as though they apply to you? If so, which parts?
- Is there anything about your experience of tinnitus which is missing from the model? If so, where would you put that in?
- Could you understand the model straight away, or was it quite difficult?

- If it was hard to understand, what do you think would make it easier?
- Do you think it's generally helpful for people with tinnitus to learn about a model like this?
- Do you think that knowing about this model has changed anything about the way in which you think about tinnitus, or anything you do?
- Is there anything else you'd like to say about it?

# **Appendix 4: Focus group schedule**

Room 249. Cog model diagram can be projected onto screen. Also have a few paper copies on table.

#### Possible questions include:

- Can you tell me your interpretation of what this model means?
- Do you think this model applies to most of your tinnitus patients? Are there parts of it that apply particularly? Why do you think that is?
- Are there parts of the model which don't feel as though they apply so much? If so, which parts?
- Is there anything important about people's experience of tinnitus which is missing from the model? If so, where would you put that in?
- Do you think the process described by this model underpins the therapy you offer?
- Do you ever refer to this model during tinnitus appointments? Do you talk patients through the diagram? How do you decide whether and when to do this?
- Do you think patients understand the model easily when you talk about it, or is it quite difficult?

- Do you think patients accept the 'messages' of the model, or not?
- Do you think that knowing about this model has changes anything about the way in which people think about tinnitus, or anything they do?
- If you don't refer to the model explicitly, do you have it in mind when talking to patients?
- Is there a different diagram or a different way of looking at things that you find more helpful?
- Is there anything else you'd like to say about it?