

**DEFINING COMPONENTS AND MEASURING THE
EFFECTS OF AUDIOLOGIST-DELIVERED
COUNSELLING FOR TINNITUS**

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**Thesis submitted to the University of Nottingham for the degree
of Doctor of Philosophy**

January 2018

ABSTRACT

Psychological treatment is effective at alleviating tinnitus distress when delivered by a psychologist. In the United Kingdom (UK), best practice guidance for tinnitus advises that audiologists should deliver Cognitive Behavioural Therapy (CBT) and other counselling techniques where psychologists are unavailable. However, there is a lack of evidence for the effectiveness of audiologist-delivered psychological tinnitus treatment, and no consensus among clinicians and researchers on what form, if any, this should take. Furthermore, training in CBT and other counselling techniques is not a part of standard audiologist training in the UK. The aims of this PhD were to define the components and measure the effects of an audiologist-delivered psychological tinnitus treatment for people with tinnitus.

Potential treatment components to include were identified in two studies. The first study was a comprehensive scoping review in which components were extracted from 64 records on psychological tinnitus treatment delivered by psychologists. The components were predominantly extracted from studies of CBT. The second study was a Delphi survey of a panel of 39 patients and clinicians who were asked to rate the importance of 160 different treatment components for an audiologist-delivered psychological tinnitus treatment. These data were used to inform the development of a treatment manual, underpinned by a cognitive behavioural model of tinnitus distress. The manual comprised tinnitus education, psychoeducation, relaxation,

graded exposure, thought challenging, physical exercise, sleep hygiene, an introduction to acceptance and defusion techniques, and sound enrichment, which could be implemented flexibly according to patient need.

To measure the effects of the psychological tinnitus treatment, appropriate outcome domains and instruments were identified by applying template analysis to the treatment manual. Potential domains were selected from a list constructed by grounded theory using existing questionnaires. Outcome instruments were identified if they were responsive to therapeutic change and possessed good content validity and internal consistency. It was predicted that the treatment would affect tinnitus-specific emotional impact and negative thoughts. Based on current evidence, the Tinnitus Functional Index (TFI) and the Tinnitus Cognitions Questionnaire (TCQ) were identified to best measure these domains.

A feasibility randomised controlled trial (RCT) was conducted over six months to determine the feasibility of a definitive RCT of audiologist-delivered psychological tinnitus treatment. Nineteen patients were recruited to the trial. Attrition rates were high, though all patient withdrawals occurred before their first appointment. The trial indicated that a definitive RCT of audiologist-delivered psychological tinnitus treatment is not feasible due to poor site compliance with returning questionnaires, and low recruitment rates in smaller trial sites.

Patients and audiologists were invited to attend post-treatment semi-structured interviews to explore treatment fidelity and experience. Patients reported that the treatment was acceptable and effective in reassuring them about their tinnitus. Audiologists reported focusing on psychoeducation with limited use of specific techniques such as thought challenging and graded exposure. Patients and audiologists thought that the TFI and TCQ comprehensively measure the important tinnitus domains and are useful for planning treatment and encouraging discussion about patients' negative thoughts. A lack of confidence due to the brevity of training was given by audiologists as a reason they avoided implementing certain treatment components.

PUBLISHED PAPERS

Publications arising from this thesis

TAYLOR, J. A., HALL, D. A., WALKER, D.-M., MCMURRAN, M., CASEY, A., STOCKDALE, D., FEATHERSTONE, D., THOMPSON, D. M., MACDONALD, C. & HOARE, D. J. 2017. A psychologically informed, audiologist-delivered, manualised intervention for tinnitus: protocol for a randomised controlled feasibility trial (Tin Man study). *Pilot and Feasibility Studies*, 3, 24. *

THOMPSON, D. M., HALL, D. A., WALKER, D. M. & HOARE, D. J. 2017a. Psychological Therapy for People with Tinnitus: A Scoping Review of Treatment Components. *Ear Hear*, 38, 149-58. †

THOMPSON, D. M., TAYLOR, J., HALL, D. A., WALKER, D. M., MCMURRAN, M., CASEY, A., STOCKDALE, D., FEATHERSTONE, D. & HOARE, D. J. 2017b. Patients' and Clinicians' Views of the Psychological Components of Tinnitus Treatment That Could Inform Audiologists' Usual Care: A Delphi Survey. *Ear Hear*, doi: 10.1097/AUD.0000000000000492 ‡

Other publications during this thesis

HALL, D. A., HAIDER, H., SZCZEPEK, A. J., LAU, P., RABAU, S., JONES-DIETTE, J., LONDERO, A., EDVALL, N. K., CEDERROTH, C. R., MIELCZAREK, M., FULLER, T., BATUECAS-CALETRIO, A., BRUEGGEMEN, P., THOMPSON, D. M., NORENA, A., CIMA, R. F., MEHTA, R. L. & MAZUREK, B. 2016. Systematic review of outcome domains and instruments used in clinical trials of tinnitus treatments in adults. *Trials*, 17, 270.

* Chapter 6 based on Taylor and colleagues (2017)

† Chapter 2 based on Thompson and colleagues (2017a)

‡ Chapter 3 based on Thompson and colleagues (2017b)

DECLARATION

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

A handwritten signature in black ink, appearing to read 'DM Thompson', is written on a light-colored rectangular background.

15th January 2018

Dean Mark Thompson

Date

ACKNOWLEDGEMENTS

I would like to begin by thanking my supervisory team, Dr Derek Hoare, Prof Deborah Hall and Dr Dawn-Marie Walker, for having patience and faith in me, sharing their passion for research, and helping me to begin to understand tinnitus.

I would also like to thank the rest of the team who worked on the RfPB grant, everyone else at NIHR Nottingham BRC for their support, and the patients and audiologists who selflessly volunteered their time to help others.

I would like to thank Dr Roland Schaette and Dr Lucy Handscomb for welcoming me and supporting my contribution to teaching at UCL, and all the members of TINNET that I have collaborated with and from whom I have learned so much.

I would also like to express my gratitude to my examiners for taking the time to act as gatekeepers for the academic community, and to improve myself as a researcher. Firstly, Prof Gerhard Andersson, for ensuring that I am not short of research to cite. Secondly, Dr Thomas Schröder, for the patience to listen to my *attempts* to convey my work in the early stages of my PhD, and again at my *viva voce*.

I would like to thank the organisations that have funded my research and training, and those that have awarded prizes for my work including the National Institute for Health Research, University of Nottingham including the Graduate School, the National Institute of

Deafness and Other Communication Disorders, American Auditory Society, and the European Union.

I would like to thank my mum for her unwavering support, and my sister, Kelly, for inspiring me to transcend my circumstances by making the idea of attending University feel like the most natural thing in the world. I would like to thank my wife, Francesca, for reminding me to look after myself, and taking care of me on all the occasions I did not listen. Finally, I would like to thank my daughter, Sora, for scribbling most of the red ink on my work and shouting the loudest at it until it was just right.

In memory of Angie Elliott

TABLE OF CONTENTS

ABSTRACT	ii
PUBLISHED PAPERS.....	v
DECLARATION	vi
ACKNOWLEDGEMENTS.....	vii
TABLE OF CONTENTS	x
LIST OF TABLES.....	xvi
LIST OF FIGURES	xviii
LIST OF ABBREVIATIONS	xix
CHAPTER 1. INTRODUCTION	1
1.1. THESIS OVERVIEW	1
1.2. TINNITUS	2
1.3. TINNITUS AND CO-OCCURRING MENTAL HEALTH PROBLEMS	5
1.4. PSYCHOLOGICAL MODELS OF TINNITUS.....	6
1.5. PSYCHOLOGICAL TREATMENTS FOR TINNITUS	10
1.6. TINNITUS CARE IN THE UK	13
1.7. AIMS.....	17
CHAPTER 2. SCOPING REVIEW OF PSYCHOLOGICAL TREATMENTS FOR PEOPLE WITH TINNITUS.....	18
2.1. INTRODUCTION	18
2.1.1. Background	18
2.1.2. Aim	19
2.2. METHODS	19

2.2.1.	Eligibility criteria	19
2.2.2.	Search strategy	20
2.2.3.	Study selection	23
2.2.4.	Charting the data.....	23
2.3.	RESULTS.....	24
2.3.1.	Types of psychological treatment reported	24
2.3.2.	Job roles of clinicians who delivered psychological therapy	28
2.3.3.	Components of psychological therapies	31
2.4.	DISCUSSION.....	39
 CHAPTER 3. DELPHI SURVEY OF THE PSYCHOLOGICAL		
COMPONENTS IMPORTANT TO INCLUDE IN AUDIOLOGIST-		
DELIVERED TINNITUS TREATMENT.....		
3.1.	INTRODUCTION	44
3.1.1.	Background	44
3.1.2.	Aim	46
3.2.	METHODS	47
3.2.1.	Study approvals.....	47
3.2.2.	Panel recruitment, size, and composition	47
3.2.3.	Survey development and piloting.....	48
3.2.1.	Survey administration	50
3.2.2.	Survey Round 1.....	51
3.2.3.	Survey Round 2.....	52
3.2.4.	Survey Round 3.....	53
3.3.	RESULTS.....	55
3.3.1.	Panellist demographics and response rates	55
3.3.2.	Components derived from Round 1	56
3.3.3.	Consensus reached in Round 2	58

3.3.4.	Consensus reached in Round 3	58
3.3.5.	Sensitivity analysis.....	66
3.3.6.	Stability of responses	68
3.4.	DISCUSSION.....	68
 CHAPTER 4. MANUALISATION OF AN AUDIOLOGIST-DELIVERED		
PSYCHOLOGICAL TINNITUS TREATMENT		75
4.1.	INTRODUCTION	75
4.1.1.	Background	75
4.1.2.	Aims	77
4.2.	METHODS	77
4.2.1.	Reference group meeting	78
4.2.2.	Audiologist Training.....	81
4.2.3.	Data collection.....	82
4.2.4.	Data analysis	82
4.3.	RESULTS.....	83
4.3.1.	Reference group meeting	83
4.3.2.	Interim prototype treatment manual	92
4.3.3.	Audiologist feedback.....	95
4.3.4.	Final treatment manual.....	98
4.4.	DISCUSSION.....	102
 CHAPTER 5. OUTCOME SELECTION PROCEDURE TO MEASURE		
THE EFFECTS OF AUDIOLOGIST-DELIVERED PSYCHOLOGICAL		
TINNITUS TREATMENT.....		107
5.1.	INTRODUCTION	107
5.1.1.	Background	107
5.1.2.	Aim	112

5.2. OUTCOME DOMAIN SELECTION	112
5.2.1. Methods of outcome domain selection.....	112
5.2.2. Results of outcome domain selection	116
5.3. OUTCOME INSTRUMENT SELECTION	121
5.3.1. Methods of outcome instrument selection.....	121
5.3.2. Results of outcome instrument selection.....	128
5.4. DISCUSSION.....	133
 CHAPTER 6. A RANDOMISED CONTROLLED FEASIBILITY TRIAL	
OF AN AUDIOLOGIST-DELIVERED PSYCHOLOGICAL TINNITUS	
TREATMENT 136	
6.1. INTRODUCTION.....	136
6.1.1. Background	136
6.1.2. Aims	138
6.2. METHODS	138
6.2.1. Trial design.....	138
6.2.2. Ethical considerations	138
6.2.3. Participants	139
6.2.4. Randomisation	140
6.2.5. Interventions	141
6.2.6. Outcomes.....	141
6.2.7. Data-handling and analysis	146
6.2.8. Treatment fidelity and experience interviews.....	146
6.3. RESULTS.....	147
6.3.1. Feasibility outcomes.....	147
6.3.2. Baseline demographic and clinical characteristics	151
6.3.3. Effectiveness outcomes.....	152
6.3.4. Treatment fidelity and experience interviews.....	154

6.4. DISCUSSION.....	190
6.4.1. Feasibility	190
6.4.2. Measurement of treatment effects.....	193
6.4.3. Fidelity.....	195
CHAPTER 7. GENERAL DISCUSSION.....	198
7.1. KEY FINDINGS	199
7.1.1. CBT is the most evidence-based psychological tinnitus treatment.....	199
7.1.2. Psychoeducation and common therapeutic skills are more important than specific CBT techniques in tinnitus treatment.....	199
7.1.3. Greater exposure of audiologists to the manual was associated with more positive treatment appraisals	200
7.1.4. Training to deliver psychological tinnitus treatment must be intensive and phased.....	201
7.1.5. The TFI and TCQ measure relevant domains in psychological tinnitus treatment.....	202
7.2. STRENGTHS AND LIMITATIONS.....	203
7.2.1. Identification of psychological components	203
7.2.2. Identification of outcome domains	207
7.2.3. Identification of outcome instruments.....	209
7.3. DIRECTION FOR FURTHER RESEARCH	211
7.3.1. A definitive RCT.....	211
7.3.2. Evaluation of brief training	213
7.4. WIDER IMPLICATIONS	214
7.4.1. UK healthcare delivery and the political context.....	214
7.4.2. Improving access to psychological therapies.....	215
7.5. CONCLUSION.....	217

FUNDING.....	218
APPENDICES	219
APPENDIX 1: A CODING MANUAL FOR THEMATIC ANALYSIS OF THE REFERENCE GROUP TREATMENT MANUALISATION MEETING (CHAPTER 4).....	219
APPENDIX 2: A CODING MANUAL FOR THEMATIC ANALYSIS OF AUDIOLOGIST TRAINING FEEDBACK (CHAPTER 4)	242
APPENDIX 3: CONSORT 2010 CHECKLIST OF INFORMATION TO INCLUDE WHEN REPORTING A PILOT OR FEASIBILITY TRIAL (CHAPTER 6).....	252
APPENDIX 4: DRAFT PATIENT INTERVIEW SCHEDULE (CHAPTER 6) 	256
REFERENCES.....	260

LIST OF TABLES

Table 2.1. An example of database search strategy terms	22
Table 2.2. The number of records using particular research methodology per type of psychological treatment	29
Table 2.3. Themes of psychological treatment for people with tinnitus	32
Table 3.1. Novel components proposed by panellists in round 1 of the Delphi survey.....	57
Table 3.2. Percentage agreement of components considered absolutely essential to include in an audiologist-delivered psychological intervention for people with tinnitus.....	59
Table 4.1. Reference group members.....	79
Table 4.2. A summary of the interim prototype manual for audiologist-delivered psychological tinnitus treatment	93
Table 4.3. A summary of the amended audiologist-delivered psychological tinnitus treatment manual	101
Table 5.1. Item analysis domains of tinnitus.....	114
Table 5.2. Tinnitus domains identified in template analysis of the psychological tinnitus treatment manual	117
Table 5.3. Tinnitus questionnaire characteristics	122
Table 5.4. Quality criteria for measurement properties of health status questionnaires.....	126

Table 5.5. Comparison of the Tinnitus Functional Index factor structure and item analysis domains	131
Table 5.6. Comparison of the Tinnitus Cognitions Questionnaire factor structure and item analysis domains.....	132
Table 6.1. Effectiveness outcome questionnaires used	145
Table 6.2. Effectiveness outcomes questionnaires time points.	146
Table 6.3. Feasibility outcomes	150
Table 6.4. Patients' baseline demographic and clinical characteristics	151
Table 6.5. Effectiveness outcomes per treatment arm and time point.....	153
Table 6.6. Change in secondary outcomes in response to psychological tinnitus treatment over time	154

LIST OF FIGURES

Figure 1.1. A cognitive behavioural model of tinnitus distress	9
Figure 2.1. Preferred reporting items of systematic reviews and meta-analyses flow diagram.....	26
Figure 2.2. The number of different types of treatment reported across included records	27
Figure 3.1. Delphi survey flow diagram	49
Figure 4.1. Simplified cognitive behavioural model of tinnitus	100
Figure 6.1. Participant flow.....	149

LIST OF ABBREVIATIONS

ACT	Acceptance and Commitment Therapy
ATA	American Tinnitus Association
BAI	Beck Anxiety Inventory
BDI	Beck Depression Inventory
BRC	Biomedical Research Centre
BTA	British Tinnitus Association
CBT	Cognitive Behavioural Therapy
CI	Confidence Interval
CONSORT	Consolidated Standards of Reporting Trials
CORE-OM	Clinical Outcomes in Routine Evaluation – Outcome Measure
COS	Core Outcome Set
CPD	Continuing Professional Development
CSRI	Client Service Receipt Inventory
CTAQ	Chronic Tinnitus Acceptance Questionnaire
DH	Department of Health
ENT	Ear Nose Throat
FTQ	Fear of Tinnitus Questionnaire
GAD	Generalised Anxiety Disorder
GP	General Practitioner
GPG	Good Practice Guidance
HUI	Health Utilities Index
iACT	Internet-delivered ACT
iCBT	Internet-delivered CBT
ITI	International Tinnitus Inventory
Kw	Weighted Kappa
M	Mean
MRC	Medical Research Council
MSC	Modernising Scientific Careers
NHS	National Health Service
NIHR	National Institute for Health Research

NPT	Normalisation Process Theory
OCD	Obsessive Compulsive Disorder
PCT	Patient-Centred Therapy
PhD	Doctor of Philosophy
PI	Principal Investigator
PPI	Patient and Public Involvement
RCT	Randomised Controlled Trial
SD	Standard Deviation
SETMQ	Self-Efficacy for Tinnitus Management Questionnaire
SMART	Specific, Measurable, Achievable, Realistic, Time-bound
STSS	Subjective Tinnitus Severity Scale
T-FAS	Tinnitus Fear-Avoidance Cognitions and Behaviors Scale
TAQ	Tinnitus Acceptance Questionnaire
TAU	Treatment as Usual
TCHQ	Tinnitus Case History Questionnaire
TCQ	Tinnitus Cognitions Questionnaire
TCS	Tinnitus Catastrophizing Scale
TCSQ	Tinnitus Coping Style Questionnaire
TEQ	Tinnitus Experience Questionnaire
TFI	Tinnitus Functional Index
THI	Tinnitus Handicap Inventory
THQ	Tinnitus Handicap Questionnaire
THS	Tinnitus and Hearing Survey
TMI	Tinnitus Magnitude Index
TPFQ	Tinnitus Primary Function Questionnaire
TQ	Tinnitus Questionnaire
TRQ	Tinnitus Reaction Questionnaires
TSG	Tinnitus Severity Grading
TVAQ	Tinnitus Vigilance and Awareness Questionnaire
UK	United Kingdom
USA	United States of America
WAI	Working Alliance Inventory

CHAPTER 1. INTRODUCTION

1.1.THESIS OVERVIEW

Following this thesis overview, I begin chapter 1 by providing a definition of tinnitus. A brief history of tinnitus is offered, including an introduction to epidemiology, explanatory models, and treatment options for tinnitus. The chapter concludes with a description of the state of present day tinnitus care, and gaps in the literature that this thesis aims to address.

Chapter 2 presents a comprehensive scoping review of the literature in which I catalogue reported components of psychological tinnitus treatments from 64 records from peer reviewed journal articles and grey literature such as theses and conference proceedings. The components are grouped together and presented in themes.

Using data from the scoping review, in chapter 3, I present a Delphi survey of patients and clinicians designed to elicit consensus on the importance of 160 different components of psychological treatments for audiologist-delivered tinnitus care.

Chapter 4 describes the development of an audiologist-delivered psychological tinnitus treatment manual. I explore how the developers used data from the Delphi survey and adapted the manual to fit with our emerging understandings of tinnitus, psychological treatments and the needs and scope of practice of the audiology

profession. The chapter concludes with a summary of the manual and an evaluation of the process taken to develop it.

In chapter 5, I describe an iterative outcome measurement selection procedure. Template analysis of the manual is presented, in which I identify tinnitus outcome domains hypothesised to respond to the treatment. Existing tinnitus outcome measurement instruments are identified and evaluated to select questionnaires that measure the domains identified by template analysis.

Chapter 6 presents a non-blinded, multicentre, feasibility randomised controlled trial (RCT). The audiologist-delivered psychological tinnitus treatment manual developed in chapters 2 to 4 is compared with treatment as usual (TAU). Tinnitus-specific treatment outcomes were measured using questionnaires identified in chapter 5. Analysis of treatment experience interviews with patients and audiologists is presented.

In chapter 7, I synthesise the findings that contribute to my thesis, and discuss these in relation to the wider literature. I identify strengths and limitations of my studies, and conclude by making recommendations for an ongoing programme of research.

1.2. TINNITUS

Tinnitus is the perception of sound in the absence of external sound. Tinnitus derives from the Latin root *Tinnire*, which means ‘to ring’. The earliest undisputed written record of tinnitus can be traced back to Hippocrates’ *Corpus Hippocraticum* in ancient Greece, where it was

described as a slight buzzing sound (Dietrich, 2004). Most people in the general population experience fleeting tinnitus at some point in their life (Oron et al., 2011). However, persistent tinnitus effects between 5.1% and 42.7% of the population (McCormack et al., 2016). The large variation in prevalence rates reported in epidemiologic studies appears, in part, to be a result of the heterogeneity of peoples' experiences of tinnitus and the different definitions used to measure presence of tinnitus. In the United Kingdom (UK), between 10% and 15% of the general population are currently experiencing persistent tinnitus (Davis and El Rafaie, 2000).

Tinnitus may be a continuous tone or a pulsatile rhythmic sound, varying in loudness and pitch, either unilaterally, bilaterally or medially. Tinnitus may be objective or subjective. Objective tinnitus arises from a physiological source that is audible to a third party. For example, in palatal myoclonus, the rapid spasm of the soft palate produces a repetitive clicking sound. The risk factors associated with objective tinnitus vary depending on the source of the tinnitus. However, in the case of palatal myoclonus, risk factors include lesions to neural pathways caused by brain tumours, cerebrovascular disease and multiple sclerosis (Deuschl et al., 1990). Subjective tinnitus is a phantom sound, audible only to the person with tinnitus. The greatest risk factors for subjective tinnitus are increasing age, noise exposure and hearing loss (Shargorodsky et al., 2010). People with co-occurring tinnitus and hearing loss often incorrectly attribute the impact of hearing loss to their tinnitus (Henry et al., 2015). Ratnayake and

colleagues (2009) found a correlation between hearing loss and the perceived impact of tinnitus on communication, suggesting some difficulty in disambiguating the effects of tinnitus and hearing loss.

The underlying mechanisms of tinnitus are not fully understood. Several mechanisms of tinnitus generation have been proposed. Peripheral (auditory) models explain that tinnitus is the result of aberrant activity in the cochlear (Mulders and Robertson, 2009); subcortical hyperactivity models state that tinnitus is explained by excessive spontaneous neural activity relayed from central neural pathways to the auditory cortex (Schaette and McAlpine, 2011); neural synchrony models explain tinnitus as the excessive synchronous neural firing in a highly localised area of the auditory cortex (Noreña and Eggermont, 2003); and 'filling in' models predict that disrupted neural connections to the auditory cortex receive reduced or no input from the subcortex, resulting in input from adjacent areas of the auditory cortex or auditory memory (De Ridder et al., 2014). However, heightened spontaneous neural activity or synchrony have not been demonstrated in comparisons between tinnitus patients and people with similar levels of hearing loss, and these models each contradict one another (Sedley et al., 2016). A common purpose of understanding the mechanisms of tinnitus is to find a cure (Henry et al., 2014a). However, an absolute cure for tinnitus remains elusive (Swain et al., 2016), thus research scientists have focused on developing treatments to help people cope with the distress associated with tinnitus.

1.3. TINNITUS AND CO-OCCURRING MENTAL HEALTH

PROBLEMS

Twenty per cent of people experiencing continuous persistent tinnitus consider it bothersome enough to seek treatment (Davis and El Rafaie, 2000). People with a history of anxiety or depression are more than twice as likely to report tinnitus (Shargorodsky et al., 2010). A systematic review of tinnitus and its association with mental health problems found that 15 of 16 studies demonstrated a higher prevalence of anxiety or depression than that observed in the general population (Pinto et al., 2014, Steel et al., 2014), with one study finding as many as 33% of consecutive tinnitus patients fulfilling criteria for major depression and 45% for an anxiety disorder (Zoger et al., 2004).

Anxiety and depression are complex problems that vary considerably between patients. Anxiety disorders associated with tinnitus include, but are not limited to, generalised anxiety disorder (GAD) typified by nervous apprehension about several issues; panic disorder typified by recurring panic attacks; and obsessive-compulsive disorder (OCD) typified by recurring unpleasant thoughts or urges that provoke anxiety or disgust, where repetitive behaviour relieves the unpleasant obsessions (American Psychiatric Association, 2013). The experiences of people with a diagnosis of major depressive disorder may involve low mood or irritability, feelings of guilt or worthlessness, anhedonia, poor concentration, fatigue, or suicidal ideation (American Psychiatric Association, 2013). Tinnitus has been reported to precipitate suicide in second-hand anecdotal accounts only (Press

Association, 2017), and there is no high-quality evidence of a direct causal relationship between tinnitus and suicide (Jacobsen & McCaslin, 2001). Moreover, suicide rates are lower for veterans with tinnitus than without (Martz et al., 2016). Nonetheless, anxiety and depression may have a negative impact on the quality of life of a person with tinnitus (Bartels et al., 2008).

The heterogeneity of tinnitus patients – and the question of why some people suffer with their tinnitus while others do not – has inspired psychological modelling of tinnitus distress (Georgiewa et al., 2006).

1.4.PSYCHOLOGICAL MODELS OF TINNITUS

Several psychological models of tinnitus distress have been proposed. Andersson (2002b), Baguley and colleagues (2013), and McKenna and colleagues (2014) argue the most influential psychological model of tinnitus distress is Hallam, Rachman and Hinchcliffe's (1984) habituation model. Hallam and colleagues proposed that tinnitus distress is caused when autonomic nervous system arousal inhibits the ability to ignore tinnitus in a reciprocal feedback loop. Habituation occurs when the response to benign stimulus diminishes over time (Kandel et al. 2000).

Kröner-Herwig and colleagues (2003) expanded on Hallam and colleagues' (1984) work in their psychophysiological model by adding an operant conditioning mechanism of tinnitus distress. In operant conditioning, a given behaviour endures if it is reinforced by its

consequences (Skinner, 1948). According to the psychophysiological model of tinnitus, operant conditioning leads to avoidance behaviours (Kröner-Herwig et al., 2003). In practice this means that a person with tinnitus may avoid noisy situations in which they fear their hearing and tinnitus may worsen (Andersson, 2002b). Alternatively, another person with tinnitus may avoid quiet environments in which they will better hear their tinnitus. Though both examples may provide immediate relief from the tinnitus percept in the short-term, in the long-term they represent a risk of reduced activation and withdrawal from day-to-day life.

Andersson (2002a) argued that existing models failed to account for cognitive processes contributing to tinnitus distress, and proposed a changing state hypothesis to address the conceptual shortfall. Andersson's changing state hypothesis proposes that the variability of the tinnitus percept in environmental noise increases the cognitive load on working memory. The person becomes aware of the resulting reduction in cognitive performance and increases attention towards tinnitus, which provokes a conditioned emotional response.

Clinicians and researchers alike have observed similarities between patients' experiences of tinnitus and chronic pain (Tonndorf, 1987, Folmer et al., 2001). In chronic pain, injury provokes a sympathetic-emotional response. Through a process of classical conditioning, threatening situations elicit avoidance or other safety-seeking behaviours that are negatively reinforced by reducing fear. Inspired by these observations, Cima and colleagues (2011) adopted a

fear-avoidance model of tinnitus from the chronic pain literature (Lethem et al., 1983, Vlaeyen and Linton, 2000). Catastrophic thoughts and fear of tinnitus are associated with increased attention towards tinnitus, and that fear mediates between catastrophising and quality of life. Hierarchical regression analysis supports this model and provides evidence for a biopsychosocial approach using a cognitive behavioural framework (Cima et al., 2011). However, Cima and colleagues did not directly evaluate the association between emotional distress and attention (McKenna et al., 2014). Furthermore, all the models introduced so far represent a description of factors without proposing any testable mechanisms between them, and as such, these models may not be considered scientific (McKenna et al., 2014).

McKenna and colleagues (2014) posit a cognitive behavioural model inspired by Harvey's (2002) model of insomnia. Excessively negative thoughts about tinnitus may cause maladaptive safety behaviours that inadvertently reinforce threat beliefs in a vicious cycle. For example, the thought, "I will never be able to complete my work because of my tinnitus", may result in maintaining obsessive control of environmental sound, which may reinforce the belief that, "I am not strong enough to cope". This cycle provokes physiological arousal and emotional distress, which increases selective attention and monitoring of tinnitus (Figure 1.1).

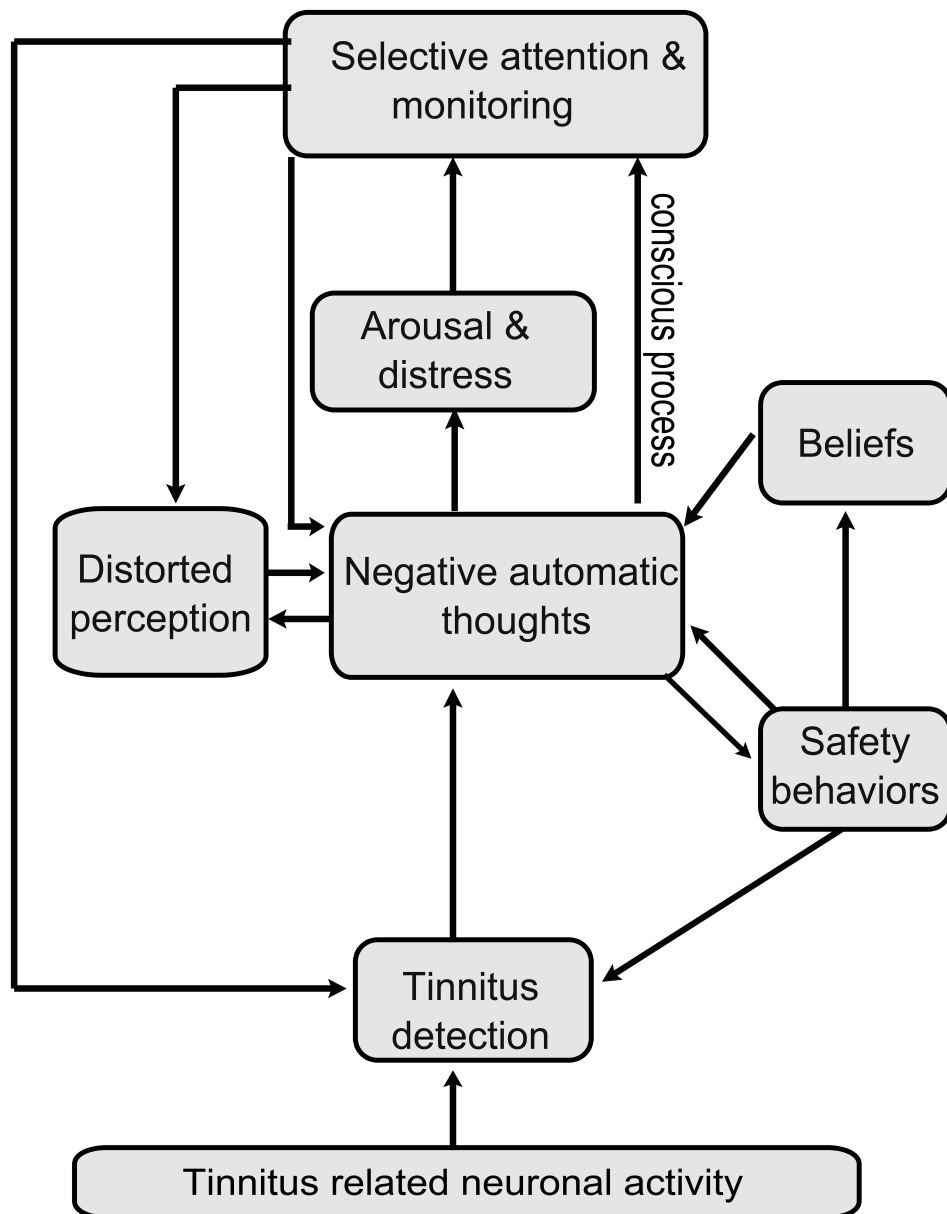


Figure 1.1. A cognitive behavioural model of tinnitus distress

Reprinted from Frontiers in Neurology, 5, McKenna L, Handscomb L, Hoare DJ, Hall DA, A Scientific Cognitive-Behavioral Model of Tinnitus: Novel Conceptualizations of Tinnitus Distress, 196, 2014, with permission from Frontiers Media SA under the terms of the Creative Commons Attribution License (CC BY)

Handscomb (2017) performed a systematic evaluation of the cognitive behavioural model by asking people with tinnitus to complete a survey comprising several questionnaires, each measuring a different part of the model. Twelve variations of the cognitive behavioural model were tested using path analysis, and all 12 were an acceptable fit with the survey data, indicating a role for negative automatic thoughts and avoidance behaviours contributing to emotional distress.

1.5.PSYCHOLOGICAL TREATMENTS FOR TINNITUS

Psychological models of tinnitus distress have inspired clinical psychologists' tinnitus care, typically comprising cognitive behavioural therapy (CBT), relaxation, and education (McKenna et al., 2014). CBT was originally developed for the treatment of depression (Beck, 1963, Beck, 1964). CBT is a talking therapy that aims to identify and challenge negative thoughts and modify maladaptive behaviours. The first controlled trial of cognitive therapy found that 79% of patients showed a marked improvement or complete remission of depressive symptoms compared to 23% of patients receiving an antidepressant (Rush et al., 1977). CBT has since been applied to other problems including, but not limited to, substance use disorder, schizophrenia and other psychotic disorders, depression and dysthymia, bipolar disorder, anxiety disorders, somatoform disorders, eating disorders, insomnia, personality disorders, anger and aggression, criminal behaviours, general stress, distress due to general medical conditions,

chronic pain and fatigue, distress related to pregnancy complications and female hormonal conditions (Hofmann et al., 2012). Cuijpers and colleagues (2016) conducted a meta-analytic update of CBT for anxiety disorders and depression, concluding that CBT is probably effective with three caveats. Firstly, they inspected a funnel plot of published outcomes in CBT trials, finding approximately a quarter of GAD trials and 14% of depression trials were missing, indicating a publication bias in favour of small studies with large effect sizes that overestimates the effect of CBT. Secondly, they found that the effect of CBT was exaggerated by making comparisons with people on a waiting list to receive treatment, rather than using genuine treatments or placebos. Thirdly, using the Cochrane risk of bias tool (Higgins et al., 2011), they evaluated the methodological quality of CBT trials, finding that only 17.4% of trials were of high-quality, suggesting that results demonstrating the effectiveness of CBT should be interpreted with caution. Furthermore, Cuijpers and colleagues found that almost a third of trials published since 2010 were rated high-quality, compared to 12% of older trials, suggesting that more recent studies provide a more accurate estimate of effectiveness. Johnsen and Friberg (2015) examined the time trends in the effect of CBT on depression across 70 studies from Rush and colleagues' seminal trial in 1977 to Kalapatapu and colleagues' contemporary research (2014). They found that the effect sizes of CBT have declined linearly, suggesting CBT for depression has become less effective. Johnsen and Friberg suggest that a tendency to report CBT trials without describing the contents of the

therapy may indicate decreasing concern with adherence to effective cognitive therapies compared to the founders of cognitive therapy (Beck, 1963, Beck, 1964, Rush et al., 1977). On the other hand, an opposite time trend has been found for anxiety trials with the effects of CBT increasing (Hofmann and Smits, 2008).

CBT emerged as a treatment option for tinnitus in the 1980s (Sweetow, 1984), and remains the only recommended psychological therapy for tinnitus in countries where clinical guidelines are in place (Fuller et al., 2017). In the first RCT of CBT, Scott and colleagues (1985) demonstrated a significant reduction in subjective tinnitus loudness, discomfort from tinnitus, depression and irritation after ten 1-hour sessions comprising relaxation, distraction and graded exposure to tinnitus. CBT for tinnitus has since been replicated extensively, with meta-analyses of CBT indicating statistically significant effects on tinnitus distress (Hoare et al., 2011), anxiety and depression (Hesser et al., 2011), and quality of life (Martinez-Devesa et al., 2010). Hence, a clinical guide in the UK (Department of Health, 2009), and clinical guidelines in Germany (Zenner et al., 2015), Netherlands (Dutch Association for Ear Nose Throat and Head surgery, 2016), Sweden (Idrizbegovic et al., 2011), and the United States of America (USA; Tunkel et al., 2014) recommend CBT for tinnitus.

Although CBT may be considered the most evidence-based treatment for tinnitus (Cima et al., 2014), there are some key limitations in that evidence. Firstly, there is a lack of consensus on what to measure in tinnitus trials, and how to measure it. This has

resulted in heterogeneity in selecting and reporting outcomes, which hinders synthesis in systematic reviews and meta-analyses (Hall et al., 2016). For example, Hoare and colleagues' (2011) review of tinnitus management strategies excluded 15 of 68 articles that did not use a standardised outcome measurement instrument. As a result, data from these studies could not be pooled to inform the discourse about treatment decisions. Therefore, it is important to carefully consider what to measure and how to measure it in any clinical trial.

Secondly, historically, tinnitus trials did not include a sample size calculation or were underpowered (Hoare et al., 2011). Underpowered studies are less able to detect statistically significant effects, and when an underpowered study does detect an effect, it is more likely that the magnitude of the effect is exaggerated (Button et al., 2013). As a result, effective treatments may be missed, or inferior treatments may be used in favour of more effective strategies. Sample size calculations can mitigate this risk, and feasibility trials can be used to generate data for sample size calculations for adequately powered trials (Thabane et al., 2010).

1.6. TINNITUS CARE IN THE UK

In the UK, the standard referral pathway for most tinnitus patients begins in primary care with a General Practitioner (GP). Most GPs examine the ear using an otoscope, measure blood pressure, and take a patient history including hearing loss, characteristics of the tinnitus percept, onset and aetiology, medication and the impact on quality of

life (El-Shunnar et al., 2011). Eighty-three per cent remove ear wax that may be contributing to hearing loss, and 87% provide information about tinnitus and offer reassurance. Only 4% offer some form of in-house tinnitus counselling (El-Shunnar et al., 2011). GPs refer 25% of tinnitus patients directly to audiologists, and refer 71% to Ear, Nose and Throat (ENT) specialists, who refer 70% of patients to audiologists (Gander et al., 2011). Only 18% of tinnitus patients are referred to clinical psychology services (Gander et al., 2011). Fifty-three per cent of tinnitus patients report feeling dissatisfied with the care they receive from their GP, with 92% of those feeling their GP did not have sufficient understanding of tinnitus (Wray et al., 2017). In contrast, audiology students are taught aetiology, epidemiology, mechanisms, and treatment options for tinnitus (Health Education England, 2016). Therefore, audiologists should be well-versed to impart knowledge about tinnitus, and to understand patients' tinnitus. Audiologists' responsibilities include assessment and treatment of people suffering from hearing loss, balance problems, and tinnitus. When faced with a probable case of tinnitus, most audiologists would conduct an audiogram to test hearing, a structured interview to assess tinnitus, and use a validated questionnaire to measure tinnitus, anxiety or depression (Hoare et al., 2012). However, not all audiologists share this approach because tinnitus care is not standardised (Hoare and Hall, 2011). Furthermore, once a diagnosis of tinnitus is made, there is a lack of tinnitus treatment options supported by high-quality evidence (Hoare et al., 2011, Zenner et al., 2017). Standardised clinical

practice would improve equity of care for patients and enable clinical auditing to inform healthcare commissioners of the cost-effectiveness of treatment (Hoare and Hall, 2011). On the other hand, standardised care may be perceived to prevent clinicians' ability to meet local demand. However, most audiologists think that standardisation is beneficial, especially for relatively inexperienced staff (Hoare et al., 2012).

The audiology profession underwent significant change with the publication of government policy for Modernising Scientific Careers (MSC; UK Health Departments, 2010). The MSC policy aims to simplify career structures and training for the healthcare science workforce by more closely aligning audiology with neurophysiology and ophthalmic and vision sciences. This was intended to replace uni-disciplinary expertise with a broader skillset and knowledge to create a more mobile workforce capable of changing with developments in science and technology. The MSC Practitioner Training Programme Healthcare Science Curriculum expects audiology students to be able to analyse the psychosocial implications of tinnitus and explain psychological models of tinnitus and the principles of counselling (Health Education England, 2016). There is currently no scope in the curriculum for the application of psychological treatments.

In the UK, the Department of Health (DH) Good Practice Guide (GPG) states that:

"Where psychologists are not available, the audiologist's role should extend to offering psychological treatment through CBT or

other appropriate counselling techniques. This will involve clear inclusion criteria, and specialised and focused CBT for patients distressed by tinnitus or associated psychological disorders such as mild depression or anxiety.” (Department of Health, 2009, p.15)

The DH is responsible for developing national policy and legislation to provide strategic direction for the National Health Service (NHS) in the UK, giving it significant influence over the provision of audiology services in the UK (Department of Health, 2013). The DH states that the purpose of the tinnitus GPG is to reduce waiting times for patients (Department of Health, 2009). However, there is a lack of psychologists to meet demand, with only a third of audiologists surveyed in England having the option to refer to a psychologist (Hoare et al., 2012). For the two-thirds who do not have access to psychologists, the GPG does not specify what ‘specialised and focused CBT’ and ‘other appropriate counselling techniques’ should comprise. One of the UK top ten uncertainties of tinnitus treatment concerns whether CBT delivered by audiologists is effective for people with tinnitus (Hall et al., 2013). Therefore, the development of an audiologist-delivered psychological tinnitus treatment is timely. A trial of this treatment should consider the limitations of previous tinnitus trials, including careful consideration of what outcomes are important.

1.7.AIMS

The overarching purpose of this thesis is to define the components and measure the effects of audiologist-delivered psychological tinnitus treatment. Specifically, this PhD aims to:

- Catalogue the components of CBT and other counselling techniques for tinnitus
- Survey patients and clinicians on which components are important and appropriate for audiologists to deliver
- Develop a treatment manual
- Identify and select tinnitus outcome domains and instruments that are best suited to measure the effects of the treatment
- Explore patients' and audiologists' experiences of the treatment, outcome domains measured, and instruments used in a feasibility trial.

CHAPTER 2. SCOPING REVIEW OF PSYCHOLOGICAL TREATMENTS FOR PEOPLE WITH TINNITUS

2.1.INTRODUCTION

2.1.1. Background

CBT and other psychological tinnitus treatments comprise diverse combinations of components selected according to the preference of the clinicians and researchers implementing them (Andersson, 2002b). Cima and colleagues (2014) reviewed the development of cognitive behavioural treatments for tinnitus from 1980 onwards, noting a trend from an emphasis on relaxation and attention refocusing exercises, to reducing the behavioural avoidance of tinnitus. More recently, Acceptance and Commitment Therapy (ACT) has emerged as a treatment for tinnitus (Westin et al., 2011). However, there remains disagreement as to whether ACT is theoretically distinct from CBT or shares the same underlying principles (Ost, 2008). Both aim to improve emotional regulation. However, if a distinction can be made, it is that CBT uses antecedent-focused techniques, whereas ACT uses a response-focused approach (Hofmann and Asmundson, 2008). Antecedent-focused techniques are implemented before the emotional response, for example by changing the environment or direction of attention, whereas response-focused techniques aim to change the experience of emotions once they have occurred (Hofmann et al.,

2010). However, there is a lack of dismantling studies to identify which components are the active ingredients that reduce tinnitus distress. Furthermore, other types of psychological treatments such as psychodynamic therapy are yet to be tested (Andersson, 2002b). Thus, it is difficult to ascertain what an audiologist-delivered 'specialised and focused CBT' and 'other appropriate counselling techniques' may comprise based on existing evidence (Department of Health, 2009), without first systematically identifying what these components may be. Therefore, I conducted a scoping review to identify the components of all types of psychological tinnitus treatment. A scoping review is a method designed, "to map rapidly the key concepts underpinning a research area and the main resources and types of evidence available" (Mays et al., 2001, p.194).

2.1.2. Aim

The primary aim of this scoping review was to catalogue the components of psychological treatments for people with tinnitus that have been used or tested. Secondary aims of this review were to identify what types of psychological treatment for people with tinnitus have been reported, and to identify the job roles of clinicians who have reportedly delivered psychological tinnitus treatments.

2.2.METHODS

2.2.1. Eligibility criteria

Records were included in which a psychological tinnitus treatment was tested or described, as in a formal protocol or expert opinion

piece. Records were eligible regardless of the type of tinnitus presented, for instance records were eligible whether subjective or objective tinnitus was presented. No records were excluded based on controls used, outcomes reached, timing, setting, or study design. Records were excluded in which the treatment included biofeedback, habituation, or hypnosis as necessary parts of the psychological treatment; or when relaxation was delivered in isolation (without other components of psychological treatment). Review articles were excluded. Eligible records were published in the English language, sampled adults only, and originated from the year 1980 onwards (because psychological tinnitus treatment emerged in the 1980s; Jun and Park, 2013). Where multiple eligible unique records pertaining to a single trial were identified, the record that was published first was included, and any secondary reports were excluded. Records were excluded when reporting on a psychological treatment if not described in sufficient detail to extract data on what it involved.

2.2.2. Search strategy

Electronic databases of peer-reviewed journals were searched on 20-21 November 2014. These included the Cochrane Ear, Nose and Throat Disorders Group Trials Register; the Cochrane Central Register of Controlled Trials; PubMed; EMBASE (Excerpta Medica Database); Cumulative Index to Nursing and Allied Health Literature; Literatura Latino Americana em Ciências da Saúde; KoreaMed; IndMed; PakMedi-Net; Centre for Agriculture and Biosciences Abstracts; Web of Science;

BIOSIS (Biosciences Information Service) Previews; the International Standard Randomised Controlled Trial Number registry; ClinicalTrials.gov; the International Clinical Trials Registry Platform; and Google Scholar. In addition, a search of the grey literature was conducted including Open Grey, Healthcare Management Information Consortium, National Technical Information Service, and PsycEXTRA. Theses were searched through Index to Theses, DART (Digital Access to Research Theses) Europe, and ProQuest Dissertations and Theses. Conferences were targeted through Cos Conference Papers, Google Scholar, Scopus, and Zetoc. Patient organisation websites were searched including Patient UK, Patient Information Forum, Expert Patients Programme, HealthWatch, INVOLVE, Health Talk Online, Patient Voices, and the national tinnitus associations of the UK and USA, the British Tinnitus Association (BTA) and the American Tinnitus Association (ATA), respectively. An Internet search was performed using metasearch engine Ixquick. Both Ixquick and Google Scholar were searched until a saturation point was reached when one page of consecutive search results contained no entries relevant to the central research question based on a visual screening of the information presented on the search result screen.

The search strategy was modelled on a systematic review of CBT for tinnitus (Martinez-Devesa et al., 2010), but expanded to capture ACT, mindfulness, and other psychological treatments. Common terms used across different databases included tinnitus (including descriptive variants of tinnitus such as buzz*), cognit*,

behav*, broader terms such as psychotherap*, and narrower terms such as mindful*. An example of the search strategy used for Web of Science is reported in Table 2.1.

Table 2.1. An example of database search strategy terms

Web of Science
#1 TS=tinnit*
#2 TS=(EAR* and (BUZZ* or RING* or ROAR* or CLICK* or PULS*))
#3 #2 OR #1
#4 TS=(cognit* AND behav*)
#5 TS=((DESENSITI* and PSYCHOLOG*) or (IMPLOSIVE* and THERAP*) or (ACCEPT* and COMMIT*) or (FUNCTION* and ANALY*) or (COMPASSION* and MIND*) or (MINDFUL*) or (DIALECTIC*) or (METACOGNIT*) or (COUNSEL*) or (PSYCHOEDUCAT*))
#6 TS=((COGNIT* or BEHAV* or CONDITIONING or RELAXATION or DESENSITI* or ACCEPT* or COMMIT*) and (THERAPY or THERAPIES or THERAPEUTIC* or PSYCHOTHERAP* or TRAIN* or RETRAIN* or TREATMENT* or MODIFICATION* or ACTIVAT*))
#7 #6 OR #5 OR #4
#8 #7 AND #3

From these database searches, the reference lists of identified review articles were scanned for additional records, and the most frequently appearing journals (determined using the interquartile rule for outliers¹) from the included records were hand searched as far back as issues published within 1 year preceding the electronic database search in November 2014. A simple outlier calculation (using the interquartile rule for outliers) was also performed in relation to the most frequently appearing authors, whose ongoing publication

¹ $Q3 + 1.5 \times IQR$, where $Q3$ is the median of the upper half of the values, and IQR is the interquartile range

record was monitored until data extraction was completed on all other included records.

2.2.3. Study selection

Returned search records were examined independently by two researchers (one of my PhD supervisors: DJH, DAH, or DMW, paired with myself), firstly, screening by title and abstract, secondly, by full text. When disagreements regarding the inclusion or exclusion of any given record arose, the two researchers discussed their rationale until agreement was reached, or a third researcher was consulted to adjudicate.

2.2.4. Charting the data

A data charting form was piloted using five articles. The procedure and extracted data fields were discussed before commencing the full data extraction procedure. Two researchers (one of DJH, DAH, or DMW, paired with myself) extracted data independently from each included record. I collected the data across all records. Data items included the type of treatment, components of psychological treatment, profession of the delivering clinician, and research methodology used. The two datasets were compared, and differences were discussed until the two researchers reached agreement on a single completed form. Where irreconcilable differences persisted, a third researcher was consulted to adjudicate.

Components of psychological treatment were defined as observable, replicable, and irreducible. Components were iteratively

grouped using inductive thematic analysis using Braun and Clarke's (2006) phases of thematic analysis. Inductive thematic analysis is a bottom-up approach to analysis involving the development of themes that are directed by the data as opposed to themes being directed by *a priori* knowledge as in top-down deductive analysis. Analysis was performed by DJH and myself.

2.3.RESULTS

Figure 2.1 displays the flow of records identified, screened, included, excluded and the reasons for exclusion. Sixty-four records were included.

2.3.1. Types of psychological treatment reported

Twenty-four different treatment types were identified (Figure 2.2). The most frequently reported were (face-to-face) CBT (n=21), tinnitus education (n=13), and internet-delivered CBT (iCBT; n=8). Within the 64 scoped records, 73 treatment arms were identified. Fourteen types of psychological tinnitus treatment have been tested in RCTs. These 14 mostly comprised CBT, including face-to-face CBT (Kröner-Herwig et al., 1995, Kröner-Herwig et al., 2003, Zachriat and Kröner-Herwig, 2004, Andersson et al., 2005, Robinson et al., 2008, Tucker, 2013), iCBT (Andersson et al., 2002, Kaldø et al., 2008, Abbott et al., 2009, Hesser et al., 2012, Nyenhuis et al., 2013, Jasper et al., 2014a), group CBT (Kaldø et al., 2008, Nyenhuis et al., 2013, Jasper et al., 2014a), bibliotherapy CBT (Kaldø et al., 2007, Nyenhuis et al., 2013), stepped-care CBT (Cima et al., 2012), group cognitive therapy (Jakes et al.,

1992), behaviour therapy (Lindberg, 1988, Lindberg et al., 1988); ACT (Westin et al., 2011); internet-delivered ACT (iACT; Hesser et al., 2012); mindfulness (Kreuzer et al., 2012); tinnitus education (Mason et al., 1996, Kröner-Herwig et al., 2003, Henry et al., 2007, Tucker, 2013, Argstatter et al., 2015), tinnitus education with cognitive therapy (Henry and Wilson, 1996); attention control, imagery training, and cognitive restructuring (Henry and Wilson, 1998); and relaxation and distraction (Kröner-Herwig et al., 2003).

Two further types of psychological tinnitus treatment were tested in trials where either a historical control group was used as a comparator, or where multiple experimental interventions were tested without a control comparator, including tinnitus education with relaxation (Dineen et al., 1997), and group eclectic therapy (Zöger et al., 2008).

Several of these psychological treatments were also detailed in case series, case reports, and in the descriptions of interventions; namely CBT (Andersson and Larsen, 1997, Wilson and Henry, 2000, Andersson et al., 2001, Lain, 2006, Grael et al., 2008, Greimel and Kröner-Herwig, 2011, Zenner et al., 2013, Hubbard, 2014), iCBT (Andersson and Kaldø, 2004), behaviour therapy (Lindberg et al., 1989), mindfulness (Sadler et al., 2008), and tinnitus education (Greimel and Kröner-Herwig, 2011).

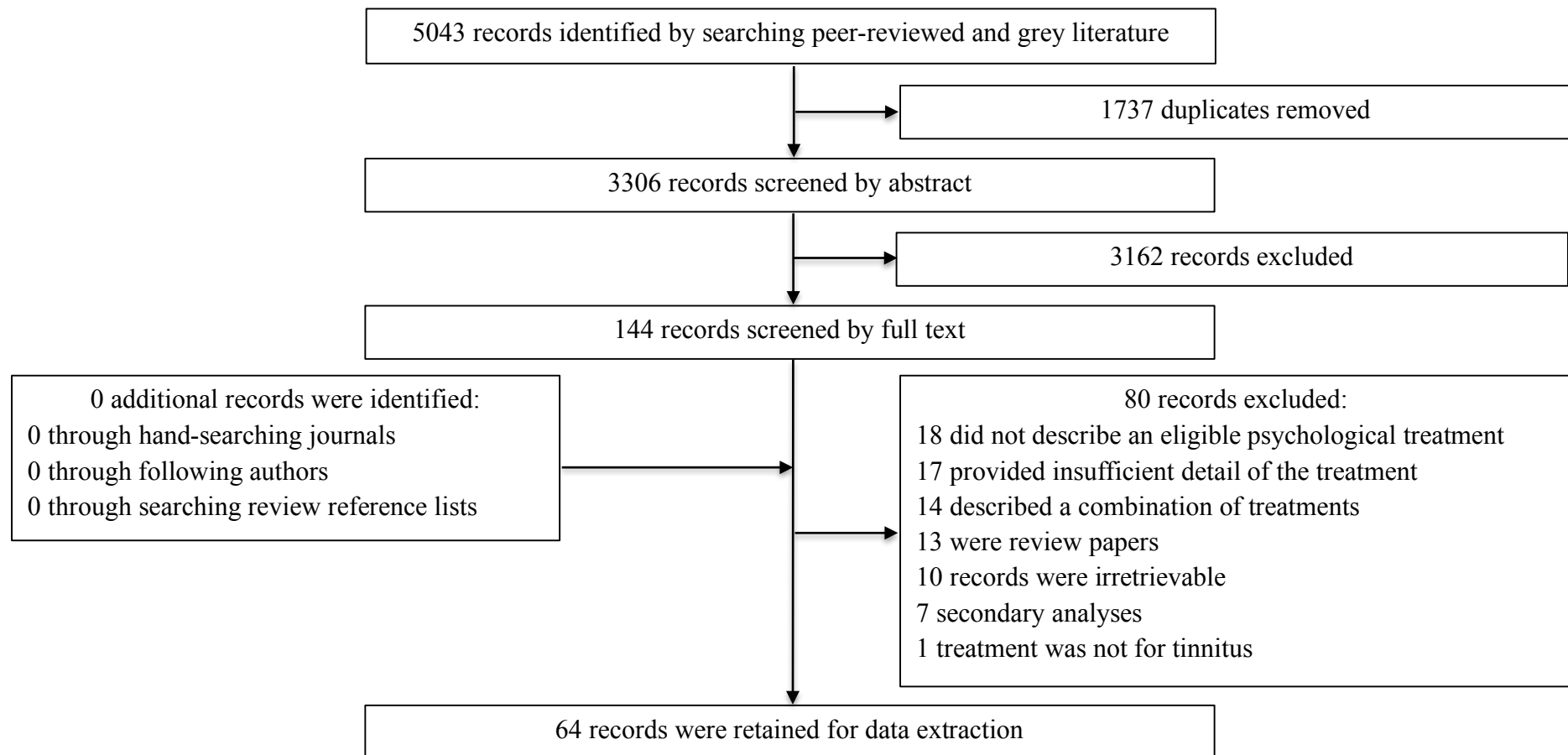


Figure 2.1. Preferred reporting items of systematic reviews and meta-analyses flow diagram

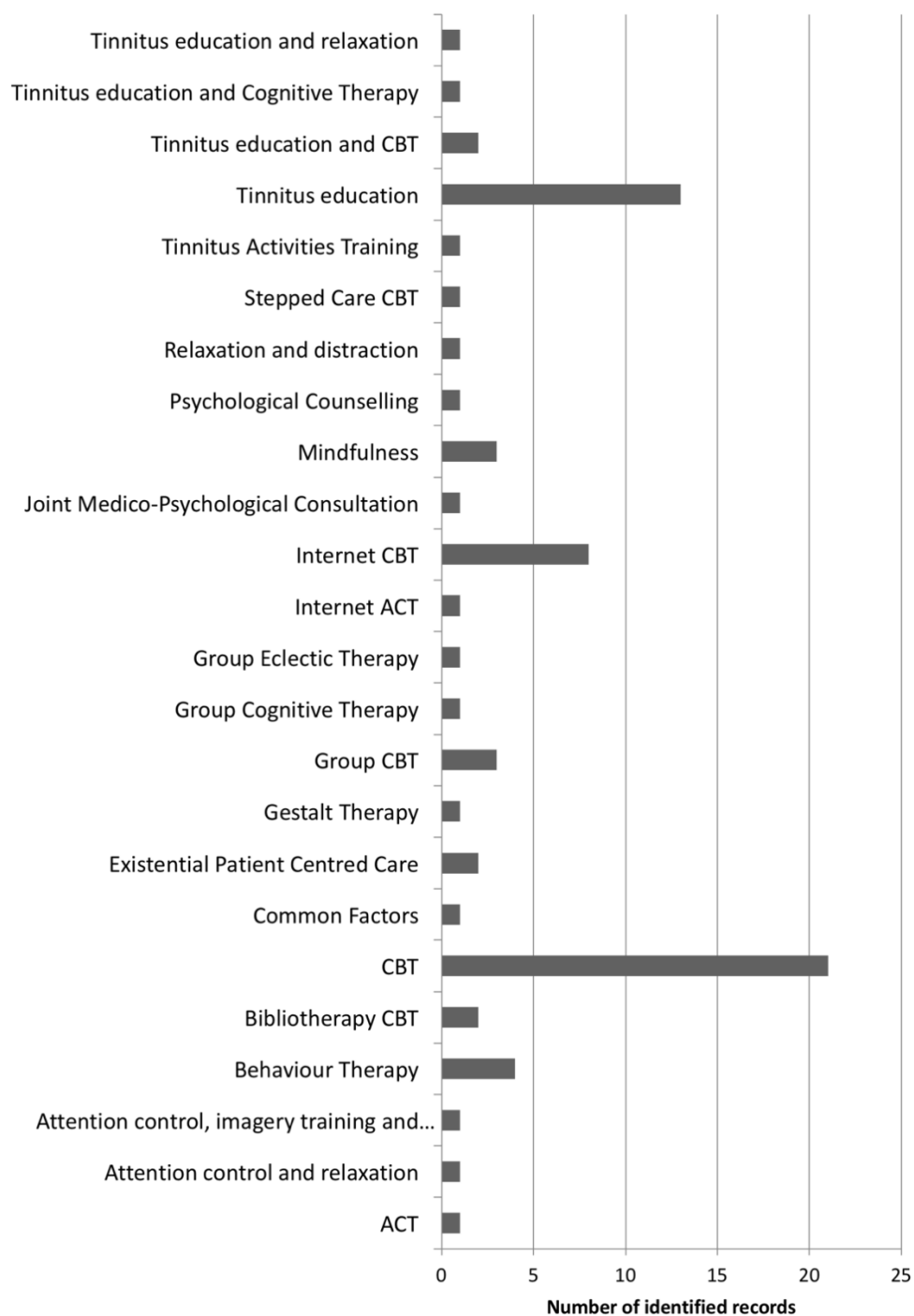


Figure 2.2. The number of different types of treatment reported across included records

ACT=Acceptance and Commitment Therapy, CBT=Cognitive Behavioural Therapy, Attention control, imagery training and...=Attention control, imagery training and cognitive restructuring

Eight different types of psychological treatment were reported but not tested in any trials, case series, or reports. These were attention control with relaxation (Jakes et al., 1986), tinnitus education with CBT (Henry et al., 2009, Henry et al., 2012), tinnitus activities treatment (Tyler, 2006), common factors (Tyler et al., 2001), joint medico-psychological consultation (Degive and Kos, 2006), psychological counselling (Lain, 2008), Gestalt therapy (Amendt-Lyon, 2004), and existential patient-centred therapy (PCT; (Mohr and Hedelund, 2006, Mohr, 2008). Description of the research design was minimal in Girard's (1992) report. Table 2.2 shows how often different levels of evidence have been reported.

2.3.2. Job roles of clinicians who delivered psychological therapy

No records reported on audiologist-delivered psychological tinnitus treatment in the context of an empirical trial in which their role was clearly delineated from that of other clinicians. However, six records did report on audiologist-delivered tinnitus education protocols or trials (Dineen et al., 1997, Henry et al., 2005a, 2007, 2009, Aazh et al., 2008, Searchfield et al., 2010), and five records of expert opinions, protocols, or grey literature proposed that audiologists may use their protocols of CBT (Andersson et al., 2001, Olsson 2001), and tinnitus education (Tyler et al., 1989, Tyler, 2006, Searchfield et al., 2011), although this remains untested.

Table 2.2. The number of records using particular research methodology per type of psychological treatment

	RCT	Non- randomised control trial	Historical control study, two or more single arm study	Case series	Case report	Ideas, opinions, editorials, background information, expert opinion
ACT	1	0	0	0	0	0
Attention control & relaxation	0	0	0	1	0	0
Attention control, imagery training and cognitive restructuring	1	0	0	0	0	0
Behaviour therapy	2	0	0	1	1	0
Bibliotherapy CBT	2	0	0	0	0	0
CBT*	6	1	0	2	4	7
Common factors	0	0	0	0	0	1
Existential Patient-Centred Therapy	0	0	0	0	0	2
Gestalt Therapy	0	0	0	0	1	0
Group CBT	3	0	0	0	0	0
Group Cognitive Therapy	1	0	0	0	0	0
Group Eclectic Therapy	0	0	1	0	0	0

	RCT	Non- randomised control trial	Historical control study, two or more single arm study	Case series	Case report	Ideas, opinions, editorials, background information, expert opinion
iACT	1	0	0	0	0	0
iCBT	6	0	0	1	1	0
Joint Medico-Psychological Consultation	0	0	0	1	0	0
Mindfulness	1	1	0	1	0	0
Psychological Counselling	0	0	0	0	0	1
Relaxation & distraction	1	0	0	0	0	0
Stepped care CBT	1	0	0	0	0	0
Tinnitus Activities Training	0	0	0	0	0	1
Tinnitus education	5	2	0	1	0	5
Tinnitus education & CBT	0	0	0	1	0	1
Tinnitus education & Cognitive Therapy	1	0	0	0	0	0
Tinnitus education & relaxation	0	0	1	0	0	0

*One conference paper on a CBT trial did not report a research methodology

ACT=Acceptance and Commitment Therapy, CBT=Cognitive Behavioural Therapy, iACT=Internet-delivered Acceptance and Commitment Therapy, iCBT=Internet-delivered Cognitive Behavioural Therapy, RCT=Randomised Controlled Trial

Three records included an audiologist or clinical physicist in audiology in stepped-care including CBT (Cima et al., 2012), tinnitus education (Henry et al., 2012), and behaviour therapy trials (Scott et al., 1985), although in a limited or unspecified capacity (e.g. involved in post-therapy interviews only; Scott et al., 1985). One record detailed a psychological treatment for audiologists to deliver using a case study (Sweetow, 1986).

Five records tested psychological treatments that were delivered by a psychology student or trainee including CBT (Kröner-Herwig et al., 1995, Robinson et al., 2008), iCBT (Abbott et al., 2009, Hesser et al., 2012), ACT (Westin et al., 2011), and iACT (Hesser et al., 2012).

2.3.3. Components of psychological therapies

Twenty-five themes of components that have been included within psychological tinnitus treatments were derived through inductive thematic analysis of the scoped literature. Table 2.3 describes these themes and presents example quotes from reviewed records. The themes were tinnitus education, psychoeducation, evaluation, treatment rationale, treatment planning, problem solving, behavioural intervention, thought identification, thought challenging, worry time, emotions, social comparison, interpersonal skills, self-concept, lifestyle advice, acceptance and defusion, mindfulness, attention, relaxation, sleep, sound enrichment, comorbidity, treatment reflection, relapse prevention, and common therapeutic skills.

Table 2.3. Themes of psychological treatment for people with tinnitus

Theme (frequency of use in the literature)	Description of theme	Example of extracted data
Tinnitus Education (137)	Concerns the provision of information about tinnitus	“Extensive explanation of neurophysiological model” (Cima et al., 2012, p.1953)
Psychoeducation (70)	Concerns the provision of education on psychological wellbeing	“A general cognitive-behavioral model (A-B-C model) is introduced and illustrated with examples given by the patients” (Hiller and Haerkötter, 2005, p.601)
Evaluation (59)	Concerns the clinician enquiring into the patient's tinnitus and other problems, advising the patient on the use of tinnitus monitoring tools and providing feedback of audiological assessment	“Are other important things going on in the patient's life in addition to tinnitus?” (Tyler, 2006, p.119)
Treatment rationale (64)	Concerns informing the patient about the psychological therapy they would undertake with the clinician, their respective roles in therapy, setting ground rules and informing them of other treatment options for their tinnitus	“The therapist ... elucidated their own role, i.e. why both took part in each session and how they as group leaders preferred to sometimes stay in the background” (Zöger et al., 2008, p.66)

Theme (frequency of use in the literature)	Description of theme	Example of extracted data
Treatment planning (56)	Concerns planning the psychological therapy with the patient, discussing the patient's expectations and setting goals and engaging in systematic problem solving with the patient	"Step eight becomes creating specific, identifiable objectives that can be realistically achieved and measured" (Olsson 2001, p.134)
Problem solving (8)	Concerns engaging the patient in collaborative systematic problem solving, breaking complex tasks into smaller more achievable ones	"engage in collaborative problem solving" (Henry et al., 2009, p.36)
Behavioural intervention (64)	Concerns the use of behavioral techniques that require change on the part of the patient, including systematically increasing the patient's general level of activity using 'behavioral activation' and 'graded exposure' to tinnitus through silence or to noise as appropriate	"Exposure to tinnitus [:] Lessen negative emotions and avoidance of tinnitus through exposure to the sound" (Kaldo-Sandström et al., 2004, p.188)
Thought identification (34)	Concerns the provision of education on negative automatic thoughts, teaching the patient how to identify their cognitive distortions	"It was explained that this was an example of the cognitive distortion of "fortune telling." How did she "know" that the remainder of the day would be miserable?" (Sweetow, 1986, p.393)

Theme (frequency of use in the literature)	Description of theme	Example of extracted data
Thought challenging (72)	Concerns cognitive techniques that require change on the part of the patient, including the clinician instructing the patient on 'thought stopping' exercises; 'cognitive restructuring' exercises that is, teaching the patient to identify and modify or replace negative automatic thoughts; and having the patient role-play other perspectives using 'Gestalt techniques'	“Cognitive restructuring of thoughts and beliefs associated with tinnitus is a necessary feature. The patient is helped to identify the content of his thoughts and is taught ways to challenge or control those thoughts usually described as unhelpful or even inaccurate” (Andersson et al., 2001, p.71)
Worry time (2)	Concerns engaging with the patient in the paradoxical psychotherapeutic technique 'worry time', involving the clinician recommending that the patient actively consider anxious thoughts for a specified regular short period of time to systematically problem-solve issues that can be resolved and returning to those that cannot in the next 'worry time'	“assign a certain time each day as worry time, with the aim of controlling the intrusive thoughts” (Andersson and Larsen, 1997, p.89)

Theme (frequency of use in the literature)	Description of theme	Example of extracted data
Emotions (9)	Concerns identifying and discussing the effect of the patient's tinnitus on their emotions and how to change them	“The eight sessions included the following themes: ... [session] 3. ... self-confidence ... The theme of the session was introduced rather briefly, after which the patients were encouraged to speak freely and interact with each other” (Zöger et al., 2008, p.66)
Social comparison (21)	Concerns the clinician normalising tinnitus distress and giving the patient reasonable reassurance that psychological therapy can be successful by sharing other's experiences	“Hope can be increased by assuring the patient that ... others have benefited from similar treatments” (Tyler et al., 2001, p.19)
Interpersonal skills (23)	Concerns the clinician exploring the patient's quality of social interaction and developing their social communication skills	“Often, the partner presents a much different appraisal of the situation than does the patient, and it is important for all lines of communication to be opened as early in the therapeutic process as possible” (Sweetow, 1986, p.392)
Self-concept (3)	Concerns addressing the patient's self-concept with respect to confidence, esteem and image	“Information typically provided ... [includes] how our self-image influences our beliefs and reactions” (Tyler, 2006, p.7)

Theme (frequency of use in the literature)	Description of theme	Example of extracted data
Lifestyle advice (21)	Concerns the provision of education on the effect of lifestyle on tinnitus, hearing and general health and how to maintain good general health	“information on ... pharmacological and dietary influences on tinnitus” (Dineen et al., 1997, p.334)
Acceptance and defusion (5)	Concerns engaging in acceptance and cognitive defusion techniques that is, to teach the patient to accept private experiences and to distance themselves from private events by attending more mindfully to the processes involved in thinking and feeling	“Specific ACT interventions included exercises that focused on ... distancing of internal experiences (i.e., defusion)” (Hesser et al., 2012, p.654)
Mindfulness (24)	Concerns the application of mindfulness meditation techniques	“mindfulness exercises involved approaching the tinnitus sound and related reactions in a non-judgmental way” (Westin et al., 2011, p.739)
Attention (95)	Concerns the clinician guiding the patient in positive visual imagery exercises, attention-shifting exercises and advising on managing difficulties with concentration	“Concentration management [:] Advice regarding concentration (i.e., taking breaks, dividing tasks into smaller steps, problem solving)” (Kaldo-Sandström et al., 2004, p.188)

Theme (frequency of use in the literature)	Description of theme	Example of extracted data
Relaxation (111)	Concerns physical techniques designed to reduce autonomic arousal including progressive muscle relaxation and breathing exercises, typically entailing the tensing and relaxing of each muscle group in turn and diaphragmatic breathing or inhalation/exhalation-timed breathing respectively	“Tuition on abdominal breathing exercises involved informing participants about bodily reactions and muscles involved in breathing. Differences between relaxed and stressed breathing were illustrated and discussed.” (Tucker, 2013, p.71)
Sleep (35)	Concerns the provision of education on sleep and practicing sleep restriction and 'sleep hygiene' that is, making behavioral, dietary and environmental changes to facilitate sleep	“education about sleep and sleep hygiene” (Gans et al., 2014, p.325)
Sound enrichment (51)	Concerns the provision of education on hyperacusis and noise sensitivity, advising the patient to avoid both silence and noise abuse and use sound enrichment while discussing its effect on the patient's thoughts	“the cognitive aspects of masking are covered, e.g., how masking of tinnitus and attention may interact)” (Andersson and Kaldo, 2006, p.100)

Theme (frequency of use in the literature)	Description of theme	Example of extracted data
Comorbidity (33)	Concerns the provision of education for the patient on hearing loss and its management through hearing tactics; unspecified comorbidities and their management through psychoeducation	“strategies to make the most of existing hearing abilities” (Abbott (Abbott et al., 2009, p.165)
Treatment reflection (39)	Concerns the clinician asking the patient to reflect on their experience of and success with psychological therapy	“rating their success in achieving their program goals” (Abbott et al., 2009, p.165)
Relapse prevention (28)	Concerns relapse prevention and how to cope with relapse when it does occur, involving summarising treatment, advising on early warning signs of relapse and maintaining learned techniques	“relapse prevention includes a proper discussion of risk factors for developing more severe tinnitus and hearing loss, and devising a plan for what to do should the tinnitus worsen” (Andersson et al., 2001, p.71)
Common therapeutic skills (21)	Concerns the clinicians use of common factors of psychological therapies that is, developing a good rapport demonstrating to the patient that positive regard is held for the patient by the clinician	“Any attempt at change, even if unsuccessful, should be praised” (Sweetow, 1984, p.52)

These 25 themes comprised 138 components, with each theme consisting of between 1 and 13 components (presented in full in Thompson et al., 2017a; Supplemental Digital Content 2, <http://links.lww.com/EANDH/A300>). For example, two of the eight components of thought challenging were thought stopping and cognitive restructuring.

2.4.DISCUSSION

In this scoping review, I catalogued components from different types of psychological treatment used for people with tinnitus. However, CBT was by far the most frequently reported psychological treatment with the greatest number of RCTs published. No psychodynamic treatment protocols were identified despite editorials recommending its use for tinnitus (Schaaf et al., 2010). Existential therapy and Gestalt therapy were identified, although these have not been tested in a clinical trial. A tacit assumption was made that all types of psychological treatment would be amenable to deconstruction into their individual components. However, Mohr and Hedelund's (2006) description of existential therapy for tinnitus states that it does not lend itself to manualisation because the existential therapist should be prepared to engage with whatever subject matter patients present with. Thus, this may act as a barrier to defining the components of an audiologist-delivered psychological treatment and designing a clinical trial. Moreover, it is not expected that audiologists will consider any and every potential psychological problem within their remit, and it is

unlikely that such breadth will lend itself to training audiologists within a culture of brief continuing professional development (CPD) courses. In contrast, CBT for tinnitus reviewed here was modular and manualised, enabling deconstruction into individual components, standardisation, and training for audiologists in a clinical trial (Westin et al., 2011, Kreuzer et al., 2012, Cima et al., 2014). Therefore, further research should explore audiologists' opinions of the boundaries of what can reasonably be expected of them in training to deliver components of a psychological treatment. This is addressed in chapter 3.

This review identified many components of psychological treatment for people with tinnitus. A large proportion of these components involved providing information about tinnitus and psychological wellbeing, attention refocusing and relaxation exercises, behavioural and cognitive techniques. This reflects the influence of Hallam and colleagues' (1984) habitation model of tinnitus and its elaborations (Andersson, 2002a, Kröner-Herwig et al., 2003), which collectively indicate the use of education, attention, relaxation, and CBT (McKenna et al., 2014). However, some of the components identified in this review are contraindicated for patients with anxiety or depression. For instance, Henry and Wilson (1998) used thought stopping, which involves the clinician interrupting negative thinking initiated by the patient, whether by shouting "stop" (Wolpe, 1958), or by flicking an elastic band on the wrist (Bakker, 2009). However, thought suppression has fallen out of favour since evidence has

emerged of its paradoxical rebound effect, whereby the targeted thought becomes more intrusive (Wegner et al., 1987, Abramowitz et al., 2001). Therefore, further research to define the components of an audiologist-delivered psychological treatment should consider the evidence underpinning the components identified here. This is addressed in chapter 4.

This review identified that psychological treatments for tinnitus often include interventions targeting two of the most reported problems co-occurring with tinnitus including poor sleep and hearing loss (Hallam et al., 1988); and the less commonly occurring, hyperacusis. Hyperacusis is a hypersensitivity or reduced tolerance to environmental sound that would not typically be bothersome to most people (Vernon, 1987). Prevalence of hyperacusis in patients attending a tinnitus clinic is estimated to be approximately 40% (Bartnik et al., 1999, Jastreboff and Jastreboff, 2000). However, the prevalence of clinically significant hyperacusis is estimated to be 2% (Baguley and Andersson, 2007). These estimates are derived from clinical experience and extrapolation. Therefore, further research is required on the relevance and how to address hyperacusis and other more commonly co-occurring problems in an audiologist-delivered psychological treatment.

This review supports the view of the James Lind Alliance Priority Setting Partnership (Hall et al., 2013), that the effectiveness of CBT delivered by audiologists remains uncertain. Some exceptions were noted in this review. Audiologists have delivered effective

tinnitus education and psychoeducation, inside and outside of stepped-care CBT. That some cognitive behavioural treatments were delivered by trainee psychologists receiving ongoing supervision suggests a complete qualification in clinical psychology is not a prerequisite to deliver psychological treatments (Abbott et al., 2009, Westin et al., 2011). The aim of clinical supervision is to ensure safe and effective treatment for patients (Wampold and Holloway, 1997). However, physical and mental health services in the UK are commissioned separately, which limits opportunities to integrate psychologist-delivered supervision in audiology services (Naylor et al., 2016). Therefore, innovative services and treatments often rely on psychologists' goodwill and unfunded time. Furthermore, since only a third of audiology services have the option to refer to a psychologist in the UK (Hoare et al., 2012), it may also be difficult to recruit psychologists to provide audiologists' supervision (MacDonald, personal communication). One alternative would be peer supervision, in which clinicians share their experiences of delivering a treatment and offer feedback to one another. However, there is a lack of high-quality studies on the effects of peer supervision and other types of supervision on clinical outcomes (Alfonsson et al., 2017). Nonetheless, audiologist-delivered psychological treatment is not unprecedented. English and Archbold (2014) designed a counselling training programme for audiologists to deliver common therapeutic skills of psychological care for people with hearing loss. The programme included training in displaying empathy and making therapeutic use of

silences during dialogue with patients. English and Archbold found that these skills were maintained in audiologists' practice 6 months after training. This scoping review identified common therapeutic skills such as displaying empathy and making therapeutic use of silences as being part of psychological treatments for tinnitus. Therefore, we may expect training audiologists in common therapeutic skills to be feasible. However, it remains unclear whether this is also the case for techniques that are specific to CBT such as cognitive restructuring and graded exposure, which psychological models predict would be necessary to reduce tinnitus distress (McKenna et al., 2014).

CHAPTER 3. DELPHI SURVEY OF THE PSYCHOLOGICAL COMPONENTS IMPORTANT TO INCLUDE IN AUDIOLOGIST-DELIVERED TINNITUS TREATMENT

3.1.INTRODUCTION

3.1.1. Background

It is apparent from the scoping review described in chapter 2, that there are many components of psychological treatment that have been used in tinnitus management. However, there is a lack of dismantling studies of CBT and other psychological treatments to identify which components are the active ingredients that reduce tinnitus distress. Such studies have been performed for depression. For example, Jacobson and colleagues (1996) demonstrated equivalent efficacy between CBT and behavioural activation. Behavioural activation targets the avoidance of day-to-day activities implicated in depression by re-establishing said activities. There is some evidence to support the theoretical basis of behavioural activation affecting people with tinnitus. Westin, Hayes and Anderssons' (2008) longitudinal analysis of tinnitus patients found that the pursuit of day-to-day activities fully mediates between tinnitus distress at baseline and depression and quality of life 7 months later. It is therefore possible that experiential avoidance may account for the increased rates of depression and reduced quality of life found in people with tinnitus (Pinto et al., 2014),

and that behavioural activation may address these problems (Westin et al., 2008). However, it is unclear whether behavioural activation or any other component of psychological treatment identified in chapter 2 would be acceptable and feasible for the patients and audiologists involved in tinnitus treatment.

Clinical trials of cognitive behavioural treatments for tinnitus involve anywhere between 7 and 22 hours of treatment per patient over a period of 6 to 15 weeks, and rates of attrition are high (Hoare et al., 2011). Therefore, it is important to minimise patient and clinician burden to improve treatment completion rates. One way to do this is to try to find agreement between patients and clinicians on what are the important components of care to deliver (Jones and Hunter, 1995, Sereda et al., 2015). Patient involvement in mental health care delivery can improve service accessibility and patient satisfaction (Crawford et al., 2002, Simpson and House, 2002). Clinicians' views would more likely reflect a broader set of components based on breadth of clinical experience and training. Although there is a lack of evidence for audiologist-delivered psychological tinnitus treatment, half of UK audiologists report that a member of staff in their audiology department has received training to provide CBT (Hoare et al., 2015). Therefore, audiologists may have clinical experience of what components of psychological treatments have been effective for their patients. Medical Research Council (MRC) guidance on developing and evaluating complex interventions states that protocols may be sourced from theory, existing evidence, or clinical experience (Craig et al.,

2013). Since there is a lack of evidence underpinning psychological models of tinnitus distress (McKenna et al., 2014), and little evidence of audiologist-delivered psychological treatment or dismantling studies of psychologist-delivered care, I chose to identify components reported from clinical experience of psychologist-delivered psychological treatments for tinnitus.

Here I examine these preferences using the Delphi survey technique (Gordon and Helmer, 1964). The Delphi survey method was developed to reach consensus of expert opinion. Specifically, the Delphi survey involves the presentation of sequential rounds of questionnaires to panellists. Traditionally this begins with an open-ended question in the first round to enable panellists to generate ideas, with subsequent rounds asking panellists to rate and re-rate these ideas after seeing panellist responses from previous rounds until consensus, or a predetermined end-point is reached.

3.1.2. Aim

The aim of this Delphi survey was to determine, from the shared perspective of patients and clinicians, which components of psychological treatments are most important to inform audiologists' usual care for people with tinnitus.

3.2.METHODS

3.2.1. Study approvals

This study was granted approval by the North West – Preston NHS Research Ethics Committee (reference: 16/NW/0047) and Nottingham University Hospitals NHS Trust (sponsor).

3.2.2. Panel recruitment, size, and composition

Patients were eligible for participation if they self-identified as having received some form of psychological treatment for tinnitus from an audiologist, hearing therapist, or clinical psychologist. They were recruited from the National Institute for Health Research (NIHR) Nottingham Biomedical Research Centre (BRC) research participant database, and via response to advertisements posted on the BTA website (<http://www.tinnitus.org.uk>).

Clinicians were eligible for participation if they self-identified as practicing audiologists, hearing therapists or clinical psychologist/psychotherapists who had any experience of delivering a psychological treatment for people with tinnitus. Clinicians were recruited by contacting regional audiologist and hearing therapist networks, and personal contacts.

Patients, audiologists, hearing therapists and psychologists were included to encompass different types of expertise from different stakeholders resulting in different perspectives. Patients' responses could be influenced by their lived experience of tinnitus and psychological treatment, and what they thought was effective for them.

Audiologists' and hearing therapists' responses could be influenced by knowledge of the UK healthcare system, the NHS, audiology services and regular clinical experience with tinnitus patients, and knowledge of their needs; hearing therapists would be expected to have a greater depth of knowledge about counselling techniques due to their specialised training compared to audiologists' short CPD courses.

Psychologists' responses would be based on a greater depth of knowledge about the theory and evidence of psychological techniques, and clinical experience of people with and without tinnitus would be considered.

Recruitment commenced in February 2016 and was completed in March 2016. The expert panel consisted of 20 patients, and 22 clinicians (14 audiologists, 6 hearing therapists, 2 psychologists) who were recruited by purposive sampling, resulting in a total of 42 experts. An equal number of each type of clinician was targeted for recruitment, however an insufficient number of psychologists consented to participate within the time allotted for recruitment. No panellist disclosed who received or delivered their care, so it is unknown whether any of the patients had consulted any of the clinicians on the panel.

3.2.3. Survey development and piloting

A three-round Delphi survey was developed (Figure 3.1). Four members of the BTA readers panel reviewed survey rounds 1 and 2 with a remit to determine face validity of the survey.

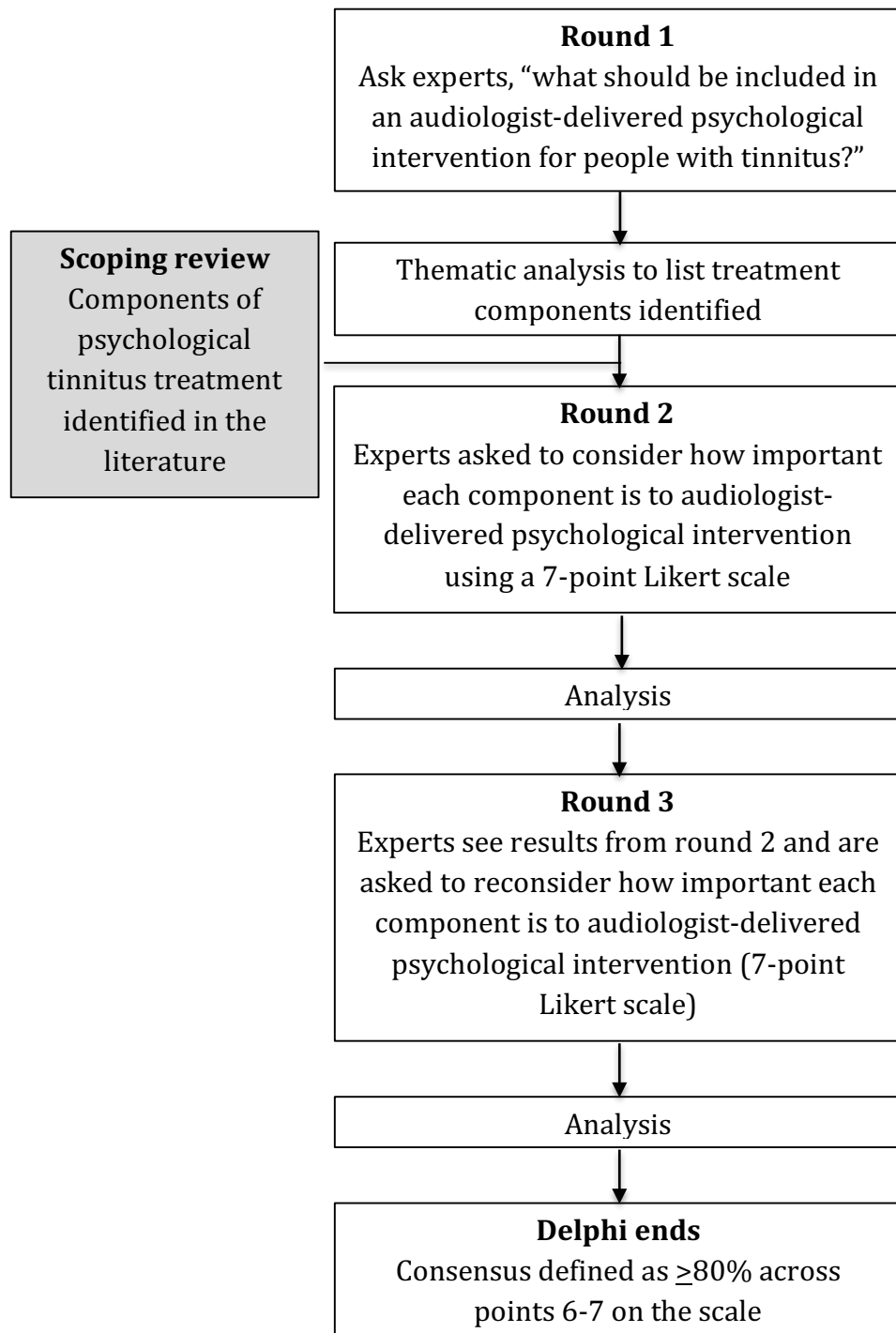


Figure 3.1. Delphi survey flow diagram

The BTA readers panel is a voluntary group of people with tinnitus that routinely reads documentation produced by the BTA. Survey items were amended according to recommendations made by the readers panel. All revisions were returned to them to confirm the acceptability of any changes.

3.2.1. Survey administration

The survey was hosted at Bristol Online Survey (BOS; University of Bristol, 2014), with round 1 commencing March 2016 and round 3 ending May 2016. Panellists were given 2 weeks to complete each round. To mitigate attrition, regular email reminders to complete each survey round within the 2-week timescale were simultaneously sent to all panellists. These emails contained the deadline and the offer of an extension being granted on a case-by-case basis when extenuating circumstances were present. No requests were refused. Panellists were granted the option to complete the survey offline using Microsoft Word and submitting their responses by email. Panellists who withdrew their participation were not replaced.

The level of consensus was set at 80% agreement so that, for example, even if clinicians unanimously agreed a component was important, most patients would also need to agree the component was important for consensus to be reached.

3.2.2. Survey Round 1

All panellists were asked the question, “what in your opinion are the essential components of an audiologist-delivered psychological intervention for people with tinnitus?” Panellists were informed that essential components would be included in a treatment manual for audiologists to deliver for patients. They were also presented with the instruction to “list and describe these components”. I also surveyed patients on how long ago they received counselling or psychological support for tinnitus, and which professional delivered it. I surveyed clinicians on their job role and length of time in that role. Panellists were given free-text response fields to respond to these questions.

3.2.2.1. Analysis of round 1

Firstly, qualitative data received in response to the open-ended question on the essential components were analysed using a modified template analysis (King, 2012). Template analysis began with the identification of *a priori* themes and their respective components taken from the scoping review presented in chapter 2 (Thompson et al., 2017a). These themes include tinnitus education, psychoeducation, evaluation, treatment rationale, treatment planning, problem solving, behavioural intervention, thought identification, thought challenging, worry time, emotions, social comparison, interpersonal skills, self-concept, lifestyle advice, acceptance and defusion, mindfulness, attention, relaxation, sleep, sound enrichment, comorbidity, treatment reflection, relapse prevention, and common therapeutic skills (Table 2.3).

Secondly, panellists' responses were coded to identify components concerning something that a clinician may actively deliver in a psychological treatment for people with tinnitus. Two independent coders (DJH and myself) performed these analyses, and any discrepancies were discussed to reach agreement. If the component was encompassed by a pre-existing theme it was added to it, otherwise, a new theme was added to the template.

3.2.3. Survey Round 2

Panellists were presented with a list of components, derived from panellists' responses in round 1 and the results of the scoping review (Thompson et al., 2017a). Components of complex psychological techniques were described using Common Language for Psychotherapy definitions (Marks and Fullana, 2014) where available. Panellists were asked to rate each component on its importance as part of an audiologist-delivered psychological tinnitus treatment, responding on a 7-point ordinal scale. Selecting points 6 or 7 indicated that, in their view, the component was important to include in the treatment, whereas selecting 1 or 2 would indicate that the component should be excluded. Selecting between 3 and 5 indicated that the component was neither essential nor unessential to include or exclude in audiologists' practice. Panellists were informed, for each item in this survey, if 80% of panellists select points 6 or 7 on the scale, we intended to include the corresponding component in a treatment manual for audiologists to deliver for patients. If 80% of panellists

selected points 1 or 2 on the scale, we intended to exclude the corresponding component from the treatment manual. All items from round 2 were retained in round 3, irrespective of the level of agreement. No survey items in round 2 or 3 were mandatory. Panellists were instructed to respond to all survey items unless they determined that they had no understanding of a given component, in which case they were asked not to respond to the item. Missing within-panellist data were not imputed.

3.2.3.1. Analysis of round 2

Percentage response rates were recorded for each item in the survey. The percentage agreement of patient, audiologist, hearing therapist, and psychologist per survey item was recorded. Components reaching consensus were reported when 80% of all panellist responses were across points 1 and 2, or 6 and 7 on the 7-point ordinal scale.

3.2.4. Survey Round 3

All panellists were presented with the same list of components as in round 2, with aggregated results indicating the preliminary level of agreement between patients and between clinicians on the importance of including each treatment component for each point of the 7-point response scale. Panellists were not presented with the individual responses of other panellists. Each panellist was also presented with their individual responses from round 2. Panellists were asked to reconsider their response to each item using the results from the previous round, responding again on a 7-point ordinal scale. Panellists

were again instructed to respond to all survey items unless they determined that they had no understanding of a given component, in which case they were asked not to respond to the item.

3.2.4.1. Analysis of round 3

Percentage response rates were recorded for each item in the questionnaire. The percentage agreement per component was recorded separately for patients, audiologists, hearing therapists, and psychologists. Components reached consensus where 80% of all panellist responses were across points 1 and 2, or 6 and 7, on the 7-point ordinal scale.

3.2.4.2. Additional analyses

Stability of panellists' responses between round 2 and 3 were measured by calculating weighted kappa (Kw; Cohen, 1968), using R Studio (R Core Team, 2011), and the 'psych' package (Revelle, 2016), where Kw=1 would indicate absolute within-panellist agreement between rounds, and Kw=0 would indicate that agreement between rounds is no better than that expected by chance.

Sensitivity analysis was carried out to account for missing data in round 3 by using corresponding panellist data from round 2.

Sensitivity analyses were also carried out in relation to the number and identity of components reaching consensus when data were limited to subgroups of panellists (patients, audiologists, hearing therapists, and psychologists). A weighted analysis was carried out on round 3 to explore the data while mitigating the underrepresentation of panellist subgroups due to limited recruitment. Clinician subgroups

were given equal weight, with the overall number of clinicians given equal weight to patients.

3.3.RESULTS

3.3.1. Panellist demographics and response rates

3.3.1.1. Patients

Patients received psychological treatment or counselling on (mean) average 2.44 years (SD=33.35) prior to completing round 1 of the survey. Most patients on the panel received psychological treatment or counselling for their tinnitus within the previous year (from one or more clinicians). Fourteen patients had received their treatment from an audiologist, seven from a hearing therapist, two from a clinical psychologist, and seven from a psychological therapist. Eight patients had seen a clinical psychologist or psychological therapist, and an audiologist or hearing therapist. Two patients had seen an audiologist and hearing therapist but not a psychologist.

3.3.1.2. Clinicians

The mean clinical experience in panellists' respective professions was 14.09 years (SD=7.69). Clinicians had between 3 and 30 years of clinical experience in their respective roles. Of the clinicians, 14 were audiologists, six were hearing therapists (one of whom withdrew their participation after completing round 1), and two were psychologists. Of the two psychologists on the panel, one reported their role as consultant clinical psychologist, and the other as cognitive behavioural therapist.

3.3.1.3. Response rates

Of the 42 panellists, 40 (95%) completed round 1, 40 [100% (cumulative response rate)] completed round 2, and 39 [98% (cumulative response rate)] completed round 3. One hearing therapist and one patient withdrew their participation without completing round 2. One further patient withdrew without completing round 3. At round 3, 149 of the 160 components had a response rate of greater than 94% of panellists. Ten components had a response rate of 92%, and one component had a response rate of 90% (complete response rate data are presented in Thompson et al., 2017b; Supplemental Digital Content 2, <http://links.lww.com/EANDH/A359>).

3.3.2. Components derived from Round 1

Panellists proposed 17 components that were not identified in the scoping review (Thompson et al., 2017a), which they thought could inform audiologists' tinnitus care (Table 3.1). Of these, four formed a new theme named 'support and resource signposting'. This theme included the provision of written materials, suggesting the use of websites, ongoing support options following discharge, and homework review. One component, 'discuss past life experiences', did not relate to any pre-defined theme, so it was defined as an independent theme.

Table 3.1. Novel components proposed by panellists in round 1 of the Delphi survey

Theme	Component
Tinnitus education	Provide information on the limbic system and how this information can be used to treat tinnitus*
	Dispel misconceptions about tinnitus*
Evaluation	Discuss tinnitus onset*
	Discuss tinnitus progression*
	Enquire about the patient's suicide risk
Treatment rationale	Engage in a cost-benefit analysis, considering both the advantages and disadvantages of the patient taking action or no action related to their tinnitus
Treatment Planning	Enquire into whether the patient is currently undergoing psychological therapy elsewhere and incorporate experiences from treatment if applicable*
Comorbidity	Discuss any factors of anxiety that the patient displays*
	Discuss any factors of depression that the patient displays*
Common therapeutic skills	Engage in Socratic questioning by asking strategic questions to understand the patients' perspectives and help them work out solutions to their problems*
	Encourage the patient to talk about whatever they wish to bring to the session
	Engage in active listening, verbally restating the patient's statements, and non verbally (for instance, eye contact, body posture)*
Support and resource signposting (new theme)	Suggest appropriate websites that the patient can access*
	Provide information about ongoing support options following discharge*
	Provide the patient with written materials to take away*
	Review the patient's homework from the previous session
Past life experiences (new theme)	Discuss the patient's past life experiences that may still be bothersome

*Components that reached consensus in round 3.

3.3.3. Consensus reached in Round 2

Forty-three of 160 components reached consensus ($\geq 80\%$ agreement) in round 2 as important to include in a treatment manual for audiologists to deliver. No components reached consensus to be excluded.

3.3.4. Consensus reached in Round 3

Seventy-six components reached final consensus ($\geq 80\%$ agreement) in round 3 as important to include in a treatment manual for audiologists to deliver. These components are presented in Table 3.2 in descending order of percentage agreement. Another 84 treatment components did not reach consensus in round 3 (Thompson et al. 2017b; Supplemental Digital Content 3, <http://links.lww.com/EANDH/A360>). No components reached consensus to be excluded. Those components with the highest percentage of agreement to exclude were Gestalt techniques (51%), and social skills training (45%). Components that reached greater than 10% agreement to be excluded are presented in descending order of percentage agreement in Thompson and colleagues report (2017b; Supplemental Digital Content 4, <http://links.lww.com/EANDH/A361>).

Table 3.2. Percentage agreement of components considered absolutely essential to include in an audiologist-delivered psychological intervention for people with tinnitus

Component	Overall	Patient	Clinician	Audiologist	Hearing Therapist	Psychologist
Tinnitus education						
14. Dispel misconceptions about tinnitus	100%	100%	100%	100%	100%	100%
5. Provide information on how tinnitus becomes a problem and how it is maintained	97%	94%	100%	100%	100%	100%
9. Provide information on habituation, the reduction in arousal following exposure to stimuli (such as tinnitus)	97%	94%	100%	100%	100%	100%
4. Provide information on the causes of tinnitus	92%	94%	90%	92%	80%	100%
10. Provide information on the difference between short-term and long-term consequences of tinnitus	87%	94%	80%	85%	60%	100%
13. Provide information on the limbic system and how this information can be used to treat tinnitus	85%	94%	76%	79%	80%	50%
† 12. Provide information on the national tinnitus association	82%	83%	80%	77%	100%	50%
† 2. Provide information on the natural history of tinnitus (how tinnitus changes over time)	82%	78%	85%	85%	100%	50%
Psychoeducation						
21. Provide information on psychological factors of tinnitus annoyance and (di)stress	100%	100%	100%	100%	100%	100%
19. Provide information on the difference between what triggers tinnitus and what maintains it	97%	100%	95%	100%	100%	50%

Component	Overall	Patient	Clinician	Audiologist	Hearing Therapist	Psychologist
20. Provide information on coping skills and strategies to manage stress	97%	94%	100%	100%	100%	100%
17. Analyse stressful events and their effect on tinnitus	95%	100%	90%	93%	100%	50%
15. Provide information on psychological models of tinnitus and mental health and on the relationship between individual factors of tinnitus	92%	94%	90%	86%	100%	100%
16. Use explanations of tinnitus and mental health when managing the patient's tinnitus	92%	100%	85%	77%	100%	100%
Evaluation						
31. Discuss tinnitus impact	100%	100%	100%	100%	100%	100%
22. Ask the patient about and discuss their tinnitus noise	97%	94%	100%	100%	100%	100%
24. Ask the patient to discuss their coping strategies and experiences of using them	97%	94%	100%	100%	100%	100%
35. Discuss tinnitus onset	95%	100%	90%	100%	80%	50%
28. Enquire into tinnitus annoyance	95%	94%	95%	100%	100%	50%
29. Enquire into tinnitus and associated problems	95%	94%	95%	93%	100%	100%
36. Discuss tinnitus progression	95%	89%	100%	100%	100%	100%
33. Enquire about what triggers the patient's tinnitus-related distress and what maintains it	92%	94%	90%	93%	100%	50%
23. Ask the patient about their understanding of tinnitus and how it relates to other facets of their life	92%	89%	95%	100%	100%	50%

Component	Overall	Patient	Clinician	Audiologist	Hearing Therapist	Psychologist
26. Enquire using open-ended questions, as opposed to closed questions that only require yes/no or short answers	92%	89%	95%	92%	100%	100%
27. Enquire into the patient's fears	90%	94%	86%	85.71%	100%	50%
† 25. Provide information on audiological assessment	85%	83%	86%	100%	60%	50%
Treatment rationale						
38. Provide information about and discuss the present psychological intervention for people with tinnitus	100%	100%	100%	100%	100%	100%
41. Provide information about treatment options	95%	100%	90%	93%	100%	50%
39. Provide information on the treatment rationale	92%	94%	90%	93%	80%	100%
Treatment planning						
46. Discuss the patient's expectations of tinnitus	97%	94%	100%	100%	100%	100%
47. Discuss the patient's expectations of treatment	95%	94%	95%	93%	100%	100%
52. Enquire into whether the patient is currently undergoing psychological therapy elsewhere and incorporate experiences from treatment if applicable	87%	89%	85%	85%	100%	50%
49. Provide a clear treatment plan	85%	83%	85.71%	78.57%	100%	100%
Behavioural intervention						
56. Discuss fear and avoidance behaviours with the patient	84%	89%	80%	85%	80%	50%
Emotion						
69. Identify and discuss the effect of the patient's tinnitus on their emotions	100%	100%	100%	100%	100%	100%

Component	Overall	Patient	Clinician	Audiologist	Hearing Therapist	Psychologist
70. Discuss how to change the patient's emotions	84%	89%	79%	75%	100%	50%
Lifestyle advice						
84. Discuss how to change the patient's environment to increase or decrease situations in which tinnitus will be better as appropriate	84%	83%	85%	77%	100%	100%
Relaxation						
96. Provide information relaxation	92%	94%	89%	92%	100%	50%
97. Discuss relaxation	87%	83%	90%	93%	100%	50%
† 99. Encourage the patient to maintain regular practice of relaxation techniques	82%	78%	85%	86%	100%	50%
Sleep						
† 112. Engage the patient in sleep hygiene (habits and practices that are conducive to good sleep)	84%	71%	95%	100%	100%	50%
Sound enrichment						
119. Exposure of sound to manage hyperacusis	95%	94%	95%	100%	80%	100%
121. Advise the patient on noise abuse	90%	94%	86%	86%	80%	100%
114. Provide information and advice on hyperacusis (an extreme aversion and hypersensitivity to sounds that are generally not an issue to other people) and noise sensitivity	89%	89%	90%	92%	100%	50%
117. Discuss the effect of sound enrichment on cognitive factors	85%	89%	81%	86%	80%	50%
† 116. Engage in sound enrichment	81%	83%	79%	92%	60%	50%

Component	Overall	Patient	Clinician	Audiologist	Hearing Therapist	Psychologist
Comorbidity						
129. Discuss any factors of depression that the patient displays	95%	94%	95%	100%	100%	50%
122. Provide information and advice on hearing loss	95%	94%	95%	100%	100%	50%
124. Provide information on hearing-loss treatments	95%	94%	95%	100%	100%	50%
123. Engage the patient in a process of developing hearing tactics (practical behavioural and environmental changes to improve communication)	92%	89%	95%	100%	100%	50%
128. Discuss any factors of anxiety that the patient displays	92%	89%	95%	100%	100%	50%
125. Provide information about problems that occur alongside tinnitus	87%	94%	80%	86%	80%	0.00%
Treatment reflection						
137. Assess the success of therapy with the patient	97%	94%	100%	100%	100%	100%
133. Review therapy with the patient at the end of the treatment	97%	100%	94%	92%	100%	100%
132. Review therapy with the patient	95%	94%	95%	92%	100%	100%
138. Ask the patient to reflect on the current or previous session and to ask questions about it	92%	94%	90%	92%	100%	50%
135. Provide feedback to the patient	92%	94%	90%	85%	100%	100%
136. Revise action plan	89%	89%	90%	85%	100%	100%
139. Check the patient's understanding of information provided	89%	94%	85%	85%	100%	50%

Component	Overall	Patient	Clinician	Audiologist	Hearing Therapist	Psychologist
130. Discuss the consequences of the patient's new behaviours and thoughts, coping strategies and any reasons they may hold for wanting to discontinue treatment	87%	89%	85%	77%	100%	100%
134. Review therapy with the patient halfway through treatment	81%	82%	79%	85%	50%	100%
Relapse prevention						
140. Advise on and plan relapse prevention with the patient	92%	100%	84%	77%	100%	100%
142. Discuss how to cope with relapse with the patient	89%	100%	79%	69%	100%	100%
141. Summarise treatment for relapse prevention	86%	94%	79%	77%	100%	50%
Common therapeutic skills						
147. Demonstrate sincerity, sympathy and empathy	100%	100%	100%	100%	100%	100%
148. The clinician should demonstrate competence and professionalism	100%	100%	100%	100%	100%	100%
149. Develop a trusting relationship with the patient	100%	100%	100%	100%	100%	100%
152. Encourage discussion between patient and clinician	100%	100%	100%	100%	100%	100%
153. Ask strategic questions to understand the patients' perspectives and help them work out solutions to their problems (Socratic questioning)	95%	94%	95%	92%	100%	100%
146. Offer verbal encouragement to the patient	92%	94%	90%	85%	100%	100%
151. Work with the patient's values and life goals	89%	89%	90%	92%	80%	100%

Component	Overall	Patient	Clinician	Audiologist	Hearing Therapist	Psychologist
150. Allow therapeutic silences following discussions	87%	78%	95%	100%	80%	100%
155. Engage in active listening, verbally restating the patient's statements, and non verbally (for instance, eye contact, body posture)	87%	78%	95%	92%	100%	100%
Support and resource signposting						
157. Provide information about ongoing support options following discharge	95%	100%	90%	92%	80%	100%
156. Suggest appropriate websites that the patient can access	92%	94%	90%	92%	100%	50%
158. Provide the patient with written materials to take away	92%	94%	89%	85%	100%	100%

† Components that did not reach consensus in weighted analysis

Weighted analysis of round 3 data (giving clinician subgroups equal weight, with the overall number of clinicians given equal weight to patients) also produced 76 components reaching consensus. However, six of these differed. Those additional components reaching consensus were, '1. Provide information on tinnitus terminology' (80%); '64. Identify and increase positive thoughts' (84%); '71. Normalise tinnitus by sharing other peoples' experiences of it' (85%); '72. Provide information about the likelihood of successful psychological therapy for tinnitus-related distress' (80%); '120. Advise the patient on masking (noise which drowns out the tinnitus) and the risks associated with it' (82%); and '145. Advise the patient on how to maintain practice of psychotherapeutic techniques' (83%). Those components not reaching consensus in weighted analysis are highlighted in Table 3.2.

3.3.5. Sensitivity analysis

One patient completed round 2 of the survey but not round 3. When imputing this patient's data from round 2, one additional component, '59. Enquire about and provide information on attitudes and beliefs, their consequences and effect on tinnitus' would have reached consensus.

Including both patients and clinicians in the survey meant that importance ratings were informed from many different experiences and perspectives. By considering only patient responses, 17 components reached consensus to be included in the treatment

manual, which was not the case when looking at all the data. These components were spread across 12 different themes, including evaluation, treatment rationale, treatment planning, behaviour intervention, thought identification, social comparison, interpersonal skills, acceptance and defusion, sleep, sound enrichment, comorbidity, and relapse prevention; with no theme represented by more than 2 components (Thompson et al. 2017b; Supplemental Digital Content 5, <http://links.lww.com/EANDH/A362>).

When considering only clinician responses, three components reached consensus that did not when all data were considered. Two of these three components concerned sleep including information on its physiological function (overall=73%; clinicians=80%); and advice on changing the sleeping environment and consumption of food, drink and medication (overall=74%; clinicians=80%). The third concerned identifying and increasing positive thoughts (overall=78%; clinicians=80%). When separating out clinicians' data by profession, one other component reached consensus if only decided by audiologists, 30 for hearing therapists, and 15 for psychologists (Thompson et al. 2017b; Supplemental Digital Content 5, <http://links.lww.com/EANDH/A362>). On average across components, the level of agreement increased from round 2 to 3 by 24% (patients 18%, clinicians 5%, audiologists 6%, hearing therapists 21%, and psychologists 44%).

3.3.6. Stability of responses

Weighted kappa (Kw) between round 2 and 3 averaged 0.67 (SD=0.152) across the 160 components. For patients Kw=0.66 (SD=0.199), for clinicians Kw=0.64 (SD=0.187) (Thompson et al. 2017b; Supplemental Digital Content 6, <http://links.lww.com/EANDH/A363>).

3.4.DISCUSION

This Delphi survey attempted to identify consensus on the important components of psychological treatment for audiologists to use for people with tinnitus. By our definition, the panel reached consensus that an extensive inventory of 76 components should be used by audiologists. Panellists were asked what would be important to include in an audiologist-delivered treatment without reference to resource limitations or dose, which may have contributed to consensus being reached on so many components. However, the feasibility of including each of these in a single audiologist-delivered treatment is questionable. The size and complexity of such a treatment may act as a barrier to the implementation of audiologist training within a culture of brief CPD courses. Furthermore, consensus was reached on these components based on the opinions of experienced patients and clinicians. These opinions may have been based on knowledge of evidence in addition to individual patient and clinical experience. However, it is unclear whether clinicians gave preferential weight to their clinical experience, or considered the literature at all.

Therefore, the development of a psychological tinnitus treatment protocol should consider these data in the context of research examining the effectiveness of the components described, not only perceived need. This is addressed in chapter 4.

Panellists tended to agree that components about psychoeducation, information on tinnitus and commonly co-occurring conditions, relaxation, sleep hygiene, sound enrichment, and common therapeutic skills are essential. The focus on attention and distraction using sound reflects the earlier cognitive behavioural treatments for tinnitus tested during the 1980s (Scott et al., 1985, Lindberg et al., 1988), and coheres with Hallam and colleagues' (1984) habituation model of tinnitus distress. This is unsurprising considering that the habituation model is the most influential psychological model of tinnitus distress (Andersson, 2002b, Baguley et al., 2013, McKenna et al., 2014). Most components concerning common therapeutic skills reached unanimous consensus. Several common therapeutic skills (those that are not unique to a single model of psychological therapy) consistently reached consensus in this Delphi survey. The common factors theory of psychological therapies posits that much or all the benefit of treatment is the result of components that are common to many of the different types of psychological therapy (Rosenzweig, 1936). Common therapeutic skills include relationship factors, expectations, and goal setting (Wampold, 2015). Several components reaching consensus appear to map onto clinician behaviours that are geared towards developing a therapeutic relationship with patients,

such as demonstrating empathy, Socratic questioning, and active listening by making eye contact and good body posture. Furthermore, the Delphi panel reached consensus on discussing patients' expectations and providing treatment plans. Thus, patients' and audiologists' preference for common therapeutic skills rather than specific cognitive behavioural techniques aligned with a common factors theory of psychological tinnitus treatment. However, there was some contradiction, with panellists not reaching consensus on collaborating with the patient on how to plan treatment and agreeing on goals together. This is in opposition to the principle of patient-centred care (Epstein and Street, 2011). In contrast also, specific cognitive behavioural techniques were conspicuous by their absence. One interpretation is that the effectiveness of contemporary CBT for tinnitus that include specific techniques like cognitive restructuring and graded exposure (Andersson et al., 2005), have not disseminated into clinical practice in the UK to influence this Delphi panel. Panellists agreed that it is essential to discuss fear and avoidance behaviours with the patient, but not to engage the patient in graded exposure to tinnitus. Giving patients information about common cognitive distortions reached a high level of agreement, but cognitive restructuring did not. These results present something of a paradox. Emotional Processing Theory states that graded exposure works by habituating the patient to a stimulus via exposure, in this case tinnitus (Rachman, 1980), and cognitive restructuring involves the identification of a patients' inaccurate thoughts before they can be

challenged (Andersson et al., 2001). This pattern suggests that this Delphi panel appreciates the importance of these factors, but hesitated before suggesting that the audiologist's role should expand to managing patients' use of the relevant cognitive behavioural techniques. Sensitivity analyses highlight that psychologists do not share this view. Fifteen components reached consensus between psychologists but did not for the whole panel. The additional components reaching consensus between psychologists indicate a psychologist preference to expand audiologists' scope of practice further to other areas that may be related to tinnitus including patients' relationships, home life, and suicide risk. Furthermore, psychologists agreed that audiologists could implement additional cognitive behavioural techniques including problem solving and behavioural activation, involving the structured and gradual increase of personally rewarding activities. Westin and colleagues' (2008) longitudinal analysis of tinnitus patients provides some support for behavioural activation for tinnitus. They found that the pursuit of day-to-day activities fully mediates between tinnitus distress at baseline and depression and quality of life 7 months later. The psychologists on the Delphi panel also agreed on the importance of warning patients about the risks associated with masking tinnitus. This opinion reflects evidence that control over background sound may increase tinnitus interference (Hesser et al., 2009).

The lack of specific cognitive behavioural techniques reaching consensus overall may reflect the complexity of training and required

competency to deliver these techniques. An alternative interpretation is that panellists lacked understanding of precisely what the components would look like in practice, and so rated them as unimportant. This uncertainty could be addressed by interviewing patients and audiologists about their use in a clinical trial. This is addressed in chapter 6. However, panellists were instructed to abstain from responding to individual components if they did not understand them, yet panellists rarely opted to do so. This suggests that the descriptions of components in the Delphi survey were mostly clear, and that the recruited patients and clinicians possessed a good degree of knowledge on the subject matter in so far as they felt confident enough to respond.

Panellists did not reach consensus on excluding any components from consideration when developing an audiologist-delivered psychological tinnitus treatment. However, some components reached a higher level of agreement about their unimportance than others. For example, thought stopping was among the components with the lowest level of agreement to include. This was consistent with evidence that using thought suppression as a coping mechanism would be associated with a paradoxical rebound effect, whereby the targeted thought becomes more intrusive (Wegner et al., 1987, Abramowitz et al., 2001). However, a third of patients on the panel thought that it should be included in tinnitus care, although this was lower for clinicians. In the absence of standardised tinnitus care in the UK (Hoare et al., 2015), this highlights the importance of

audiologists maintaining up-to-date knowledge of the efficacy of psychological interventions.

Eight of 14 components concerning tinnitus education reached consensus. Providing the patient with information about the auditory system, neural networks, and the neurophysiological model did not reach consensus, whereas components concerning aetiology, maintenance and natural history of tinnitus did. In contrast, six of seven psychoeducational components reached consensus. This highlights the importance of audiologists retaining a good level of knowledge about the possible psychological reactions to tinnitus and not only about the physiological mechanisms. However, the only component of tinnitus education to reach unanimous agreement was to 'dispel misconceptions about tinnitus'. Far from providing patients with a rigid set of information, this would require audiologists to take a dynamic approach by first asking for patients' beliefs about tinnitus. Therefore, further research involving periodic surveys of the common misconceptions held by tinnitus patients would be instructive for audiologists.

The Delphi method was used to find consensus between patients and clinicians. Analysis of panellists' responses between round 2 and 3 indicated substantial agreement according to Landis and Koch's (1977) interpretation of weighted kappa values. Nevertheless, this resulted in an increase in components reaching consensus from 43 to 76. Stability of patients' and clinicians' responses

were similar, suggesting that opinions of each stakeholder type were equally swayed by those of other stakeholders.

CHAPTER 4. MANUALISATION OF AN AUDIOLOGIST-DELIVERED PSYCHOLOGICAL TINNITUS TREATMENT

4.1.INTRODUCTION

4.1.1. Background

The Delphi survey described in chapter 3 identified many components that were considered important for audiologists to include in their treatment of tinnitus. However, these components represent a list of information about tinnitus and psychological techniques without the rationale underpinning their use, guidance on how to implement them, or the format in which they should be delivered. Furthermore, the components were identified based on patients' and clinicians' experience of tinnitus care without explicit regard for existing evidence and with input from only two psychologists. Therefore, it is important to consolidate these components into a treatment manual, discarding those that are likely to be ineffective, and retaining those that are considered effective based on existing evidence.

A treatment manual is a written guide to the prescribed actions of a clinical procedure. Manuals have become ubiquitous in clinical trials of psychological treatments, providing benefits for research and clinical practice (Luborsky and De Rubeis, 1984, Ball et al., 2002). Treatment manuals provide systematic instructions to enable replication from a feasibility trial to a definitive RCT to routine clinical

practice; comparison between research teams and clinical sites; and minimises therapist effects. Therapist effects are systematic differences across therapists that modify patient outcomes beyond the treatment modality or therapeutic technique applied (Lutz and Barkham, 2015). Green and colleagues (2014) found that therapist effects including resilience, organisation, knowledge, and confidence explained 9% of the variance in patient outcomes in brief psychological treatments. Crits-Christoph and colleagues' (1991) meta-analysis of therapist effects demonstrated small differences in outcomes between experienced therapists using a manual, and larger differences between relatively inexperienced therapists not using a manual. Therefore, developing a manual to guide audiologist-delivered psychological tinnitus treatment may minimise extraneous therapist effects.

Psychological tinnitus treatment manuals are often written by expert clinicians according to their understanding of psychological theory of tinnitus distress (Andersson et al., 2002, Kaldo-Sandström et al., 2004, Kreuzer et al., 2012, Westin et al., 2011). However, these treatments often have high patient attrition rates in clinical trials (e.g. 51% in Andersson et al., 2002; 30% in Kaldo-Sandström et al., 2004), with most patients reporting a lack of time to continue treatment (Andersson et al., 2002, Kaldo-Sandström et al., 2004). Exploring the acceptability of the treatment manual with patients and audiologists during development may mitigate high attrition. For example, Finch and colleagues (2014) performed a process evaluation of the

intervention development phase of CBT for fear of falling in older adults to explore patient and clinician acceptability and feasibility. Finch and colleagues found that their process evaluation sensitised the intervention developers to contested understandings about fear of falling, and provided solutions to maximise the odds of their cognitive behavioural treatment becoming an effective and sustainable part of routine healthcare delivery for fear of falling. For example, they concluded that the heterogeneity of older adults' experiences of fear of falling required a more individualised approach to treatment. Similarly, the tinnitus patient population is also heterogeneous, and there is a lack of evidence to support the different psychological theories and models of tinnitus (McKenna et al., 2014). Therefore, a similar approach may be appropriate for developing an audiologist-delivered psychological tinnitus treatment that is acceptable for patients and feasible for audiologists to deliver.

4.1.2. Aims

The aims of this chapter were to describe and evaluate the development process of an audiologist-delivered psychological tinnitus treatment manual. This chapter also presents a summary of the treatment manual.

4.2.METHODS

Manual development included a reference group meeting, a period of writing and internal peer-review, and feedback received from the audiologists trained to deliver the treatment.

4.2.1. Reference group meeting

A reference group was responsible for the development of the psychological tinnitus treatment manual. The reference group consisted of 12 members including tinnitus patients, audiologists, hearing therapists, psychologists, and research scientists (Table 4.1). Two patients were recruited from the BTA readers panel, a voluntary group of people with tinnitus that routinely reads documentation produced by the BTA.

A reference group meeting was convened to discuss and agree on the content of the treatment manual. The reference group was provided with a summary of the Delphi survey results from chapter 3 (Thompson et al., 2017b). The summary included a written copy of the level of agreement for each component of psychological treatment identified in the Delphi survey. I verbally summarised the aim, methodology and results of the Delphi survey, including the number of components reaching consensus.

The reference group discussed each component to identify any they perceived to already be part of audiologists' usual care for patients with tinnitus. Components that were part of usual care were excluded from the manual to avoid reintroducing aspects of care that audiologists already routinely deliver.

Table 4.1. Reference group members

I (DMT) am a PhD student in Otorhinolaryngology at the National Institute for Health Research (NIHR) Nottingham Biomedical Research Centre (BRC). I am a qualified Psychological Wellbeing Practitioner with experience of using cognitive behavioural interventions for people with anxiety, depression, and tinnitus.
Dr John Taylor (JT) is Research Fellow at the NIHR Nottingham BRC. He has experience of project managing RCTs and feasibility studies, and expertise in qualitative methodology to assess the feasibility, acceptability, and effectiveness of interventions.
Dr Derek Hoare (DJH) is Associate Professor managing tinnitus research at the NIHR Nottingham BRC. He has led on tinnitus service evaluations in primary care and audiology, was principal investigator (PI) on a phase 2 clinical trial of sound therapy, and has supervised several PhD projects examining psychological aspects of tinnitus distress and management.
Prof Deborah Hall (DAH) is Deputy Director of the NIHR Nottingham BRC. Her primary research goals are to improve the quality of evidence for hearing-related treatments and is developing a core outcome set for tinnitus trials.
Dr Dawn-Marie Walker (DMW) has experience of conducting Delphi and review studies. She is Associate Professor at University of Southampton and Deputy Programme Director on the Healthcare: Management Policy and Research undergraduate degree.
Ms Amanda Casey (AC) has worked as an NHS Hearing Therapist for 25 years. She is Director of the Audiology Programmes at Aston University. She was involved in the development of the tinnitus Good Practice Guidance (Department of Health, 2009) and the curriculum working group for Modernising Scientific Careers (UK Health Departments, 2010).
Ms Debbie Featherstone (DF) is a psychotherapist and hearing therapy practitioner. She established the Clitheroe Therapies Clinic in 2010 after 17 years as an NHS Hearing Therapist. She delivers an accredited tinnitus rehabilitation course and lectures at University of Manchester.
Mrs Carol MacDonald (CM) is a Lecturer in Clinical Psychology at the University of Stirling. She is a British Association for Behavioural and Cognitive Psychotherapies accredited CBT psychotherapist, treating patients with audiological and mental health problems. She has research experience in tinnitus, hyperacusis and misophonia. She is a member of the NHS Scotland Tinnitus Advisory Group, and has experience of training audiologists in the application of CBT.

Prof Mary McMurran (MM) is a clinical psychologist with experience of manualising, delivering and evaluating complex psychological interventions.

Mr David Stockdale (DS) is Chief Executive of the British Tinnitus Association representing a membership of thousands of people with tinnitus.

Of those components not considered a part of usual care, an *a priori* decision was made that components would be included in the manual if they reached consensus in the Delphi survey to be included. For example, the component instructing audiologists to ‘discuss fear and avoidance behaviours with the patient’ reached consensus in the Delphi survey with an agreement of 84% of patients and clinicians as essential to include, and was included in the manual.

For those components that did not reach consensus, I read the description of each component to the reference group, and invited reference group members to discuss including or excluding each component based on theory, evidence, and clinical experience. Components were included or excluded once no further objections or qualifications were raised by any reference group members. The reference group organised the included components into chapters.

Reference group members volunteered to author specific chapters of the manual, citing their preference, expertise, and availability as rationale. The reference group unanimously agreed that authors should identify and use pre-existing copyright-free materials to populate their chapters. I reviewed drafts of each chapter and

returned them to their authors for further revision and approval.

Chapters that I authored were edited by JT.

4.2.2. Audiologist Training

A brief training programme was developed to train audiologists to deliver the manual in a feasibility trial. Training was designed and led by AC and DF to be interactive by using a constructive alignment approach, whereby knowledge is created by the students' activities, and determined by their motives and previous knowledge rather than transmitted from one person to another (Biggs, 2003). AC developed lesson plans using Race's (2015) lecturer toolkit including learning outcomes for each session; resources needed to deliver the session; and the structure, content and method of delivery. Race's model requires participants to be active in their learning and provides opportunities for feedback and reflection on the experience.

Three senior audiologists working in NHS audiology services received training in the use of the manual during a 2-day workshop. One of the audiologists was trained separately after the initial workshop due to availability limitations. Following AC's lesson plans, trainees and trainers took turns to read sections of the manual to develop a collaborative relationship where they could also safely share areas of uncertainty, or a lack of knowledge. Learning was informally assessed using the teach back technique, whereby the trainees were asked to 'teach back' the information they had received (Wu et al., 2005). JT and I were in attendance to answer questions about the

research and treatment components. Trainees were asked for feedback on what they would change about the treatment manual. Recommendations about the style, structure, and presentation of the manual were implemented.

4.2.3. Data collection

The reference group meeting was audio recorded by JT. IP² and I performed intelligent verbatim transcription in which repeated words and fillers such as 'err' and 'hmm' were removed (McLellan et al., 2003). Feedback on the treatment manual received from audiologists during their training was recorded in hand-written notes by JT.

4.2.4. Data analysis

The reference group meeting transcript and audiologist feedback notes each underwent deductive thematic analysis (Braun and Clarke, 2006). Deductive thematic analysis is a 'top-down' approach to analysis involving the development of themes that are directed by theory as opposed to the data as in 'bottom-up' inductive analysis. Analysis was guided by Normalisation Process Theory (NPT; May and Finch, 2009). NPT is concerned with the mechanisms of action involved in the development of complex interventions, and understanding the collaborative work that needs to be done for a new intervention to become embedded within a given context.

² IP is Ms Iskra Potgieter, a research assistant with experience of thematic analysis, who was not a member of the reference group

I performed the analysis beginning with generating initial codes from the data. Codes are shorthand labels representing a passage of the transcript. Codes are used to search for, review, name, and define themes. These themes represent a meaningful pattern interpreted from the data. I produced a coding manual, including a table of themes, codes, description of the codes, and representative quotes (Appendix 1, Appendix 2). I gave the coding manual to IP who performed a secondary analysis of the transcript using pre-existing codes from the coding manual, and to identify and amend ambiguous codes, duplicate codes, under-used codes, data that did not fit a stated code, data that did not fit any code, inaccurate code names, and inaccurate use of quotes to represent codes. DMW adjudicated on themes and codes where IP and I did not reach agreement.

4.3.RESULTS

This results section consists of 4 subsections. The first explores how the reference group determined the content of the manual, followed by a summary of an interim prototype treatment manual. The third section explores the audiologists' recommended changes to the manual during their training, ending with a summary of the final treatment manual for use in a feasibility trial.

4.3.1. Reference group meeting

Four themes about the acceptability of the treatment manual emerged from thematic analysis. These concerned (1) the coherence of the manual content, (2) the flexibility with which audiologists should

implement the manual, (3) the scope of audiologists' practice and what is and what is not appropriate to be delivered by audiologists, and (4) the professional development of audiologists, including training and supervision, to deliver the intervention.

4.3.1.1. Coherence of manual content

The initial view of the treatment was that it would be based on therapeutic principles or skills that are common to different psychological models rather than taking a single fixed perspective. However, components of CBT became predominant in discussions:

"I don't know whether that's how [the treatment] emerged or how its looking based on these components [from the Delphi survey], but I was looking for common principles or common components across all approaches to tinnitus management – which is what our starting point to the Delphi was – of which CBT is one approach." (DJH, researcher)

This reflects the frequent use of CBT for tinnitus and a lack of evidence for other psychological treatments. However, it emerged that a single psychological model would be useful to help patients understand their tinnitus distress:

"There's a kind of hiddenness of a model here and I think is this a moment to be explicit about which model we will be thinking in terms of. If we are framing CBT, are we not looking at the most recent model? Are we not looking at McKenna et al. [2014] just to use a tool for CBT to frame the impact that your thoughts have on how things progress? I think there needs to be some conceptual

reach for something at the cognitive level no matter what you then go on to do. Some framework to help patients conceptualise things in quite a holistic way. I think it's kind of implied... And I think you deny yourself access to one of the most constructive strategies for delivering CBT if you don't include it." (CM, CBT psychotherapist)

It also became apparent that using a cognitive behavioural model to train audiologists would be important to differentiate the treatment from other approaches:

"I think that [information about the theory or model used] will form quite an important part of the training for this because audiologists historically have their training in a particular model, which doesn't acknowledge the agency of the individual in all of this, and really we need a paradigm shift in audiology, in thinking about tinnitus, else none of this is going to be effective." (DAH, researcher)

A shared understanding emerged that the treatment should take a cognitive behavioural perspective of tinnitus, providing a framework by which to develop the treatment manual. However, it also became clear from the Delphi survey data that cognitive components of psychological treatments may not be acceptable to patients and audiologists, and that this may present a conflict between using a cognitive behavioural model to help the patient to understand their tinnitus distress, while not further exploiting treatment components of cognitive psychology:

“One striking observation from the [Delphi survey] consensus list was that we didn't see any items that specifically asked about how people think about their tinnitus. How they interpret what their tinnitus means – the cognitions in CBT – and I don't know whether there are any of those kinds of aspects that were considered by the Delphi panel but they got excluded, but it seems that was kind of lacking.” (DAH, researcher)

This conflict was resolved by including components that did not reach consensus in the Delphi survey if they cohered with other components already considered essential to the treatment:

*“I think we'll have much easier justification for including things that actually link or support what we have already included.”
(DJH, researcher)*

A rationale for including or excluding other components that did not reach consensus in the Delphi was otherwise largely based on evidence for and against the use of specific components:

“There's a very good reason for [thought stopping not being included in the treatment manual]. The evidence is there. Wegner [and colleagues] (1994) is the evidence for ironic thoughts. So, there's a really good reason why that shouldn't be included by anyone ever.” (CM, CBT psychotherapist)

4.3.1.2. Flexibility of the treatment

It became apparent that integrating cognitive behavioural treatment components with usual care would be difficult to achieve:

"You can't separate [psychological tinnitus treatment and usual care] easily. You get somebody who says, 'I am desperate for a noise generator,' or whatever. You can't sort of say, 'well that's Tuesdays session, you'll just have to wait.'" (MM, clinical psychologist)

The emerging view was that the manual should enable audiologists to deliver the treatment flexibly. However, this raised the question of how much autonomy audiologists should have. It was suggested that a highly-structured manual giving audiologists little or no autonomy could present an obstacle to developing a rapport between patient and audiologist, and patient satisfaction:

"Sitting down and doing sort of structured programmes, four sessions or whatever it might be, you're calling it a manual, boring. You know people get really cheesed off doing it that way." (MM, clinical psychologist)

Concerns were also raised that a preoccupation with maintaining fidelity to an over-prescriptive manual would present a barrier to feasibility and should be avoided:

"For sessions, they've then got the furniture, they've got an artefact of the therapy with them as a referral. [Some clinicians] practically hang onto it sometimes." (CM, CBT psychotherapist)

The solution was to develop an unstructured manual:

"Maybe what needs to be done is get away from the notion of a specified treatment but actually, given the psychologically-informed aspects of style, of interaction, more psychological

assessment, integrating the material, addressing the emotions... but not actually making it into a structured programme. You would just give the audiologist the skills and then see what they did with them.” (MM, clinical psychologist)

It was agreed that a culture of shared responsibility should be adopted with the patient to identify what components of the treatment are relevant to them:

“It’s a particular attitude of shared responsibility with a goal. So, the map might be different for everybody, they’ve got different features highlighted, but they’re going to target what bothers them the most in the process.” (CM, CBT psychotherapist)

The role of standardised assessment was also considered important to inform audiologists to target areas of tinnitus impact that are relevant to individual patients. It was agreed that the Tinnitus Functional Index (TFI; Meikle et al., 2012) would be a useful questionnaire for audiologists to assess how patients are affected by tinnitus due to the range of tinnitus-related problems it asks about:

“[The TFI] should be easy to check. So, if you identify the problem areas you can check it at the assessment. Is it still the same, or is it [different]?” (MM, clinical psychologist)

4.3.1.3. Scope of practice

A key issue raised by audiologists and psychologists in the reference group was the need to determine the level of severity and complexity of mental health problems that audiologists should work with. There was a shared understanding that patients who are experiencing

tinnitus distress may be experiencing anxiety or depression, and that the treatment should extend to considering these problems:

"I'd say co-occurring problems or connected problems or something like that, like anxiety and depression and relationship issues." (MM, clinical psychologist)

However, there was some concern that working with anxiety and depression could increase the likelihood of audiologists encountering patients with a risk of suicide or self-harm, which some audiologists may feel uncomfortable about exploring. Although concerns were raised about assessing risk, it was accepted that this was a delicate issue that could not be ignored:

"[Audiologists] would be very uncomfortable [asking about risk of suicide or self-harm]... I think it's the way it's phrased. So, I think there are different ways of pulling out that depth." (AC, hearing therapist)

It was agreed that training could increase audiologists' competence to support patients with co-occurring mental health problems. However, it was understood that there are limits to how much further training would be feasible in addition to what audiologists already receive:

"But we've got to be mindful that some people just want to get on with their job and they don't want too much theory, probably don't want too much reading, but the training looks like well everything is very pragmatic, if this is embedded in clinical practice in the future then you don't want it to be so convoluted."

You know they're not going to be doing degrees in this." (MM, clinical psychologist)

There were also concerns about the level of complexity of some psychological techniques and limited available clinical time when used by audiologists alongside components of usual care:

I think [cognitive restructuring is] too complicated. This is four sessions with people who haven't got any therapy training. I think you will be identifying negative thoughts and negative beliefs and gradually shifting them but I think to go into cognitive restructuring is too much." (MM, clinical psychologist)

However, this could be mitigated using homework assignments, which were endorsed as a format to improve the effectiveness of psychological treatment:

"There is research evidence to suggest that people who do homework, I don't call it that, assignments, whatever you want to call it, actually fare better in psychological interventions and that is definitely something you need to contract in." (DF, psychotherapist/hearing therapy practitioner)

Furthermore, it became apparent that introducing areas of psychological impact to patients without implementing psychological techniques to affect positive treatment-related change on those areas would be unhelpful:

"You don't want to get [audiologists] to raise a point when then you haven't got the wherewithal to do anything about it, and there's nothing worse than identifying a problem and then saying,

'well that's not in my manual mate, off you go,' so that's my concern." (MM, clinical psychologist)

Thus, the reference group agreed to include psychological components of care that did not reach consensus in the Delphi survey, if they addressed common areas of tinnitus impact.

4.3.1.4. Professional development

One group member with experience of training people to deliver cognitive behavioural treatments advocated the use of clinical vignettes and video demonstrations to enhance audiologists' training to use the manual:

"Is it possible to think about scenarios as well? Are we going to have training scenarios, training videos? It's just so we can exemplify or operationalise, for example, 'it might look like this, Mr X turns up saying blah, blah, blah.'" (CM, CBT psychotherapist)

However, the clinical psychologist and research scientist in the reference group noted that the training should be uncomplicated to enable replication:

"And I think training has to be kind of fairly sort of stick to the, it's got to be replicable." (MM, clinical psychologist)

Clinical supervision was considered as a source of information to develop the manual further beyond an initial feasibility trial of the treatment:

"We've discussed including two things. One of which is training... and the second is supervision, and I do think that if you can organise group supervision you will identify some of the issues

that need to be thrashed out in terms of finalising the programme, and you can follow that up, and they should have onsite supervision clinical supervision as well, from whoever they should.” (MM, clinical psychologist)

4.3.2. Interim prototype treatment manual

The manual written following the reference group meeting uses McKenna and colleagues’ (2014) cognitive behavioural model of tinnitus (Figure 1.1) to guide the audiologist to make sense of tinnitus distress and inform treatment options to primarily address the emotional impact of tinnitus. The manual contains multiple treatment options that can be implemented according to individual patient need, determined through a process of shared decision-making between patient and audiologist. The manual comprised nine sections (Table 4.2) and a book of resources including information sheets and worksheets. Each section (excluding the introduction, bibliography, and common therapeutic skills) comprises aims, rationale, learning outcomes, resources, topic overview, session content, and a suggested amount of time to spend on each chapter.

Table 4.2. A summary of the interim prototype manual for audiologist-delivered psychological tinnitus treatment

1. Introduction
 - 1.1 Background
 - 1.2 Overview of manual
 2. Rationale for psychologically informed treatment
 3. Patient assessment
 4. Goal setting/treatment planning
 5. Patient education
 6. Patient management/self-management
 - 6.1 Managing the emotional consequences of tinnitus
 - 6.2 Managing fear and avoidance behaviours
 - 6.3 Rapid relaxation
 - 6.4 Changing unhelpful (negative) thoughts and beliefs
 - 6.5 Promoting physical exercise
 - 6.6 Promoting good sleeping habits
 - 6.7 Attention, monitoring and acceptance
 - 6.8 Sound therapy (enrichment)
 7. Relapse prevention
 8. Common therapeutic skills
 9. Bibliography
-

The introduction section describes the background of psychological treatment for tinnitus, the role of audiologists, and who the manual should be used by and for whom.

The rationale section explores the patient's expectations, sets ground rules, and introduces the cognitive behavioural model of tinnitus to frame the rationale of the treatment. This section also contains information about the evidence underpinning the use of cognitive behavioural techniques for tinnitus distress.

The assessment section describes the steps to take in performing a standardised assessment including the use of the TFI (Meikle et al., 2012), Tinnitus Case History Questionnaire (TCHQ; Stouffer and Tyler, 1990), formulation worksheet based on the

cognitive behavioural model (McKenna et al., 2014), and how to identify appropriate components of treatment according to the assessment.

The goal setting section focuses on agreeing specific, measurable, achievable, realistic, and time-bound (SMART) goals for treatment with the patient.

Tinnitus education consists of information about the causes and maintenance of tinnitus and associated conditions including hyperacusis, common misconceptions about tinnitus, things to avoid (e.g. noise abuse), hearing aids, habituation, and information about masking.

Patient management techniques include the use of McKenna and colleagues' (2014) cognitive behavioural model of tinnitus and the patient's personal formulation as a tool for psychoeducation; relaxation; graded exposure; cognitive restructuring; physical exercise planning; sleep hygiene; an introduction to acceptance and defusion techniques including the use of metaphors and mindfulness; and an introduction to sound therapy as a technique for sleep, and as a potentially counterproductive approach when tinnitus co-occurs with hyperacusis. The patient management technique section content included example scripts to aid audiologists' learning and treatment delivery.

The relapse prevention section contains guidance for assessing outcomes using the TFI and formulation worksheet completed at the beginning of treatment; information to help the patient consider early

warning signs that their tinnitus distress may be worsening; and information to plan for relapse including the ongoing use of any techniques learned in treatment.

The common therapeutic skills section describes skills on how to develop a therapeutic relationship with the patient based on Midwinter and Dickson's (2015) guide to embedding counselling and communication skills in treatment. This includes but is not limited to active listening, paraphrasing and summarising the patient's words, verbalising empathy, and therapeutic use of silence.

The bibliography includes a list of evidence for the effectiveness of CBT and ACT for tinnitus, and case studies of people with tinnitus distress to provide examples of formulation from a cognitive behavioural perspective.

4.3.3. Audiologist feedback

The audiologists we trained recommended changes to the interim prototype manual that fit into 4 themes. These concerned (1) changes to how much flexibility they would be afforded in delivering the treatment, (2) the scope of audiologist practice and what is appropriate for them to offer, (3) changes to the content of the manual, and (4) improvements to the quality of presentation of the manual. All documented recommendations were implemented.

4.3.3.1. Flexibility of the treatment

The audiologists thought that assessments should explore patients' health and wellbeing before tinnitus onset, including levels of physical exercise and quality of sleep, stating that the manual should contain:

"A learning outcome to establish what the patient's sleep has been like throughout the lifespan, including before tinnitus onset."

Furthermore, the audiologists were concerned the manual may curtail their freedom to deliver the treatment flexibly to meet individual patient needs, and requested that certain details in the manual were removed including:

"Recommended durations for delivering components of the treatment, and scripted information to relay to patients."

It was also recommended that suggested scripts should be less prominent and that:

"The audiologist instead should be encouraged to use their own words."

4.3.3.2. Scope of practice

The audiologists expressed concerns that the manual referred to CBT, and that it should be stressed that the treatment is not CBT:

"Reference is made to components of CBT in the manual, though it should be made clearer that this intervention is not CBT."

The audiologists also expressed concern that a Socratic approach to teaching patients about tinnitus may be infeasible in the amount of time available and suggested that tinnitus education should be didactic:

“Remove the point where the audiologist is encouraged to have the patient explore why one person may be ‘stressed’ by tinnitus while another is not. The passage assumes that the patient will come to the realisation (which they may not) that it is due to the response of the patient rather than the severity of the tinnitus percept.”

The audiologists also noticed that parts of the manual implied that the treatment was not relevant to people with severe hearing loss, which should be considered within the scope of psychological tinnitus treatment:

“The sound therapy section does not appear to accommodate patients with severe or profound hearing loss, though it should.”

4.3.3.3. Manual content

The audiologists advised that some of the components of the manual could be simplified to enable patient understanding:

“Explicit mention of the role of the limbic system should be removed to make discussion with the patient user-friendly.”

The audiologists also recommended replacing the cognitive behavioural model with something easier to understand:

“Remove the cognitive behavioural model of tinnitus illustration (McKenna et al., 2014) from the manual because this is too difficult and patients do not like schematics.”

4.3.3.4. Manual presentation

The audiologists recommended several changes to improve the presentation of the manual, including amending text to improve clarity

and conciseness. One observation was that the manual contained duplicated information:

“Learning outcomes and topic overview replicate each another so either one of these subsections should be revised into a shorter summary.”

The audiologists also noticed that some learning outcomes of the manual were not measureable and recommended that:

“All learning outcomes should contain ‘explain’ and ‘describe’ etc. to enable measurable outcomes.”

The audiologists expressed a preference for some parts of the manual to be converted into materials that could be used in-session:

“Remove the illustration on page 40 and use as a handout.”

The audiologists advised that the manual may be difficult to navigate, and recommended changes to help them to move from chapter to chapter:

“Refer audiologist to the relaxation section of the manual as one means of addressing sleep problems.”

It was also recommended that some of the content was interspersed within the manual. For example:

“Reminders to refer to common therapeutic skills information in the manual should be added throughout the specific techniques.”

4.3.4. Final treatment manual

The final version of the manual uses McKenna and colleagues' (2014) cognitive behavioural model to guide the audiologist to understand

patients' tinnitus distress. However, at the request of the audiologists trained to deliver the treatment, the cognitive behavioural model was simplified in patient handouts to focus on the thoughts, behaviours, and emotions implicated in maintaining tinnitus distress (Figure 4.1). The manual comprised nine sections, although the chapters were rearranged from the interim prototype version, with the patient assessment section moved before the treatment rationale (Table 4.3). Furthermore, guidance on using common therapeutic skills was summarised in the introduction section and integrated in the session content throughout, and teaching materials on delivering common therapeutic skills were added in appendices. Scripts and suggested amounts of time to spend on each chapter were removed from the session content of the manual.

Additions to the manual included a description of the structure of the manual and resource toolkit in the introduction section, and an instruction to use initial TFI subscale scores to help identify appropriate components of treatment in the assessment section. The final manual emphasises the need to conduct a more in-depth assessment of patients' levels of physical exercise and sleep predating their tinnitus to determine whether these problems may be unrelated to tinnitus.

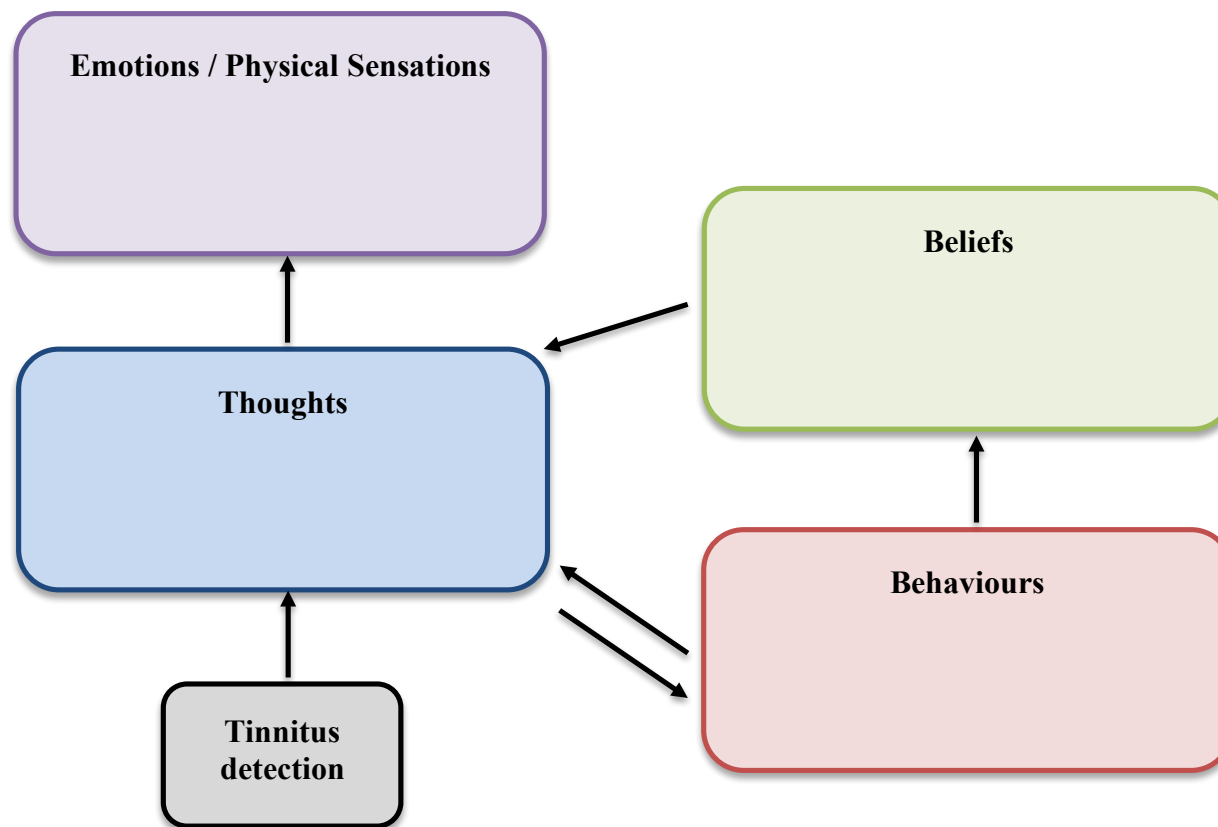


Figure 4.1. Simplified cognitive behavioural model of tinnitus

Table 4.3. A summary of the amended audiologist-delivered psychological tinnitus treatment manual

1. Introduction
1.1 Background
1.2 Overview of manual
2. Patient assessment
3. Rationale for psychologically informed treatment
4. Goal setting/treatment planning
5. Patient education
6. Patient management/self-management
6.1 Managing the emotional consequences of tinnitus
6.2 Rapid relaxation
6.3 Managing fear and avoidance behaviours
6.4 Changing unhelpful (negative) thoughts and beliefs
6.5 Promoting physical exercise
6.6 Promoting good sleeping habits
6.7 Attention, monitoring and acceptance
6.8 Sound therapy (enrichment)
7. Relapse prevention
8. Bibliography
9. Appendices
A1 Communication in rehabilitation
A2 The relational skills model – setting up the relationship
A3 The relational skills model – developing the relationship
A4 The relational skills model – working with the relationship
A5 The relational skills model – the established relationship
A6 Providing explanations
A7 Teach-back technique

A note of caution was added to the rationale section, stating that although the treatment is based on cognitive behavioural treatments for tinnitus, it is not CBT and this should be made clear to patients. A further note of caution was added to the manual referring to the potential for psychological treatment to cause harm.

The tinnitus education section was changed to reduce complex terminology (e.g. on the limbic system), and content from the manual was removed and replaced with handouts in the resource toolkit,

including patient vignettes presented within the simplified cognitive behavioural model of tinnitus.

4.4.DISCUSSION

The aim of this chapter was to provide an account of the collaborative work undertaken to manualise an audiologist-delivered psychological tinnitus treatment. The analysis presented in this chapter provides transparency for the treatment development process. Furthermore, the analysis highlights various points of agreement with and divergence from patient and audiologist preferences identified in the Delphi survey, and the audiology and psychology literature.

During the development process, the reference group recognised that the heterogeneity of the tinnitus patient population posed an obstacle to developing a highly-structured manual to guide audiologists. Therefore, it was agreed that the manual should be underpinned by principles of patient-centred care with components used according to individual patient need indicated by the audiologist's assessment and patient preference. The principle of patient-centred care was shared by the audiologists trained to use the manual, reflecting questionnaire data of audiologists' preference for patient-centred care in Australia (Laplante-Lévesque et al., 2014), Portugal, India, and Iran (Manchaiah et al., 2014).

The manual resembles a low-intensity cognitive behavioural treatment. There is no unanimously agreed definition of what constitutes low-intensity interventions. However, they are often

delivered by healthcare workers without formal professional mental health training, and typically require less clinician time than CBT by using written materials to enable patients to practice techniques they have learned outside of appointments (National Collaborating Centre for Mental Health, 2011). Low-intensity interventions informed by cognitive behavioural models typically involve using individual techniques like thought challenging or graded exposure as is the case here. This conforms to good practice guidance for tinnitus services in the UK (Department of Health, 2009), which recommends audiologists use a 'specialised and focused' CBT.

The reference group meeting frequently referred to patient and audiologist treatment preferences reported in the Delphi survey when deciding whether to include certain psychological treatment components. For example, providing patients with information about a psychological model to help make sense of their tinnitus was considered one of the most useful components of psychological treatment by reference group members, reflecting the high level of agreement in the Delphi survey. Furthermore, this is one of the few areas of psychological treatment addressed in the audiology curriculum (Health Education England, 2016). However, the reference group went further by specifying the use of McKenna and colleagues' (2014) cognitive behavioural model. The cognitive behavioural model is unique among psychological models of tinnitus in so far as it implicates specific mechanisms between tinnitus and cognitive behavioural processes (McKenna et al., 2014). Thus, the cognitive

behavioural model is testable, although it had not been validated at the time the decision was made to include it in the treatment manual.

Since the reference group meeting, Handscomb (2017) performed a systematic evaluation of the cognitive behavioural model by administering a battery of questionnaires to measure each component of the model (e.g. negative automatic thoughts) with people with tinnitus. Two different versions of the model were a good fit with the questionnaire data, suggesting that the predictions made by the cognitive behavioural model are accurate, and suitable for use in psychological tinnitus treatments.

The audiologists we trained to deliver the manual believed that the cognitive behavioural model may be too difficult for some patients to understand, and that patients do not like 'schematics'. However, this contradicts tinnitus patients' opinions of the cognitive behavioural model (Handscomb, 2017). Handscomb interviewed 11 patients with tinnitus who unanimously thought that the model was easy to understand and accurately reflected their experiences of tinnitus. This discrepancy in views between tinnitus patients and the audiologists trained to deliver the manual highlights the importance of patient involvement in treatment development. The audiologists recommended that the cognitive behavioural model be simplified for patients, focusing on thoughts, behaviours, and emotions. Therefore, further research should explore whether a simplified cognitive behavioural model possesses sufficient explanatory power to help make sense of patients' experiences of tinnitus during treatment.

The reference group agreed to include the TFI (Meikle et al., 2012) as a clinical tool to identify the impact of tinnitus on patients to inform which psychological component to use, and to measure if the component used has had an effect. The reference group highlighted the TFI's easy interpretability, responsiveness to therapeutic change, and range of subscales measuring different areas of tinnitus impact. However, the reference group did not cite research on the psychometric properties of the TFI, nor did it compare the TFI to other tinnitus questionnaires. Therefore, it is unclear whether other tinnitus questionnaires may measure relevant areas of tinnitus impact that the TFI does not. Further work was needed to identify what areas of tinnitus impact the treatment is likely to effect, and to identify which tinnitus questionnaires are most appropriate to measure that effect. This is addressed in chapter 5.

The reference group acknowledged that the training offered to audiologists to deliver the manual in the feasibility trial should be didactic without modelling of skills, role-play, or feedback to enable replication. Furthermore, the manual does not specify standards for clinical supervision from a clinical psychologist to support audiologists' delivery of the psychological components of care. This approach limits the potential additive effects of training and supervision on treatment effectiveness. However, it reflects the reality of audiology in the UK, with the absence of psychological treatment in the audiology curriculum (Health Education England, 2016), and limited access to clinical psychologists (Hoare et al., 2012). The lack of

recommended training and supervision standards fits with Carroll and Nuro's (2002) stage model of psychotherapy manual development. The stage model specifies that manuals should be written in 'broad strokes' during preliminary evaluation of feasibility, including treatment components, goals, and format. Only later should supervision standards be specified so that process and outcome data can be synthesised to inform a more detailed specification of the manual so that it may be useful to practicing clinicians and to encourage dissemination in the clinical community (Carroll and Nuro, 2002). Therefore, a feasibility trial of the manual should include process evaluation that explores how the manual should be further developed, including specification of supervision standards. This is addressed in chapter 6.

CHAPTER 5. OUTCOME SELECTION

PROCEDURE TO MEASURE THE EFFECTS OF AUDIOLOGIST-DELIVERED PSYCHOLOGICAL TINNITUS TREATMENT

5.1.INTRODUCTION

5.1.1. Background

The treatment manual described in chapter 4 includes details of several components of psychological treatment. However, it is not clear what tinnitus domains (constructs that classify a cluster of symptoms, feelings, limitations, or problems that are theoretically similar) are expected to be most affected by treatment-related change. Tyler and Baker (1983) asked 97 members of a tinnitus self-help group to list problems caused by their tinnitus. Four domains were identified including lifestyle, hearing difficulties, health effects, and emotion. These comprised subdomains including difficulties initiating sleep, understanding speech, depression, inability to relax, poor concentration, anxiety, social withdrawal, and avoidance of quiet situations. Sanchez and Stephens (1997) replicated Tyler and Baker's study with a sample of 467 patients attending a tinnitus clinic. Their findings were largely consistent with those of Tyler and Baker, with some additional domains including tiredness, and nausea.

Kennedy and colleagues (2004) reorganised the items from tinnitus questionnaires into categories based on Tyler and Baker's

(1983) and Sanchez and Stephens' (1997) tinnitus domains. They found a wide variation in the domains measured by each questionnaire, highlighting the importance of identifying tinnitus questionnaires that best measure the tinnitus domains that are expected to undergo treatment-related change.

Valid and reliable outcome measurement before and after treatment is crucial to provide evidence for effective tinnitus management options to inform commissioners of what works to improve patient care. Outcome domains classify broad aspects of *what* to measure when evaluating an intervention, whereas an outcome instrument represents *how* to measure it (Williamson et al., 2017). Tinnitus can be measured objectively by matching tinnitus loudness and pitch to an external sound (Henry et al., 2005b). However, tinnitus characteristics such as loudness and pitch do not necessarily correlate with tinnitus distress (Hiller and Goebel, 2007). Furthermore, loudness matching is prone to practice effects, variability of pitch likeness matching across different frequencies is high, and dominant tinnitus pitch assessment lacks reliability for individuals across 3 months (Hoare et al., 2014). As a result, it is difficult to objectively measure the impact of tinnitus. Thus, 83% of audiology services in England use self-report questionnaires to measure tinnitus outcomes (Hoare et al., 2015). However, the questionnaire used varies from service to service (Hoare et al., 2015), and research group to research group (Hall et al., 2016).

A core outcome set (COS) is “an agreed minimum set of outcomes that should be measured and reported in all clinical trials of a specific disease or trial population” (Prinsen et al., 2016, p.2). In 2006, a meeting of tinnitus clinicians and research scientists was convened to reach agreement on standard treatment outcome instruments for tinnitus (Langguth et al., 2007). Langguth and colleagues agreed that tinnitus outcomes should be measured using either the Tinnitus Handicap Inventory (THI; Newman et al., 1996), Tinnitus Handicap Questionnaire (THQ; Kuk et al., 1990), Tinnitus Reaction Questionnaire (TRQ; Wilson et al., 1991), or the Tinnitus Questionnaire (TQ; Hallam et al., 1988). The aims of the THI (Newman et al., 1996), and THQ (Kuk et al., 1990) were to measure the functional impact of tinnitus. The TRQ was designed to measure tinnitus-related psychological distress (Wilson et al., 1991), and the TQ was designed to measure complaints about tinnitus and ratings of its perceptual characteristics (Hallam et al., 1988). These questionnaires have been used to measure outcomes in clinical trials (Henry and Wilson, 1996, Andersson et al., 2002, Kröner-Herwig et al., 2003, Cima et al., 2012). However, they were designed for intake assessment, not for responsiveness to treatment-related change. Furthermore, their relevance varies from treatment to treatment (Langguth et al., 2007). For example, the TRQ may not be best suited for assessing the effect of drug treatments for tinnitus that may not directly target psychological distress (Hoekstra et al., 2011). Therefore, selecting the most appropriate questionnaire in any given trial requires further

consideration. Langguth and colleagues agreed that a better questionnaire that was specifically designed to measure treatment-related change was required.

During the manual development described in chapter 4, the reference group agreed to use the TFI (Meikle et al., 2012) as an assessment and treatment planning tool. The TFI is uniquely designed for intake assessment *and* to be responsive to treatment-related change. This enables audiologists to identify the most appropriate interventions for patients, and enables researchers to evaluate the effects of a treatment. The initial prototype of the TFI was developed by 19 experts who evaluated the content validity of 175 items from nine existing tinnitus questionnaires. The panel of experts identified 43 items across 13 domains that they considered most likely to be responsive to treatment-related change. The questionnaire underwent psychometric evaluation across two prototypes with 673 patients until the questionnaire was scaled down to 25 items across eight subscales including intrusiveness, sense of control, cognitive, sleep, auditory, relaxation, quality of life, and emotion. Each subscale was designed to include 3-4 items to keep the number to a minimum without sacrificing construct validity, test-retest reliability, responsiveness, and increased sample size requirements when reducing the number of items to 1-2 per factor (Moran et al., 2001). Meikle and colleagues deemed the final TFI to have good responsiveness based on a lack of extreme item means ($M=3.7-7.2$ on a 0-10 scale) and large standard deviations ($SD=2.3-3.7$).

Building on Langguth and colleagues' (2007) consensus meeting, an EU COST (European Union Cooperation in Science and Technology) Action for tinnitus (TINNET; tinnet.tinnitusresearch.net) is working towards a COS for psychological, pharmacological, and sound-based treatments for tinnitus (Hall et al., 2015). The first stage involved a systematic review of outcome domains and instruments used in tinnitus trials (Hall et al., 2016). Alongside this, Fackrell (2015) conducted a study to identify outcome domains solely using the wording of individual items of existing tinnitus questionnaires. Their aim was to collate a comprehensive list of outcome domains to inform an international Delphi survey to establish consensus between patients, clinicians and research scientists on the minimum set of outcomes that should be measured and reported in all tinnitus trials (Hall et al., 2015).

Terwee and colleagues (2007) developed quality criteria for selecting outcome instruments for a COS and later refined the criteria using a Delphi survey to reach consensus between experts in outcome measurement on what psychometric properties are important to evaluate when selecting an outcome instrument for a COS (Prinsen et al., 2016). The Delphi panel reached 99% agreement that the first step should be to determine what outcome domains to measure, before identifying existing outcome instruments using an up-to-date systematic review of outcome instruments (94% agreement). Based on their Delphi survey results, Prinsen and colleagues recommended that a minimum of content validity, internal consistency, and feasibility

should be evaluated when selecting an outcome instrument for a COS. Furthermore, they suggested that a lower standard for selecting outcome instruments for an individual clinical trial may be justified because it may not be feasible to perform these steps for each trial.

5.1.2. Aim

The aims of this chapter were to select tinnitus domains that are conceptually relevant to the anticipated targets and expected benefits of audiologist-delivered psychological tinnitus treatment, and to select existing outcome instruments best suited to measure the effects of treatment on the domains of interest.

5.2.OUTCOME DOMAIN SELECTION

5.2.1. Methods of outcome domain selection

The treatment manual underwent modified template analysis to identify tinnitus domains (Brooks et al., 2015). Each chapter of the manual was analysed excluding the introduction, goal setting and bibliography chapters as they lacked unique active ingredients of the treatment, referring only to other chapters of the manual. Template analysis began by identifying *a priori* tinnitus domains. The source of tinnitus domains was the subject of a study that was independent to this thesis in which domains were organised according to the constructs assessed by individual tinnitus questionnaire items (Fackrell, 2015). Fackrell used grounded theory to group the items according to their underlying theoretical constructs (Glaser and Strauss, 1967). An initial 42 questionnaires were gathered from a

systematic review of tinnitus research (Hall et al., 2016).

Questionnaires were excluded if (1) a development report had not been published, (2) they had not been used as an outcome instrument in a clinical trial and, (3) the individual items were not publicly available. This eligibility filtering resulted in 23 questionnaires comprised of 456 items. All 456 items were reviewed by three investigators and sorted into conceptually similar groupings. This process was conducted iteratively, with a final step involving consultation with patients, clinicians, and research scientists. At the point at which I took the domain grouping information, there were 21 domains describing the underlying theoretical constructs in the individual items. Twelve of these domains were multidimensional, which further specify the overarching domains, comprising 44 subdomains. Six of these subdomains were multidimensional, comprising 18 final domains (Table 5.1). This information source is hitherto referred to as the 'item analysis domains'.

DJH and I independently identified passages of the treatment manual that referenced a tinnitus domain, and we each produced a list of tinnitus domains that were identified for each chapter of the manual. DJH and I discussed any discrepancies between analyses to reach agreement on a single list of domains. I recorded the number of chapters of the manual that each domain was coded in as a measure of the relevance of each tinnitus domain to the whole treatment manual.

Table 5.1. Item analysis domains of tinnitus

Domain	Subdomain	Final domain
Ability to relax		
Awareness		
Change in sense of self		
Cognition (thought processes)	Ability to ignore	
	Confusion	
	Concentration	
Coping	Reconceptualise the problem/habituating - neutralising tinnitus	
	Active task to distract or cope with tinnitus	
	General	
	Positive reassurance	
	Pre-occupation	
	Purposely protecting or reducing the chance of potential problems	
	Suppressing thoughts of tinnitus	
	Wishful thinking	
	Anger	
	Annoyance	
Emotional impact	Anxious	Anxiety
		Nervous
		Worries/Concerns
	Discomfort	
	Fear/afraid	Fear (of tinnitus)
		General fears
		Fear for Health (Psychological/Physical)
		Fear for quality of life
		Fear of tinnitus becoming worse
	Frustration	
	Irritability	
	Low mood	Bothered
		Depression

Domain	Subdomain	Final domain
		Low mood
		Upset
	Stress	
Enjoyment/Quality of life		
Fatigue		
Impact on physical health	Bodily complaints	
	Ill health	
Interference or impact on activities and relationships	Impact on relationships	
	Interfere with social activities	
	Interfere with work activities	
	Interferes with personal activities	
Knowledge/understanding of consequences of tinnitus		
Masking of tinnitus		
Negative thoughts/beliefs		
Other hearing complaints	Hearing (not tinnitus)	
	Reduced sound tolerance (not tinnitus)	
Perceived support	Nobody understanding my experience	
	Seeking support	
	Support from family and friends	
Perceptual characteristics of tinnitus	Laterality	
	Loudness	Changes in loudness
		Loudness of tinnitus
	Quality of sound	Changes in sound quality
		Type of sound
Sense of control	Helplessness (lack of control)	
	Sense of control	

Domain	Subdomain	Final domain
Sleep difficulties	Difficulties getting to sleep	
	General sleep	
	Quality of sleep (disrupted sleep)	
Speech	Communication	Impact on listening ability
		Interference following group conversations
		Interference with conversations (one-to-one)
	Hearing	
	Locating sounds	
Tinnitus history	Causes of tinnitus	
	Tinnitus Duration	
Unable to code (ambiguous)		

5.2.2. Results of outcome domain selection

Fifteen tinnitus domains were identified in template analysis of the treatment manual (Table 5.2). An *ad-hoc* discussion was held between DJH, JT and I to reach agreement on whether each domain would undergo equivalent treatment-related change between patients receiving the psychological tinnitus treatment and usual care. This step was intended to reduce the likelihood of spurious findings borne out of excessive measurement of irrelevant domains, which would dilute treatment-related effects by using outcome instruments that include an excessive number of domains that are not relevant to the mode of action of the treatment.

Table 5.2. Tinnitus domains identified in template analysis of the psychological tinnitus treatment manual

Domains	Extract from manual	Number of chapters
Emotional impact	Explain that these negative automatic thoughts and core beliefs can increase emotional distress (e.g. anxiety, irritability) (p. 31)	12
Negative thoughts	Catastrophising is one style of negative thinking. Catastrophic misinterpretations are a central factor in the maintenance of tinnitus distress (p. 29)	10
Coping	Can they help other people to understand more about tinnitus and what helps them to cope? (p. 48)	6
Interference/Impact on activities/relationships	State that each patient's symptoms and how they impact on daily functioning vary widely across different patients, so it is important to establish how tinnitus manifests itself for the individual patient. This will help you and the patient to decide together on the best form of treatment for their specific needs. (p. 8)	5
Ability to relax	Firstly, take approximately three normal breaths and slowly exhale. (p. 26)	4
Awareness	Explain that, whilst many people have tinnitus, only some are aware of it all the time or distressed by it. This is because people often get used to the noises just as we get used to other noises around us (e.g. air conditioning, a clock ticking). This is known as habituation. If our attention is focused on something else, it may be possible to 'forget' the tinnitus at times and thus reduce its impact. (p.19)	4

Domains	Extract from manual	Number of chapters
Ability to ignore	Without avoiding and without getting caught up in a struggle to control tinnitus, it is possible just to let awareness of tinnitus be, and then focus on valued goals and activities. If they can accept the tinnitus without judging it, change how they see it, it can start to move into the background (p. 40)	4
Sleep difficulties	Try to create a relaxing bedtime routine, such as taking a bath, listening to soft music, and drinking a warm drink every night. These activities will be associated with sleep and will cause drowsiness. (p. 38)	2
Cognition	Inform the patient that it is also likely that thoughts will become very focused on the thing that is causing the emotional reaction. It may therefore be difficult to concentrate on other things. One result of this is that the problem will seem to grow in importance. This process is known as selective attention. (p. 22)	2
Other hearing complaints	Some people with tinnitus also experience hyperacusis and may be in the habit of avoiding sounds. Although avoiding sounds might provide short-term relief, it can also undo any progress a person has made to adapt to sound. It can actually make the problem worse in the long term by making a person even more sensitive to sound. (p.45)	2
Sense of control	Acceptance is a cognitive-behavioural-emotional process which involves a willingness to experience internal events (i.e. thoughts, feelings or physical sensations) without using strategies that aim to avoid or control such sensations. (p. 40)	2

Domains	Extract from manual	Number of chapters
Enjoyment/Quality of life	Explore the patient's baseline level of activity and if this has changed since tinnitus onset. Ask the patient what exercise they have previously done and what they enjoy to help generate ideas for reintroducing activities. (p. 34)	1
Masking of tinnitus	Discuss that sound therapy can be particularly useful at night if the patient is experiencing difficulties getting to sleep or needing a soothing distraction from their tinnitus if waking up in the early hours. (p. 45)	1
Sense of self	Inaccurate negative beliefs about the self or tinnitus may also fuel negative thoughts. Such beliefs are based on others' experience of tinnitus or derive from general beliefs about health, the self, or the world. As these conscious cognitive processes have a central role in generating and maintaining tinnitus distress, they are key targets for therapeutic change. (p. 29)	1
Knowledge/understanding of consequences of tinnitus	Based on their assessment, dispel any misconception the patient may have about tinnitus. (p. 17)	1

DJH, JT and I discussed each domain and discarded any that reached majority agreement of a null hypothesis that, 'patients receiving psychological tinnitus treatment will experience equivalent treatment-related change to participants receiving TAU in domain 'x''. We hypothesised that the psychological tinnitus treatment and usual care would result in equal outcomes across three of these 15 domains including other hearing complaints, masking of tinnitus, and knowledge/understanding of consequences of tinnitus, which were excluded from further consideration.

A second *ad-hoc* discussion was held between DJH, JT and I to identify any domains that were identified in all or nearly all chapters of the treatment manual. The treatment manual was designed to be implemented flexibly with different components (represented by different chapters of the manual) used according to individual patient need. Therefore, if a tinnitus outcome domain were identified in all or nearly all chapters of the manual, then we would be confident that the domain can be affected by the psychological tinnitus treatment irrespective of which component of treatment is implemented. Of the remaining 12 domains, only the emotional impact of tinnitus was referenced in every manual chapter, and negative beliefs/thoughts about tinnitus was referenced in 11 of 12 manual chapters. No other outcome domain was identified in more than half of the chapters. An interquartile outlier calculation was performed. The emotional impact and negative thoughts domains were the only upper outliers. Therefore, we agreed to discard 10 of the remaining 12 outcome

domains. Thus, two outcome domains were selected to measure treatment-related change; emotional impact and negative thoughts.

5.3.OUTCOME INSTRUMENT SELECTION

5.3.1. Methods of outcome instrument selection

Existing tinnitus questionnaires were selected from a systematic review of tinnitus outcome domains and instruments (Hall et al., 2016). Twenty-three questionnaires were identified (Table 5.3). The Tinnitus Severity Index (TSI; Meikle et al., 1995) was excluded from further consideration following correspondence with a member of the questionnaire development team, who stated that the TSI had not been designed to measure treatment-related change and was replaced by the TFI (Griest, 2015, personal communication). The Tinnitus Severity Scale (TSS; Sweetow and Levy, 1990) was excluded because the questionnaire developer recommended against its use because it has weaker psychometric properties compared to other tinnitus questionnaires (Sweetow, 2013).

An outcome instrument selection workshop was convened by DJH, JT and I to discuss and reach majority agreement on what tinnitus questionnaires should be used to measure emotional impact and negative thoughts about tinnitus.

Table 5.3. Tinnitus questionnaire characteristics

Questionnaire	Subscales	Number of items	Content validity	Internal consistency
Chronic Tinnitus Acceptance Questionnaire (CTAQ; Moreland, 2007)	(1) Engagement, (2) Willingness	20	-	0.90
Fear of Tinnitus Questionnaire (FTQ; Cima et al., 2011)	None	17	0	0.82
International Tinnitus Inventory (ITI; Kennedy et al., 2005)	(1) hearing, (2) health, (3) sleep, (4) peace of mind, (5) other people, (6) activities, (7) enjoyment of life, (8) annoyance	8	+	0.91
Self-Efficacy for Tinnitus Management Questionnaire (SETMQ; Smith and Fagelson, 2011)	(1) Routine Tinnitus Management, (2) Emotional Response, (3) Internal Thoughts and Interaction with Others, (4) Tinnitus Concepts, (5) Devices	40	?	0.98
Subjective Tinnitus Severity Scale (STSS; Halford and Anderson, 1991)	None	16	-	0.84
Tinnitus Acceptance Questionnaire (TAQ; Weise et al., 2013b)	(1) Activity engagement (2) Tinnitus suppression	15	1	0.89
Tinnitus and Hearing Survey (THS; Henry et al., 2015)	(1) Tinnitus, (2) Hearing, (3) Sound Tolerance	12	-	(1) 0.86, (2) 0.94

Questionnaire	Subscales	Number of items	Content validity	Internal consistency
Tinnitus Catastrophizing Scale (TCS; Cima et al., 2011)	None	26	0	0.93
Tinnitus Cognitions Questionnaire (TCQ; Wilson and Henry, 1998)	(1) Positive cognitions, (2) Negative cognitions	13	?	0.91
Tinnitus Coping Style Questionnaire (TCSQ; Budd and Pugh, 1996)	(1) Effective coping, (2) Maladaptive coping	40	0	(1) 0.90, (2) 0.89
Tinnitus Experience Questionnaire (TEQ; Bauer and Brozoski, 2006)	None	7	0	0
Tinnitus Fear-Avoidance Cognitions and Behaviors Scale (T-FAS; Kleinstäuber et al., 2013)	(1) Fear-Avoidance Cognitions, (2) Tinnitus/Ear-related, (3) Fear-Avoidance Behaviours	25	0	0.85
Tinnitus Functional Index (TFI; Meikle et al., 2012)	(1) Intrusiveness, (2) Sense of Control, (3) Cognition, (4) Sleep, (5) Auditory, (6) Relaxation, (7) Quality of Life, (8) Emotional	25	+	0.97
Tinnitus Handicap Inventory (THI; Newman et al., 1996)	(1) Functional, (2) Emotional, (3) Catastrophic	27	?	0.93
Tinnitus Handicap Questionnaire (THQ; Kuk et al., 1990)	(1) Physical, emotional & social effects, (2) Hearing and communication ability, (3) Individual perception of tinnitus	9	+	0.94

Questionnaire	Subscales	Number of items	Content validity	Internal consistency
Tinnitus Magnitude Index (TMI; Schmidt et al., 2014)	None	3	+	0.86
Tinnitus Primary Function Questionnaire (TPFQ; Tyler et al., 2014)	(1) Thoughts and emotion, (2) Hearing, (3) Sleep, (4) Concentration	20	+	0.92
Tinnitus Questionnaire (TQ; Hallam et al., 1988)	(1) Emotional and cognitive distress, (2) Intrusiveness, (3) Auditory Perceptual difficulties, (4) Sleep disturbance, (5) Somatic complaints	52	?	0.91
Tinnitus Reaction Questionnaire (TRQ; Wilson et al., 1991)	None	26	?	0.96
Tinnitus Severity Gradings (TSG; Coles et al., 1992)	(1) Tinnitus affect, (2) Day-vs-night intrusiveness	10	0	0
Tinnitus Vigilance and Awareness Questionnaire (TVAQ; Cima et al., 2011)	None	18	0	0.81

+ = positive rating; ? = indeterminate rating; - = negative rating; 0 = no information available

A priori plan was to keep the number of questionnaires included in the feasibility trial to a minimum to lessen the burden on patients. The TFI was already included in the treatment as an assessment and treatment planning tool. Therefore, the TFI was used as a benchmark by which to compare other tinnitus questionnaires. *A priori* plan was to evaluate the psychometric properties of each tinnitus questionnaire using Terwee and colleagues' (2007) quality criteria including a minimum of content validity, internal consistency, and feasibility. I examined each questionnaire development report and rated each for content validity and internal consistency according to Terwee and colleagues' quality criteria (Table 5.4). Content validity was rated as good if the questionnaire was developed with a clear aim, target population, domains being measured, and the item selection process was clearly described including patient and expert involvement. Internal consistency was rated good if a factor analysis was performed on a sample size equal to or greater than 100 or the number of questionnaire items multiplied by seven. This is a 'rule of thumb' minimum sample size for factor analysis. Feasibility was rated by the number of questions in each questionnaire. Since there is no rule of thumb for the optimal number of questions in a questionnaire, relative feasibility of a questionnaire was defined as fewer questions than the upper boundary of a simple outlier calculation using the interquartile rule.

Table 5.4. Quality criteria for measurement properties of health status questionnaires

Reproduced from Journal of Clinical Epidemiology, 60, Terwee CB, Bot SD, de Boer MR, van der Windt DA, Knol DL, Dekker J, Bouter LM, de Vet HC, Quality criteria were proposed for measurement properties of health status questionnaires, 34-42, 2006, with permission from Elsevier.

Property	Definition	Quality criteria
Content validity	The extent to which the domain of interest is comprehensively sampled by the items in the questionnaire	+ A clear description is provided of the measurement aim, the target population, the concepts that are being measured, and the item selection AND target population and (investigators OR experts) were involved in item selection; ? A clear description of above-mentioned aspects is lacking OR only target population involved OR doubtful design or method; – No target population involvement; 0 No information found on target population involvement.

Property	Definition	Quality criteria
Internal consistency	The extent to which items in a (sub)scale are intercorrelated, thus measuring the same construct	+ Factor analyses performed on adequate sample size (7 * # items and ≥ 100) AND Cronbach's alpha(s) calculated per dimension AND Cronbach's alpha(s) between 0.70 and 0.95; ? No factor analysis OR doubtful design or method; - Cronbach's alpha(s) <0.70 or >0.95, despite adequate design and method; 0 No information found on internal consistency.

+ = positive rating; ? = indeterminate rating; - = negative rating; 0 = no information available

Furthermore, I examined the item analysis domains (Fackrell, 2015) to count the total number of items per questionnaire used to create each domain (Table 5.1). *A priori plan* was to use these totals as an additional measure of validity. For example, if a questionnaire comprised more items about negative thoughts than the TFI then it would be considered to have greater content validity, and provides justification for including an additional questionnaire.

Questionnaires were excluded by a process of elimination based on discussion and majority agreement of the quality criteria ratings between DJH, JT and myself. The order in which each criterion was discussed was improvised during the workshop because it was unclear which psychometric property should be prioritised. For example, it was unclear whether a 0.1 difference in Cronbach's alpha (internal consistency) is equivalent to patient involvement in

questionnaire item generation (content validity). Therefore, the quality criteria were not weighted, and ratings were not combined into a composite score. We discussed which questionnaire should be used to measure emotional impact first, and negative thoughts second.

5.3.2. Results of outcome instrument selection

5.3.2.1. Selection of a measure of emotional impact

The interquartile outlier calculation indicated that any questionnaire with more than 45 questions could be considered an outlier. We agreed that the TQ, consisting of 52 questions, would be excluded from further consideration to minimise the burden placed on patients by minimising the number of items to respond to.

An *ad hoc* decision was made to exclude the FTQ because it was designed to measure the fear subdomain of emotional impact (Table 5.1). We agreed it would not be feasible to measure all nine emotion subdomains using different questionnaires, and that a questionnaire designed to comprehensively measure emotional impact would be preferable.

A further *ad hoc* decision was made to exclude questionnaires that measure emotional impact with fewer than three items based on the item analysis domains data (Fackrell, 2015). Therefore, we excluded the ITI, TAQ, TCQ, TCS, TCSQ, TDQ, THS, THSS, TMI, and TVAQ from measuring emotional impact. We also agreed to exclude questionnaires that measured emotional impact with fewer questions

than the TFI based on the item analysis domains data. Therefore, we excluded STSS, TPFQ, and T-FAS from measuring emotional impact.

An *ad hoc* decision was made to exclude questionnaires whose domain-specific items load onto more than one factor so that a validated unidimensional subscale could be included in the feasibility trial. I compared the item analysis domain data with the original factor structure in the questionnaire development reports of the questionnaires remaining at this stage: the TCQ, TFI, THI, THQ, TRQ, and SETMQ. Only the TFI measured items about the emotional impact of tinnitus comprising a single factor (Table 5.5).

At this stage, the only remaining questionnaire to measure emotional impact was the TFI. DJH, JT and I discussed the content validity and internal consistency ratings of the TFI (Table 5.3). The TFI's content validity was rated positive for giving a clear description of the measurement aim, target population, domains being measured and the item selection process. However, the TFI's overall internal consistency was rated negative due to an extremely high internal consistency of $\alpha=0.97$, suggesting redundant items are present in the questionnaire that are measuring the same concept. On the other hand, the emotion factor has good internal consistency ($\alpha=0.94$). Therefore, it was agreed to use the TFI emotional distress subscale to measure change in the emotional impact of tinnitus in response to audiologist-delivered psychological tinnitus treatment.

5.3.2.2. *Selection of a measure of negative thoughts*

The TQ was excluded from further consideration to minimise the burden placed on patients, and the FTQ was excluded because it was designed to measure the fear subdomain of emotional impact.

An *ad hoc* decision was made to exclude questionnaires that measure negative thinking with fewer than three items based on the item analysis domains data (Fackrell, 2015). Only the TCQ measured negative thinking with three (or more) questions compared to the TFI, which does not directly measure negative thoughts.

The TCQ was examined to assess whether domain-specific items load onto more than one factor. The TCQ's negative cognitions factor mostly measured negative thoughts and sense of control domains (Table 5.6). The TCQ's positive cognitions factor measured coping with 12 of its 13 items.

At this stage, the only remaining questionnaire to measure negative thinking was the TCQ. DJH, JT and I discussed the content validity and internal consistency ratings of the TCQ (Table 5.3). The TCQ's internal consistency was rated positive for falling within the range of $\alpha=0.70-0.95$, based on data received from 189 participants, which was greater than seven multiplied by its 26 items. However, the TCQ's content validity was rated as indeterminate because the development report did not clearly describe the item selection process. Nonetheless, we agreed to use the TCQ to measure negative thoughts in a feasibility trial of audiologist-delivered psychological treatment.

Table 5.5. Comparison of the Tinnitus Functional Index factor structure and item analysis domains

		Tinnitus Functional Index factor structure (Meikle et al., 2012)																								
		Intrusiveness			Sense of control			Sleep			Cognition			Hearing			Relaxation			Quality of life				Emotional distress		
		1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25
Item analysis domains	Emotional impact																									
	Negative beliefs/thoughts																									
	Coping																									
	Interference/Impact on activities/relationships																									
	Ability to relax																									
	Awareness																									
	Ability to ignore																									
	Sleep difficulties																									
	Cognition																									
	Other hearing complaints																									
	Sense of control																									
	Enjoyment/Quality of life																									
	Masking of tinnitus																									
	Sense of self																									
	Knowledge/understanding of consequences of tinnitus																									

Table 5.6. Comparison of the Tinnitus Cognitions Questionnaire factor structure and item analysis domains

		Tinnitus Cognitions Questionnaire factor structure (Wilson and Henry, 1998)																									
		Negative cognitions													Positive cognitions												
Item analysis domains		1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26
	Emotional impact																										
	Negative beliefs/thoughts																										
	Coping																										
	Interference/Impact on activities/relationships																										
	Ability to relax																										
	Awareness																										
	Ability to ignore																										
	Sleep difficulties																										
	Cognition																										
	Other hearing complaints																										
	Sense of control																										
	Enjoyment/Quality of life																										
	Masking of tinnitus																										
	Sense of self																										
	Knowledge/understanding of consequences of tinnitus																										

5.4.DISCUSSION

The audiologist-delivered psychological tinnitus treatment is predicted to affect emotional impact and negative cognitions associated with tinnitus. These would appear to be best measured by the TFI emotional distress subscale and TCQ negative cognitions subscale respectively. The TFI had already been selected during treatment development to be used as a clinical assessment tool to inform treatment decisions because of its comprehensive coverage across several tinnitus domains, although it does not appear to measure negative thoughts about tinnitus. This is important because template analysis of the treatment manual indicated that managing negative thoughts is a core part of the treatment. This reflects the cognitive behavioural model, which suggests that negative thinking is instrumental in initiating a cycle of avoidance behaviours, emotional distress, and selective attention (McKenna et al., 2014).

The original factor structure and psychometric properties of the TFI development report were used in this outcome instrument selection process (Meikle et al., 2012). However, the TFI was developed with a disproportionately large number of veterans based in Veterans' Affairs clinics in the USA, so the original factor structure and psychometric evaluation may not be valid for a sample of UK-based tinnitus patients (Fackrell et al., 2017b). Fackrell and colleagues (2016, 2017a) conducted a validation of the TFI for use in the UK with research and clinical samples. Fackrell and colleagues found that the

auditory subscale does not contribute to the global score in the same way as other factors of the TFI, and recommended that the auditory subscale should be excluded when calculating the total score for the TFI. Applying Fackrell and colleagues' alternative factor structure to this outcome instrument selection process would have had no effect on selecting the TFI to measure the emotional impact of tinnitus because the emotional distress factor of the TFI was the same in both versions. Furthermore, Fackrell and colleagues' evaluation of the TFI's internal consistency with a UK-based clinical sample was consistent with Meikle and colleagues' analysis ($\alpha < 0.95$). Nonetheless, comparing the two versions of the TFI (with and without the inclusion of the auditory subscale) in a feasibility trial may provide some evidence to indicate which version may be more responsive to treatment-related change for a definitive RCT.

The TCQ was designed to assess the content of a person's cognitions in relation to tinnitus (Wilson and Henry, 1998). The TCQ was evaluated with 189 participants. Factor analysis indicated two domains, negative and positive cognitions, each comprising 13 items. They found that the two domains were unrelated ($r = 0.09$) and that the TCQ possesses good internal consistency ($\alpha = 0.91$). Wilson and Henry interpreted the lack of correlation between negative and positive tinnitus cognitions as evidence for a states-of-mind model of tinnitus (Schwartz, 1986). The states-of-mind model posits that there is an ideal balance between negative and positive thoughts and that an imbalance is characteristic of psychopathology. Handscomb and

colleagues (2017) performed an independent evaluation of the TCQ with 342 members of the public. Their findings were largely consistent with Wilson and Henry's research. However, Handscomb and colleagues found that only the negative cognitions subscale was associated with problematic tinnitus, suggesting that interventions should focus on reducing negative thoughts, not on increasing positive thoughts. Contrary to Handscomb and colleagues' findings, this outcome domain selection process indicated that half of the chapters of the psychological tinnitus treatment manual refer to an effect on the coping domain of tinnitus, which comprehensively mapped onto the positive cognitions factor of the TCQ. A definitive RCT of the psychological tinnitus treatment summarised in chapter 4 would provide evidence to address this contradiction by comparing outcomes in the positive and negative subscales of the TCQ with patient-reported outcomes in post-treatment interviews.

CHAPTER 6. A RANDOMISED CONTROLLED FEASIBILITY TRIAL OF AN AUDIOLOGIST- DELIVERED PSYCHOLOGICAL TINNITUS TREATMENT

6.1.INTRODUCTION

6.1.1. Background

It is apparent from the outcome selection process described in chapter 5, that it is critical to measure emotional impact and negative thoughts to evaluate the effectiveness of an audiologist-delivered psychological tinnitus treatment. Effective treatments are typically included in clinical guidelines based on RCTs or systematic reviews of RCTs (National Institute for Health and Care Excellence, 2014, Tunkel et al., 2014). However, RCTs are often undermined by poor delivery and compliance with treatment manuals, and as many as half of reported trials involve difficulty in recruitment and retention of participants leading to underpowered studies (Prescott et al., 1999). A feasibility trial is a study designed to determine whether and how an adequately powered effectiveness RCT can be conducted by measuring variables such as compliance, and rate of recruitment (Craig et al., 2008). Furthermore, MRC guidance on developing and evaluating complex interventions recommends that feasibility trials also include qualitative methodology such as interviews with clinicians and patients to explore the reasons for poor delivery of and compliance

with treatments (Craig et al., 2006). In 1996, a Consolidated Standards of Reporting Trials (CONSORT) statement was developed to improve the transparency and quality of reporting on RCTs (Begg et al., 1996). These guidelines have since been updated and endorsed by hundreds of journals, the International Committee of Medical Journal Editors, the Council of Science Editors and the World Association of Medical Editors (Schulz et al., 2010). In 2016, the CONSORT group developed an extension of these standards to address the distinct aims of feasibility trials (Eldridge et al., 2016). In contrast to definitive RCTs, the CONSORT guideline states that evaluating an intervention using effect sizes estimates is not appropriate in feasibility trials because they are inherently underpowered, comprising small sample sizes which are more likely to result in false-positive or false-negative outcomes (Button et al., 2013).

In chapter 1, I introduced the good practice guide for adult tinnitus services, which recommends audiologists offer specialised CBT or other appropriate counselling skills for people with tinnitus despite a lack of evidence of its effectiveness (Department of Health, 2009). In the Delphi survey described in chapter 3, patients and clinicians agreed on what such a specialised psychological treatment should comprise. However, it is unclear whether the treatment manual described in chapter 4 would be acceptable to the audiologists and patients implementing it, and whether a definitive RCT to measure the effectiveness of an audiologist-delivered psychological tinnitus treatment is feasible.

6.1.2. Aims

The aims of this chapter were to estimate the feasibility of a definitive RCT of manualised audiologist-delivered psychological tinnitus treatment, and to explore fidelity to the treatment manual and acceptability of the treatment to patients and audiologists.

6.2.METHODS

6.2.1. Trial design

A non-blinded, multicentre, parallel randomised controlled feasibility trial was conducted. Audiologist-delivered psychological tinnitus treatment and TAU were compared. The trial was registered with ISRCTN (registration number: ISRCTN13059163), and a trial protocol was published in Pilot and Feasibility Studies (Taylor et al., 2017). The trial is reported here in accordance with the CONSORT feasibility trial statement checklist (Eldridge et al., 2016) (Appendix 3).

6.2.2. Ethical considerations

Ethical approval was granted by North West – Preston Research Ethics Committee (reference: 16/NM/0047). Information about the trial was provided by a researcher (JT) or site Principal Investigator (PI), and informed consent was sought from patients in accordance with Good Clinical Practice (International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH), 2016). The PI at each site was responsible for reporting any adverse events to the Chief Investigator. The Chief Investigator (DJH) was responsible for

informing the Research Innovation Manager and Trust Governance Manager.

6.2.3. Participants

6.2.3.1. Recruitment

Participants were recruited in three audiology services situated in Nottingham University Hospitals NHS Trust, Derby Hospitals NHS Foundation Trust, and Sherwood Forest Hospitals NHS Foundation Trust. The audiologists delivering the psychological tinnitus treatment and TAU at each site were senior audiologists with several years of experience of managing tinnitus.

A sample size of 30 participants was estimated. Audiologists at the three sites were consulted to estimate that a recruitment rate of two participants per month per site was considered feasible over a period of 5 months. This total is between the 24-50 participants recommended for feasibility trials to calculate standard deviation to determine the requisite sample size for an adequately powered definitive RCT (Sim and Lewis, 2012).

6.2.3.2. Eligibility

Patients were eligible for inclusion in the trial if they met the following criteria:

- At least moderately problematic tinnitus (TFI score >24)
- Tinnitus not of medically treatable origin
- Able to communicate in the English language

- Not participating in other research at the time of consenting to the feasibility trial
- No co-occurring conditions such as dementia, severe enough to prevent informed consent
- Willing to complete a research questionnaire battery
- Willing to take part in a follow-up semi-structured interview about their experience of the treatment and tinnitus questionnaires used to measure its effects

6.2.4. Randomisation

After signing the study consent form, patients were randomly allocated to specialised care or TAU on a 1:1 basis. Firstly, each participant was assigned a unique whole number between one and ten for each of the three trials sites, in chronological order of recruitment. Secondly, a random number was generated for each participant using the Microsoft Excel RAND function. For each site, participants with one of the five lowest randomly generated numbers were allocated to the psychological tinnitus treatment arm. The randomly generated numbers were held by an administrative member of staff who was otherwise uninvolved in the trial. Participants' treatment allocation was confirmed at the point of enrolment by contacting the administrative staff member by telephone.

6.2.5. Interventions

6.2.5.1. Specialised care

Specialised care was a manualised audiologist-delivered psychological tinnitus treatment integrated with TAU. The manual is described in detail in chapter 4. In brief, the treatment primarily aimed to address the emotional impact of tinnitus using a cognitive behavioural model of tinnitus. The three trial sites were consulted to estimate that patients would be offered approximately five sessions, each lasting approximately 1 hour with one of the audiologists who participated in a 2-day treatment manual training workshop.

6.2.5.2. Treatment as usual

The three trial sites were consulted on the content of their usual care. In each site, TAU was non-manualised education with management of co-occurring hearing loss with hearings aids, or the provision of ear-level sound generators to partially mask the tinnitus percept.

6.2.6. Outcomes

6.2.6.1. Feasibility outcomes

Feasibility of a definitive RCT was indicated if the following primary outcomes were met:

- Recruitment rate of $\geq 10\%$ of eligible patients at screening
- Recruitment rate of $\geq 65\%$ of the target number of participants
(at least 20 out of 30 participants recruited)

- Retention rate of $\geq 80\%$ of enrolled participants between baseline and end of treatment
- Primary effectiveness outcome questionnaire data provided by $\geq 80\%$ of enrolled participants at baseline, end of treatment, and 6-month follow-up

6.2.6.2. *Effectiveness outcomes*

The primary effectiveness outcome domain was overall tinnitus impact which was measured using the TFI (Meikle et al., 2012). Several secondary effectiveness outcomes were measured including:

- The emotional impact of tinnitus was measured using the TFI emotional distress subscale.
- Tinnitus-related cognitions were measured using the TCQ (Wilson and Henry, 1998).
- Negative thoughts associated with tinnitus were measured using the TCQ negative cognitions subscale.
- General psychological distress was measured using the Clinical Outcomes in Routine Evaluation – Outcome Measure (CORE-OM; Evans et al., 2002).
- Health-related quality of life and cost-utility was measured using the Health Utilities Index (HUI) 15Q (Furlong et al., 2001).
- The therapeutic alliance between the patient and audiologist was measured using the Working Alliance Inventory (WAI) including the patient and clinician forms (Horvath and Greenberg, 1989).

- Patients' use of health and social care was measured using the Client Service Receipt Inventory (CSRI) service receipt section 4 (Beecham and Knapp, 2001).

The rationale for the selection of tinnitus-specific outcome instruments to measure the emotional impact of tinnitus and tinnitus-related cognitions is presented in chapter 5.

A measure of general psychological distress was included to enable comparison with trials of other conditions (Versteegh et al., 2012). Trials of psychological tinnitus treatments have produced varied outcomes for general emotional distress. Although some trials report significant reductions in general psychological distress (Robinson et al., 2008, Cima et al., 2012, Hesser et al., 2012, Conrad et al., 2015), others do not (Kaldo et al., 2008, Weise et al., 2008). Most of the trials that found no significant reduction in general psychological distress used condition-specific outcome instruments such as the Beck Depression Inventory (BDI; Beck et al., 1961) and Beck Anxiety Inventory (BAI; Beck et al., 1988). Therefore, outcome instruments such as the BDI and BAI may not be sensitive enough to detect changes in sub-clinical psychological distress (Handscomb et al., 2016). In contrast, the CORE-OM is designed to measure general psychological distress, has been validated with a sample of tinnitus research volunteers, and possesses good content validity and high internal consistency (Handscomb et al., 2016) (Table 6.1).

A measure of health-related quality of life was used to provide a utility score that can be used to calculate quality-adjusted life years for

economic evaluation. The HUI was selected because of evidence indicating it is more responsive with tinnitus patients than alternative health utilities such as the EQ-5D (The EuroQol Group, 1990, Maes et al., 2011). HUI scores were not calculated in the feasibility trial due to prohibitive financial expense, though responses were collected to gauge compliance. A measure of service receipt was also used to capture duplication of resource use to complement economic evaluation. The CSRI service receipt sections gathers retrospective information on the use of inpatient and outpatient services, including the name of any services used, number of admissions, and total number of days of inpatient care or units of outpatient care received (Beecham and Knapp, 2001).

Therapeutic alliance was measured to examine the effect of the patient-audiologist relationship on other treatment outcomes. The WAI (Horvath and Greenberg, 1989) is one of the most frequently used outcome instruments of therapeutic alliance. The WAI measures generic rather than therapy-specific alliance (Martin et al., 2000). Moreover, patient and therapist agreement on a short-revised version of the WAI and tinnitus distress were significantly correlated in a trial of CBT (Jasper et al., 2014b). Patients were asked to complete paper-based questionnaires at three time points including at baseline (before the first appointment), at the end of treatment, and at 6-months from baseline (Table 6.2).

Table 6.1. Effectiveness outcome questionnaires used

Questionnaire	Subscales	Number of items	Content validity	Internal consistency
Clinical Outcomes in Routine Evaluation – Outcome Measure (CORE-OM; Evans et al., 2002) *	(1) Wellbeing, (2) Social functioning, (3) Problems/symptoms, (4) Risk	34	+	0.95
Health Utilities Index (HUI) 15Q (Furlong et al., 2001)	(1) Vision, (2) Hearing, (3) Speech, (4) Ambulation, (5) Dexterity, (6) Emotion, (7) Cognition, (8) Pain/complaints	17	+	0
Working Alliance Inventory (WAI; Horvath and Greenberg, 1989)	(1) Task, (2) Bond, (3) Goal	36	-	0.93 (client) 0.87 (therapist)
Client Service Receipt Inventory (CSRI) Section 4: Service Receipt (Beecham and Knapp, 2001)	None	5	n/a	n/a

* Subscales, number of items and internal consistency calculated with a tinnitus sample (Handscomb et al., 2016)

+ = positive rating; ? = indeterminate rating; - = negative rating; 0 = no information available (see Table 5.4 for quality criteria)

Table 6.2. Effectiveness outcomes questionnaires time points

	Baseline	End of treatment	6-months follow-up
TFI	✓	✓	✓
TCQ	✓	✓	✓
CORE-OM	✓	✓	✓
HUI	✓	✓	✓
WAI	✓	✓	-
CSRI	-	-	✓

6.2.7. Data-handling and analysis

As set out in the published trial protocol (Taylor et al., 2017), no hypothesis testing was undertaken. The purpose of the trial was to assess the feasibility of conducting a definitive effectiveness RCT. Comparing the effectiveness of two treatment arms in an inherently underpowered feasibility trial risks producing spurious findings. Means, standard deviations, and confidence intervals were calculated in accordance with the CONSORT randomised feasibility trial statement checklist (Eldridge et al., 2016) (Appendix 3).

6.2.8. Treatment fidelity and experience interviews

Patients and audiologists in the psychological tinnitus treatment arm of the trial were invited to attend a semi-structured interview to discuss fidelity to the treatment manual and their experience of the treatment, including the tinnitus-specific outcome instruments. Two interview schedules were developed and tailored to patients and audiologists (Appendix 4). The interview schedules were designed to explore which components of the psychological tinnitus treatment were successfully or unsuccessfully implemented.

Patients were interviewed within 4 weeks of their last appointment. This timescale was designed to strike a balance between being able to assess continued practice of psychological techniques learned in the treatment since the patients' final appointment, and recency of their final appointment to enable recall of the treatment. Audiologists were interviewed after discharging their final patient. Each interview was audio-recorded and performed by JT. Recordings were transcribed, and analysed using inductive thematic analysis (Braun and Clarke, 2006). Each interview transcript was analysed by one member of the research team (DMW or myself) and one person with tinnitus recruited from the Patient and Public Involvement (PPI) panel at NIHR Nottingham BRC. PPI members received a 1-day thematic analysis course from DMW and myself. Course content included information about the thematic analysis procedure, and practice analysing interview transcripts that were unrelated to this trial. Each researcher and PPI panel member completed their analysis independently of one another before meeting to discuss differences in analyses to agree on a single consolidated analysis.

6.3.RESULTS

6.3.1. Feasibility outcomes

Participant flow is presented in Figure 6.1, and feasibility outcomes are presented in Table 6.3. Participants were screened from September 2016 to April 2017. Six-month follow-up occurred between April and September 2017.

A definitive trial of an audiologist-delivered psychological tinnitus treatment is not feasible based on recruitment rate of target participants, retention rate of enrolled participants, and receipt of primary outcome effectiveness questionnaires. The Sherwood Forest and Derby sites did not return their screening records. However, the recruitment rate of eligible participants surpassed the feasibility target at the Nottingham site where 16 patients were screened, representing 63% of participants who were eligible for inclusion (feasible=10%). Participants chose not to participate due to the time commitments involved, and geographical distance between home and the audiology service.

Informed consent was given by 19 participants, representing a 63% recruitment rate (feasible=65%). The Nottingham site surpassed the target with a 100% recruitment rate. The audiology service in Nottingham is one of the largest in the UK, whereas the two sites that recruited below the feasibility target serve comparably smaller populations.

Nine out of 19 participants were retained in the trial until the end of treatment, representing a retention rate of 47% (feasible=80%). All withdrawals from the trial occurred between screening and patients' first appointment. Reasons for withdrawing include spontaneous remission, identification of Alzheimer's disease, and trial site error in allocating patients to treatment arms.

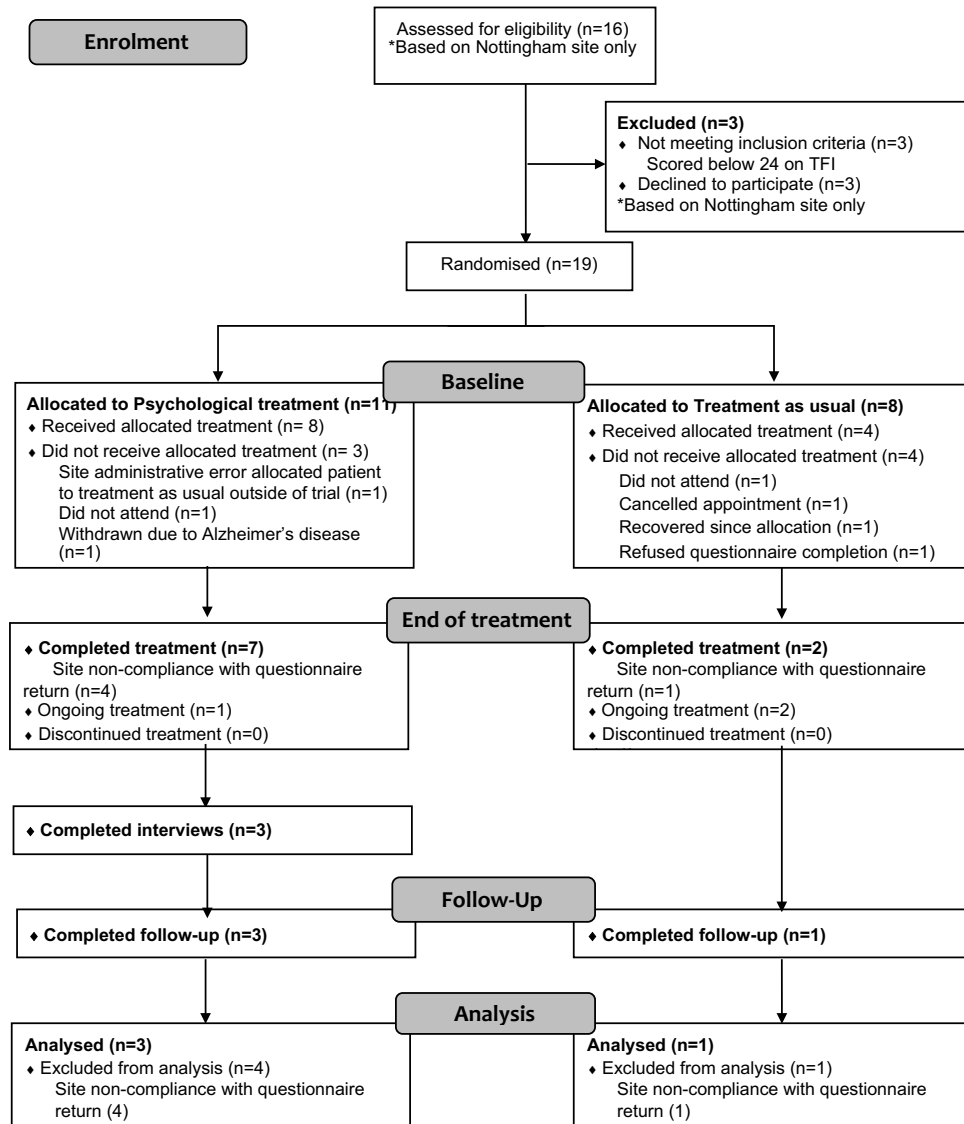


Figure 6.1. Participant flow

Table 6.3. Feasibility outcomes

	Not. Site	She. site	Der. site	Psychological treatment	TAU	Total
Recruitment rate of eligible participants	63%	*	*	-	-	*
Recruitment rate of target participants	100%	30%	60%	73%	53%	63%
Retention rate of enrolled participants	30%	67%	67%	64%	25%	47%
Primary effectiveness outcome questionnaire received	100%	50%	0%	43%	50%	44%

Not. site = Nottingham University Hospitals NHS Trust; She. site = Sherwood Forest Hospitals NHS Foundation; Der. site = Derby Hospitals NHS Foundation Trust; TAU=Treatment as Usual; * = screening data not provided by sites; - = Not applicable

Noticeably more participants completed treatment in the psychological treatment arm compared to TAU, with a retention rate of 64%. Fewer participants completed treatment at the Nottingham site compared to Sherwood Forest and Derby sites, with a retention rate of 30%.

Complete primary outcome data (TFI) were collected from four out of nine participants, representing a data collection rate of 44% overall (feasible=80%). There was substantial variation in data collection between sites, with 100% of data received from Nottingham, and 0% for Derby. Communication with trial sites indicated that the Derby site's PI audiologist changed clinical roles within the same department during the trial, though with an agreement in place to

continue to treat trial patients. Complete HUI data were received from four patients. Three CSRs were returned. One patient receiving TAU visited a primary care physician twice, and other outpatient services twice during the trial. Two patients in the psychological tinnitus treatment arm reported no other service use during the trial.

6.3.2. Baseline demographic and clinical characteristics

The demographic characteristics of recruited patients are reported in Table 6.4. Mean baseline TFI scores were 67.08 (SD=23.644). Seven patients scored between 25-50 on the TFI, indicating significant problems with tinnitus with a possible need for treatment (Henry et al., 2014b). Eleven patients scored above 50, indicating tinnitus severe enough to qualify for more intensive treatment. Only, one of these patients completed treatment.

Table 6.4. Patients' baseline demographic and clinical characteristics

	Psychological treatment (SD)	Treatment as usual (SD)	Overall (SD)
Sex	3 female 7 male	3 female 5 male	6 female 12 male
Age	59 (10.989)	44 (18.330)	53 (16.092)
Baseline TFI	67.08 (23.644)	50.00 (23.849)	59.49 (23.644)

SD = Standard Deviation; TFI = Tinnitus Functional Index

N.B. Demographic data for one patient was not provided by trial site

6.3.3. Effectiveness outcomes

Descriptive statistics are presented in Table 6.5. Confidence intervals were calculated in accordance with the CONSORT feasibility trial statement, and are presented in Table 6.6. TFI, TCQ, TCQ negative thoughts subscale, and CORE-OM scores decreased between baseline and the end of treatment. TFI scores continued to decrease between the end of treatment and 6-month follow-up, whereas TCQ and CORE-OM scores were maintained between the end of treatment and 6-month follow-up. TFI emotional distress subscale scores increased between baseline and the end of treatment, but decreased below baseline by 6-month follow up. Patients' and audiologists' scores on the WAI task, bond, and goal subscales all increased between baseline and end of treatment. No adverse events or adverse reactions occurred during the trial.

Table 6.5. Effectiveness outcomes per treatment arm and time point

	Baseline Psychological treatment	TAU	Post-treatment Psychological treatment	TAU	6-month follow-up Psychological treatment	TAU
	Mean (SD)	Mean (SD)	Mean (SD)	Mean (SD)	Mean (SD)	Mean (SD)
TFI	67.08 (21.669)	50.00 (23.849)	26.53 (32.027)	8.80 (-)	22.48 (25.065)	10.40 (-)
TFI-E	59.00 (37.648)	38.75 (28.000)	25.56 (38.634)	0.00 (-)	15.56 (21.430)	3.33 (-)
TCQ	64.67 (24.378)	59.00 (56.569)	49.67 (12.097)	56.00 (-)	60.00 (-)	8.00 (-)
TCQ-N	46.17 (26.164)	48.50 (61.518)	32.67 (22.811)	36.00 (-)	54.00 (-)	3.00 (-)
CORE-OM	8.58 (7.425)	6.47 (4.575)	2.94 (2.080)	1.76 (-)	2.94 (2.080)	1.47 (-)
WAI-C Task	74.40 (7.162)	80.00 (4.243)	79.00 (6.928)	83.00 (-)		
WAI-C Bond	76.20 (8.843)	73.00 (15.556)	76.00 (6.928)	84.00 (-)		
WAI-C Goal	73.40 (7.369)	80.50 (3.536)	78.67 (9.238)	75.67 (7.234)		
WAI-T Task	38.75 (37.677)	6.00 (-)	75.00 (7.071)	50.67 (37.846)		
WAI-T Bond	74.50 (9.110)	84.00 (-)	77.50 (6.364)	72.00 (7.810)		
WAI-T Goal	62.50 (11.958)	54.00 (-)	73.00 (7.071)	54.00 (-)		

TAU = Treatment as usual; SD = Standard deviation; TFI = Tinnitus Functional Index; TFI-E = Tinnitus Functional Index-Emotion subscale; TCQ = Tinnitus Cognitions Questionnaire; TCQ-N = Tinnitus Cognitions Questionnaire-Negative subscale; CORE-OM = Clinical Outcomes in Routine Evaluation – Outcome Measure; WAI-C = Working Alliance Inventory-Client form; WAI-T = Working Alliance Inventory-Therapist form; - = Standard deviation could not be calculated due to a sample of 1

Table 6.6. Change in secondary outcomes in response to psychological tinnitus treatment over time

	Change over time (baseline minus end)	Change over time (baseline minus follow-up)
	Mean [95% CI]	Mean [95% CI]
TFI	17.61 [-17.39, 52.60]	21.65 [-6.42, 49.72]
TFI-E	-6.67 [-25.53, 12.19]	3.33 [-6.65, 13.31]
TCQ	9.33 [-14.41, 33.08]	-1.00 [-41.28, 39.28]
TCQ-N	13.67 [-32.16, 59.50]	2.00 [-56.44, 60.44]
CORE-OM	0.74 [-3.01, 4.48]	0.74 [-3.01, 4.48]
WAI-C Task	-12.50 [-34.70, 9.70]	
WAI-C	-8.50 [-65.92, 48.92]	
Bond		
WAI-C Goal	-15.50 [-32.86, 1.86]	
WAI-T Task	-4.00 [-15.92, 7.92]	
WAI-T	-6.50 [-30.86, 17.86]	
Bond		
WAI-T Goal	-0.50 [-12.44, 11.44]	

TAU = Treatment as Usual; CI = Confidence Interval; TFI = Tinnitus Functional Index; TFI-E = Tinnitus Functional Index-Emotion subscale; TCQ = Tinnitus Cognitions Questionnaire; TCQ-N = Tinnitus Cognitions Questionnaire-Negative subscale; CORE-OM = Clinical Outcomes in Routine Evaluation – Outcome Measure; WAI-C = Working Alliance Inventory-Client form; WAI-T = Working Alliance Inventory-Therapist form

6.3.4. Treatment fidelity and experience interviews

Thematic analysis of patients' and audiologists' interview transcripts were handled together. Six themes emerged concerning (1) the acceptability of and fidelity to treatment components, (2) factors affecting treatment fidelity and effectiveness, (3) extra-treatment components and redefinition of treatment manual, (4) factors affecting feasibility of wider implementation of treatment, (5) training and supervision, and (6) measurement of tinnitus outcomes.

6.3.4.1. *Acceptability of and fidelity to treatment components*

Overall, the psychological tinnitus treatment was generally well received by patients:

"I've told other people who I know who suffer from tinnitus that they need to go to the hospital and talk to somebody about it because [psychological tinnitus treatment] does make a difference. A huge difference really." (Patient 3)

However, patients and audiologists use, appreciation of, and fidelity to the treatment components varied. Here, I address each component in the order in which they appear in the manual.

Assessment. All three audiologists used the TCHQ (Stouffer and Tyler, 1990) to take patients' history, and reported that they continued to use it following the trial because of its comprehensive and structured presentation:

"I've continued to use it, and actually I've got a member of staff who's currently training up to do tinnitus clinics. That questionnaire has been really useful for him to get a structured history out of a patient. Because it's not too lengthy, it asks the right questions, it gives you enough detail for them to have an idea of where they need to go from there." (Audiologist 2)

The audiologists also thought the 5 areas cognitive behavioural model (Greenberger and Padesky, 1995) was useful to gather more information from the patient than is accessible via the TCHQ (Stouffer

and Tyler, 1990), and that it can empower the patient by helping them to identify solutions to address their tinnitus distress:

“It was quite engaging in a way because you almost get the patient to take ownership of that model. So, at a time where they might not have given you a lot of information in the history, when you start to fill the 5 areas [cognitive behavioural] model in together [with the patient’s experiences] they start to waffle more. They also then are able to offer more of their own personal solutions because I guess one of the things about my practice before [the feasibility trial], we gave a lot of advice where actually I think the best thing for patients is when they figure things out for themselves, then you can always see that light bulb moment where they go, ‘ah yeah that makes sense and this [model] really helps that.’” (Audiologist 3)

The patients reflected the audiologists’ appraisal of the 5 areas cognitive behavioural model (Greenberger and Padesky, 1995) to understand the connection between their thoughts and behaviours:

“Suddenly lots of pennies started dropping and I thought, ‘well that’s linked, and that’s linked,’ and that’s been so useful.”
(Patient 2)

Thus, the combination of the TCHQ (Stouffer and Tyler, 1990) and 5 areas cognitive behavioural model (Greenberger and Padesky, 1995) appear to be feasible and acceptable, and reduces variation in quality of assessment introduced by bespoke templates and a variety of competing tinnitus models.

Goal setting. One audiologist and one of their patients stated that they did not formally set any goals for treatment, thereby deviating from the treatment protocol:

"We didn't set any formal goals, it was just a case of, I would go away and see... whether it's got any worse or whether it got any better and in actual fact it's stayed about the same." (Patient 2)

Another audiologist explained that goal setting can be challenging without first engaging in tinnitus education to explain to the patient that they cannot cure their tinnitus:

You can't say to somebody, 'you have or haven't achieved your goals unless you can measure [them].' So, I think patient goals are often quite vague or over aspirational. And you've got to try and bring them down to an absolute more realistic thing. So, if you say to somebody, 'what would be an ideal end-point for you,' and the majority will say, 'well no tinnitus.' So, then you almost have to say, 'so assuming that can't be done,' which is then putting it right down to a negative point isn't it. So, I find the preliminary bit of goal setting a bit difficult because you've got to start by saying, 'we can't cure your tinnitus, so with that in your mind, what would you like to do?'" (Audiologist 3)

However, fidelity to setting specific, measurable, and realistic goals as set out in the treatment manual was poor:

"Did we actually set a SMART goal? No. I don't think I formalised goals with any of the patients. It didn't seem relevant or necessary." (Audiologist 3)

Therefore, the treatment manual should be reviewed to ensure it emphasises goal setting as an essential part of treatment, providing a clear rationale for its use.

Tinnitus education. All the patients appreciated receiving information about the causes, maintenance, and change in tinnitus over time to provide them with reassurance:

“I think what was reassuring... how variable it is and how it varies from day to day, and what you’re doing, and how quiet it is, what’s going on in there.” (Patient 2)

Furthermore, the audiologists suggested that reassuring patients using tinnitus education is sufficient for some patients:

“I think that’s the bit that the patients really like, and often patients will say at the end of the appointment, ‘I feel so much better because I know more about it.’ So, sometimes for some patients that’s all they need, and it does depend where they’ve come from. So, if they’d come directly from the GP they might know nothing about tinnitus, so sometimes, just by giving them all that information, they go away quite reassured and happy that they know a bit more about it.” (Audiologist 2)

This quote also illustrates a belief that patients receive little or no information about tinnitus from primary care physicians, and that patients’ care pathways should be taken into account when tailoring treatment to patients.

Psychoeducation. All the patients and audiologists involved in the trial commended the cognitive behavioural model of tinnitus for being understandable:

I think [the cognitive behavioural model is] quite a nice one because it's quite logical, the language that it uses is fairly easy, is nothing too sort of technical or too medical and you can [work] through [the treatment manual] in a logical way." (Audiologist 2)

Furthermore, the patients thought that the model reflected their experiences of tinnitus:

"One of the things he did talk to me about, I found quite remarkable really was the fact that stress makes it worse. And I've never heard, never associated the two things together... When you're in work and things are getting a little bit on top of you and your hearing starts to ring slightly louder than it has done in the past hour or so and you start to notice – get up and leave and go walk or go outside... and just take yourself away from the environment, just 5-10 minutes... think about something different ... Where it starts to get loud and whatever it is that you're doing, your concentration [goes to] your tinnitus and then your productivity falls slightly so he is completely right in that and I do that." (Patient 3)

This suggests that patients could make sense of their tinnitus distress using the cognitive behavioural model of tinnitus, and that the model has value as a treatment tool.

Relaxation. Relaxation was acceptable to audiologists although it was used sparingly and briefly in and outside of appointments:

"I used rapid relaxation more than I expected. I'm quite a technical, medical kind of tinnitus person, so they fit in sort of the alternative therapies bit as far as I'm concerned. That's more my thoughts about them but I did use rapid relaxation with several of the patients because I felt it was not patronising like some of the relaxation stuff that you do... If it lasts for anything more than half a minute I fear it's getting patronising. I don't know why I feel that, maybe that's just my own personal view but rapid relaxation doesn't do that, because you can almost, you can explain it in detail and demonstrate it and get them to do it in a very short amount of time that makes you feel like you're just doing it off the cuff." (Audiologist 1)

Patients mostly reported using relaxation to improve sleep:

"I was using the relaxation to get to sleep, and then occasionally I get woken up and its tinnitus that I can hear, and I do the relaxation then in the middle of the night sometimes to get back to sleep... If it was bothering me through the day particularly? I would do that yeah." (Patient 2)

Thus, the use of rapid relaxation without more prolonged applied relaxation appeared to be useful for patients.

Avoidance behaviours and exposure. Some but not all patients expressed an understanding of avoidance as a mechanism of

tinnitus distress and demonstrated recognition of when they were engaging in avoidance behaviours:

"I avoided noisy environments. So, like if friends invited me round for a party, I always used to make excuses not to go because I always found if I was in a noisy environment when I came out, you always get ringing in your ear and things like that. A noisy environment used to make my tinnitus worse. Whether it was the fact that I was concentrating on it, or you listen hard when you're in a noisy environment, or loads of people talking together, I did used to come away from the situations like that. So, my hearing of my tinnitus did used to affect me socially. Not so much now."

(Patient 3)

However, patients' awareness of avoidance strategies did not appear to transfer to all contexts:

"I go outside or I go away... just to get me out of the situation so I'm not in it, and then I go back... no [I didn't use an exposure worksheet]." (Patient 3)

The audiologists also demonstrated an awareness of safety behaviours like avoidance. However, some were not always able to consistently recognise avoidance in various contexts:

"Safety behaviours for example, it seems very obvious when you read the words 'safety behaviours,' what that might be. But then actually when the patient starts talking about the things that they do, and their feelings, and their attitudes, and how they deal with things you don't necessarily think that's a safety behaviour."

And then I find it a bit hard to say, 'here's the model of safety behaviours,' but actually I can't think of what you said was a safety behaviour. So that might be part of the training that we could list safety behaviours and list beliefs, and if the patient says, 'I find it really difficult when I go to the supermarket because my hearing isn't quite good enough, I feel I might miss what the cashier says, and the humdrum of the noises in the market makes my tinnitus feel like it's worse, so I started ordering things online,' for example. I obviously can sort of dress it up as a safety behaviour, but it might not register as that [during appointments]." (Audiologist 1)

Thus, there was an effort by the audiologists to provide information about the importance of reducing avoidance, but a lack of skill in identifying patients' avoidance behaviours. Therefore, the manual could be amended by adding a list of examples of avoidance behaviours to assist audiologists.

Thought challenging. Fidelity to the thought challenging component in the manual varied between audiologists, but was often limited to identifying negative thoughts without challenging them:

"I didn't use the thought record sheets. I used the unhelpful thinking styles [material], and patients do find this one quite useful, and quite often they'll point out, 'yeah, that's me,' and so that helps us to address some of these thoughts." (Audiologist 3)

At least one of the audiologists found the thought challenging prompts included in the treatment manual useful:

“One of the questions... a nice one to ask a patient is, ‘if you had a friend in this situation and they were telling you this, what would your advice be to them?’ That was a very good opening question to maybe challenging some of the thoughts because... we’re a lot kinder to our friends and family than we are to ourselves.”

(Audiologist 1)

However, when thought challenging was used, including prompts provided in the manual, some audiologists found the technique ineffective:

“Most of the time [patients] don’t [think of a more helpful realistic thought]. And I don’t know whether that’s because I’m not enabled enough or whether they just can’t do it.” (Audiologist 1)

When thought challenging was perceived to be effective, concerns remained that any improvement may be short lived once treatment had ended:

“I would say the majority of patients leave very happy that they’ve been able to talk to someone, and so I’d say that most of them grasp [thought challenging] very quickly. When they leave the hospital and they live their lives day to day, that’s a different question, different story.” (Audiologist 3)

This reflects the reduction in positive therapeutic change in negative thoughts about tinnitus between the end of treatment and 6-month follow-up.

Physical exercise. Patients reported engaging in physical exercise during the trial despite it increasing their tinnitus awareness:

“When I walk, if I’m on my own I’ll listen to the ringing in my ear, so it’s one of those things where I’m not certain that being on my own or walking is the right thing to do because I listen to it. Obviously the louder it gets the more I listen, the more I listen, the louder it gets... at the end of it I’m thinking, ‘I shouldn’t have done this, I should have stayed at home or put hearing aids on or listen to music or something like that.’” (Patient 3)

The audiologists consistently reported that they informed their patients of the rationale for physical exercise for tinnitus, which may have encouraged patients’ adherence:

“So, I will talk about physical exercise and I’ll promote physical exercise with them and explain to them why it’s good.”
(Audiologist 1)

Thus, physical exercise was well adhered to by patients despite temporary worsening of tinnitus. This highlights the need to amend the treatment manual to warn of these effects to reassure patients.

Sleep hygiene. Patients and audiologists unanimously favoured the inclusion of education about sleep cycles:

“This [sleep cycle handout] I give out, very useful... The sleep cycle wasn’t new. However, it was nice to have something visual to give the patient. I wouldn’t say that my practice changed because of this.” (Audiologist 3)

Sleep diaries were not used by patients in the trial in favour of sleep monitoring devices, although the principle of monitoring sleep to identify poor sleeping habits was maintained:

“No, I’ve been using [a fitness watch and not the sleep diary] because that records in quite reasonable detail the amount of sleep you’ve had.” (Patient 1)

The effectiveness of sleep monitoring devices and their similarity to sleep management diaries is unclear, so any further trial should either specify the use of sleep management diaries included in the manual or investigate the fidelity of any devices to the manualised treatment.

Attention and acceptance. One audiologist introduced the concept of mindfulness, and two audiologists used metaphors when they thought it would be acceptable to patients:

“I did use the acceptance metaphors particularly, not all of the time but for some patients who seem quite receptive. Some patients are more receptive to this type of approach. I would read out the quicksand [metaphor]. So, I would say, ‘I’m going to give you this bit of information, but I want to read you this’... and read it in that very calm voice, and patients would often say, ‘ah yes, I understand that,’ if they were receptive to it.” (Audiologist 3)

However, one audiologist appeared to use metaphors as an imagination exercise rather than as a defusion technique:

“We didn’t go through too many metaphors, obviously the metaphors of aligning the sounds of your tinnitus to natural sounds. We didn’t talk about particular river banks.” (Patient 1)

Therefore, the rationale of defusion techniques may have been lost during audiologists’ training or patients’ treatment. Thus, the feasibility of these techniques is not supported by this trial.

Sound enrichment. All the audiologists involved in the trial stated that the sound enrichment section of the manual was equivalent to usual treatment:

“Sound therapy is something I’ve talked about with the majority of patients, avoiding the silence, fill in the silence with sounds, whether that’d be sound therapy in terms of wearable [devices] or hearing aids, or whether it’s just generally having an environment that’s full of sounds, or opening the window when they’re at home, putting the radio or the TV on. So, all those things within that section I would talk about anyway. And I don’t think there was anything in there that I didn’t think that I wouldn’t have said.” (Audiologist 2)

This suggests that the inclusion of sound enrichment in the treatment manual may be superfluous. Furthermore, patients and audiologists reported that hearing aids and other devices were insufficient or counterproductive:

“When I first had my hearing aids on, because I could hear, it took away from the fact that I’ve got tinnitus... The following day I could still hear ringing in my ear when I was on my own and not in an environment where there was noise to distract me. The hearing aids don’t really take away from the fact that I’ve got tinnitus. It’s only through talking about it and discussing ways to ignore it or distract yourself away from it that I think it’s paid the benefit – ok my hearing is better now I wear hearing aids, I can

hear what people are saying, but it's not taken away from the tinnitus." (Patient 3)

Relapse prevention. Relapse prevention was generally not addressed:

"I don't think [the audiologist] did [share the relapse prevention handout] actually, no because I don't think we go onto that point actually." (Patient 1)

Rather, the audiologist relied on advising the patient to return for further treatment if their symptoms worsened if self-management were ineffective:

"We said, 'there's no guarantee that won't happen again, and he may go back to the place that he was [before treatment], he may well then be able to sort of pull himself back together using the strategies that we've used this time round, but actually he may need to come back to us because we may need to revisit different things.'" (Audiologist 2)

Despite the lack of relapse prevention, the overall impact of tinnitus and tinnitus-specific emotional impact on patients improved between the end of treatment and 6-month follow-up. However, tinnitus-specific negative thoughts increased between end of treatment and 6-month follow-up, indicating a potentially useful role in encouraging patients to engage in thought challenging once treatment has ended. Thus, the relapse prevention section of the treatment manual should be amended to encourage audiologists to use it with patients.

Common skills. All the patients involved in the trial highlighted the importance of just having someone to talk to about their tinnitus:

“The best thing that I’ve done from the tinnitus point of view is talk to somebody.” (Patient 3)

Treatment satisfaction was reported despite concern that some patients forgot what was discussed during appointments:

“It’s that relationship that means so much more, and just to substantiate that, you can see a patient for a follow-up and say, ‘well what did we talk about,’ and always ask them to recount it, and they’ll say, ‘well I don’t really remember. What you said was really good, I went away and I was really happy.’ That’s what counts.” (Audiologist 3)

This argument is in agreement with that the common factors theory of psychological therapies, which posits that much or all the benefit of treatment is the result of components that are common to many of the different types of psychological therapy irrespective of the specific treatment components used (Rosenzweig, 1936). A rationale for this was given:

“I have a more controversial reasoning for that, which is – I don’t want my words to be a misconstruance – I sometimes think that it doesn’t matter what model you use. What really counts here is, are you showing the patient empathy, are you showing them that you are interested? You could use any model. Are you believable

as a clinician? [If] you've got that rapport, I don't think it really matters." (Audiologist 3)

This suggests that the treatment manual could be amended to focus on training audiologists to develop a strong working alliance with patients. All patients reported that their audiologist displayed good listening skills and empathy:

"[I] thought it was great, she understood, she listened and made me feel reassured... I think it was body language and her tone and just the way that she interacted with me. I just felt comfortable with her, and I felt as if she did understand, and I didn't feel as if I was just another number, another person passing through."

(Patient 2)

It is unclear from these data whether the treatment manual contained enough information about developing a strong working alliance with patients, or audiologists possessed good baseline common therapeutic skills as illustrated by the patient in this quote. Therefore, any further definitive trial should aim to quantify audiologists' baseline skills before training to evaluate the generalisability of any effectiveness findings to less experienced audiologists.

Toolkit of educational and treatment monitoring materials.

The audiologists each used different handouts, though sometimes they were conveyed to patients without offering them a copy:

"I probably didn't give that one out very often... but I would have talked through that generally." (Audiologist 2)

However, they recognised the benefit of handouts to encourage patients to take ownership of their treatment and to make treatment a collaborative endeavour:

“That’s how the tools are helpful. If the patients actually got something, a little plan or something written down that you’ve mutually agreed, they actually then don’t feel as if the treatment is necessarily completely directive. They actually feel as if they’ve participated in coming to that decision, and I think sometimes if you do that just orally it doesn’t have quite the same impact, whereas if actually you’ve got something to say, ‘this is what we’ve discussed, this is what we’ve decided, are you happy this is the route we’re going to take?’ Actually, then they’re taking some ownership of it.” (Audiologist 2)

The use of diaries to monitor the effects of treatment divided opinion. One audiologist expressed a bias against monitoring behaviour change, which prohibited the use of worksheets:

“It’s very interesting, keeping diaries. A lot of people wear kits and technology and whatnot and I’m perhaps a little bit biased in that I kind of think well, ‘why do you need a record, or why do you need a gadget to tell you how healthy you are?’ If you sat around all day and have been a couch potato and eat loads, you feel rubbish at the end of the day. You don’t need a watch, or you don’t need a diary to tell you that. Maybe it’s for some people, but it’s just my personal bias.” (Audiologist 3)

However, the patients and other audiologists preferred to use smartphone applications rather than toolkit diaries to support treatment:

"I'd start listening to this [relaxation app], and once I listened to it a couple of times I thought I can do this without putting it on."

(Patient 2)

When handouts were used during treatment, audiologists expressed a preference for materials produced by the BTA due to the reliability of the source:

"Most tinnitus patients want information. They want information that they know is reliable and evidenced, and certainly the BTA stuff is definitely along those lines, so I use that a lot."

(Audiologist 1)

Therefore, the perceived reliability of treatment resources could be enhanced by evaluating their quality before further inclusion in any definitive RCT.

6.3.4.2. Factors affecting fidelity

Patients recognised that they need the support of a clinician to structure their use of psychological techniques to be effective:

"But whether I would do that [technique without guidance] or not, I don't know whether I'd need to go talk to someone and say, 'you need to give me a structure to be able to do that.'" (Patient 3)

This indicates that patients prefer guided psychological tinnitus treatment, despite some evidence of equivalent outcomes between guided and unguided iCBT for tinnitus (Rheker et al., 2015).

Furthermore, the preference for guided treatment appears to be based in part on having a clinician provide structure.

Audiologists reported a lack of confidence as a reason for not implementing treatment components including relaxation, acceptance-based components, and goal setting:

"I don't use a lot of relaxation with patients. I sort of talk about relaxation generally, but I think it's a level of confidence in myself." (Audiologist 2)

Therapist confidence has been shown to predict patients' anxiety and depression outcomes (Green et al., 2014). However, it is unclear from these data whether avoiding certain components protected patients from poorer outcomes, or prevented greater effectiveness by limiting the scope of the treatment. Two out of three patients' tinnitus-specific emotional distress and negative thoughts improved despite audiologists' selecting treatment components based on their confidence to use them successfully. However, confidence with the treatment increased with increasing experience during the trial for one audiologist:

"You're always a little bit nervous to start with. However, I found that after the first few appointments it's just flown. You develop your own pattern in appointments and I guess I developed a pattern very, very quickly and that's because it was very intense training, and I was very keen to start it pretty much straight away. So, this wasn't about just those patients that committed to the study, this is now my practice. It's what I use now. I started it

pretty much the week after we finished the training, and so [that] actually probably meant that I had more confidence by the time I saw the study patients.” (Audiologist 3)

In contrast, another audiologist reported insufficient practice to familiarise themselves due to the small-scale of the feasibility trial:

“[The treatment manual] was quite new to me, and it’s difficult to implement it into your general practice when you’re not familiar with it. Having such very few numbers in our study actually made it – it never really seemed to become the thing that flowed because I guess what I probably need to have is say 50 people.” (Audiologist 1)

Therefore, effectiveness outcomes reported in this trial may be an underestimation of potential effectiveness due to insufficient time for audiologists to familiarise themselves with the treatment at the start of the trial. Therefore, any further definitive trial of an audiologist-delivered psychological tinnitus treatment should include a period of familiarisation of the treatment in practice before including patients in analyses.

The audiologists suggested that inexperienced audiologists may find it difficult to implement the treatment without it negatively affecting the therapeutic relationship with patients:

“It’s a very dynamic situation when you’re with a patient, and as an experienced practitioner you just can’t afford to let something that might just get in the way. Yes, I’ve got this model always in the back of my head, I’m aware of the tools within the toolkit, and

I can take those out at any time, but it didn't affect the rapport between me and the patient. I could see how it might do if I was inexperienced, if you were going to stick rigidly to this toolkit"
(Audiologist 3)

This is reflected by improvement in working alliance measured by the WAI in the trial. However, the audiologists recruited to the trial were all senior audiologists with several years of experience working with tinnitus patients. Therefore, the feasibility results in this trial may lack generalisability to less experienced audiologists. On the other hand, one audiologist thought that the treatment manual would help inexperienced audiologists by providing a structure to follow.

"Sometimes if you are less experienced and you're not quite sure where to go with the patient, the manual gives you those signposts. If [patients] are talking about [a specific problem] then perhaps you need to discuss it. So, it sort of gives you a little bit of a pointer in the right direction." (Audiologist 2)

Thus, the structure of the treatment manual was acceptable to audiologists involved in the trial and may be generalisable to less experienced audiologists.

Patients sometimes resisted the use of treatment components including thought challenging, physical exercise, and mindfulness. The audiologists stated their patients would sometimes give reasons such as not having enough time to engage with the treatment outside of appointments, or a belief that the treatment would be unsuccessful:

“I think often they embrace the fact that they’re [thinking negatively], but are often reluctant to accept that they might be able to stop doing it. So often they know that they’re doing it, but say, ‘I’ve got this real belief about my tinnitus and I’m not sure you’re going to be able to change that.’” (Audiologist 2)

Tinnitus-specific negative thoughts about tinnitus decreased during treatment, but then worsened slightly in the following 6 months. One interpretation is that any reassurance provided by tinnitus education was short-lived, and the lack of thought challenging limited patients’ ability to challenge negative thoughts about tinnitus once the treatment ended.

The audiologists were also unsure whether patients would want to engage in specific psychological techniques outside of sessions due to the perceived burden:

“Some [patients] like recording things, others won’t do that. [It] depends what our goal is. Are we all trying to set the patient homework, which adds another thing into their lives, and sometimes they want it? They’re just happy that they’ve come to offload on you, and you’ve listened to them, and you’ve tried to give them some practical advice. Do they want to think this over and actually record the thoughts? [I] don’t know.” (Audiologist 3)

This audiologist’s uncertainty could be addressed by amending study information sheets to emphasise the requirement to engage with the treatment outside of appointments.

Patients and audiologists expressed the importance of tailoring the treatment to individual patient need, for example, by providing different information about tinnitus to address different patients' misconceptions:

"It's all very personal to the patient, isn't it? If they come with lots of misconceptions, then I'm guessing that when you address those, that's useful to the patient." (Audiologist 3)

Patients and audiologists involved in the feasibility trial shared the view that thought challenging was not necessary for most patients involved in the trial:

"I didn't [use thought records], not for the patients that I saw, no. I think for those patients that went through the programme with me that they weren't particularly things that those patients necessarily needed." (Audiologist 2)

This suggests that patients without negative thoughts about tinnitus were recruited to receive a treatment designed to reduce negative thoughts about tinnitus. Therefore, a further definitive trial should consider including a minimum TCQ cut-off score to exclude patients who may not require the treatment.

However, two patients came to the realisation that they held some negative thoughts about their tinnitus after the end of treatment:

"Yes, we did [look at negative thoughts about tinnitus]. He asked me all about how I feel about it. Does it ever get me down, does it get me depressed, does it wear me down? And at the time – probably for the first two times out of three – I said 'no, it's not

happened to me at all.' Now when I look back, yeah, I do think it was [a problem]. I do think I was slightly depressed from the fact that I've got ringing in my ears and I couldn't cope with it."

(Patient 3)

This would suggest that the treatment was unsuccessful at identifying patients' negative thoughts about tinnitus.

There was a perception between audiologists that some treatment components were out of their scope of practice and require a psychologist:

"To me [thought challenging is] a logical skill and I don't know that's my leaning at all. To say to somebody, 'well, that thought you are having there is very unhelpful.' Why not think at the same time, 'hang on a minute, surely what I think is what I think, I can't put a new thought in there,' but clearly you can if you're a psychologist, you could do that, but I can't." (Audiologist 1)

Furthermore, audiologists considered some components (e.g. the use of metaphors as a defusion technique) to be the remit of hearing therapists:

"I think as an audiologist seeing a tinnitus patient, as opposed to [being] a hearing therapist, the backgrounds are slightly different. I think some of the [components] I class as the fluffy stuff, and some of the more structured knowledge based stuff – empowering the patient in terms of giving them information rather than the fluffy 'imagine your whatever' – that's just a

matter of taste and what you're comfortable with." (Audiologist 2)

This suggests that audiologists may prefer not to use the response-focused techniques based on ACT, which aim to change the experience of emotions once they have occurred.

The audiologists diverged in their opinion on the flexibility of the treatment manual. One audiologist thought the treatment manual was inflexible:

"I think I find [the psychological treatment] a bit too prescriptive. Lots too prescriptive. I didn't feel like it would allow me to just explore things naturally with patients, but then maybe that's because I don't know enough about [it], maybe I'm not experienced enough and I'm showing... maybe this is where I'm different to other people. Some people like a very structured method to do their stuff, but I like to be guided by the patient. So, if the patients says, 'I'm having this difficulty or that difficulty,' I don't like to stop and then say, 'well hang on a minute, first thing I've got to record these things down.' I find that quite restrictive." (Audiologist 1)

In contrast, the two other audiologists thought the manual afforded them the freedom to select treatment components:

"I can skip this bit for this patient, and being able to tailor it to the individual patient, and because it sort of went in a logical form it was quite easy to do that. It was easy to disregard sections that for that patient weren't relevant." (Audiologist 2)

6.3.4.3. *Redefining treatment components*

The audiologists endorsed certain additional treatment components to improve the manual, including techniques to increase engagement in enjoyable activities as a distraction:

“If they’ve taken up hobbies that have enabled them to be more distracted, sort of reinforcing those things and said, ‘these are the things that you know are going to enable you in the long term to sort of ignore your tinnitus and live with it happily.’” (Audiologist 2)

Patients and audiologists recommended expanding physical exercise to include lifestyle changes including diet and alcohol:

“That’s something that we do anyway. So, within the tinnitus therapy process we always talk about lifestyle choices. So, physical exercise comes into that, but we also talk about things like diet. We might also talk about where patients are maybe drinking excessively.” (Audiologist 3)

One audiologist found that some patients’ lack of motivation was a barrier to their engagement in the treatment, and that a technique to improve motivation would be useful:

“How can we break this down. And it would have been nice maybe in the training to talk more about this. About what happens when you can’t motivate a patient... How far do you go? So that would be useful... Because how do you tackle somebody who is clearly giving you excuses? How do you tackle that? Beause there’s a harsh way which is, ‘look, you’re just giving lots of excuses.’ But

that's not the way to do it. That doesn't help anybody. But then is it up to us to go into maybe the deeper reasons why they're doing that? Is it a confidence issue [for example], and it's that thing that's stopping that patient from getting better?" (Audiologist 3)

All interviewed patients mentioned their hearing loss when talking about the psychological tinnitus treatment. Some patients recognised that addressing fears about their hearing loss was useful:

"I was interested to confirm actually from an emotional perspective my hearing in general was average for my age. So, it's nice to hear that. It's reassuring." (Patient 1)

Reassurance on dizziness and a fear of falling was also considered helpful:

"It was good because I understood it a lot more, understood the interconnections between everything. It's like the last time I went to her I suddenly thought - because I had a couple of times when I've been a bit wobbly and a bit dizzy and she's been able to explain those in terms of my ears and my hearing." (Patient 2)

The relevance of hearing loss and fear of falling to the psychological tinnitus treatment suggests that an audiologist-delivered psychological treatment addressing other audiological problems may be useful for some patients.

6.3.4.4. Feasibility of audiologists' implementation

The audiologists unanimously agreed the treatment did not lengthen the amount of time spent with patients throughout their care:

"I think it just made you approach [tinnitus care] slightly differently, but I think looking at the patients that I saw, I don't think their pathways were necessarily any longer than they would have been if I hadn't used the manual." (Audiologist 2)

However, they also thought the frequency of appointments ought to increase to maximise the benefit of the treatment in routine clinical practice:

"I guess what I think works and should be implemented more widely is this idea that you see a patient for an initial appointment, but you see them very quickly afterwards so that you're addressing any issues quite early on. So, actually that's quite big, and that's something that we've sort of tried to implement across the board. So, before we'd have an initial appointment, and for the majority of patients a follow-up about 12 weeks afterwards, but trying to bring that down to actually book their follow-up about 6 weeks after the initial appointment. So that was quite an interesting one, and it works because patients either take on board everything you say or they struggle with it, and if you've kind of let them go for 3 months, you're almost back to square one sometimes." (Audiologist 1)

However, concern was expressed that more frequent appointments may not be feasible in other audiology services where resources are limited:

"It's not going to be easy for everyone, and I think we were fortunate in the fact that as a department we don't have long

waiting lists for anything, so we can change things. I don't know how well this would work elsewhere. I know of departments for example, who've got year-long waits for initial appointments so the issue really is about funding of tinnitus. It's a brilliant model but you've got to have the resources to be able to implement it."
(Audiologist 3)

Therefore, feasibility of this trial may not be generalisable to audiology services with limited resources. Furthermore, it is important to establish cost-effectiveness of an audiologist-delivered psychological tinnitus treatment to make a case for increasing resources in tinnitus clinics. Although there is insufficient data to demonstrate cost-effectiveness for an audiologist-delivered psychological tinnitus treatment in this trial, CSRI data indicated that patients did not seek additional treatment from a psychologist.

Continuity of care, with patients seeing one audiologist throughout their care was also considered beneficial:

"I think what it probably made me think was that some patients, even though they are hearing aid patients, probably would benefit from being fitted by the tinnitus audiologist rather than an audiologist because some of the reasoning behind why we're fitting the hearing aid has to be related to the tinnitus, and perhaps that was lost when you were sending them to an audiologist to fit hearing [aids]." (Audiologist 2)

TAU was also delivered by one audiologist in this trial, so the working alliance scores may not be generalisable to routine clinical practice in

audiology services where patients receive treatment from more than one audiologists.

Taking part in the psychological tinnitus treatment arm of the trial affected usual appointment structures. For example, the audiologists delayed hearing aid fitting to allow time to gather information about underlying mental health problems first:

“You can’t do the assessment justice and the fitting justice altogether... You have to keep the fact-finding bit to the first appointment, the fitting to the second appointment. So, in a way that was good because it allowed the first assessment to be very structured, very searching with the patient, and well planned so that you could justifiably postpone the fitting to the next time.”

(Audiologist 1)

A hearing-specific outcome questionnaire was not used in the trial, so it is not clear whether the delay in fitting hearing aids affected hearing-specific outcomes. Therefore, any further definitive trial may consider the effects of the psychological treatment on commonly co-occurring problems such as hearing loss.

6.3.4.5. Audiologist training and supervision

Audiologists thought that the amount of content covered across the 2 days training was overwhelming:

“I was feeling quite overwhelmed by the amount of stuff that there was [in the treatment manual]. I think that would be my summary statement. It was very overwhelmingly large. If we

could have done it in stages it might have felt more manageable.”

(Audiologist 1)

Audiologists were introduced to the manual across 2 days of training. A phased introduction to each treatment component may have reduced the sense of feeling overwhelmed. This may have also increased audiologists' familiarity with each component to improve fidelity.

The small group training format was well-received and was perceived to counteract difficulty of covering a large amount of training material in a short space of time. However, the audiologists involved in the trial suggested that it may not be feasible to implement this format outside of the trial for routine clinical practice:

“I thought it was excellent. It was excellent, one-to-one with a group of experts, what else could you ask for? I've got no complaints about that whatsoever. Feasibility-wise, would that work in practice? Probably not. However, I would hope that if this is rolled out that you don't... I don't know, we don't have very big groups. We're not training very big groups because having that one-to-one allowed for some very interesting discussions.”

(Audiologist 3)

Role-play was recommended to improve the training to provide practice and feedback on techniques in a range of scenarios that would have helped audiologists to understand how the treatment components would work in practice:

"I think role play would have helped a bit definitely, and not just one role play but three or four goes. Let's think about a patient who might have sudden tinnitus following an acoustic shock, or someone who might have had tinnitus for years but actually it's got worse in the last six months and they don't understand why."

(Audiologist 1)

In addition to the lack of feedback during training, all audiologists involved in the trial highlighted a lack of supervision and suggested that some form of indirect supervision would have been helpful to check adherence to the treatment manual:

"I didn't feel that it would have been helpful to have somebody over my shoulder for one or two of these sessions... maybe someone to go to at the end of the morning and say, 'I've had these patients, I did this with them, was that the right thing?'"

(Audiologist 1)

However, the audiologists noted that the difficulty in accessing supervision for usual care would also act as a barrier to receiving supervision for psychological tinnitus treatment:

"In adult audiology, we work in a silo... we don't have anyone else except our colleagues to turn to, we don't have any formal supervision like you would if you were a therapist, and I think we should try and encourage more clinical supervision within the field of tinnitus. I mean it's a whole different subject, it's not specific to this. I think that's very general, and I think it would

make a very interesting research project actually.” (Audiologist 3)

Although there was no supervision to ensure safe and effective clinical practice, no adverse reactions occurred during the trial. Audiologists’ avoidance of certain treatment components due to a lack of confidence may have acted as a protective factor against adverse reactions.

The potential for the treatment manual to be used as a training tool for inexperienced audiologists was raised repeatedly during interviews:

“I found [the manual] quite useful in terms of training somebody new to sort of say, ‘do you want to delve a bit deeper, is there something in these questions that perhaps is relevant for the patient you’ve got sat in front of you?’ So, you can get that level of detail, and I think it has been a really good training tool. That is one of the things that I think it will have massive benefit [for]. The current qualification for audiologists doesn’t really give them much in the way of tinnitus experience, so I think it is very much down to us to train those people and this will be one of the things that will be a useful tool, and actually you know I’ve been really grateful.” (Audiologist 2)

6.3.4.6. Measurement of tinnitus and treatment effects

The TFI was favoured as an assessment tool by patients and clinicians because of its broad coverage across tinnitus domains to enable identification of relevant treatment options:

"We used to use the THI, but actually we now use the TFI routinely, and one of the reasons we do that is because I think it enables you to focus your treatment options. So, if you've got an area where the scores are very low, actually do you need to even think about that?" (Audiologist 2)

The audiologists were less familiar with the TCQ, although one appreciated it as a means to encourage patients to talk about their negative thoughts about tinnitus:

"Sometimes patients are quite reluctant to give [negative thoughts], some patients don't like feelings, but to get them to write it down and to score it, you get a bit more of an overview of about where they are and how severe really the tinnitus is and how much it is affecting them psychologically. So that again, I've not used that one routinely, but I do think that one is one that I would probably use for those patients where I'm perhaps struggling to see how much is affecting them psychologically. You know there's patients that it takes ages for you to get them to open up – that might be a questionnaire you might think, 'oh actually I'm going to use this because this might just tease it out and allow us to start that conversation.'" (Audiologist 2)

Patients also welcomed the use of tinnitus questionnaires to monitor their improvement during treatment:

"It makes you start to realise how well you're doing and it gives you a chance to measure that... it makes you think, it makes you

start to score things so you get a picture how bad it is or how you're managing really well." (Patient 2)

Patients and audiologists had diverging views on the difficulty of completing tinnitus questionnaires. Patients thought that support should be offered to complete any questionnaires:

"When you give a questionnaire like this and just give it to somebody – and I was put in another room to do it – I think there's an assumption made that everyone can do that task." (Patient 2)

Whereas audiologists perceived the questionnaires to be more accessible:

"I think from a professional point of view, the TFI is a really good tool to get a lot of information and it's not a massively long questionnaire, so it enables you to get quite a lot of information about a lot of things by doing a fairly easy questionnaire. I think the way that that's written, patients can see the relevance of it." (Audiologist 2)

However, one audiologist highlighted that some patients conflate hearing loss and tinnitus when completing the TFI which may limit its ability to distinguish between tinnitus-related and hearing-related distress:

"There are definitely limitations so for example the hearing [domain] is a limitation. Patients do get confused sometimes particularly to start with, if they have this belief that their tinnitus stops them from hearing when they have an identifiable

sensory loss they might score very low on that or score high on it anyway! It doesn't, the questionnaire doesn't resolve everything. Sometimes patients don't always understand the questions, but as far as I can see there isn't anything much better than that."

(Audiologist 3)

Confirmatory factor analysis of the TFI suggests the auditory subscale may measure ability to hear rather than tinnitus *per se* (Fackrell et al., 2016). Therefore, a *post-hoc* calculation of confidence intervals for the TFI auditory subscale were performed. Scores decreased between pre-treatment and end of treatment by $M=36.67$, 95% CI [-21.40, 94.74], between pre-treatment and 6-month follow-up $M=38.89$, 95% CI [-15.03, 92.81]. These reductions were greater than for overall tinnitus impact measured by the TFI (Table 6.6). Furthermore, auditory subscale scores fell by more than the smallest detectable change for the auditory subscale (26.6). This suggests that the treatment may also be effective for addressing patients' co-occurring hearing-loss.

Relevant domains emphasised by patients and audiologists varied, but included emotions, intrusiveness, and understanding of tinnitus. Furthermore, sense of control, quality of life, sleep, thoughts, and beliefs were important to patients and audiologists. Patients and audiologists recognised that all the domains measured by the TFI and TCQ could be relevant to someone:

"No I think [all of the domains on the TFI] they were all quite valid because you know different people have different levels that's normal." (Patient 2)

One patient specified that patients' perception of others' understanding of their tinnitus is important to measure:

"I suppose for some people it might be about other peoples' understanding of their [tinnitus]. I think if you're suffering really badly, and because it's not visible and because people can't see it, it might be [that people think], 'I wish other people would understand how bad it is for me.'" (Patient 2)

However, this domain appears to be captured in TCQ item 5 about others' understanding of how bad the noise is (Wilson and Henry, 1998). This patient's concern reflects the importance of audiologists displaying empathy during treatment, sharing information on the prevalence of tinnitus to normalise the experience, and signposting to support groups for patients who score highly on this item.

Furthermore, no tinnitus domains were identified that do not appear to be measured by the TFI and TCQ, suggesting that these questionnaires are sufficient to comprehensively measure the desired effects of the psychological tinnitus treatments.

6.4.DISCUSSION

6.4.1. Feasibility

The aims of this trial were to estimate the feasibility of an RCT of audiologist-delivered psychological tinnitus treatment, and explore patients' and audiologists' views on the fidelity to and acceptability of the treatment. The recruitment rate of eligible participants indicated feasibility for a definitive trial to be conducted. This suggests that

there is a substantial number of patients referred to audiology services who may want access to psychological tinnitus treatment, and there is sufficient interest from patients to participate in a trial of psychological tinnitus treatment. However, a definitive trial appears to be infeasible based on the recruitment rate of target participants, retention rate of enrolled participants, and receipt of primary effectiveness outcome questionnaires. However, the overall recruitment rate was one patient fewer than the target for feasibility. Furthermore, full recruitment was achieved at the Nottingham University Hospitals NHS Trust site. The audiology service in Nottingham is one of the largest in the UK, whereas the two sites that recruited below the feasibility target serve comparably smaller populations. Therefore, low recruitment in these sites may be due to smaller populations to recruit from and fewer resources. This suggests that a definitive RCT may be feasible if larger services are used, and each should over-recruit to accommodate patient attrition. However, the overall retention rate was substantially below the target and was comparable with trials of psychological tinnitus treatment with the highest attrition rates (35-72%; Andersson et al., 2002, Abbott et al., 2009, Malouff et al., 2010). Abbott and colleagues' (2009) rationale for poor retention was that the treatment was not engaging enough. Although attrition rates were also high for this feasibility trial, all patient withdrawals occurred before their first appointment, suggesting the reason for missed appointments was not due to the delivery of the treatment. Retention rates may be maximised by re-

randomising patients to the trial after withdrawing if they want to return at a later date (Kahan, 2016). Furthermore, information about the trial was given to patients predominantly by JT at the Nottingham site, whereas this was done by the PI audiologists at the Derby and Sherwood Forest sites where retention rates were higher. The role of the audiologist in recruitment may give an opportunity to develop a rapport with patients before treatment, which may have acted as a protective factor from cancelling or missing appointments. Indeed, poor therapeutic relationship is often given as a reason for failing to attend appointments in service audits (Binnie and Boden, 2016). This suggests that recruitment to any further definitive trial should primarily be carried out by the PI audiologist at each trial site.

It is also worth noting that of the 11 patients who scored above 50 on the TFI (indicating severe tinnitus qualifying for more intensive intervention), only one completed their treatment and returned questionnaires. This suggests the patients who cancelled or did not attend their first appointment did not do so because of a lack of need for treatment. Whether these patients sought more intensive treatment following withdrawal from the trial is unknown.

Receipt of primary effectiveness outcome questionnaire data was comparable with trials of psychological tinnitus treatments with the highest rates of assessment attrition (50-52%; Abbott et al., 2009, Malouff et al., 2010). The Derby site did not return any end of treatment or follow-up questionnaires. Communication with the site indicated that the Derby site's PI audiologist changed clinical roles

within the same department during the trial, though with an agreement in place to continue to treat trial patients. Therefore, any further trial should make contingency plans for staff turnover, assess the principal investigators' understanding of trial procedure, and review compliance at regular intervals.

Although a definitive trial of audiologist-delivered psychological tinnitus treatment is not feasible based on these data, the caveats discussed here warrant further investigation.

6.4.2. Measurement of treatment effects

Overall tinnitus impact (TFI), and negative thoughts about tinnitus (TCQ-N) improved on average for patients receiving the audiologist-delivered psychological tinnitus treatment between baseline and the end of treatment, and were maintained at 6-month follow-up. However, the emotional impact of tinnitus (TFI-E) only improved between baseline and 6-month follow-up. One interpretation of this finding is that the brevity of the treatment did not allow patients enough time to practice thought challenging in day-to-day life for any change in negative automatic thoughts to begin to influence emotional distress by the end of treatment. On the other hand, the 6 months following treatment may have given patients sufficient time to apply what they had learned, and for any reduction in negative thoughts to have an impact on emotional distress. The cognitive behavioural model of tinnitus (McKenna et al., 2014) predicts that negative thoughts cause emotional distress. Weise and colleagues (2013a)

found an association between negative thoughts and emotional distress in recent onset tinnitus, and suggested a causal relationship. A recent systematic review found that perseverative negative thoughts such as worry and rumination predicted subsequent emotional distress in people with long-term conditions (including chronic pain, fibromyalgia, rheumatoid arthritis, and cancer), and that studies controlling for confounders were more likely to result in significant associations (Trick et al., 2016). However, general psychological distress (CORE-OM) also improved on average between baseline and the end of treatment. These findings contradict the evidence that condition-specific outcome questionnaires are more sensitive than generic outcome questionnaires to condition-specific treatment-related change (Versteegh et al., 2012). One interpretation is that any treatment effects may have transferred to patients' broader emotional experiences. Indeed, one patient reported feeling generally happier than they ever had been before treatment. However, the psychological treatment components were focused on patients' tinnitus. So, it is not clear why the treatment would affect general psychological distress before tinnitus-specific emotional distress. One interpretation is that common skills (e.g. displaying empathy) used by the audiologists to develop the therapeutic relationship improved patients' mood. Indeed, the working alliance (WAI) between patients and audiologists improved between the first appointment and the end of treatment. Moreover, improved bond subscale scores were reflected by interviews with patients that indicated they had a good therapeutic

relationship with their audiologists. However, two of the three audiologists involved in the psychological tinnitus treatment arm of the trial stated that they did not formally set collaborative goals with their patients, which is at odds with improving scores on the goal subscale of the WAI. Therefore, further research should aim to validate the WAI for the tinnitus patient population.

Only one patient improved by more than the smallest detectable change for the primary effectiveness outcome – overall tinnitus impact measured by the TFI (22.4; Fackrell et al., 2016) – reflecting genuine therapeutic improvement above measurement error. However, the small sample size limits external validity of these findings. Therefore, no conclusions should be drawn on the effectiveness of the treatment.

6.4.3. Fidelity

Patients reported that the cognitive behavioural model was understandable and was relatable to their experiences of tinnitus. Audiologists gave a favourable appraisal of the cognitive behavioural model compared to other models. However, they reported focusing on psychoeducation with limited use of thought challenging, graded exposure, and acceptance and defusion techniques during treatment. The audiologists felt confident enough to advise patients to reduce avoidance of tinnitus, and about the role of negative thoughts in maintaining tinnitus distress, but reported a bias against monitoring patients' gradual exposure to tinnitus-specific stressful situations, or

following cognitive restructuring protocol. Although, patients reported feeling reassured by the information they received, any initial positive therapeutic change in negative thoughts diminished by 6-month follow-up. The lack of structured thought challenging during treatment may have left patients without the capacity to address misconceptions about tinnitus that arise after treatment without further reassurance from the audiologist. However, interviews with patients were conducted shortly after the end of treatment, so it is unclear whether patients continued to apply what they had learned during treatment. Therefore, further research should explore the reasons for transient improvement in treatment outcomes between the end of treatment and follow-up in tinnitus patients receiving psychological tinnitus treatment to generate lasting treatment-related change.

Patients and audiologists did not engage in formal collaborative goal setting with patients to identify which treatment components to work on, instead relying on patient preference to direct treatment towards sleep management, relaxation, and physical exercise to manage tinnitus distress. Interviews with patients and audiologists were conducted to provide an account of the underlying reasons for fidelity to or deviation from the treatment. However, patients and audiologists were not always able to describe in detail what they did during the trial. This may have reflected a lack opportunity to practice the treatment due to low retention of patients. This trial was limited by a lack of in-session observation. Direct in-session observation of clinicians is often considered the gold standard for evaluating fidelity

to psychological treatments (Beidas et al., 2016). It does not rely on patients' and audiologists' memory of treatment, and it would enable a detailed component analysis to determine which parts of the treatment result in better outcomes. Furthermore, agreement between direct observation and clinician self-report can be low (Hurlburt et al., 2010). Therefore, any definitive RCT should include direct observation of audiologist treatment behaviours in a small subset of appointments to evaluate treatment fidelity.

CHAPTER 7. GENERAL DISCUSSION

The psychological treatment of tinnitus has evolved over the 4 decades preceding this thesis. Scott and colleagues (1985) conducted the first RCT of a psychological treatment for tinnitus. Since then, CBT has become the most evidence-based treatment for tinnitus (Cima et al., 2014). ACT and mindfulness for tinnitus have also been evaluated (Gans et al., 2014, Kreuzer et al., 2012, Westin et al., 2011), and innovations in technology have enabled psychological treatments to be delivered remotely via the Internet with minimal guidance by a psychologist (Kaldo et al., 2008).

There is a lack of psychologists to meet demand for treatment of tinnitus distress (Hoare et al., 2012). Therefore, in the UK, audiologists are expected to deliver tinnitus-focused CBT or other counselling techniques for tinnitus patients (Department of Health, 2009). However, Department of Health guidance does not specify what these techniques should be, and does not present evidence as to whether an audiologist-delivered approach is feasible. This thesis is the first to explore what an audiologist-delivered psychological tinnitus treatment should comprise, and how it should be measured. The aim of this chapter is to discuss the key findings in the context of the wider literature, strengths and limitations of this thesis, and directions for further research.

7.1.KEY FINDINGS

7.1.1. CBT is the most evidence-based psychological tinnitus treatment

The scoping review of the literature presented in chapter 2 indicated that CBT is the most evidence-based psychological treatment for tinnitus, and that psychologist-delivered tinnitus-focused CBT often includes psychoeducation and specific techniques including graded exposure, cognitive restructuring, attention control, applied relaxation, sleep management, and sound enrichment. These findings reflect Cima and colleagues' (2014) review of CBT for tinnitus.

7.1.2. Psychoeducation and common therapeutic skills are more important than specific CBT techniques in tinnitus treatment

Patients and audiologists surveyed in the Delphi study presented in chapter 3 considered it important to include psychoeducation and common therapeutic skills (aimed at informing the patient and displaying empathy) in psychological tinnitus treatment. For example, Delphi panellists agreed that it is essential to discuss fear and avoidance behaviours with the patient, but not to engage the patient in graded exposure to tinnitus. Giving patients information about common cognitive distortions reached a high level of agreement, but cognitive restructuring did not. This pattern suggests that patients and audiologists understand the contribution of maladaptive behaviours and negative thoughts to tinnitus distress, but did not think that the

audiologist's role should expand to managing patients' use of specific cognitive behavioural techniques. Although it was not possible to discern the reasons for panellists' preferences in the Delphi survey, the audiologists and patients involved in delivering and receiving the psychological tinnitus treatment in the feasibility trial expressed several reasons for not using specific techniques such as cognitive restructuring and graded exposure. These reasons included, (1) a lack of confidence in using psychological techniques due to the brevity of training provided to learn how to implement them safely and effectively, (2) a perception that patients do not want to record, monitor, and challenge specific negative thoughts and behaviours, and (3) a belief that certain components will be ineffective. However, the specific components used varied from patient to patient and audiologist to audiologist based on personal preference and patient need.

7.1.3. Greater exposure of audiologists to the manual was associated with more positive treatment appraisals

When asked in post-treatment interviews about their overall thoughts on the treatment they delivered, two of the three audiologists involved in delivering the psychological tinnitus treatment in the feasibility trial gave a positive appraisal of the manual. The distinguishing factor separating positive from negative appraisals appeared to be audiologists' self-report of familiarity, practice, and confidence with the treatment manual. The two audiologists who gave a positive

appraisal of the manual stated they had used the treatment manual with patients before recruiting patients to the trial, and reported that it could be implemented flexibly without interfering with the development of therapeutic relationships with patients. In contrast, the audiologist who gave a negative appraisal of the manual stated he did not have enough time to familiarise himself with it, and did not use it outside of the trial. The audiologist also thought that the manual could not be implemented flexibly. This divergence of opinion reflects Forbat and colleagues' (2015) systematic review of therapists' views of manualised psychological treatments, which found that increasing exposure to treatment manuals increases positive appraisal of their capacity to facilitate flexibility without negatively affecting the therapeutic relationship with the patient.

7.1.4. Training to deliver psychological tinnitus treatment must be intensive and phased

The trial presented in chapter 6 was a pragmatic feasibility RCT, designed to reflect routine clinical practice rather than highly controlled conditions. The brief training for audiologists in this trial is compatible with the lack of any substantive psychological content on the undergraduate Healthcare Science curriculum (Health Education England, 2016), and the reliance on brief CPD courses in the UK (Hoare et al., 2015). However, the audiologists involved in delivering the psychological treatment reported that the amount of training was insufficient and lacked role-play and feedback from a supervisor to

increase understanding of how to deliver the treatment effectively. These findings support other studies of brief CBT training. For example, 4 half-days of training for GPs on CBT techniques for depression found no significant increase in GP knowledge or patient outcomes (King et al., 2002). Surveys of experienced cognitive behavioural therapists indicate that reading a manual is useful for declarative knowledge, whereas role-play is more helpful to develop procedural skills to deliver treatment (Bennett-Levy et al., 2009). Sholomskas and colleagues (2005) found that psychologists adhere more to CBT manuals following supervised case management compared to psychologists who receive a copy of the manual only. Thus, a phased introduction to each treatment component may have reduced audiologists' sense of feeling overwhelmed by the amount of content to learn, which was reported in post-treatment interviews presented in chapter 6. This may have also increased audiologists' familiarity with each component which may improve treatment fidelity.

7.1.5. The TFI and TCQ measure relevant domains in psychological tinnitus treatment

Audiologist-delivered psychological tinnitus treatment is predicted to affect emotional impact and negative cognitions associated with tinnitus. These would appear to be measured by the TFI emotional distress subscale and TCQ respectively. It was not possible to quantitatively evaluate the responsiveness of the TFI and TCQ in the

feasibility trial due to the small sample size. However, interviews with audiologists indicated unanimously positive appraisals of the TFI as a tool to comprehensively assess tinnitus domains to inform treatment decisions, and that the TCQ can be useful to help identify negative thoughts about tinnitus that patients are not immediately aware of. Patients also stated that the TFI and TCQ adequately capture tinnitus domains.

7.2.STRENGTHS AND LIMITATIONS

7.2.1. Identification of psychological components

This thesis began by identifying components of psychological tinnitus treatments that may be important to include in audiologist-delivered care *before* identifying McKenna and colleagues' (2014) cognitive behavioural model to underpin the treatment components. Beukes and colleagues (2016, 2017) developed and piloted an audiologist-guided iCBT programme for tinnitus concurrently with this thesis. In contrast to this thesis, Beukes and colleagues' treatment components were selected to comprehensively map onto "proven conceptual models" (Beukes et al., 2016, p.7), namely cognitive theory (Henry and Wilson, 2001), the habituation model of tinnitus (Hallam et al., 1988), and audiological theory (Jastreboff, 2007). Although McKenna and colleagues (2014) argued that it is not possible to test Hallam and colleagues' habituation model directly, it has been used to underpin effective psychological tinnitus treatments (Kaldo et al., 2008). On the other hand, the cognitive behavioural model used in this thesis had not

been applied in a clinical trial before now. However, Handscomb (2017) performed a systematic evaluation of the cognitive behavioural model concurrently with this thesis. Handscomb asked people with tinnitus to complete a survey comprising several questionnaires, each measuring a different part of the model (Figure 1.1). Twelve variations of the model were tested using path analysis, and all 12 were an acceptable fit with the survey data, indicating a role for negative automatic thoughts and avoidance behaviours contributing to emotional distress as described by McKenna and colleagues (2014). Therefore, the use of the cognitive behavioural model has ultimately proven to be a strength to this thesis. Audiologists who used the model with patients in the feasibility trial reported that it was useful in helping to make sense of tinnitus distress, and that they would continue to use it in routine clinical practice. Nonetheless, the treatment components used by Beukes and colleagues (2016) and myself overlap to a large extent, with each including relaxation, sound enrichment, sleep management, thought challenging, and exposure to tinnitus.

Components were extracted from articles referring to tinnitus-specific psychological treatments to ensure that there was some evidence underpinning the components used in the audiologist-delivered psychological treatment. However, this prevented the possibility of finding novel psychological treatments that have been used for similar conditions like chronic pain and insomnia that may be applicable to tinnitus. For example, McKenna and colleagues cognitive

behavioural model of tinnitus was inspired by Harvey's model of insomnia (2002). Jansson-Fröjmark and Norell-Clarke's systematic review of CBT for insomnia (2016) identified several components in common with those I found for tinnitus. However, they noted additional components including behavioural experiments, medication management and motivational interviewing. Motivational interviewing is a style of patient-centred therapy designed to engender change by expressing empathy, developing confidence, identifying patients' strengths, promoting autonomy in developing solutions to problems, and identifying discrepancies between patients' values and behaviour (Treasure, 2004; Rollnick, 2010). One audiologist recruited to the feasibility trial reported that some patients resist change, and that the treatment manual may be improved by including guidance on how to motivate patients to engage in treatment. Zarenog and colleagues (2016) evaluated the effects of motivational interviewing as an adjunct to hearing rehabilitation for patients with tinnitus in an RCT. They found that patients receiving motivational interviewing and hearing rehabilitation experienced a greater improvement in tinnitus distress than patients who received hearing rehabilitation alone.

The recruitment of only two psychologists to the Delphi survey increased potential bias towards personally preferred psychological modalities. One of the psychologists was a cognitive behavioural therapist, which may explain why the sensitivity analysis of psychologists' opinions resulted in a greater number of specific cognitive behavioural techniques reaching consensus as important.

Moreover, the recruitment of too few psychologists may have limited the breadth and depth of understandings of tinnitus distress, co-occurring mental health problems, and the theory and evidence underpinning the techniques deployed to address them. The overall levels of agreement in the Delphi survey are biased towards patients, audiologists and hearing therapists' who may not have access to this privileged information. Furthermore, the findings presented in this thesis are limited in their generalisability to UK audiology practice and local patient need.

Unlike condition-specific CBT, transdiagnostic CBT aims to identify and address cognitive behavioural mechanisms that are common to different conditions. Transdiagnostic CBT is a relatively recent innovation in psychological treatments, and there is a modest amount of evidence to support its use, with methodological concerns including unclear allocation concealment, and selective reporting of outcome data, which may have exaggerated treatment effectiveness (Andersen et al., 2016). However, audiologists recruited to the feasibility trial in this thesis reported that it could be difficult to partition the impact of tinnitus and hearing loss during treatment. Given the common co-occurrence of tinnitus and hearing loss (Shargorodsky et al., 2010), the aim to develop a tinnitus-focused psychological treatment may have been a limitation of this thesis, whereas an audiological transdiagnostic CBT may have been a more efficient way to investigate the effects of psychological treatment in

audiology services, compared to examining each audiological problem in discrete research silos.

7.2.2. Identification of outcome domains

Research towards a core outcome set (COS) for clinical trials of psychological tinnitus treatments was conducted concurrently with this thesis (Hall et al., 2015). Since performing the outcome selection procedure for this thesis, five core outcome domains have been endorsed by a group of patients, clinicians, and researchers that should be measured in every trial of a psychological treatment for tinnitus (Hall et al., 2017). These are (1) mood, (2) negative thoughts and beliefs, (3) acceptance, (4) tinnitus intrusiveness, and (5) sense of control. Mood was defined as a subdomain of emotional impact and represents a 'general sense of well-being, ranging from feeling very low or negative to very positive'; and negative thoughts and beliefs was defined as 'thinking tinnitus will affect you in a negative way'. Mood (as a subdomain of emotional impact) and negative thoughts were also measured in this thesis. This suggests the outcome selection procedure was sensitised to detect the hypothesised effect of the psychological tinnitus treatment, and that this treatment was designed to target two tinnitus domains that are important to patients, clinicians, and researchers.

With respect to the other three core outcome domains, although intrusiveness and sense of control were not explicitly measured outcome domains, the TFI includes intrusiveness and sense

of control subscales. However, the TFI and TCQ do not appear to measure acceptance of tinnitus. Budd and Pugh (1996) identified a subscale their Tinnitus Coping Style Questionnaire (TCSQ) as a measure of acceptance. However, this subscale includes questions such as “thinking of things to do to distract yourself from your tinnitus” (Budd and Pugh, 1996, p. 223), which is at odds with definitions of acceptance:

“The concept is often referred to as a process that involves a willingness to experience internal events (i.e., thoughts, feelings or physical sensations) without using strategies that aim at avoiding or controlling such sensations.” (Weise et al., 2013b, p.2).

The Tinnitus Acceptance Questionnaire (TAQ) was designed to measure tinnitus-specific acceptance, and has been validated by confirmatory factor analysis in Germany, though not in a UK-based tinnitus patient population (Weise et al., 2013b). The definition of acceptance used by Weise and colleagues (2013b) to develop the TAQ coheres with the definition used by Hall and colleagues (2017) – recognising that tinnitus is a part of your life without having a negative reaction to it – to develop a COS for tinnitus trials. Since acceptance was identified as core outcome domain, further research should systematically appraise the TAQ as a potentially viable questionnaire to be used in every trial of a psychological tinnitus treatment.

7.2.3. Identification of outcome instruments

The process of identifying an instrument to measure emotional impact involved comparing item analysis domains with the factor structure reported in tinnitus questionnaire development reports (Figure 5.5 and Figure 5.6). Tinnitus questionnaires have been developed with various populations. For example, the THI was developed with a disproportionately large number of USA veterans (Newman et al., 1996), whereas the TQ was developed with a sample of neuro-otology outpatients in the UK (Hallam et al., 1988). Therefore, the factor structures in questionnaire development reports may not be generalisable to UK populations visiting audiology services. Baguley and Andersson (2003) performed a principal component analysis of the THI with a sample of UK tinnitus patients and patients awaiting surgical excision of vestibular schwannoma. Most THI items loaded onto a single factor rather than the original 3-factor solution (emotional distress, functional impact and catastrophising thoughts). They concluded that the total THI score should be used in research and clinical practice, and that this score may represent a general complaint of negative affect. Negative affect is a heightened sensitivity to negative stimuli resulting in a broad range of negative emotions including fear, sadness, guilt, and anger. Negative affect appears to relate to the emotional impact item analysis domain, and a unifactorial THI would measure it within a single factor. Therefore, based on Baguley and Andersson's principal component analysis, the THI may be a more targeted instrument to specifically measure that which is most

relevant to psychological tinnitus treatments, and on this basis, its omission in this thesis may be a weakness. However, principal component analysis should be used when the researchers' goal is to reduce the number of items and factors in a questionnaire, whereas confirmatory factor analysis is recommended when the researcher possesses knowledge of the underlying latent variable structure represented in an outcome instrument and can state a hypothesis about it. Kleinstäuber, Frank and Weise (2015) performed confirmatory factor analysis on the THI, replicating the original 3-factor structure. Furthermore, the response scale of the THI includes only three response options, which may provide an insufficient number of gradations to detect small but clinically meaningful change. Therefore, outcome instruments should ideally possess a high resolution scale (Kirshner and Guyatt, 1985), as is the case for the TFI.

The psychological tinnitus treatment was hypothesised to particularly affect the emotional impact of tinnitus, although patients were included in the feasibility trial if they scored 24 or greater on the TFI overall, representing at least moderately problematic tinnitus (Henry et al., 2014b). This resulted in recruitment of some participants with high overall scores but low scores on the emotion subscale. This reflects Fackrell and colleagues' (2016) UK validation of the TFI, which found notable floor effects for all three items of the TFI emotion subscale, with 41% of participants reporting that they are not at all depressed about their tinnitus (scoring 0/10). Consequently, patients were recruited who may not find the treatment useful. The floor

effects of the TFI may be mitigated in future clinical trials by adjusting the threshold for participant inclusion to greater than or equal to the smallest detectable change. The TFI's smallest detectable change in a UK research population is 22.4 (Fackrell et al., 2016). For emotional impact, the figure is 36.8. Therefore, a definitive RCT should consider excluding patients with scores below 36.8 on the TFI emotional distress subscale. However, it is worth noting that any increase in the threshold for including patients based on the severity of the emotional impact of tinnitus may reduce the recruitment rate of target participants, which already fell below targets in the feasibility trial.

7.3.DIRECTION FOR FURTHER RESEARCH

7.3.1. A definitive RCT

Based on the feasibility trial presented in chapter 6, it is tentatively suggested that any further evaluation of audiologist-delivered psychological tinnitus treatment should comprise information about tinnitus and psychoeducation underpinned by McKenna and colleagues' (2014) cognitive behavioural model, including information about negative thought patterns and avoidance behaviours. Specific cognitive behavioural techniques should be included only for patients who indicate a preference and need for thought challenging, graded exposure, relaxation, sleep management, physical exercise, and sound enrichment, in addition to behavioural activation and motivational interviewing. Components based on ACT such as the use of metaphors

should be omitted until there is more evidence for brief ACT delivered by non-psychologist professionals.

Any definitive trial should be conducted with an internal pilot study. An internal pilot study designates a portion of a definitive trial as a pilot phase (Wittes and Brittain, 1990). At the end of a pilot phase, refinements to the trial protocol suggested here could be assessed against predefined parameters, before making any further refinements and proceeding, or terminating the study early if the trial appears to be futile. Furthermore, an internal pilot study would allow the use of pilot phase data rather than discarding it.

A definitive trial should recruit larger audiology services that serve larger populations to emulate the high recruitment rate of target participants at the Nottingham site. Contingency plans should be prepared and enacted in the event of audiologist attrition during the trial by recruiting reserve sites or reserve audiologists. Treatment fidelity may be improved and more accurately monitored by including an audiologist familiarisation phase of treatment implementation before including patients in analyses, and by including direct in-session observation of a random selection of treatment sessions using standardised fidelity evaluation forms based on the treatment manual.

Sample size for a definitive RCT was calculated in SampSize (Julious, 2004) using a non-inferiority procedure with a parallel group design and a 1:1 allocation ratio. Power was set to 90%, and significance level at 0.025. Based on the TFI, the non-inferiority limit was set to 22.4 (smallest detectable change for the TFI; Fackrell et al.,

2016), and standard deviation at 17 (based on trials of similar tinnitus treatments; Beukes et al., 2017). Assuming only large trial sites are recruited to deliver the treatment, and experience a similar participant attrition rates to the Nottingham trial site in the feasibility trial, 47 patients should be recruited to each treatment arm. Additional treatment arms could be added to compare audiologist and psychologist-delivered psychological tinnitus treatment to evaluate equivalence of outcomes, and to compare the effectiveness of individual cognitive behavioural techniques in a component analysis.

7.3.2. Evaluation of brief training

Since audiologists' training for this trial was designed to reflect the brevity of existing CPD courses on psychological tinnitus treatment, further research is needed to evaluate its effect on audiologist learning and patient outcomes. Moreover, any definitive trial of audiologist-delivered psychological tinnitus treatment should include training with role-play and supervision from qualified clinical psychologists. Training should be conducted over a longer period, with treatment content introduced gradually to allow audiologists to practice individual components to reduce the risk of feeling overwhelmed and to increase familiarity with each treatment component. Further research may directly compare the cost-effectiveness of this enhanced training with the CPD courses presently used by UK audiologists. However, it is not clear how enhanced training would be implemented in routine practice without increasing resources. Moreover, interviews

with audiologists raised concerns that some services may lack the capacity to implement a psychological tinnitus treatment. Long waiting-times in some services were perceived to be a barrier to allowing more frequent appointments with patients to monitor and encourage their use of treatment components to prevent relapse between sessions. Therefore, a definitive RCT should include a calculation of cost-effectiveness to make a case for increasing resources for tinnitus clinics.

7.4.WIDER IMPLICATIONS

7.4.1. UK healthcare delivery and the political context

In the 'Equity and Excellence: Liberating the NHS' white paper (Department of Health, 2010), the UK government instigated a set of reforms to the healthcare delivery system to make unprecedented efficiency savings to meet fiscal limitations, an ageing population, and technological developments. The Modernising Scientific Careers (MSC) policy contributes to these efficiency savings by simplifying career structures and training for the healthcare science workforce by more closely aligning audiology with neurophysiology, and ophthalmic and vision sciences. This was intended to replace uni-disciplinary expertise with a broader skillset and knowledge to create a more mobile workforce capable of changing with developments in science and technology. However, the addition of tinnitus-focused psychological treatment to healthcare scientist training would be a highly-specialised niche that runs counter to the broad remit of MSC policy

and the efficiency savings it is intended to achieve. Therefore, the current political context in the UK may prohibit the uptake of adequate undergraduate training in audiologist-delivered psychological tinnitus treatment. In this thesis, post-treatment interviews with patients and audiologists in chapter 6 highlighted the effect of the psychological treatment on tinnitus *and* hearing loss and the potential utility of audiological transdiagnostic psychological treatment. However, the addition of psychological treatment to healthcare scientist training may require a broader pan-audio-neuro-ophthalmic formulation to integrate with the direction outlined in the white paper (Department of Health, 2010). One alternative may be compulsory CPD on psychological tinnitus treatment for practicing audiologists. Post-treatment interviews with audiologists indicated that brief training may be insufficient to develop the competencies and confidence required to effectively deliver psychological treatment, and that more intensive training may be necessary. However, the resulting loss of clinical contact time would need to be recouped by reinvesting efficiency savings into front-line services by training more audiologists just to maintain current levels of clinical provision.

7.4.2. Improving access to psychological therapies

The Health and Social Care Act 2012 mandated the NHS to deliver parity of esteem between physical and mental health. Funding, excess mortality, waiting times and access to treatment for mental health problems trail behind that of physical health conditions (Thornicroft,

2011, Centre for Economic Performance, 2012, Mind, 2013). The employment and training of healthcare scientists (such as audiologists) in the provision of psychological treatments presents one approach to close the gap. The good practice guide for the provision of tinnitus services recommends that audiologists offer psychological treatment to reduce waiting times and increase access to 'talking therapies' (Department of Health, 2009). Anxiety and depression are risk factors associated with tinnitus (Pinto et al., 2014). Addressing these factors in audiology services may divert patients from long-waiting lists in psychological therapy services. However, it is not clear how many people waiting to receive psychological therapies are living with tinnitus, nor is it clear whether audiology services could cope with any increase in demand. However, economic evaluations of stepped-care CBT for tinnitus in the Netherlands (Maes et al., 2014), and psychological therapies services for anxiety and depression in the UK (Mukuria et al., 2013), indicate comparable cost-effectiveness.

In this thesis, post-treatment interviews with patients indicated that the audiologist-delivered psychological tinnitus treatment helped them to recognise symptoms of depression and to challenge negative thoughts. Internet-delivered CBT programmes for tinnitus are designed to help patients to identify and challenge negative thoughts, and reduce clinical contact time to improve access to psychological treatment (Andersson et al., 2002, Nyenhuis et al., 2013, Beukes et al., 2017). However, by reducing clinical contact time, they can limit the opportunity for patients to benefit from feeling listened to and

understood, which patients and audiologists emphasised the importance of in this thesis. This suggests that audiologists may play a role in identifying and alleviating co-occurring mental health problems that would otherwise remain untreated to help to improve access to psychological therapies and achieve parity of esteem.

7.5.CONCLUSION

Audiologist-delivered psychological tinnitus treatment appears to be acceptable to tinnitus patients and audiologists. In the feasibility trial, the recruitment rate of eligible patients was high, no participants dropped-out of treatment after their first appointment, and each interviewed patient gave a favourable appraisal of the treatment. However, this thesis highlights several qualifications to this conclusion. Treatment components used should vary from patient to patient due to the heterogeneity of peoples lived experience of tinnitus. Moreover, the ongoing research discussed in this thesis highlights that deciding upon the components of audiologist-delivered psychological tinnitus treatment and how to measure it is a dynamic process, no sooner is it defined than it is redefined.

FUNDING

The work presented in this thesis was supported through a PhD studentship award from the University of Nottingham and contains independent research funded by the National Institute for Health Research (NIHR) under its Research for Patient Benefit (RfPB) Programme (grant reference number PB-PG-0613-31106). The views expressed are those of the author and not necessarily those of the NHS, the NIHR or the Department of Health.

APPENDICES

APPENDIX 1: A CODING MANUAL FOR THEMATIC ANALYSIS OF THE REFERENCE GROUP TREATMENT

MANUALISATION MEETING (CHAPTER 4)

CODING MANUAL

Aims of research:

Describe, explore and evaluate the development process of the audiologist-delivered psychological tinnitus treatment manual for use in a feasibility trial.

What to look for:

- **Ambiguous codes** – not sure what the code means or how to code to it
- **Duplicate codes** – sometimes you will code one quote with two different codes. If you find you are constantly using the same two codes for certain material, it may be that these codes are duplicates.
- **Data that does not fit** any of the listed codes
- **Under-used codes** – codes that have not be used at all or only once or twice. Can this code be combined with another one?

- **Disconfirming cases** – actively look for data that does not fit a particular code.
- Do the **code names** accurately capture the content of this code?
- Do the **quotes** I have used in the coding manual accurately represent this code?

List of themes

1. Flexibility of the intervention
2. Scope of practice
3. Coherence of manual content
4. Professional development

Code	Description	Example
Theme 1: Flexibility of the intervention		
Individualise the intervention to patients	The extent to which the intervention should be tailored to individual patients in practice, how this should be achieved, and the rationale underpinning recommendations.	<i>You would give them [audiologists] a recipe, psychological areas and this is what you might address but there would be a responsibility to the individual needs as well. So, if they weren't having trouble sleeping or if they've already got their sound thing [generator] and what not, and that wasn't an issue you wouldn't focus on that.</i> <i>Your principle of meeting patient need, it avoids the one size fits all prescriptive approach. There is a</i>

		<i>difference between being over-prescriptive and actually addressing common problems because research ought to have identified what common problems people with tinnitus suffer besides emotionally and the stuff that psychology can help with and you would certainly focus on common problems but that's different from being prescriptive like, "we are going to deal with this today regardless of whether it's a problem for you because that's in my manual". So, I think the flexibility of the psychologically-informed approach gets right into some of the research issues as well as some of the practice issues I would say.</i>
Patient involvement in decision-making	Concerns patient agency and the capacity of the intervention to be led by patient preference and the use of shared decision-making between patient and audiologist. This may include how the patient contributes to the selection of optional components of the intervention.	<i>It's a particular attitude of shared responsibility with a goal. So, the map might be different for everybody, they've got different features highlighted, but they're going to target what bothers them the most in the process.</i> <i>So you would look at current [coping skills] and then new coping skills, so that there would be two aspects of self-management I guess. It's more like the way of saying, you know if you can identify what people</i>

		<i>already do it shows them that coping skills can work and that they already do them, it gives them a bit of hope and self-efficacy and then you can, it's a good platform to introduce new skills.</i> <i>Ideally at that stage you're kind of saying these are the range of things that we can offer you and you, again, what tends to happen in audiology, the audiologist just decides this is what's going to fit you rather than saying this is what's available and what would you like to, to do.</i>
Assessment methods	The use of assessment techniques or tools to inform decision-making during the intervention. Techniques or tools may include but are not limited to theory and evidence-based formulation, or the use of an outcome questionnaire such as the TFI.	<i>That [essential information for the patient] frames the parameters of what you are doing in 'this room' what you can achieve, what's realistic and what really isn't realistic because you know you can be with people who persistently think magic might happen. It's not going to. There will be sometimes the more passive people who you can't engage properly with. They're hanging on. Sometimes that becomes obvious when you ask them about problems for living and you realise that their life is on hold. And then when you ask them why their life is on hold, it's because they are waiting to get</i>

		<i>cured or better and it becomes apparent that way. So, I think in a funny way the problem list helps you to work out how to manage your education.</i> <i>-What does the TFI ask? What kind of questions?</i> <i>-It's in sections so you've got there's questions about sleep there's questions about.</i> <i>-So, it's all the problems.</i> <i>I think we ought to ask if there has been any harm or worsening caused by anything because we just can't make an assumption that things are going to get better so at some point whether it's in the training or in some kind of document we need to ask the patient if they have gotten worse in a sensitive kind of way.</i> <i>Yeah exactly. So, it does help to. One thing you need to do is ask, "ok you've gotten worse, what are you, how do you account for that?" And they'll tell you oh it wasn't to do with you it was [because] my partner left me and everything. So, asking people what they attribute any kind of deterioration to.</i>
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		<i>I suppose it's prudent: 'is there's any harm', in an ongoing fashion.</i> <i>What some people will do is take the TFI as their baseline [rather than exploring it through]</i> <i>It [the TFI] should be easy to check. So, if you identify the problem areas you can check it at the assessment. Is it still the same, or is it?</i>
Sequencing care	The order (if any) in which different components of the intervention should be delivered or presented in the manual.	<i>In terms of presenting the manual, we have to present education in a block, just to convey that this is a component but this is not a recipe for how you would interact with your patient, you just don't go from one to two sequentially.</i>

Specificity of the intervention	The extent which the treatment should be specified in the manual, or open to clinical judgement. This includes the extent to which audiologists may resist standardisation of care.	<i>Maybe what needs to be done is get away from the notion of a specified treatment but actually given the psychologically-informed aspects of style, of interaction, more psychological assessment, integrating the material, addressing the emotions... but not actually making into a structured programme. You would just give the audiologist the skills and then see what they did with them, so that would be the psychologically-informed usual treatment.</i> <i>I'm just kind of wondering if it does make more sense to you know have a psychologically informed usual treatment both from a research point of view and a clinical point of view actually because sitting down and doing sort of structured programmes, 4 sessions or whatever it might be, you're calling it a manual, bloody boring. You know people get really cheesed off doing it that way.</i> <i>So you could be going into. I don't know. I've talked to people they don't really understand what tinnitus is. So actually, social support, you don't know what you're</i>
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		<i>letting them into with that I think it's a bit of a tricky topic.</i> <i>For sessions, they've then got the furniture, they've got an artefact of the therapy with them as a referral, [some clinicians] practically hanging onto it sometimes.</i> <i>You are looking for things that are comparable and you're introducing things that are not, if you're only looking at 4 sessions of psychologically-informed audiology treatment you can't realistically limit to four sessions really, you've just got to let it go.</i> <i>As a feasibility study, it depends how much you're specifying, that you are telling people what they must do in treatment as usual. It sometimes can be extremely difficult to get sites, clinical services to play ball because they don't want to change anything. You know in terms of the treatment as usual. Ideally it should be a specified treatment as usual so you know what you are comparing against.</i>
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Monitoring standardisation	How adherence to the manual is monitored and measured.	<i>I don't know how you are going to measure it but there would be some clinical records about who did what, so you maybe need to get into whatever the systems are.</i> <i>The basic problem is reliant on peoples' good will and you know you get such you know, some people will do it quite thoroughly and other people will sort of say, "usual stuff".</i>
Theme 2: Scope of practice		
Boundaries of audiologist competence	The capabilities of audiologists to deliver the intervention. This includes competencies and capacity to learn competencies within the context of the feasibility trial (a brief intervention with minimal training).	<i>-It does strike me as, I mean I don't know if I, the impression I'm getting is that sometimes audiologist will asked pertinent questions about the psychological issues but then just leave them hanging in the air.</i> <i>-Because they don't necessarily know what they are talking about.</i> <i>-So with a psychologically-informed, you know add-on just sounds like 'well hasn't anyone thought of it before?'</i> <i>-Well they have but it's not systematically available. That's the problem. It comes back to this standardisation.</i>

		<i>I think that [Worry time, typically used for Generalised Anxiety Disorder], again that's a boundary thing because I would be saying, I'd be thinking I don't think you're for me.</i> <i>I mean I think it's, when you're doing an open assessment on the persons experience I think what'll happen there is that they'll say it's causing terrible trouble with my partner because whatever, and I you know if we are doing a kind of assessment protocol you can put it in there but I think you need to keep that quite low-level, I mean I'm mindful that this is just a brief intervention with relatively unskilled people in this psychology domain so I would keep that out.</i> <i>you've got to be mindful if you open a can of worms you've got to deal with it.</i> <i>you don't want to raise, get them to raise a point when then you can't haven't got the wherewithal to do anything about it and you there's noting worse than</i>
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		<i>sort of identifying a problem and then sort of saying, "well that's not in my manual mate, off you go" so that's my concern.</i> <i>In order to implement CBT in an effective way [you need common therapeutic skills], because they are not therapists.</i>
Complexity of intervention	The degree of complexity that prospective components of the intervention pose to implementation within the context of the feasibility trial (a brief intervention with minimal training).	<i>I think that's [cognitive restructuring] too complicated. This is 4 sessions with people who haven't got any therapy training. I think you will be identifying negative thoughts and negative beliefs and gradually shifting them but I think to go into cognitive restructuring is too much.</i> <i>But we've got to be mindful that some people just want to get on with their job and they don't want too much theory, probably don't want too much reading, but the training looks like well everything is very pragmatic, when you're looking to, if this is actually embedded in clinical practice in the future then you don't want it to be so convoluted, you know they're not going to be doing degrees in this.</i>

		<i>that's too complicated. I think there is going to be some, I just, it is too c, this is for sessions with people who haven't you know got any therapy training I mean I think you will be ask, identifying negative thoughts and negative beliefs and gradually shifting them but I think going into cognitive restructuring is too much.</i> <i>No you can't do that [graded exposure] in 4 sessions.</i> <i>We've not got time [for applied relaxation in sessions]. We need something generic... It's got to be speed relaxation.</i>
Reach of intervention	Conceptual reach of the intervention into wider psychological domains or co-occurring health or social problems. Reference may be to domains or problems, correlated or uncorrelated to tinnitus. Such correlations may include but are not limited to casual associations. This also includes the perceived acceptability to audiologists of working with complex or sensitive mental health issues that arise, including risk of harm through self-harm or suicide.	<i>It depends on what you mean by associated problems. Because if it was hearing, then definitely in usual [care] but whether it goes beyond that.</i> <i>Are you talking about things that occur but are separate like relationship issues? ... I mean you might have something that kind of interferes or has an impact on something like ingrowing toenails but they're not actually connected, do you know what I mean... You</i>

		<i>know if your ingrowing toenail is grinding you down and your tinnitus is grinding you down its kind of exacerbating the problem but they're not connected or they are connected. I just wondered, and then there are things like relationships where if you're not getting any sleep and you're grumpy and all the rest of it. I don't know if you need to distinguish.</i> <i>I'd say co-occurring problems or connected problems or something like that, like anxiety and depression and relationship issues.</i> <i>They [audiologists] would be very uncomfortable [asking about risk or suicide or self-harm]... I think it's the way its phrased. So, I think there are different ways of pulling out that depth.</i>
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Theme 3: Coherence of manual content		
Cohesiveness of components	The extent to which the components of the intervention theoretically hold together. This does not concern the inclusion of specific components, rather how they are selected with respect to other components or theoretical modalities. For example, the inclusion of 2 or more components that complement one another to address different areas within a cognitive behavioural paradigm.	<i>I personally think those ACT-type mechanisms for chronic conditions are much more useful than challenging negative thoughts... I think the principle of that approach is something you might consider briefly touching on.</i> <i>One striking observation from the [Delphi survey] consensus list was that we didn't see any items that specifically asked about how people think about their tinnitus. How they interpret what their tinnitus means – the cognitions in CBT – and I don't know whether there are any of those kind of aspects that were considered by the Delphi panel but they got excluded. But it seems that was kind of lacking in the list we've just considered.</i> <i>I think we'll have much easier justification for including things that actually link or support what we have already included.</i> <i>You can't do that [cue-controlled relaxation] unless you've done all the other [parts of applied relaxation].</i>

Evidence-base of the intervention	The evidence-base underpinning prospective components of the intervention.	<i>There's a very good reason for that [thought stopping not being included in the intervention manual], the evidence is there Wagner (1994) is the evidence for ironic thoughts. So, there's a really good reason why that shouldn't be included by anyone ever.</i> <i>Well it's [cost-benefit analysis] a motivational technique but to be honest no [do not include it in the intervention manual]. One of the things about cost-benefit analysis is that some of the recent thinking in addictions is why bother with the costs you're only asking them to say the negatives so it doesn't actually, it's not favoured anymore in that form.</i> <i>Not everybody likes that [progressive muscle relaxation]. I mean there are some people for whom its contraindicated... Yeah, high blood pressure.</i> <i>I don't know what the evidence for effectiveness of worry time is do you?</i>
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		<i>I also think we're not doing that [social skills training] anymore anywhere for any reason. That's a no.</i>
Model of understanding patients' problems	Reference to any model (e.g. cognitive behavioural modality) to understand the presenting problems of patients who are eligible for enrolment into the feasibility trial of this intervention.	<i>An audiologist would not think about formulating an explanation in that [cognitive behavioural 5 areas model] way. We would do that because of having had CBT training and it was an absolute revolution and a major unlocker.</i> <i>There's a kind of hiddenness of a model here and I think is this a moment to be explicit about which model we will be thinking in terms of if we are framing CBT, are we not looking at the most recent model. Are we not looking at McKenna et al. just to use a tool for CBT to frame the impact that your thoughts have on how things progress, your expectation. I think there needs to be some conceptual reach for something at the cognitive level no matter what you then go on to do. Some framework to help patients conceptualise things in quite a holistic way. I think it's kind of implied... And I think you deny yourself access to one of the most constructive strategies for delivering CBT if you don't include it.</i>

		<i>I think that [information about the theory or model used] will form quite an important part of the training for this. Because audiologists historically have their training in a particular model, which doesn't acknowledge the agency of the individual in all of this. And really we need a paradigm shift in audiology in thinking about tinnitus, else none of this is going to be effective.</i> <i>And the way that it is written here, it's more in line with the neurophysiological model which is not psychological. It [how the component is delivered] could be re-couched.</i> <i>And how you frame that [relaxation techniques]. Are you going to go back to Jastreboff's model or are you going to go into some other strategy, which talks about active self-management? Not booming and busting, slightly more complicated and behavioural. There's several ways to cut that one up.</i> <i>I think with some caveats about taking a light touch and not promising too much. I don't see how you can do</i>
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		<i>behavioural work unless you look at the context at which they are at.</i> <i>We don't do thought controlling anymore. We deal with awareness.</i> <i>The other thing that is kind of being touched on a couple of times is that theoretic framework behind these [components]. So, if you started training audiologists about this, they're not tapped into the theoretical thinking around this and then keeping up to date with what. It's that side of it as well.</i> <i>I think in the cognitive model it's important theoretically that you think of that as part of the cycle of maintenance that you experience reduced cognitive effectiveness. You think you're losing the plot and then catastrophise it.</i> <i>I think audiologists would discuss these things but they wouldn't think of it as relapse prevention so it's more saying, "right we've come to the end of the journey and</i>
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		<i>this is what you do in the future, i.e. go back to your GP and come back into the system" which isn't the same.</i> <i>That's the culture of audiology which is you come back to us when you have a problem not you deal with it yourself.</i> <i>It's about engagement isn't it... it's also about effacing that medical model.</i>
Presentation of the manual	How the content of the manual is presented in print. This may include the structure of the manual, or the language used therein. This also concerns the use of pre-existing materials that could be used to deliver the intervention. Materials may include, but are not limited to, worksheets for patients to fill in, educational supplements or diagrams.	<i>But I think most of the size of it [the manual] should be in the materials rather than the writing because I think the best way forward is to make the materials self-explanatory and that helps form the patient's point-of-view also from the, I think you have to almost treat the therapist as having the same needs as the, you know. It's got to be so clear that not only the patient understands it but the therapist understands it, not only does the therapist understand it but both have, because both are coming to it new to be honest, just about the same.</i> <i>And the manual has to be user friendly, not unwieldy, not jargony, nice to look at. It's important. I know you might think that's an unimportant issue and I'm not saying we</i>

		<i>have to start off like this because it does evolve and you can, but it's got to be user-friendly. We're trying to get the therapist to motivate the patients but we have to motivate the therapists and we have got to use the same techniques you would use with a patient and we've been talking about graphics and we've been talking about motivation interviewing techniques and so on, that's what we've got to do with, you know to motivate these people to do this intervention and not, not make it unpleasant.</i> <i>I don't like that term, I think it's (comorbidity) a horrible word</i> <i>I have loads of stuff from other manuals on some of these, these issues that are common components of interventions for other issues they will have to be adapted because you say they would be directed at people, they wouldn't be aimed as they are with people with tinnitus but it shouldn't be too difficult to reword and stuff. So I think that might be stage 1.</i>
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Integration of specialised care and usual care	How the intervention is integrated with usual care.	<i>We need to know what it [treatment as usual] is particularly when we are thinking about the training side of it just so we can make reference to it as required.</i> <i>How they [audiologists] integrate it [specialised and usual care], that will be the biggest question. Because this could be all psychology quite easily but they've got to do the treatment as usual as well so how we kind of get that kind of pinned down is challenging.</i> <i>You can't maybe separate the 2 [specialised and usual care] easily. You get somebody who says, "I am desperate for a noise generator" or whatever, you can't sort of say "well that's Tuesdays session, you'll just have to wait".</i>
Theme 4: Professional development		
Complexity of training	Concerns the degree of complexity and approach to training audiologists to deliver the intervention.	<i>And I think training has to be kind of fairly sort of stick to the, it's got to be replicable, so once we agree what the training is you two will have to stick to that too or you'll be in trouble.</i> <i>Is it possible to think about scenarios as well? Are we going to have training scenarios, training videos? It's just</i>

		<i>so as we can exemplify or operationalise you know for example 'it might look like this', 'Mr X turns up saying blah, blah, blah'.</i> <i>The other thing we need at the back of this course is, for people who do want to go on and learn more, where do they go. That's what they need as well.</i>
Supervision	The use of supervision for the intervention. This may include a description of what form any proposed supervision may take, or barriers to implementing supervision.	<i>But we've discussed including two things. One of which is training, and there's the issue broadly that will need to come up and the second is supervision. And I do think that if you can organise group supervision, you will identify some of the issues that need to be thrashed out in terms of finalising the programme. And you know, you can follow that one up and they should have onsite supervision you know clinical supervision as well, from whoever they should.</i>
Enhancing credibility of the intervention and associated audiologists	Concerns what can be done to increase the credibility of the intervention to patients, audiologists and any other actors, and those who deliver the intervention.	<i>I think it's worth reminding people as a general skill to explain what you are doing as you go along so that people will not do, well are more likely to do stuff when they know why you are getting them to do so that information given all along the line</i>

		<i>I do think it's got to be translated into plain English and not be too highfalutin, you know I think thoughts, feelings, behaviour, whatever, you know and you can give people further reading if they want proof that you are not talking crap.</i> <i>Partly the training manual will need to be bits about the principles of the research, the people who are doing this intervention will need to know about the research and what they have to do and they can't just shoot off at any old angle.</i>
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APPENDIX 2: A CODING MANUAL FOR THEMATIC ANALYSIS OF AUDIOLOGIST TRAINING FEEDBACK (CHAPTER 4)

CODING MANUAL

Aims of research:

Describe, explore and evaluate the development process of the audiologist-delivered psychological tinnitus treatment manual for use in a feasibility trial.

What to look for:

- **Ambiguous codes** – not sure what the code means or how to code to it
- **Duplicate codes** – sometimes you will code one quote with two different codes. If you find you are constantly using the same two codes for certain material, it may be that these codes are duplicates.
- **Data that does not fit** any of the listed codes
- **Under-used codes** – codes that have not be used at all or only once or twice. Can this code be combined with another one?
- **Disconfirming cases** – actively look for data that does not fit a particular code.
- Do the **code names** accurately capture the content of this code?
- Do the **quotes** I have used in the coding manual accurately represent this code?

List of themes

1. Flexibility of the intervention

2. Scope of practice
3. Manual content
4. Manual presentation

Code	Description	Example (codes refer to manual page and comment numbers)
Theme 1: Flexibility of the intervention		
Assessment methods	Any changes to how assessment is performed to inform treatment choices.	3 [11c] Use TFI as part of clinical protocol with feedback at the point of assessment rather than using purely as a research measure 6.4 [28a] Add learning outcome to establish what the patient's sleep has been like throughout the lifespan, including before tinnitus onset 6.5 [32a] Include an exploration of patients baseline level of activity i.e. what did they do before tinnitus (distress) onset 7 [48a] Use TFI as part of clinical protocol with feedback rather than using purely as a research measure
Patient-involvement in decision-making	Refers to any recommended change ensure a patient-involvement in treatment decision-making	6.2 [25a] This section should not include approach to help the patient to unearth fears about tinnitus if they are finding it difficult to elicit any examples as this may be too complicated and unnecessary when other specific techniques are available within the manual that may be more readily applicable

Sequencing	Concerns the order in which parts of the manual are presented, and how different parts of the manual reference their order in relation to one another.	<i>0[9a] Move Patient assessment section to before Rationale for treatment section</i> <i>0[23a] Move Relaxation section to before Fear and avoidance chapter</i> <i>1 [54a] Move common therapeutic skills from end to beginning</i> <i>2 [7a] Contracting/setting ground rules should be moved earlier in the section (the rationale section was made more concise so that contracting/setting ground rules were more apparent)</i> <i>6.7 [43a] Reference to 'earlier sessions' should be removed</i> <i>6.8 [42a] Move sound therapy section into the manual tinnitus education section</i>
Specificity of the intervention	And reference to adding to removing content of the manual to increase prescriptiveness or allow flexibility in how the manual is presented and the treatment is delivered	<i>0[9b] Remove 'recommended durations' for each manual chapter</i> <i>1 [3a] The introduction should make clear that this audiologist-delivered intervention is not a replacement for a qualified cognitive behavioural therapist</i>

		6.4 [29b] Remove specification of suggested type of “milky” drink 6.4 [29c] Remove specificity of recommended amount of exercise in this section due to number of potential caveats such as age 6.7 [44b] Stress that other metaphors can be used and encourage the audiologist reading the manual to use their own examples or search for others 7 [45aii] Manual contains script that the audiologist should read out, however this is taken from text in a handout. The audiologist should instead be encourage to use their own words L [a] More examples of metaphors should be included in the Attention, monitoring and acceptance section (text added in manual encouraging audiologist to use their own examples or search for new ones)
Theme 2: Scope of practice		
Boundaries of audiologist competence	Concerns any changes to accommodate audiologist skillset and knowledge following training	2 [6a] Reference is made to components of CBT in the manual, though it should be made clearer that this intervention is not CBT

		<i>6.6 [34a] Remove point where audiologist is encouraged to have the patient explore why one person may be 'stressed' by tinnitus while another is not. The passage assumes that the patient will come to the realisation (which they may not) that it is due to the response of the patient rather than the severity of the tinnitus percept.</i>
Complexity of intervention	Concerns amendments to simplify the manual to ensure that it remains within the scope of audiologist practice	<i>0[5c] Do not include both the [cognitive behavioural] 5 areas model and cognitive model of tinnitus (McKenna et al., 2014) together due to discrepancies between the two that may cause confusion. Retain only one model (The cognitive model of tinnitus was retained with new 'zoomed in' versions replacing the [cognitive behavioural] 5 areas model and the full McKenna model should be retained for audiologist reference for context of the intervention)</i> <i>6.1 [21a] Remove complex 'Managing stress, managing tinnitus' worksheet and replace with 'zoomed in cognitive model of tinnitus' example formulations and blank worksheets</i> <i>6.7 [44a] This section should be simplified with less text in fewer points</i>
Reach of intervention	Concerns amendments to restrict or extend the manual into wider psychological	<i>5 [16a] Remove mention of Ménière's disease</i>

	domains or co-occurring health or social problems.	<i>6.8 [43a] Sound therapy section does not appear to accommodate people with severe or profound hearing loss, though it should</i>
Training	Refers to the inclusion of training materials used during the 2-day audiologist training in the manual.	<i>0[54b] Include training materials at the end of the manual</i>
Supervision	Concerns the addition of any guidance on supervision for audiologists delivering the intervention	<i>L [b] Guidance on supervision for audiologists should be included (for the purposes of the feasibility trial, audiologists were advised that peer-supervision was permissible)</i>
Theme 3: Manual content		
Cohesiveness	Any reference to removing components of care that do not fit with the cognitive behavioural model and adding information that provides context for the delivery of components of care	<i>5 [15c] Explicit mention of the role of limbic system should be removed to make discussion with the patient user-friendly.</i> <i>6.4 [30b] Include information on the normal sleep cycle to give recommended changes context and include a patient handout</i>
Elaboration	Any addition to the manual that elaborates on the manual content to add greater explanatory power	<i>6.2 [24c] Add an example formulation for fear and avoidance of tinnitus</i> <i>6.3 [27b] Add a recommendation of frequency that relaxation should be practiced by patient per day</i>

		<i>6.4 [28c] Add a cautionary note that the sleeping diary should not be used excessively or at inappropriate times such as when attempting to sleep, in the evening</i> <i>6.5 [32c] Emphasis should be added that increase physical exercise should be gradually increased</i> <i>6.7 [41aii] Add a disclaimer that mindfulness is not for everyone and may have side-effects</i>
Patient accessibility	Amendments to simplify the content to make the manual more accessible	<i>5 [19a] Remove cognitive model of tinnitus illustration from manual. This is 'too difficult' and patients 'do not like schematics'</i> <i>6.1 [22a] Remove reference to autonomic nervous system sympathetic activity while discussing the fight or flight mechanism in the context of explaining the stress response</i> <i>6.1 [22b] Use the model on the patient handout (this is essentially the same as zoomed-in McKenna model)</i>
Theme 4: Manual presentation		
Clarity	Any changes to the manual to improve the clarity of the written content	<i>0[5b] All learning outcomes should contain 'explain', 'describe' etc to enable measurable outcomes</i>

		<i>6.2 [24b] One Topic overview subsection point was unclear</i> <i>6.6 [29a] Amend negative automatic thoughts and core beliefs text so that the difference between the two is clearer</i>
Conciseness	Any changes to make the manual content more concise, without removing whole components of the treatment	<i>5 [15a] 'Learning outcomes' and 'Topic overview' replicate one another so either one of these sub-sections should be revised into a shorter summary</i> <i>6.6 [33a] This section should be simplified with less texts in fewer points</i>
Materials	Refers to recommendations for additional materials to add to the toolkit of resources	<i>6.2 [24a] Remove illustration on page 40 and use as a handout</i> <i>6.3 [25a] Handout for patient on relaxation procedure</i> <i>6.3 [32a] Provide audiologist with further relaxation materials</i> <i>L [a] Include an illustration on the connection between the ear and the brain using existing materials already used by audiologists</i>
Navigation	Concerns and amendments that are designed to help the patient navigate with and across the sections and pages of the manual,	<i>0[5a] Replace bullet points with numbered system</i> <i>1 [3a] An overview of the manual including structure</i>

		<i>6.4 [29a] Refer audiologist to the relaxation section of the manual as one means of addressing sleep problems</i> <i>6.4[30a] Refer audiologist to the sound therapy section of the manual as one means of addressing sleep problems</i> <i>L [d] Reminders to refer to common therapeutic skills information in the manual should be added throughout the specific techniques sections</i>
Terminology	Concerns any changes to the manual	<i>6.3 [27c] “Deep breaths” should be replaced with “normal breaths” due to fear that the audiologist would induce hyperventilation if the patient is already in anxious state</i> <i>6.4 [28b] Remove the use of the term ‘sleep hygiene’</i> <i>L [c] The term “peace and quiet” should be removed from the text on mindfulness as this implies that peace cannot be found in noise</i>
Quality	Amendments to the manual to address typographical errors	<i>0[10a] Various typographical errors</i> <i>1 [3bii] Various typographical errors</i>

Enhancing credibility	Refers to any recommended amendment that may improve the credibility of the intervention to patients or audiologists	<i>2[11a] Provide audiologist with McKenna et al. (2014) paper on cognitive behavioural model of tinnitus</i> <i>6.3 [26a] The rationale for relaxation should include reference to change in brain-wave patterns to provide credibility to patients</i>
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APPENDIX 3: CONSORT 2010 CHECKLIST OF INFORMATION TO INCLUDE WHEN REPORTING A PILOT OR FEASIBILITY TRIAL (CHAPTER 6)

Section/Topic	Item No	Checklist item	Reported on page No
Title and abstract			
	1a	Identification as a pilot or feasibility randomised trial in the title	136
	1b	Structured summary of pilot trial design, methods, results, and conclusions (for specific guidance see CONSORT abstract extension for pilot trials)	iii
Introduction			
Background and objectives	2a	Scientific background and explanation of rationale for future definitive trial, and reasons for randomised pilot trial	136-137
	2b	Specific objectives or research questions for pilot trial	138
Methods			
Trial design	3a	Description of pilot trial design (such as parallel, factorial) including allocation ratio	138
	3b	Important changes to methods after pilot trial commencement (such as eligibility criteria), with reasons	n/a
Participants	4a	Eligibility criteria for participants	139
	4b	Settings and locations where the data were collected	139

	4c	How participants were identified and consented	140
Interventions	5	The interventions for each group with sufficient details to allow replication, including how and when they were actually administered	141
Outcomes	6a	Completely defined prespecified assessments or measurements to address each pilot trial objective specified in 2b, including how and when they were assessed	142-146
	6b	Any changes to pilot trial assessments or measurements after the pilot trial commenced, with reasons	n/a
	6c	If applicable, prespecified criteria used to judge whether, or how, to proceed with future definitive trial	141
Sample size	7a	Rationale for numbers in the pilot trial	139
	7b	When applicable, explanation of any interim analyses and stopping guidelines	n/a
Randomisation:			
Sequence generation	8a	Method used to generate the random allocation sequence	140
	8b	Type of randomisation(s); details of any restriction (such as blocking and block size)	140
Allocation concealment mechanism	9	Mechanism used to implement the random allocation sequence (such as sequentially numbered containers), describing any steps taken to conceal the sequence until interventions were assigned	140
Implementation	10	Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions	140
Blinding	11a	If done, who was blinded after assignment to interventions (for example, participants, care providers, those assessing outcomes) and how	n/a
	11b	If relevant, description of the similarity of interventions	146
Statistical methods	12	Methods used to address each pilot trial objective whether qualitative or quantitative	146-147
Results			

Participant flow (a diagram is strongly recommended)	13a	For each group, the numbers of participants who were approached and/or assessed for eligibility, randomly assigned, received intended treatment, and were assessed for each objective	148-150
	13b	For each group, losses and exclusions after randomisation, together with reasons	148-149
Recruitment	14a	Dates defining the periods of recruitment and follow-up	147-148
	14b	Why the pilot trial ended or was stopped	n/a
Baseline data	15	A table showing baseline demographic and clinical characteristics for each group	151
Numbers analysed	16	For each objective, number of participants (denominator) included in each analysis. If relevant, these numbers should be by randomised group	148-151
Outcomes and estimation	17	For each objective, results including expressions of uncertainty (such as 95% confidence interval) for any estimates. If relevant, these results should be by randomised group	153-154
Ancillary analyses	18	Results of any other analyses performed that could be used to inform the future definitive trial	154
Harms	19	All important harms or unintended effects in each group (for specific guidance see CONSORT for harms)	152
	19a	If relevant, other important unintended consequences	n/a
Discussion			
Limitations	20	Pilot trial limitations, addressing sources of potential bias and remaining uncertainty about feasibility	190-197
Generalisability	21	Generalisability (applicability) of pilot trial methods and findings to future definitive trial and other studies	169, 174, 182-183, 195
Interpretation	22	Interpretation consistent with pilot trial objectives and findings, balancing potential benefits and harms, and considering other relevant evidence	190-197
	22a	Implications for progression from pilot to future definitive trial, including any proposed amendments	190-197

Other information			
Registration	23	Registration number for pilot trial and name of trial registry	138
Protocol	24	Where the pilot trial protocol can be accessed, if available	138
Funding	25	Sources of funding and other support (such as supply of drugs), role of funders	218
	26	Ethical approval or approval by research review committee, confirmed with reference number	138

APPENDIX 4: DRAFT PATIENT INTERVIEW SCHEDULE

(CHAPTER 6)

[Hand patient a copy of the manual and toolkit as a reminder. Present laminated cards for patient to select areas of importance for discussion]

Opening

Purpose of the interview is to get constructive feedback (positive and negative) on this new manualised treatment. From taking to you, we may hear of ways to adapt the treatment to better suit patients' needs. With your permission, we will audio record the interview, but everything will be fully confidential and anonymous. Any questions?

General

1. What did you expect to get from the treatment?
 - 1.1. *What were your individual needs around your tinnitus prior to treatment?*
2. What did you cover during your treatment?
3. Have you had any treatments like this before? If so, what?
4. Overall, what are your thoughts about the treatment you received?
 - 4.1. *What was good about it? What wasn't?*
 - 4.2. *Did the treatment do what you expected? In what ways did it meet/not meet your expectations?*
 - 4.3. *Have you found out anything new about treatments for tinnitus you didn't know before? What?*
 - 4.4. *What do you think about the length of time/number of sessions?*

Patient assessment (Chapter 2)

1. When you started talking to your audiologist about your tinnitus and related problems, what sort of questions did they ask you?
 - 1.1. *How relevant were these questions to you?*
2. How well were your own needs dealt with?
 - 2.1. *How well did the audiologist listen to you and take on board your concerns?*
 - 2.2. *How well did the audiologist understand your individual needs?*
 - 2.3. *How did the audiologist show that they understood/didn't understand your concerns/needs?*
 - 2.4. *How well did your treatment focus on your main areas of concern?*
 - 2.5. *Could anything have been improved? If so, what/how?*

3. How was the interaction between you and the audiologist?
 - 3.1. *What was the rapport with your audiologist like?*
 - 3.2. *How were they in terms of displaying empathy? How did they demonstrate/not demonstrate this?*
 - 3.3. *How would you describe your experience with the audiologist?*

Rationale for psychologically informed treatment (Chapter 3)

1. What did the audiologist explain about the ideas behind the treatment?
 - 1.1. *How clear and understandable was this? Was anything unclear? What could have been improved?*

Goal setting/treatment planning (Chapter 4)

1. How involved did you feel in the decision making about your treatment?
2. How well did you understand the decisions that were made? What was unclear?
3. How relevant and realistic were your goals for treatment (SMART)?

Treatment (Chapters 5 & 6)

Patient education (5)

Managing the emotional consequences of tinnitus (6.1)

Rapid relaxation (6.2)

Managing fear and avoidance behaviours (6.3)

Changing unhelpful thoughts (6.4)

Promoting physical exercise (6.5)

Promoting good sleeping habits (6.6)

Attention, monitoring and acceptance (6.7)

Sound therapy (6.8)

[Go through each section the patient covered during treatment, asking the following questions]

1. What did you think about this aspect of treatment?
 - 1.1. *How clearly was the content explained?*
 - 1.2. *Did any of the skills or ideas stand out as being helpful to you? Which/How?*
 - 1.3. *Did you get any unexpected benefits not directly related to your tinnitus?*
 - 1.4. *Did any of the skills or ideas stand out as being unhelpful or irrelevant to you? Which/How?*
 - 1.5. *How well did the audiologist deal with this aspect of treatment?*

- 1.6. *Is there anything you would have liked to have been done differently? Any improvements? What/How?*
2. Which handouts/materials were you given?
3. What did you think about the handouts/materials you were given?
 - 3.1. *Did you use them?*
 - 3.2. *How did you use them?*
 - 3.3. *What got in the way of you using them?*
 - 3.4. *What would you change about them?*
 - 3.5. *Would you prefer not to use them at all?*
 - 3.6. *Did you review what you had done on the worksheets with your audiologist?*

Relapse prevention (Chapter 7)

1. How confident do you feel about carrying on using the ideas from the sessions?
2. How much were you encouraged to find ways to help yourself? Have these helped? If so, how?
3. Were you directed to different places or resources to go at the end of your treatment?
4. What were these? Have you taken up any of these options?
5. What have you got from these?
6. In your opinion, what is the best format to provide self-help information for patients following such treatment?
7. How well have your goals been met?
 - 7.1. *Are you still measuring progress towards your goals?*
 - 7.2. *Are you moving towards meeting these goals?*

Bibliography (Chapter 8)

1. Have you done any further reading from the list of references? If so, what, and has this helped? How?
2. Would you improve what you were given? How?

Outcomes and questionnaires

1. You received care from an audiologist as part of a trial. What effect has this care (or parts of it) had on you?
 - 1.1. If the patient does not offer any specific domains here refer back to domains that have come up throughout interview on the intervention if possible. [Use laminated cards of domains to help them pick any out if they cannot think of a domain]
 - 1.2. [Provide TFI scores] This is how your score changed on the TFI that measures severity and impact across several domains including (1) Intrusiveness, (2) sense of control, (3) sleep, (4) cognition (thoughts) (5) hearing, (6) relaxation, (7) emotional

- distress, and (8) quality of life. Why do you think this has changed? How accurate do you think the change in score is?
- 1.3. [Provide TCQ scores] This is how your score changed on the TCQ that measures you positive and negative thoughts in relation to your tinnitus. Why do you think this has changed? How accurate do you think the change in score is?
 - 1.4. Improvement, worsening, no change in tinnitus-related health?

TFI

1. [Provide TFI] What are your overall impressions of this questionnaire?
 - 1.1. [Remind the patient of questionnaire's domains] Do you think these domains are relevant to you, and if so, how are they relevant to you?
 - 1.2. Was anything missing from this questionnaire that you would add to the questionnaire?

TCQ

1. [Provide TCQ] What are your overall impressions of this questionnaire?
 - 1.1. [Remind the patient of questionnaire's domains] Do you think this domain is relevant to you, and if so, how are they relevant to you?
 - 1.2. Was anything missing from this questionnaire that you would add to the questionnaire?

End

1. Do you have any further thoughts you would like to share about the questionnaires?

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