Evaluation and optimisation of the Tinnitus E-Programme, an internet-based intervention for tinnitus self-management

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

March 2017

ABSTRACT

Internet-based self-management interventions have the potential to reduce the current disparity in access to psychological support for people with tinnitus. One example is the Tinnitus E-Programme, which was developed in the United Kingdom to support self-management in people with tinnitus. Although freely available online, there was little understanding of how the intervention is used, its active ingredients, how it works, the circumstances in which it works best, and whom it works best for. This PhD aimed to address these issues by evaluating and optimising the Tinnitus E-Programme.

A systematic review of self-help interventions for tinnitus was conducted, which concluded that there was a need for further evaluations of unguided self-help interventions in UK populations. A mixed methods study explored past, current, and new users' (*n*=40) views and usage of the Tinnitus E-Programme (1.0), demonstrating that it was acceptable to people with tinnitus. However, its implementation was limited by instances of poor usability, user engagement, and adherence to behavioural goals.

Consistent with a person-based approach, the findings from this mixed methods study were used alongside evidence-based (i.e. systematic and literature reviews) and theory-based (i.e. behavioural analysis and logic modelling) approaches to develop the Tinnitus E-Programme 2.0. Think aloud interviews with 19 people with tinnitus evaluated this new version of the intervention and findings revealed that the Tinnitus E-Programme 2.0 was acceptable to its target users. The two primary research studies highlighted how users' pre-existing beliefs regarding tinnitus and self-management, their perceptions of relevance, and the nature of tinnitus can influence users'

engagement with the Tinnitus E-Programme 1.0 and 2.0. Several cognitive factors (e.g. illness beliefs), behavioural factors (e.g. practicing relaxation), and behavioural determinants (e.g. motivation to practice relaxation) were identified by users to explain how changes in intervention outcomes may occur.

Further development and implementation work is needed that introduces and evaluates additional intervention content and design features, and explores how the intervention can fit into current clinical service models for tinnitus. Future evaluation work should test the hypothesised mechanisms of impact and contextual factors proposed in this work, and assess the acceptability and feasibility of procedures for subsequent randomised controlled trials that will assess the efficacy of the intervention.

DEDICATION

I would like to dedicate this thesis to the late Brian Greenwell. This thesis would not have happened if not for you.

ACKNOWLEDGEMENTS

I would like to express my gratitude to my excellent supervisory team - Dr Derek Hoare for his invaluable support throughout and making sure that I kept quality at heart of everything I did; Dr Magdalena Sereda for challenging me every step of the way and teaching me to 'write what I say'; and Dr Neil Coulson for sharing his wealth of expertise in health psychology and online research methods.

I would also like to thank Debbie Featherstone for her cooperation and expertise on this research; Dr Adam Geraghty for his training, enthusiasm, and motivation when developing the Tinnitus E-Programme 2.0; and my colleagues at the NIHR Nottingham Hearing Biomedical Research Unit for their knowledge and support. I would also like to acknowledge the National Institute for Health Research for funding my PhD and providing training throughout.

In addition, I am extremely grateful for my family and friends - my mam, for her never-ending support and keeping me entertained on my endless car journeys to Nottingham; Kathryn, for providing just the right balance of laughs, guidance, and chocolate that kept me sane throughout; and, above all, Rebecca for her absolutely unwavering faith, love, and patience, which got me to the finish line!

Most importantly, this research would not have taken place without the people who took part in my research and the members of the PPI panel and Nic Wray from the British Tinnitus Association who provided invaluable guidance on the mixed methods study.

PUBLICATIONS

Publications arising from this thesis:

Greenwell, K., Featherstone, D. & Hoare, D.J. (2015). The application of intervention coding methodology to describe the Tinnitus E-Programme, an internet-delivered self-help intervention for tinnitus. *American Journal of Audiology, 24*(3), 311–315.

Greenwell, K., Sereda, M., Coulson, N. & Hoare, D.J. (2016). Understanding user reactions and interactions with an Internet-based intervention for tinnitus self-management: Mixed-methods process evaluation protocol. *JMIR Research Protocols, 5*(1), e49.

Greenwell, K., Sereda, M., Coulson, N., El Refaie, A. & Hoare, D.J. (2016). A systematic review of techniques and effects of self-help interventions for tinnitus: Application of taxonomies from health psychology. *International Journal of Audiology, 55*(Suppl 3), S79–S89.

Other publications:

Greenwell, K. & Hoare, D.J. (in press). Use and mediating effect of interactive design features in audiology rehabilitation and self-management internet-based interventions. *American Journal of Audiology, 25*(3S), 278-283.

Hoare, D. J., Watts, E., Broomhead, E., Stockdale, D., & Greenwell, K. (in preparation). Clinician's attitudes to self-help interventions for tinnitus.

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.

Kate Greenwell Date

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LIST OF ABBREVIATIONS

ACT	Acceptance and Commitment Therapy
BCT	Behaviour Change Techniques
BCTv1	Behaviour Change Techniques Taxonomy v1
BCW	Behaviour Change Wheel
CBT	Cognitive Behaviour Therapy
CHERRIES	Checklist for reporting results of internet surveys
COREQ	Consolidated criteria for reporting qualitative research checklist
ENT	Ear, Nose and Throat
GHQ-12	General Health Questionnaire - 12
GP	General Practioner
GPG	Good Practice Guidelines
GRAMMS	Good Reporting of A Mixed Methods Study guidelines
HADS	Hospital Anxiety and Depression Scale
IMR	Internet-Mediated Research
MRC	Medical Research Council
NRCT	Non-Randomised Controlled Trial
NICE	The National Institute for Health and Care Excellence
NIHR Nottingham Hearing BRU	National Institute for Health Research Nottingham Hearing Biomedical Research Unit
PHQ-D	German version of patient health questionnaire
PICOS	Participants Intervention Control Outcomes Study design
PPI	Public and Patient Involvement
PRISMA	Preferred Reporting Items for Systematic reviews and Meta-Analyses
PRISMS	Practical systematic review of self-management support

PROSPERO	International prospective register of systematic reviews
RCT	Randomised Controlled Trial
TDF	Theoretical Domains Framework
TEQ	Tinnitus Effects Questionnaire
THI	Tinnitus Handicap Index
TQ	Tinnitus Questionnaire
TRQ	Tinnitus Reactions Questionnaire
UK	United Kingdom

CHAPTER 1. INTRODUCTION

Subjective tinnitus (or ringing in the ears) can be chronic, distressing, and has no known cure. As such, management aims to improve quality of life, mainly through reducing the associated emotional distress. Psychological therapies are acknowledged as beneficial to people with tinnitus; however, such therapies are not always readily accessible. Internet-based interventions, with their global reach, have the potential to reduce this disparity and improve access to psychological support for people with tinnitus. One such example is the Tinnitus E-Programme, an Internet-based intervention to support tinnitus self-management that was developed in the United Kingdom. Although freely available online, there is currently little understanding of how the intervention is used, its active ingredients, how it works, the circumstances in which it works best, or for whom it works best for. This PhD aims to address these issues by evaluating and optimising the Tinnitus E-Programme.

1.1. THESIS OVERVIEW

Chapter 1 presents a broad literature review on tinnitus, self-help interventions, and digital health interventions. The chapter starts by defining tinnitus, its risk factors, prevalence, causal mechanisms, impact, and current recommendations for management. The self-help section includes a definition of self-help interventions, discussion of the potential advantages, and description of the available evidence on the efficacy of these interventions. The current evidence-base on digital health interventions is then discussed, with regards to their efficacy, challenges and debates facing the field, and current gaps in our understanding of this area of research. Finally,

a brief description of the Tinnitus E-Programme is provided and the intervention is positioned within the Medical Research Council's guidelines for developing and evaluating complex interventions.

Chapter 2 discusses the broad methodology used for developing and evaluating complex and digital interventions, including process evaluations and the different, but complementary, approaches to intervention development. Finally, the aims and objectives, research paradigm, and the study design of this PhD is presented.

Chapter 3 presents a systematic review on the effects and techniques of unguided self-help interventions for tinnitus. This review of the current evidence-base provided the wider context in which the findings of this research were placed. Unique to this tinnitus review was the use of taxonomies from behavioural science and health psychology to systematically identify the intervention techniques used within the self-help interventions. This work enabled a comparison of the content of the Tinnitus E-Programme with other self-help interventions reported in the literature and the identification of additional techniques or components that could be included in future optimisation work.

Chapter 4 provides a comprehensive description of the Tinnitus E-Programme and highlights potential causal mechanisms by which the intervention may exert its effect. Three taxonomies were used to systematically and reliably describe the intervention components, techniques, and modes of delivery of the intervention. A literature review complemented this work by identifying potential causal mechanisms. This

intervention description was used to inform the evaluation and optimisation work in the subsequent chapters.

Chapter 5 reports on the two mixed methods studies that explored users' views and usage of the Tinnitus E-Programme. Study 1 used an online survey, with open and closed questions, with past and current intervention users (n=27), which included people with tinnitus and hearing health professionals. Study 2 recruited 13 people with tinnitus who completed the intervention for the first time, took part in a semi-structured interview, and maintained a relaxation log. Quantitative findings were analysed using descriptive statistics, and qualitative findings were analysed using thematic analysis. Findings from both studies were triangulated to compare and contrast the two complementary user perspectives. Potential mechanisms of impact of the intervention, and any implementation or contextual factors that strengthen or impede its delivery and functioning were identified.

Chapter 6 reports on the development of the Tinnitus E-Programme 2.0, an optimised version of the Tinnitus E-Programme. The Tinnitus E-Programme 2.0 was developed systematically and drew upon person-, theory-, and evidence-based approaches to intervention development to maximise its acceptability and efficacy, and ensure successful implementation. The intervention development process is reported to enable replication by other researchers and intervention developers.

Chapter 7 described the final research study, a think aloud interview study that tested the Tinnitus E-Programme 2.0 by exploring users' reactions and interactions with the

intervention. Nineteen people with tinnitus, who had not previously used the intervention, were recruited and interview data was analysed using thematic analysis. Similar to Chapter 5, findings are summarised in terms of potential mechanisms of impact of the intervention and any implementation or contextual factors that strengthen or impede its delivery and functioning.

Chapter 8 brings together the key findings from the previous chapters, generates implications for the development of digital interventions for tinnitus, and highlights future research in this area. This research was the first to systematically apply evidence-, theory- and person-based approaches to the development and evaluation of internet-based self-management interventions for tinnitus. The value and challenges of using this methodology in this context are also discussed. Recommendations are made regarding future optimisation and evaluation work for the Tinnitus E-Programme 2.0.

1.2. DEFINING TINNITUS

Tinnitus is a common medical symptom that affects approximately 10-18% of the adult population (Davis & El Refaie, 2000; McCormack et al., 2014; Park et al., 2014). The word tinnitus is derived from the Latin word ‘tinnire’ (to ring) and is defined as “the conscious perception of an auditory sensation in the absence of a corresponding external stimulus” (Baguley et al. 2013, p.1600). Commonly reported tinnitus sounds include ringing, whistling, buzzing, and hissing. In some rare cases, people have reported hearing musical sounds. Tinnitus can be continuous or intermittent and it can vary in pitch and loudness, with some people being able to hear more than one sound.

Sounds can be heard in one ear (unilateral), both ears (bilateral), or centrally within the head. Prevalence is similar across men and women and is higher with increasing age (Davis & El Refaie, 2000).

Most people experiencing tinnitus do not find it bothersome and their everyday lives remain relatively unaffected. However, for others, tinnitus can be debilitating, causing high levels of emotional distress and a significant reduction in their quality of life. In their large-scale prevalence study, Davis and El Refaie (2000) found that 2.8% of respondents described their tinnitus as moderately annoying, 1.6% as severely annoying and 0.5% at a level that severely affected their ability to lead a normal life. Tinnitus can impact an individual's quality of life in various ways including sleep disturbances, hearing difficulties, difficulties with concentration, social isolation and emotional difficulties including, anxiety, depression, irritation, or stress (Andersson & Edvinsson, 2008; Hoffman & Reed, 2004; Langguth, 2011; Tyler & Baker, 1983).

Tinnitus can be objective or subjective. Objective tinnitus is less common and is caused by a sound originating from a physical abnormality within the body that can often be heard by an observer. Most instances can be explained by vascular abnormalities or involuntary contractions of the middle ear muscles, which produce a rhythmical or pulsatile sound (Bhimrao, Masterson, & Baguley, 2012; Sonmez, Basekim, Ozturk, Gungor, & Kizilkaya, 2007). For the majority of cases, objective tinnitus can be treated medically. In contrast, the more common subjective tinnitus cannot be attributed to a physical sound source and can only be heard by person experiencing it. The causes of subjective tinnitus are less clear, leading some

researchers to categorise the disorder as ‘idiopathic’ or a 'medically unexplained symptom’ (Hiller, Janca, & Burke, 1997; Ullas, McClelland, & Jones, 2013). Subjective tinnitus is categorised as a chronic condition, as there is currently no cure or effective medical treatment. This PhD focuses on subjective tinnitus.

The main risk factors for developing tinnitus are hearing loss and prolonged noise exposure (Nondahl et al., 2011). Other conditions are associated with tinnitus including otological diseases such as Ménière’s disease, otosclerosis, and vestibular schwannoma (tumour of acoustic nerve) (Moffat, Baguley, Beynon, & da Cruz, 1998; Nondahl et al., 2011; Stouffer & Tyler, 1990). Ototoxic medications, obesity, arthritis, hypertension, head injury, anxiety, depression, and alcohol consumption have also been implicated as possible risk factors (Michikawa et al., 2010; Nondahl et al., 2011; Shargorodsky, Curhan, & Farwell, 2010; Zöger, Svedlund, & Holgers, 2001).

1.3. MODELS OF TINNITUS

1.3.1. Neurophysiological mechanisms of tinnitus

The heterogeneous nature of the tinnitus sound (i.e. variations of pitch and loudness) and its multiple risk factors has meant that its causal mechanisms are not well understood. Current concepts of the neurophysiological mechanisms of tinnitus are derived from observations of the common co-morbidity of tinnitus with hearing loss. It is hypothesised that the sensory deprivation resulting from hearing loss causes physiological and organisational changes within the central nervous system (Eggermont & Roberts, 2004). Further evidence of the involvement of central neural

mechanisms is provided by the finding that tinnitus persists, even when the auditory nerve is severed, separating the peripheral auditory system from the brain (House & Brackmann, 1981).

Research using animal models suggests four key neural changes involved in the generation of tinnitus: (1) increased neural firing rate (Chen & Jastreboff, 1995; Eggermont & Kenmochi, 1998; Seki & Eggermont, 2003); (2) increased synchronous firing patterns (i.e. neurons firing together; Ochi & Eggermont 1997; Noreña & Eggermont 2003; Bauer et al. 2008); (3) reorganisation of the frequency (tonotopic) map (Eggermont & Komiya, 2000; Rajan, Irvine, Wise, & Heil, 1993; Robertson & Irvine, 1989); and (4) abnormal neural hyperactivity in response to external sounds (Diesch, Andermann, Flor, & Rupp, 2010; Gerken, Hesse, & Wiorkowski, 2001). More recently, the homeostatic plasticity model has been developed to conceptualise how such changes within the central auditory system can lead to tinnitus generation. The model proposes that hyperactivity results from increases in central gain as the central auditory system attempts to stabilise mean firing rate in response to reduced sensory input (Noreña, 2011; Schaette & Kempter, 2006, 2012).

1.3.2. Biopsychological mechanisms of tinnitus

Although neurophysiological studies have produced promising findings, their preoccupation with tinnitus sensation fails to explain why some individuals experience greater tinnitus-related distress than others, irrespective of the sound quality of the tinnitus (Jakes, Hallam, Chambers, & Hinchcliffe, 1985), and furthermore, why not all individuals with hearing loss experience tinnitus (Nondahl et al., 2011). Recent

theoretical models argue that, although the tinnitus sensation may be caused by functional and structural neural changes, its perception, maintenance, and subsequent distress is dependent upon the involvement of larger cortical networks (i.e. prefrontal, parietal and limbic regions). These networks are responsible for emotion, conscious awareness and memory (De Ridder, Elgoyhen, Romo, & Langguth, 2011; Jastreboff, 1990, 1999; Rauschecker, Leaver, & Mühlau, 2010). Such models distinguish between the *perception* of tinnitus and an individual's subsequent *reaction* to the perceived sound. Further support for this distinction is provided by findings that have identified predisposing personality and psychological factors, such as depression, anxiety, neuroticism and life satisfaction, as early warning signs for later tinnitus distress (Andersson & Westin, 2008; Langenbach, Olderog, Michel, Albus, & Köhle, 2005; McCormack et al., 2014; Zöger et al., 2001).

The majority of what is known about the neurophysiological mechanisms of tinnitus is derived from animal models, the validity of which has been questioned (Eggermont, 2013). To date, attempts to test these mechanisms in humans using neuroimaging have been inconsistent or contradictory (Adjamian, Sereda, & Hall, 2009; Lanting, de Kleine, & van Dijk, 2009).

1.3.3. Cognitive-behavioural model of tinnitus

A cognitive-behavioural model of tinnitus has been proposed to explain how an individual's cognitions and behaviours can contribute to the development and maintenance of tinnitus distress (McKenna, Handscomb, Hoare, & Hall, 2014). Cognitive behaviour models of illness argue that individuals experience persistent

anxiety about their condition because they misinterpret the symptoms, or information about them. A combination of cognitive and behavioural processes helps to maintain these overly negative interpretations, causing the anxiety to persist. Specifically, the cognitive-behavioural model of tinnitus distress is based on Harvey's (2002) cognitive model of insomnia. It posits that people with tinnitus become distressed because they hold overly negative thoughts about tinnitus. Such negative thinking leads to physiological arousal and emotional distress and motivates a set of maintaining factors, including distorted perceptions, beliefs about tinnitus, selective attention and monitoring, and counterintuitive safety behaviours (e.g. avoiding quiet environments), that interact to further negative appraisals of tinnitus and exacerbate distress (Figure 1.1). McKenna et al. (2014) summarises the current evidence supporting their proposed components and the associated relationships but, as they highlighted themselves, the current evidence-base is modest at best. This model is currently being tested using the data from validated questionnaires with people with tinnitus and results so far have demonstrated the model to be an acceptable fit (Handscomb, Hall, Hoare, & Shorter, 2016).

1.4. MANAGEMENT OF TINNITUS

1.4.1. Limitations of a purely biomedical approach to tinnitus management

Traditionally, medicine has been dominated by a biomedical model of health and illness in which the focus is on understanding the underlying pathology of illness and curing illness through medical intervention.

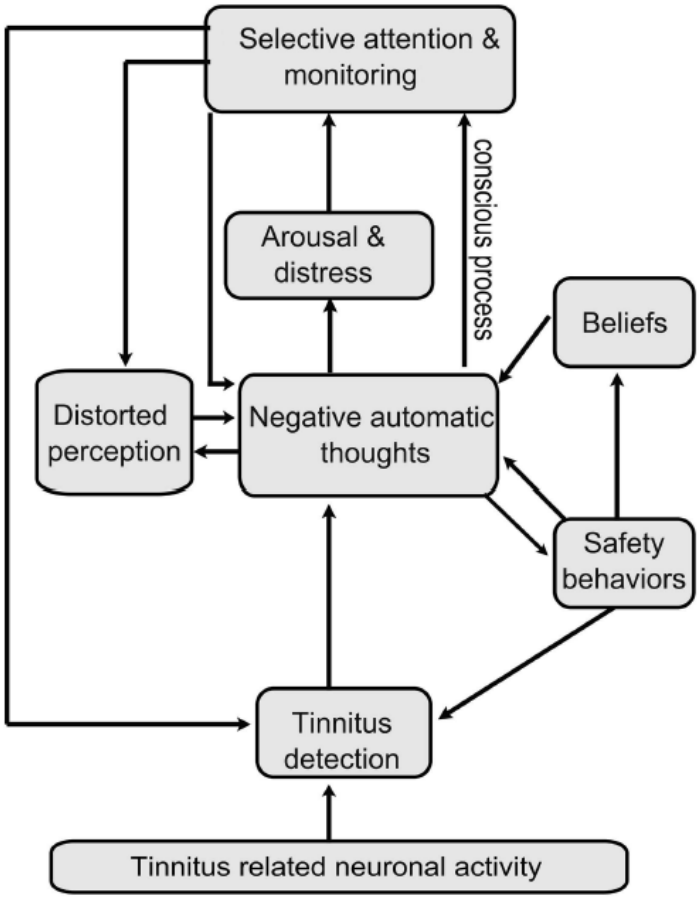

Figure 1.1 The cognitive-behavioural model of tinnitus distress (Taken from McKenna et al., 2014, p. 3)

A purely biomedical approach has limited value for tinnitus management due to the lack of medical certainty surrounding its aetiology and treatment and its subjective nature. These limitations will now be explored in turn. First, challenges associated with researching a phantom experience with multiple risk factors mean that our understanding of the pathophysiological mechanisms of tinnitus is limited and a biomedical 'cure' remains elusive. Although clear progress is being made in the field, research into biomedical therapies or treatments for tinnitus (e.g. brain stimulation, drug treatments) is still in its infancy. There is little conclusive evidence that current management options are effective (Hoare, Edmondson-Jones, Sereda, Akeroyd, & Hall, 2014; Hobson, Chisholm, & El Refaie, 2012; Meng, Liu, Zheng, & Phillips,

2011) and, in some cases, a lack of agreement among clinicians regarding the most effective management strategies for patients (Hoare, Gander, Collins, Smith, & Hall, 2012; Sereda, Hoare, Nicholson, Smith, & Hall, 2015).

Second, tinnitus sounds can only be heard by the person experiencing them, making its objective measurement (e.g. via physical examination or blood tests) impossible (Jacobson, 2000). Consequently, health professionals rely on the patient's medical history and self-report of tinnitus sensation. This poses challenges for diagnosis and assessing the appropriateness and effectiveness of various management strategies. Moreover, a sole focus on the measurement of tinnitus sensation is perhaps unhelpful, given that the characteristics of tinnitus (e.g. tinnitus loudness) are generally unrelated to an individuals' subsequent experience of distress (Jakes et al., 1985).

1.4.2. The United Kingdom model of tinnitus management

In the United Kingdom (UK), a biopsychosocial model, which takes a multidisciplinary, individual and holistic approach to tinnitus management, is generally recommended (Hoare & Hall, 2011). Although not a guide to clinical practice, the Good Practice Guide (GPG) for the provision of adult tinnitus services (Department of Health, 2009) was produced to guide commissioning of tinnitus management services, offering a first step towards standardising tinnitus care. The GPG recommends a stepped care approach in which patients enter the system at the primary care level, are triaged and managed by their general practitioner (GP) before being referred to local audiology, specialist, or supra-specialist services, depending on assessment outcome. A multidisciplinary team approach is recommended, comprising

GPs and audiologists at the early stages, with later access to consultant audiovestibular physicians, ear, nose, and throat (ENT) surgeons, hearing therapists, nurses, and clinical psychologists for those with the most complex care needs.

For subjective tinnitus, the health professionals' role is to support the patient to identify individualised management strategies that are based on a holistic assessment of the individual's subjective experience and biopsychosocial needs. Clinical assessments typically rely on structured interviews and questionnaires to measure tinnitus distress (e.g. the Tinnitus Handicap Inventory [THI]; C. W. Newman, Jacobson, & Spitzer, 1996) and psychological co-morbidity (e.g. Hospital Anxiety and Depression Scale; Zigmond & Snaith 1983) to guide management decisions (Hoare et al., 2012).

Recommended management strategies aim to address underlying hearing loss (e.g. provision of hearing aids), or reduce the tinnitus percept (e.g. provision of ear-level sound generators) or associated levels of distress, depression or anxiety. Psychological approaches are recommended that seek to understand and treat tinnitus under a cognitive behavioural model in which the identification and manipulation of cognitive beliefs is at the forefront (Hallam, Rachman, & Hinchcliffe, 1984). As such, therapies following this approach have focused on reducing physiological arousal (e.g. relaxation) and other stresses, and changing the emotional meaning of tinnitus (McKenna, 2004). For example, cognitive behaviour therapy (CBT) has demonstrably led to reduced depression and improved quality of life in people with tinnitus (Martinez-Devesa, Perera, Theodoulou, & Waddell, 2010). Acceptance-based therapies, such as Acceptance and Commitment Therapy (ACT) and mindfulness-

based cognitive therapy, have also been shown to significantly reduce tinnitus distress and improve psychological well-being, sleep, and self- efficacy (Philippot, Nef, Clauw, Romrée, & Segal, 2012; Westin et al., 2011). These therapies use acceptance-based strategies to reduce an individual's efforts to control or avoid internal experiences and pose an alternative to traditional CBT approaches.

Few audiology services have regular access to clinical psychologists as part of their service (Gander, Hoare, Collins, Smith, & Hall, 2011; Hoare, Broomhead, Stockdale, & Kennedy, 2015), which is surprising given the high rate of comorbid psychiatric symptoms among this population (Sullivan et al., 1988; Zöger et al., 2001). Furthermore, a survey of English NHS audiology departments found that the psychological support offered is variable, including stress management (67%), some form of CBT (46%) and other psychological support (9%; e.g. relaxation, acceptance and commitment therapy) (Hoare et al., 2012).

In line with current healthcare policy around chronic conditions (Department of Health, 2013) the GPG also recommends self-management as a first line of support, asserting that a patient "needs to take some responsibility for their tinnitus and hearing condition" (p.17). The emphasis is on increasing patients' knowledge of tinnitus and available management strategies through "contacting the British Tinnitus Association [a national charity], reading appropriate self-help booklets, consulting the Internet or the RNID [The Royal National Institute for Deaf People, now Action on Hearing Loss]" (p.17). Further self-management support may include advice regarding managing hearing loss or seeking medical attention for any treatable conditions such

as ear wax or infections, hypertension or medication that may cause tinnitus. Reassuringly, a recent survey of the provision of tinnitus services in the UK found that the majority of services (82%) offer written information to their patients (Hoare et al., 2015).

Although the GPG makes a positive step towards standardising tinnitus care, an evidence-based guideline for the clinical management of tinnitus does not currently exist in the UK. As such, there is little guidance regarding the most effective self-management interventions for people with tinnitus. Self-help interventions, with their patient-centred focus and independence from the medical sector, have been suggested as a potentially cost-effective form of self-management for tinnitus (Andersson et al., 2008; Tunkel et al., 2014). The concept of 'self-help' will be explored in the following section.

1.5. SELF-HELP

1.5.1. Concept of self-help

The term 'self-help' is generally poorly defined, but most commonly used to describe condition management support delivered with minimal or no contact from a health professional. This is in contrast to most forms of self-management, which are generally performed with the collaboration and guidance of an individual's health professional (Clark et al., 1991). Historically, self-help interventions have arisen to address unmet patient needs or gaps in the health service, providing alternative services when access to health professional-led interventions is limited or insufficient (Damen, Mortelmans,

& Van Hove, 2000). On the other hand, self-help can act alongside mainstream healthcare, offering additional and complementary sources of support traditionally delivered outside of the medical encounter. Throughout the literature, self-help is discussed within two main contexts: (1) Self-help as a *substitute* for health professionals; and (2) Self-help to *complement* the care provided by health professionals. Each context will be discussed in turn.

1.5.2. Psychological models: Self-help as a substitute for health professionals

Within this context, self-help interventions aim to overcome healthcare resource issues by improving access to psychological services. Such self-help interventions offer an alternative to traditional face-to-face services and involve "an individual progressing unaided through print or online evidence-based therapeutic resources in their own time and at their own pace" (Beatty & Lambert 2013, p. 610). Therapeutic resources are available in a variety of media, including self-help books (bibliotherapy), the internet, smartphones, computer packages, DVDs, and audiotapes.

The provision of self-help is recommended within several National Institute for Health and Care Excellence (NICE) guidelines for mental health services (NICE, 2009, 2011a, 2011b) as a relatively low-cost way of improving access to psychological services for common mental health conditions, such as depression, anxiety, and panic disorder (Department of Health, 2011). Through a stepped care approach, self-help tends to be aimed at those experiencing mild-to-moderate distress with more time- and resource-intensive face-to-face services being reserved for those with the most complex needs (NICE, 2011a). Self-help interventions have also been used to reduce

distress and improve disease-control among those with physical health conditions (Beatty & Lambert, 2013).

Resources can be identified and accessed by individuals independently (e.g. via libraries, bookshops, the Internet) or prescribed by health professionals (e.g. 'Reading Well Books on Prescription' scheme; The Reading Agency 2016). Guided self-help can also be offered where progression through the self-help resources is supported by minimal guidance from a health professional, whereas 'pure' self-help is delivered without health professional contact.

Psychological self-help can offer particular benefits over face-to-face therapy. It allows patients to work at their own pace, offers an alternative service to those unwilling to access traditional psychotherapeutic interventions due to the anticipated stigma associated with doing so, and improves access for those hard of hearing or unable to travel to clinical consultations (Cuijpers, Van Straten, & Andersson, 2008; M. G. Newman, Szkodny, Llera, & Przeworski, 2011; C. Williams & Whitfield, 2001). Self-help also allows patients to revisit treatment to reinforce or consolidate learning or deal with relapse (C. Williams & Whitfield, 2001).

1.5.3. Empowerment models: Self-help to complement the care provided by health professionals

The term self-help has also been discussed within an empowering context whereby self-help provides an additional and complementary form of support not typically

offered within mainstream healthcare services. In this context, the term self-help is used to define the mutual aid and informal support provided by individuals within a community who share common experiences, such as addiction or having a chronic condition (Finn, 1999; White & Dorman, 2001). Such support is generally offered in the form of self-help groups, which are largely independent of the medical sector, typically controlled by its members, rather than professionals (Humphreys & Rappaport, 1994).

With rising computer use, increasing numbers of people with chronic conditions are now accessing online support groups, including discussion groups or chat rooms. Similar to psychological self-help, online support groups allow individuals to participate when it suits them and at their own pace, and provide alternative access for those unable or unwilling to attend to face-to-face groups (Coulson, 2013; Coulson, Buchanan, & Aubeeluck, 2007; Coulson & Knibb, 2007). Furthermore, the greater anonymity provided by these groups allow members to self-disclose or discuss sensitive issues which they may have felt unable to do in face-to-face groups (Campbell, Coulson, & Buchanan, 2013; Coulson, 2013; Coulson et al., 2007).

Several authors have suggested that empowerment mechanisms, by which individuals gain mastery and control over issues affecting their lives, are central to these models of self-help (Rappaport, 1987; Zimmerman, 1995). van Uden-Kraan et al. (2008) identified several empowering processes associated with participation in online support groups including exchanging information, encountering emotional support, finding recognition, helping others, and amusement. Furthermore, self-help groups

offer valuable opportunities for social comparison, allowing individuals to evaluate their own situation (Dibb & Yardley, 2006).

Irrespective of their underlying motivations, a key component of both contexts is the lack of (or minimal) contact with health professionals, whether the aim is to substitute or complement the care they provide. Furthermore, these two contexts are not mutually exclusive. For example, an intervention developed in response to poor access to psychological services (substitution) can also influence empowerment processes (complementary).

1.5.4. Efficacy of self-help interventions for tinnitus

Nyenhuis, Golm, and Kröner-Herwig (2013) carried out a systematic review and meta-analysis of minimal contact CBT self-help interventions for tinnitus. They identified ten randomised controlled trials (RCTs) of self-help interventions delivered via books or the internet. Meta-analysis demonstrated that self-help interventions significantly reduced tinnitus distress and depressiveness compared to passive control conditions (waiting list, information only, online discussion forums). However, their sensitivity analysis suggested that publication bias might have led to an overestimation of effect sizes for this comparison. There was no difference in outcomes between self-help interventions and active controls (face-to-face counselling or group treatments), but only four studies were included in this analysis. Moreover, the presence of the therapist in the guided self-help approaches did not influence the results. The findings of this review must be interpreted with caution as none of the studies met the criteria for high methodological quality.

1.6. DIGITAL HEALTH INTERVENTIONS

Digital health interventions are a specific type of self-help intervention that utilise a range of technology mediums (e.g. websites, smartphones, email, DVDs, SMS text messaging) to promote behaviour change and/or support self-care or self-management (Bradbury, Watts, Arden-Close, Yardley, & Lewith, 2014; West & Michie, 2016). Interventions may use one or a combination of these different mediums. Compared to other self-help intervention mediums such as books, digital health interventions can be easily updated and distributed to a vast audience, and can incorporate a variety of interactive design features (e.g., e-mail, online support forums, tailored content) that may improve user engagement with the intervention (Alkhaldii et al., 2016; Morrison, Yardley, Powell, & Michie, 2012). It is argued that digital interventions are a relatively low-cost intervention, as most of the costs are limited to the initial development phase. However, evidence on the cost-effectiveness of these interventions is limited (Kaltenthaler et al., 2006; Tate, Finkelstein, Khavjou, & Gustafson, 2009).

Systematic reviews and meta-analyses have demonstrated the efficacy of digital interventions across a variety of health outcomes (e.g. health behaviour, disease control, and psychological distress) and heath conditions (e.g. mental health, chronic pain, hypertension) (Beatty & Lambert, 2013; Kaltenthaler et al., 2006; Macea, Gajos, Daglia Calil, & Fregni, 2010; Spek et al., 2007; Webb, Joseph, Yardley, & Michie, 2010). Within the tinnitus field, internet-based CBT interventions targeted at reducing tinnitus distress have shown promising results (Andersson, 2002; Nyenhuis, Zastrutzki, Weise, Jäger, & Kröner-Herwig, 2013). They have delivered outcomes that

are comparable to those observed in traditional face-to-face therapy (Jasper et al., 2014; Kaldo et al., 2008).

Although digital health interventions have great potential, there are also several challenges and debates facing the field. One advantage of self-help, and specifically digital interventions, is that they have the potential to be far reaching so promote equity of access to health services. However, some have argued that a move towards digital interventions could in fact widen the health inequalities gap (Eng et al., 1998; McAuley, 2014). Although the 'digital divide' is ever-decreasing (Office for National Statistics, 2014a, 2014b), internet usage remains low among the most elderly among the general population (37% among those above 75; Office for National Statistics, 2014b) and those with hearing difficulties (30% among those 63-74 years; Henshaw et al., 2012).

Engaging in digital interventions requires a high level of motivation and users must possess an ability to work on their own (Bendelin et al., 2011; Macea et al., 2010). The intervention's reliance on written content may also pose barriers to those with poor health literacy. However, progress in this area is being made. Researchers who have paid particular attention to overcoming issues of access, accessibility, and health literacy in their digital interventions have shown that these can reach disadvantaged groups such as vulnerable elderly adults (Billipp, 2001) and those with poor health literacy (Rowsell et al., 2015).

Digital health interventions have also been criticised for being prone to dropout and non-usage attrition (Eysenbach, 2005), especially those followed independently by the user without any contact with a health professional (Baumeister, Reichler, Munzinger, & Lin, 2014). Studies of internet-based tinnitus interventions have reported high attrition rates (up to 38% in some studies [e.g. Andersson et al., 2002]). However, these rates are comparable to those found in their face-to-face group therapy conditions (Jasper et al., 2014; Nyenhuis, Zastrutzki, Jager, & Kroner-Herwig, 2013) suggesting that this disadvantage is not unique to digital interventions.

A widely debated issue in self-help and digital interventions is the role of the therapist or health professional. Unguided self-help interventions have been found to have smaller effect sizes compared with therapist-guided interventions (Baumeister et al., 2014; Spek et al., 2007), but in tinnitus studies the evidence is mixed (Nyenhuis, Golm, et al., 2013). Ebert et al. (2014) argued that effect sizes may be larger at the population level due to the improved accessibility of unguided interventions to individuals unable or unwilling to access therapist-guided interventions. In a UK context, unguided internet-based interventions for tinnitus are also consistent with a local model of care in which access to psychology services is extremely limited.

1.7. GAPS IN THE CURRENT EVIDENCE-BASE

Across digital interventions research, there is little understanding about the mechanisms of impact of these interventions (Murray, 2012). In tinnitus, most research has focused on the efficacy of self-help and digital interventions and, as such, there is little understanding about what makes these interventions successful (or not). Such an

understanding is important for two reasons. First, identifying an intervention's 'active ingredients' enables improved replication in clinical practice or research (Michie & Abraham, 2004). Second, it can contribute to our understanding of why an intervention worked, did not work as intended, or resulted in unexpectedly small effect sizes (Craig et al., 2008; Michie & Abraham, 2004). This knowledge can subsequently be used to improve failed interventions or maximise the success of newly developed interventions.

Researchers have suggested several broad intervention features that are associated with better outcomes for self-help and digital interventions, including the presence of a theoretical foundation (Albarracín et al., 2005; Webb et al., 2010), greater use of behaviour change techniques and provision of specific techniques (e.g. CBT, stress management, goal setting, action planning) (Gellatly et al., 2007; Webb et al., 2010), therapist contact (Gellatly et al., 2007), provision of social support (e.g. through online support forums), tailoring (Morrison et al., 2012), and intervention adherence and credibility (El Alaoui et al., 2015).

Quantitative studies of tinnitus digital interventions found that the following factors were associated with intervention outcomes: intervention adherence or attrition (Jasper et al., 2014; Kaldo-Sandström, Larsen, & Andersson, 2004; Kaldo et al., 2013), external referral to the intervention, amount of previous tinnitus treatments, number of emails between therapist and patient about negative aspects of the intervention (e.g. incomplete homework, technical problems) (Kaldo-Sandström et al., 2004), stage of change (i.e. readiness to change behaviour and attitudes in relation to tinnitus; Kaldo

et al., 2006), and beliefs that the intervention will be of benefit (Rheker, Andersson, & Weise, 2015). In contrast, other research found that user ratings of intervention credibility and satisfaction (Kaldo et al., 2008), therapist time spent delivering the intervention, perceptions of intervention suitability, and fear of change (Rheker et al., 2015) did not affect the treatment outcome. Hesser et al. (2013) also found that acceptance of tinnitus mediated changes in outcome for internet-based CBT and ACT interventions. One study explored the impact of the characteristics of people with tinnitus on digital intervention outcomes and found that higher self-reported ratings of tinnitus loudness at pre-intervention (but not age, sex, or tinnitus duration) predicted more improvement in tinnitus distress post-intervention (Rheker et al., 2015). Although this research provides a promising start, further work is needed to determine the factors that make a tinnitus digital intervention successful.

With a focus on efficacy in the tinnitus literature, there is also a dearth of research into the perspective of the target user, that is, people with tinnitus. Some intervention studies for tinnitus have assessed user satisfaction and perceptions of intervention credibility, with mixed results. Nyenhuis, Zastrutzki, Jager, et al. (2013) found that user satisfaction was comparable between those who received their internet-based and group therapy tinnitus interventions. In contrast, Jasper et al. (2014) found that user satisfaction was higher among those who received their group therapy, compared to those who received their internet-based intervention. Moreover, participants in the group therapy also rated this intervention as more credible and helpful, and more participants preferred the group therapy (46%) to the internet-based intervention (21%; the remaining participants had no preference) at baseline. Both studies assessed self-reported quantitative ratings of satisfaction, credibility, and preferences, thus

providing little understanding on why users gave the ratings they did, what caused the differences in ratings, and how these ratings could be improved.

Beukes et al. (2016) carried out an online survey to explore tinnitus users' satisfaction with their internet-based CBT intervention to test the technical functionality of the intervention and demonstrated a high level of satisfaction among users. Unlike the other two studies, they did include open-ended questions to explore user satisfaction in more depth. This qualitative data identified some suggested improvements from users, including modifying the rating scales and response options for the weekly and screening questionnaires, and providing personalised, instead of anonymised, communications. Research that develops an in-depth understanding of the users' perspective is important for maximising user engagement, and the acceptability and effectiveness of digital interventions (Yardley, Ainsworth, Arden-Close, & Muller, 2015; Yardley, Morrison, Bradbury, & Muller, 2015).

1.8. THE TINNITUS E-PROGRAMME

One digital intervention that is currently available in the UK is the Tinnitus E-Programme (Featherstone 2015; Greenwell et al. 2015; www.webcitation.org/6a16EjlqD), an internet-based intervention for tinnitus self-management (see Appendix 1 for screenshots). It was developed by a hearing therapist/psychotherapist based in private practice. It was launched in 2009 and is free at point of access. The intervention is delivered over ten-weeks and consists of education about tinnitus, CBT techniques, and relaxation techniques (Appendix 2). The programme is delivered using various methods including information sheets,

digital relaxation music, and optional CBT workbooks (provided at a cost). Participants have the option to join a professional- and lay-moderated online support forum where they can communicate with other intervention users. The intervention content is delivered over six weekly sessions, followed by a four-week maintenance period during which participants are expected to practice the relaxation skills they learned during the first six weeks. Although a recommended course structure is given, participants have a free choice regarding which components they access and in what order. Users do not need to register to gain access to the programme but are encouraged to do so in order to provide feedback on the intervention and submit their individual scores on the THI (Newman et al. 1996).

The Tinnitus E-Programme was chosen as a focus of this research for several reasons. First, it is the only internet-based intervention that is currently available in the UK. Hearing professionals in the UK are aware of the intervention and currently refer patients to it (Hoare, Watts, Broomhead, Stockdale, & Greenwell, 2016). Second, its intervention components are based on CBT, directive counselling (i.e. information/education), and relaxation therapy. These treatments are recommended in the GPG and there is good evidence for the effectiveness of CBT in reducing tinnitus distress (Hoare, Kowalkowski, Kang, & Hall, 2011; Martinez-Devesa et al., 2010; Nyenhuis, Golm, et al., 2013). Third, with its use of an online support forum and self-help materials, it can be argued that the intervention provides a bridge across the two self-help contexts outlined earlier (Section 1.5.2-1.5.3). Fourth, a preliminary evaluation carried out by the intervention developer has already demonstrated promising findings (Featherstone, 2012), and the intervention's reasonably high usage (the website is visited by approximately 1000 people per month; Featherstone, 2014)

demonstrates an element of acceptability to its target group. Although this preliminary data establishes a reasonable proof of concept, the intervention has not yet undergone any formal or independent evaluation. Providing a strong evidence-base for health interventions is important for developing standards for high quality care, facilitating sound decision-making by patients and health professionals, providing accountability for service providers and avoiding patient harm (Sackett, Rosenberg, Gray, Haynes, & Richardson, 1996; Spring, 2007).

Finally, the decision to evaluate an established intervention, rather than develop an original intervention from conception has certain practical advantages. It can be difficult to elicit users' views on an intervention they have not fully experienced as these views can quite often change once the users have tried the intervention (Gray, Barfield, Haselkorn, Spyridakis, & Conquest, 1990; Karlin & Klemmer, 1989). Moreover, the research team has an established relationship with the intervention developer, which would allow us access to the intervention for the purposes of evaluation and future optimisation work. For distinction, the intervention is referred to as Tinnitus E-Programme 1.0 from this point forward.

1.9. POSITIONING THE INTERVENTION WITHIN THE FRAMEWORK FOR DEVELOPING AND EVALUATING COMPLEX INTERVENTIONS

Digital health interventions can be defined as complex interventions through their use of multiple interacting components and potential outcomes (Craig et al., 2008). For example, a CBT-based intervention may have cognitive (e.g. changing negative

thoughts) and behavioural (e.g. practicing relaxation) components, leading to potential changes in emotional (e.g. reduced psychological distress), functional (e.g. improved sleep), or behavioural (e.g. increased use of relaxation) outcomes.

In 2008, the Medical Research Council (MRC) published a highly influential framework to provide guidance to researchers on overcoming some of the unique challenges associated with developing and evaluating complex interventions (Craig et al., 2008). The framework recommends four key stages of the development and evaluation process (Figure 1.2). These stages are not linear but represent an iterative process whereby researchers move back and forward between the stages. This ensures that interventions are systematically tested and improved, with any modifications being informed by an evolving evidence-base. The framework emphasises that intervention development should be informed by the current evidence-base and appropriate theory. Through this, researchers can outline the causal mechanisms that identify the active ingredients within the intervention and explain how they exert their effect.

All of the stages are equally important. For example, paying inadequate attention to the development and feasibility/piloting phase can lead to weak interventions that are difficult to evaluate. The framework recommends that interventions should be tested using a phased approach through a series of pilot and exploratory studies that address any 'uncertainties' in the intervention design before carrying out a definitive RCT to assess effectiveness ('evaluation stage') and implementing the intervention into practice ('implementation stage').

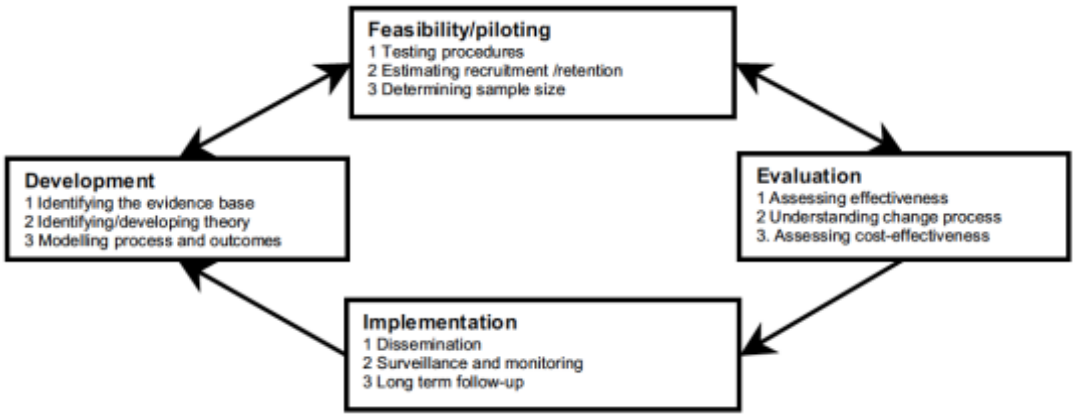

Figure 1.2 The key elements of the development and evaluation process for complex interventions (Taken from Craig et al., 2008, p.8)

Such piloting work avoids repetitive trialling-modification-trialling cycles which can be time consuming and expensive (Collins, Murphy, Nair, & Strecher, 2005).

In terms of the Tinnitus E-Programme 1.0's position in this framework, the intervention is currently at the 'implementation stage', because it is currently being delivered to people with tinnitus. However, there are many uncertainties surrounding the intervention, as the intervention is yet to undergo a formal process or outcome evaluation. Mainly, little is known regarding the intervention's usage and acceptability among its target users, whether the intervention is being implemented as intended, and the causal mechanisms by which it exerts its affect. Addressing these key uncertainties will provide the missing evidence-base needed to guide future development or evaluation work (e.g. choosing appropriate assessment measures), thus maximising its likelihood for success during a definitive efficacy trial.

This PhD aims to evaluate and optimise the Tinnitus E-Programme 1.0. The next chapter discusses the broad methodology used for developing and evaluating complex and digital interventions. This discussion informed the development of the PhD objectives and study design, which are outlined in Sections 2.4 and 2.6, respectively.

CHAPTER 2. METHODOLOGY

This chapter provides a broad introduction to the methodology used in the development and evaluation of complex and digital interventions.

2.1. INTERVENTION DEVELOPMENT

Intervention development is a broad term used to describe the planning, designing, creation, and modification (or optimisation) of an intervention. In some cases, it can be extended to include the evaluation and implementation stages as these stages can lead to further modifications to the intervention. In line with this, the development, evaluation and implementation of an intervention is seen as an iterative process, with each stage informing the other. There are three main approaches that have been used to develop or optimise complex interventions: evidence-, theory-, and person-based approaches. These approaches have also been used to develop digital interventions.

2.1.1. Evidence-based approaches

Consistent with an evidence-based approach, systematic reviews and meta-analyses of the existing literature have been used to identify determinants of behaviour change and effective intervention techniques (Band et al., 2017; Yardley, Ainsworth, et al., 2015). The MRC guidelines for developing and evaluating complex interventions recommend that intervention development should be informed by an up-to-date evidence-base, ideally collected through a systematic review (Craig et al., 2008).

2.1.2. Theory-based approaches

In theory-based approaches, theories from behavioural science and health psychology provide frameworks for deciding on the likely influences on outcome and the most appropriate techniques for improving these outcomes. The MRC guidelines also recommend the use of appropriate theory in intervention development (Craig et al., 2008). Indeed, more extensive use of theory is shown to predict larger effect sizes for behaviour change interventions (Albarracín et al., 2005; Webb et al., 2010). There are two main methodologies used in theory-based approaches: behavioural analysis and logic modelling. Behavioural analysis involves examining what needs to change in a person or their environment to facilitate behaviour change and comprehensively mapping out all of the elements of an intervention that are required for this change to occur. A logic model is a diagrammatical method that describes the hypothesised mechanisms of impact and/or maps the behavioural determinants and behaviour change techniques. Its use is recommended by the MRC process evaluation guidelines (Moore et al., 2014; Section 2.2). Two main theory-based tools that have been used for guiding intervention development: the behaviour change wheel and the behaviour change technique taxonomy.

2.1.2.1 Behaviour change wheel

One theory-based tool was developed by Michie et al. (Michie, Atkins, & West, 2014; Michie, Van Stralen, & West, 2015). Their behaviour change wheel (BCW; Figure 2.1) provides a systematic framework for designing and describing behaviour change interventions and has been recommended for use in audiology (Coulson, Ferguson,

Henshaw, & Heffernan, 2016). The wheel helps the intervention developer to identify what needs to change in the person or environment in order to achieve the desired behaviour (e.g. improve users' capabilities to perform a behaviour), and the intervention content that needs to be in place for this change to occur (e.g. provide education or skills training). To ensure intervention development is grounded in theory, it also links the changes that need to occur to specific theoretical domains. A theoretical domain is defined as "a group of related theoretical constructs" (Michie et al., 2005, p. 33), where a theoretical construct is a component part of a theory. For example, the constructs of 'goal setting' and 'action planning' come under the domain of 'goals'.

The inner most circle of the BCW includes the three inter-related components (or 'sources of behaviour') that are proposed to generate behaviour: (1) Capability – an individual's physical and psychological capabilities (e.g. knowledge and skills) for performing the behaviour; (2) Opportunity – all of the physical and social aspects of the environment, outside of the individual, that make the behaviour possible; (3) Motivation – an individuals' drive to perform the behaviour, including automatic (e.g. habit, desires, and impulses) and reflective (e.g. planning and choice) processes (named the COM-B model; Figure 2.2). Each component can be broken down further into two types of capability (physical or psychological), motivation (reflective or automatic), and opportunity (physical or social).

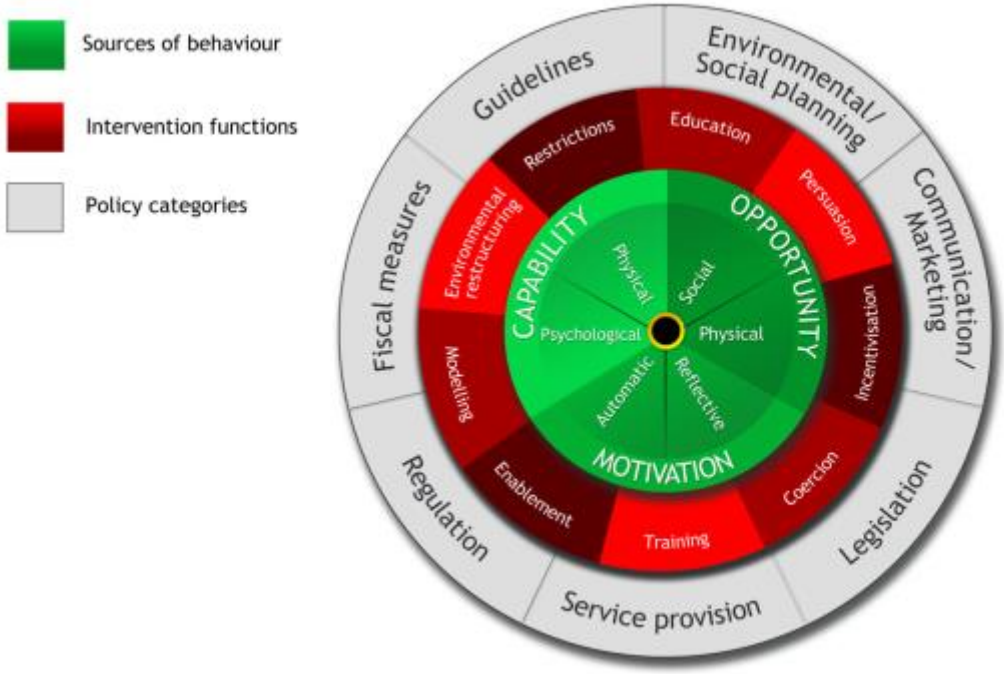

Figure 2.1 Behaviour change wheel (Taken from Michie et al., 2015, p.7)

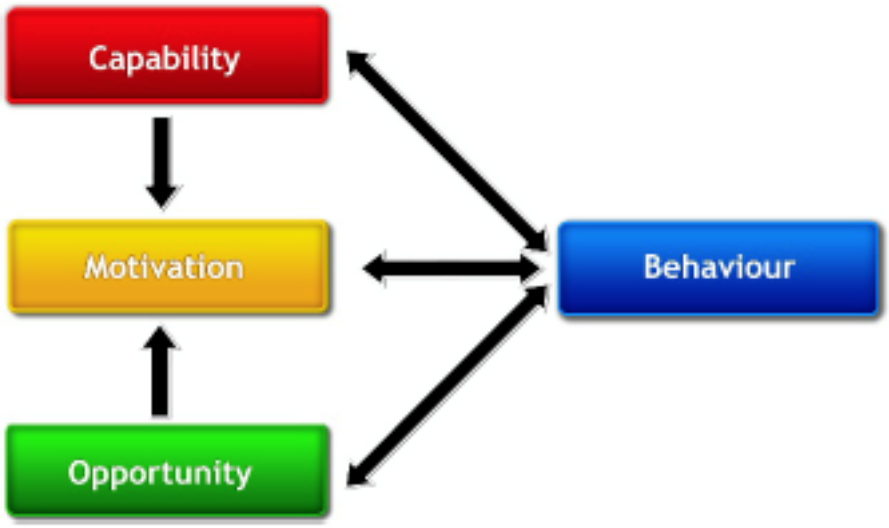

Figure 2.2 The COM-B model (Taken from Michie et al., 2015, p. 4)

To identify what specifically needs to change, the BCW links the three components of the COM-B model to the Theoretical Domains Framework (TDF; Michie et al., 2005; Cane et al., 2012), which lists 14 different theoretical domains (Table 6.3; not detailed in Figure 2.1). The TDF is an integrative framework that brings together the key theoretical constructs used in behaviour change theories. It was developed collaboratively between psychologists and health service researchers.

The middle layer of the BCW provides nine different 'intervention functions', which include nine broad categories of ways by which an intervention can change behaviour (e.g. education, training). Finally, the outer layer details seven types of policy that can be used to deliver the intervention functions (e.g. service provision, guidelines).

2.1.2.2 Behaviour change techniques taxonomy

The BCW also links the intervention functions to one or multiple behaviour change techniques (BCTs), which are defined as "the smallest components of behaviour change interventions that on their own in favourable circumstances can bring about change" (Michie, Johnston, et al., 2014, p.2). For example, the broad intervention function 'training' may include several behaviour change techniques, such as 'demonstration of the behaviour' and 'instruction on how to perform the behaviour'. To help identify and report the BCTs present in an intervention, the behaviour change techniques taxonomy (BCTv1; Michie et al., 2013) was developed. It lists 93 BCTs that can be used in any given behaviour change intervention. The main limitation of the behaviour change wheel and BCTv1, regarding this research, is that it is specific to behaviour change interventions. As such, it may miss some of the theoretical

domains or techniques unique to self-help or self-management of long-term conditions (e.g. education about the condition, illness perceptions, acceptance). However, an alternative approach that will overcome these limitations is currently lacking. Other available taxonomies and frameworks for identifying self-management components (e.g. Taylor et al., 2014), the design features (e.g. Morrison et al., 2012) or modes of delivery (Webb et al., 2010) in digital interventions are not as comprehensive as the BCW and BCT. These alternatives will be discussed in more detail in Sections 3.3.8, 4.3, 6.3.2, and 8.4.

Typically, theory-based approaches, such as the BCW and BCTv1, are used in a top-down manner, whereby the findings of the behavioural analysis dictate the intervention techniques used. However, other researchers have also taken a bottom up approach where they map their current intervention onto the techniques and theoretical domains (Band et al., 2017).

2.1.3. The person-based approach

The person-based approach was developed by Yardley et al. (2015) to complement and enrich theory- and evidence-based approaches. It achieves this by providing an understanding of the most effective way of applying the theoretical models and intervention techniques or exploring which of the many intervention techniques are most appropriate for a specific target group. It asserts that intervention development should be grounded in "a profound understanding of the perspective and psychosocial context of the people who will use them, gained through iterative in-depth qualitative research" (Yardley, Morrison, Bradbury, & Muller, 2015, p.2). Through this, the

person-based approach aims to maximise intervention acceptability, feasibility, and user engagement.

Yardley et al. (2016) defines engagement with digital health interventions on a 'micro' and 'macro' level. The micro level of engagement is concerned with the "moment-to-moment engagement with the intervention" (p.834). This type of engagement typically focuses on the technology, specifically intervention usability and usage, and the factors that influence these concepts. Comparatively, the macro level of engagement is concerned with the wider intervention goals, such as behaviour change or self-management, and the factors that strengthen or impede users' abilities to achieve these goals. Yardley et al. (2016) proposes that these two levels are closely linked and that their relationship will vary depending on the intervention, the user, and their context.

Consistent with these definitions, the person-based approach goes beyond the usability testing typically used in this field, where the focus is on ensuring the technology is usable and engaging to its users. It also explores the acceptability and satisfaction with intervention content and the extent to which the intervention leads to changes in behaviour or enhanced well-being. Since the publication of the person-based approach in 2015, the use of this approach has been reported in several intervention development papers (Band et al., 2017; Essery et al., 2015; Yardley, Ainsworth, et al., 2015) and it has been adopted into recommendations for developing digital interventions (West & Michie, 2016).

The person-based approach can be used at any stage of the intervention's lifespan, including the planning (e.g. to identify user needs and potential challenges the intervention must overcome), development and evaluation of acceptability and feasibility (e.g. understanding users' reactions to the various intervention components and modifying the intervention accordingly), and implementation and trialling (e.g. to identify further modifications to improve implementation in future contexts) stages. The approach recommends creating a set of 'guiding principles' to guide design. The intention is that these guiding principles are consulted throughout intervention development to ensure that the intervention is underpinned by a coherent focus. Guiding principles consist of a set of intervention design objectives and the key intervention features that can achieve these objectives.

Yardley, Morrison, Bradbury, and Muller (2015) suggests three common guiding principles that are important for improving the acceptability and engagement in all digital interventions: (1) To promote user autonomy; (2) To promote user competence; and (3) To promote a positive emotional experience and sense of relatedness. These common guiding principles were informed by Yardley et al.'s experience of intervention development, as well as the self-determination theory (Ryan & Deci, 2000). The self-determination theory proposes that people are more likely to engage in behaviour (e.g. engagement with the intervention, practicing relaxation) if they have the intrinsic motivation to do so. That is, they are choosing to do the behaviour themselves, rather than responding to external pressures to do so. Moreover, it is argued that intrinsic motivation can be enhanced by promoting user autonomy (i.e. behaviour is under volitional control), a sense of relatedness (i.e. support from and

connection to others), and user competence (i.e. confidence and ability to perform a behaviour).

The person-based approach provides some example design features that can be used to address the three common guiding principles. First, user autonomy can be promoted by providing users with a choice regarding how they use the intervention or practice the behaviours (e.g. provide a choice of relaxation exercises). Second, a positive emotional experience and sense of relatedness can be promoted by providing online support forums or information about other users, using positive (autonomy-supportive) language, giving rationale for advice, and acknowledging and addressing user concerns. Furthermore, it is recommended that interventions follow best practice guidelines for maximising accessibility, usability, and credibility to improve the user experience. Finally, user competence can be enhanced by providing clear structure and guidance, and minimising conscious effort and lifestyle disruption, where possible.

2.1.4. Combining evidence-, theory-, and person-based approaches

Yardley, Morrison, Bradbury, and Muller (2015) proposes that the person-based approach should be complemented by theory- and evidence-based approaches. However, as the person-based approach was only published in 2015, there is currently little guidance on how to do this in practice. Band et al. (2017) were the first to describe attempts to integrate the person-based approach with theory- and evidence-based approaches for their 'HOME BP' intervention, a digital intervention for primary care patients with hypertension. Consistent with the person-based approach, they carried out primary qualitative research and synthesised relevant qualitative literature to

gather an in-depth understanding of the user perspective. The findings from this work were integrated with additional evidence collected through consultations with experts and a quantitative systematic review to inform intervention design. Complementary to this work, Band et al. (2017) also used person-based (i.e. creation of guiding principles) and theory-based approaches (i.e. behavioural analysis, logic modelling) to theoretically model the intervention, in order to identify and target the determinants of behaviour.

2.1.5. Approaches currently used in tinnitus

In the field of tinnitus, few researchers have reported on how their digital interventions were developed, so little is known about the approaches used. Recently, Beukes et al. (2016) provided the first comprehensive description of the development of an internet-based intervention for tinnitus. Although they did not explicitly reference the approaches used, they did integrate elements of the three approaches outlined above. To some extent, the intervention was theoretically-based because it was informed by the principles of CBT and these principles broadly informed the techniques that were included (e.g. cognitive restructuring). They also used Ritterband, Thorndike, Cox, Kovatchev, and Gonder-Frederick's (2009) behaviour change model for internet interventions to guide development, but details on how the model was used were not provided. Although they referenced the use of ‘behaviour change techniques’, they do not explicitly report the specific techniques used. Moreover, no attempts were made to describe or understand the underlying mechanisms by which the behaviour change and CBT techniques provided in the intervention exerted their effects.

With regards to evidence-based approaches, the authors did attempt to integrate evidence on the most effective intervention design features, although this evidence was not collected systematically and derived mainly from research and clinical experience (e.g. Andersson et al., 2009). Similar to the person-based approach, the authors generated eight principles that guided their development. Although the users' perspective was not incorporated during the initial development phase, they did explore users' satisfaction with the first version of the intervention and used these findings to further optimise the original intervention.

In the field of audiology, taxonomies have been used to identify the BCTs employed by audiologists during hearing-aid fitting consultations (Barker, MacKenzie, & de Lusignan, 2016). However, to date, they have not been used for reporting the techniques used in audiology digital interventions.

2.2. PROCESS EVALUATION

Outcome evaluations provide information on whether the intervention is effective, but leave many unanswered questions. For example, if an intervention is found to be ineffective, is this because the intervention does not work, or is it because the intervention was not implemented as intended? A useful first step when evaluating established interventions is to carry out a process evaluation. The MRC guidelines on process evaluation for complex interventions (Moore et al., 2014) outlined three different components of the intervention that a process evaluation should address: (1) mechanisms of impact; (2) implementation; and (3) contextual factors that influence the delivery and outcome of the intervention.

Mechanisms of impact is concerned with the processes by which the intervention components, and a user's interactions with them, produces the desired outcome (Moore et al., 2014). That is, how do the interventions work and what are the factors that are important for making them work? Exploring users' reactions and interactions with interventions can be particularly helpful. Typically, participant reactions are explored in terms of 'satisfaction' or 'acceptability' of the intervention. Qualitative methods can be particularly helpful for exploring how change is produced in the short- and long-term and identifying unintended and/or unanticipated intervention consequences (Grant, Treweek, Dreischulte, Foy, & Guthrie, 2013). This may include identifying negative intervention outcomes or benefits not initially anticipated by the intervention developers or evaluators. For example, in a mixed-methods evaluation of psychological therapies for multiple sclerosis, Dennison et al.'s (2013) qualitative interview findings uncovered a disparity between participants' perceptions of what the therapy changes were and the predetermined outcomes measured in the parallel efficacy trial.

Implementation is concerned with how delivery is achieved (i.e. the structures and resources required for successful implementation) and the quality and quantity of what is actually delivered (Moore et al., 2014). It is typically conceptualised in terms of fidelity (i.e. was the intervention delivered and used as intended?), dose (i.e. how much of the intervention was delivered and received?), and reach (i.e. to what extent did the intervention reach its target audience?). In the view that users are not merely passive recipients of these interventions, other researchers have extended the definition of fidelity to include the concepts of user engagement (i.e. the quality of the user experience), adherence (i.e. the extent to which users adhere to the intervention as it

was outlined by its developers), and enactment (i.e. the extent to which the knowledge or skills users acquired during the intervention were applied to everyday life) (Bellg et al., 2004; Carroll et al., 2007; Lichstein, Riedel, & Grieve, 1994). Enactment is more commonly explored in behaviour change research where integrating new actions into everyday life is the ultimate outcome of interventions (Webb et al., 2010). It has rarely been studied in research on interventions addressing psychosocial outcomes (Lichstein et al., 1994), with most research focusing on dropout or non-usage attrition (Geraghty, Wood, & Hyland, 2010a; Kaldo et al., 2013; Nyenhuis, Zastrutzki, Jager, et al., 2013).

Another important aspect of implementation is the extent to which the intervention was embedded or 'normalised' into everyday healthcare practice (May & Finch, 2009). In the context of digital interventions, it can be helpful to carry out usability testing to identify and eliminate any barriers to easy and effective use by its target population (Bradbury et al., 2014). Exploring intervention usage or attrition can also provide useful implementation insights (Arden-Close et al., 2015).

Context is concerned with how factors that are external to the intervention may strengthen or impede its delivery and functioning (Moore et al., 2014). External factors may include pre-existing conditions, skills, resources, or attitudes. A thorough understanding of the intervention context is helpful for explaining any variability in intervention outcomes, for example, why the intervention worked for some users but not others.

Across the literature, the concepts of mechanisms of impact, implementation, and context are not clear-cut. For the purposes of this thesis, mechanisms of impact will be used to describe user acceptability and satisfaction with the intervention, and factors relating to the intervention that may influence user engagement or enactment. Implementation will refer to users' actual intervention usage and enactment. Contextual factors include any factors external to the intervention that may influence a user's engagement, enactment, or benefits gained from the intervention.

The MRC guidance also proposes two complementary components that may influence a process evaluation. Process evaluations should be informed by, and make a contribution to, a clear description of the intervention and its causal assumptions (Section 2.1.2) and, an understanding of the intervention outcomes. The ultimate aim of a process evaluation is to identify the pathways by which the intervention and its underlying causal assumptions are linked to the intervention outcome. This process is iterative and intervention descriptions and causal assumptions may need to be modified as the evaluation progresses.

2.3. METHODS FOR EVALUATING INTERVENTIONS

There are several available methods for testing interventions. This section discusses the evaluation methods used in this PhD study – online surveys, retrospective semi-structured interviews, and think aloud interviews – as well as alternative and complementary methods that were considered but not used. The choice of methods used was guided by the person-based approach, which recommends the use of in-depth qualitative methods to understand the users' perspective.

2.3.1. Online surveys

Online surveys are a type of internet-mediated research (IMR), which is defined as "any research involving the remote acquisition of data from or about human participants using the Internet and its associated technologies" (Hewson et al., 2013, p.3). Other examples of IMR methods include interviews carried out by email or online chat rooms and the analysis of the data gathered from online support forum posts. Coulson (2015) outlines several advantages that IMR has over alternative offline methods such as paper questionnaires, or face-to-face focus groups or interviews. First, the remote nature of IMR means that it can be relatively cost- and time-efficient. Second, IMR can reach a vast and international target audience, including some hard-to-reach populations who might be difficult to identify or are resistant or unable to take part in face-to-face methods. Third, IMR provides participants with greater anonymity, which may encourage greater disclosure and reduce social desirability effects, as well as helping ensure participant confidentiality. Finally, IMR can be carried out by participants in their own space (e.g. at home) and at a time convenient for them, which may help facilitate greater participation.

Coulson (2015) also highlight several limitations of IMR. First, IMR may exclude those who may be unwilling or unable to use the Internet, thus leading to a potentially biased and unrepresentative sample. Nevertheless, it can be argued that non-internet users are unlikely to use digital interventions and would therefore not be representative of their target population. Second, as IMR is carried out remotely, researchers will have less control over the research procedures and participant environment. Researchers cannot control where the participant carries out the IMR (e.g. at home or

in a busy workplace) or the technical set-up at the participants' end (e.g. software or hardware configuration, network performance). Third, the lack of researcher presence can make it difficult to build rapport with participants from the lack of non-verbal cues (e.g. body language) that would be present in face-to-face encounters. Moreover, the researcher is less able to deal with any participant distress resulting from the research.

2.3.2. Retrospective semi-structured interviews

Retrospective semi-structured interviews are recommended in guidelines for testing internet-based intervention (Bradbury et al., 2014; West & Michie, 2016). As a qualitative method, it is consistent with a person-based approach (Yardley, Morrison, Bradbury, & Muller, 2015). For this method, participants use the intervention completely unobserved and are then interviewed about their experiences and usage, usually at a different point in time. This method is commonly used to evaluate user experiences of a health intervention that require a substantial time commitment or require participants to act out certain techniques. The advantage of this method is that it allows people to use the intervention on their own and in their own environment (e.g. at home), thus maximising ecological validity. However, as the interview is not carried out immediately after the participant uses the intervention, its validity may be limited by participants' ability to recall their experiences, thought processes, or problems they encountered.

2.3.3. Think aloud interviews

Another qualitative method used for testing interventions is *think aloud interviews*, which involve participants using the intervention, in the presence of a researcher, while simultaneously verbalising their immediate reactions to all or part of the intervention. The aim is to provide insight into participants' cognitive, behavioural and affective processes (Branch, 2000). The main advantage of the think aloud interview, over retrospective interviews, is that participants are verbalising their thoughts as they occur, thus maximising recall. Moreover, as the observation and interview occur concurrently, think aloud interviews are relatively time- and cost-efficient. They have been successfully used in previous studies to explore users' reactions and interactions with digital interventions and identify content and navigational problems (Pearson, Walsh, Carter, Koskela, & Hurley, 2016; Rowsell et al., 2015; Yardley, Ainsworth, et al., 2015; Yardley, Morrison, Andreou, Joseph, & Little, 2010). It has been suggested that think aloud interviews are not suitable for tasks that require a large amount of cognitive processing (Branch, 2000).

Researchers have suggested that think aloud interviews should also be complemented by retrospective 'exit interviews' to triangulate and explain the think aloud data and provide more rich accounts and additional insights into users' acceptability (Charters, 2003). Several researchers have used complementary semi-structured interviews, which proceed think aloud interviews (Anthierens et al., 2012; Essery et al., 2015; Morrison, Joseph, Andreou, & Yardley, 2009; Morrison, Moss-Morris, Michie, & Yardley, 2013; Rowsell et al., 2015; Yardley et al., 2013; Yardley, Miller, Teasdale, & Little, 2011).

Different think aloud interview protocols have been used across the literature. These protocols typically specify the role of the interviewer, the prompts and questions used, and the type of tasks that users are engaged in during the interview. Generally, decisions about the type of protocol used are influenced by the aims and type of research. Think aloud interviews have traditionally been used as a usability method where the focus is on identifying 'usability flaws' (Jaspers, 2009) or in educational and psychological research to explore the underlying thought processes when completing a particular task (e.g. decision-making) (Aitken, Marshall, Elliot, & McKinley, 2011; Charters, 2003). In these studies, the role of the interviewer is mainly as a passive observer who resists from intervening (Charters, 2003; Ericsson & Simon, 1993; Jaspers, 2009). Think aloud speech should be largely spontaneous and prompts only used to remind the participant to continue talking if they stop verbalising their thoughts (e.g. 'what are you thinking now?'). This is to avoid distorting or disrupting the participants' thought processes and actions, thus enhancing ecological validity. Users are typically given a set of moderately cognitively demanding tasks that will uncover the maximum amount of usability flaws and/or expose participants' underlying cognitive processes. Data analysis is typically quantitative in nature, focusing on the number or type of usability problems identified (van den Haak, De Jong, & Schellens, 2007) or decisions made (Aitken et al., 2011).

Think aloud interviews have also been used to explore users reactions to and perceived usefulness of digital health interventions (Bolle et al., 2016; Morrison et al., 2013; Yardley et al., 2011; Yardley, Morrison, et al., 2010). Specifically, the person-based approach uses think aloud interviews to explore users' engagement with the wider intervention goals, such as behaviour change and self-management, and the factors

that may strengthen or impede them (Section 2.1.3; Yardley et al., 2013; Yardley, Morrison, Bradbury, & Muller, 2015). Using this protocol, the interviewer plays a more involved role and may ask minimal and timely evaluative questions to provide guidance and explore users' views on the intervention content (Bolle et al., 2016; Morrison et al., 2013). Cotton and Gresty (2006) found that participants found it easier to think aloud if they are given guidance on the kind of thoughts the researcher is looking for. Consistent with a qualitative paradigm, qualitative analysis, such as thematic analysis, is commonly used.

The main strength of this protocol is that it allows the in-depth perspective of the user to be explored. It is also consistent with the recommendation made by West and Michie (2016) that states that intervention testing should go beyond mere development to generate new knowledge (e.g. exploring mechanisms of impact). One disadvantage is that the increased involvement of the interviewer may reduce ecological validity, thus providing a less reliable representation of how users will interact with the intervention outside of the research context.

2.3.4. Alternative and complementary methods

An alternative to the think aloud interview is the *think after interview*, in which participants use the intervention alone and then are interviewed immediately after. The advantage of these interviews, over the think aloud interview, is that the participant is able to use the intervention without being influenced by the presence of the researcher, thus maximising ecological validity. Unlike the retrospective semi-structured interviews, the user is observed using the intervention, which allows the user to better

understand how users interact with the intervention. On the other hand, this method has been criticised for being prone to poor participant recall and fabrication (Russo, Johnson, & Stephens, 1989). To overcome this, researchers have used a 'stimulated recall' technique (van den Haak et al., 2007; van den Haak, De Jong, & Schellens, Peter, 2003) in which participants are videotaped using the intervention and then asked to comment on their video recordings afterwards. The videos subsequently provide users with an aide memoire to maximise recall. However, Cotton and Gresty (2006) argued that it is unlikely that participants' intervention usage will be completely unaffected by the presence of a video camera.

Several studies have compared both think aloud and think after studies. Some studies have shown that think after interviews are less prone to reactivity (Russo et al., 1989; van den Haak et al., 2003), whereby participants are likely to perform better or worse than usual when using the intervention. In contrast, other studies have found no difference in participants' task performance when using these two methods (van den Haak, De Jong, & Schellens, 2004; van den Haak et al., 2007). van den Haak et al. compared think aloud interviews and think after interviews (with stimulated recall) for an informational web site (van den Haak et al., 2007) and an online library catalogue (van den Haak et al., 2004, 2003). They demonstrated that that there was no significant difference in the mean number of problems detected, participants' awareness of the researcher, or participants' views on the research environment (i.e. how pleasant and natural it was) and whether their usage of the intervention differed from usual. This suggests that the presence of the researcher in the think aloud interviews did not significantly affect the users' research experience or ability to detect intervention problems or complete intervention tasks.

Expert-based methods, such as heuristic evaluation and cognitive walkthrough, are also popular for testing the usability of health technologies (Jaspers, 2009). These methods involve usability experts inspecting an intervention and applying a set of guidelines to uncover usability problems (Jaspers, 2009). However, these methods do not allow problems to be explored from the users' perspective and are, therefore, not consistent with a person-based approach.

Quantitative analysis of participant usage data, can provide useful insights into how the intervention is actually used over time (Arden-Close et al., 2015; van Gemert-Pijnen, Kelders, & Bohlmeijer, 2014). This data can also be used to identify factors that are related to intervention usage and explain how usage relates to intervention outcomes. For example, in their analysis of the usage and outcomes data of an internet-based weight-management intervention, Arden-Close et al. (2015) identified a drop in intervention usage after use of the initial core intervention modules. They also identified particular user characteristics (e.g. higher baseline body mass index, age) that were related to usage or non-usage of some of the intervention components and found that usage of certain intervention tools (e.g. physical activity diary) led to greater weight loss. It has been suggested that usage data can be used alongside qualitative methods to provide a more complete picture of implementation and contextual factors that impede its delivery (Arden-Close et al., 2015). This method may be helpful at later stages of the optimisation process, perhaps as part of a RCT to assess the intervention's efficacy.

2.4. PHD AIMS AND OBJECTIVES

This PhD aimed to evaluate and optimise the Tinnitus E-Programme 1.0. The objectives were:

1. To systematically review the current evidence-base to assess the effects of self-help interventions for tinnitus and identify the self-help techniques used;
2. To develop an understanding of the Tinnitus E-Programme's[1] mechanisms of impact, outcomes, and identify any implementation or contextual factors that strengthen or impede its delivery and functioning;
3. To develop the Tinnitus E-Programme 2.0, an optimised version of the Tinnitus E-Programme 1.0.

2.5. RESEARCH PARADIGM

This research adopted pragmatism (Creswell & Plano Clark, 2011) as its overarching methodological paradigm. Pragmatism is primarily concerned with the aims and consequences of the research. Unlike other paradigms, such as post-positivism and constructivism, it is not tied to one particular epistemology or data collection method (i.e. qualitative or quantitative), rather, methods are chosen based on their ability to successfully answer a particular research question (i.e. 'what works'). Consistent with this, research methods were chosen based on a judgement of how well they address each individual research aim and whether they are in line with the recommended guidelines for developing and evaluating digital interventions.

[1] This includes the original Tinnitus E-Programme 1.0 and the optimised version (2.0)

2.6. STUDY DESIGN

Consistent with the guidelines for developing and evaluating complex and digital interventions (Craig et al., 2008; West & Michie, 2016; Yardley, Morrison, Bradbury, & Muller, 2015), the evaluation and optimisation of the Tinnitus E-Programme was iterative, with each stage informing the other. This research is the first to systematically apply theory-, evidence- and person-based approaches (Section 2.1.4) to develop an internet-based intervention for tinnitus (Aim 3). Consistent with evidence-based approaches, the literature review on tinnitus management (Section 1.4.2) and the determinants of tinnitus distress (Section 4.4), and a systematic review of the effects and techniques of self-help interventions (Chapter 3; Aim 1) were used to identify the current evidence-base relevant to this intervention. This work was used to assess the effects of self-help interventions for tinnitus (Aim 1) and identify potential mediators of the intervention outcomes, broad issues, needs, and challenges that the optimised intervention must address, and effective intervention techniques that should be considered in the optimisation work (Aim 2 and 3).

Theory-based tools, including taxonomies for reporting the elements of interventions, behavioural analysis, and logic modelling, were used to describe each version of the intervention (Chapter 4 and 6) and the potential causal mechanisms (Aim 2 and 3). A person-based approach was used to understand (Chapter 5 and 7) and accommodate (Chapter 6) the users' perspective on the intervention and additional issues, needs, and challenges that the optimised intervention must address (Aim 2 and 3).

To evaluate the Tinnitus E-Programme, a mixed methods study (Chapter 5) and think aloud interview study (Chapter 7) developed an understanding of the Tinnitus E-Programme's (including version 1.0 and 2.0) mechanisms of impact and identified implementation or contextual factors that strengthen or impede its delivery and functioning (Aim 2). Table 2.1 outlines how each of research aims were addressed using the different research methods and whether these methods belonged to an evidence-, theory-, or person-based approach.

Table 2.1 Outline of how each of research aims were addressed using the different research methods and whether these methods belonged to an evidence-, theory-, or person-based approach

PhD aims	Evidence-based		Theory-based	Person-based		
	Literature review (Ch. 1 & 4)	**Systematic review (Ch. 3)**	**Taxonomies/ behavioural analysis/logic modelling (Ch. 4 & 6)**	**Mixed methods evaluation (Ch. 5)**	**Creation of guiding principles (Ch. 6)**	**Think aloud interview study (Ch. 7)**
1. To systematically review the current evidence-base to assess the effects of self-help interventions for tinnitus and identify the self-help techniques used	-	✔	-	-	-	-
2. To develop an understanding of the Tinnitus E-Programme's mechanisms of impact and outcomes, and identify any implementation or contextual factors that strengthen or impede its delivery and functioning	✔	–	✔	✔	-	✔
3. To develop the Tinnitus E-Programme 2.0, an optimised version of the Tinnitus E-Programme 1.0	✔	✔	✔	✔	✔	✔

Key: Ch. = Chapter

CHAPTER 3. A SYSTEMATIC REVIEW OF TECHNIQUES AND EFFECTS OF SELF-HELP INTERVENTIONS FOR TINNITUS

3.1. INTRODUCTION

As discussed in Section 2.1.1, an important first stage of developing and evaluating complex interventions is to carry out a systematic review to identify the current evidence-base. Systematic reviews are helpful for two reasons. First, they are important for putting evaluation findings in the context of the wider evidence-base (Craig et al., 2008). Second, consistent with an evidence-based approach to intervention development, systematic reviews can inform intervention development by identifying potentially effective self-help techniques that should be integrated into new, or optimised, interventions. This would be helpful for informing future optimisation work on the Tinnitus E-Programme 1.0. As research on digital interventions for tinnitus is still in its infancy, this review focused on all types of self-help interventions for tinnitus.

There is one previous systematic review on self-help interventions for tinnitus (Nyenhuis, Golm, et al., 2013), which focused on CBT interventions only. The current review adds to the evidence-base by including studies that assessed self-help interventions delivered without therapist contact only. These interventions were deemed to be most relevant for a tinnitus population as they have the scalability necessary for equitable access. Unlike the review from Nyenhuis, Golm, et al, there

are no exclusions based on the intervention approach used. This review aimed to apply taxonomies from behavioural science and health psychology to systematically identify what intervention techniques are used within these self-help interventions, a methodology that has not been applied to the tinnitus self-help literature previously.

3.2. AIM

The primary aim of this systematic review was:

- to assess the effects of self-help interventions on levels of tinnitus distress, functional management, depression, anxiety, or quality of life of adults with chronic tinnitus.

The secondary aim of this review was:

- to identify what intervention techniques are used within these self-help interventions.

3.3. METHODS

The review protocol was registered with PROSPERO, the international prospective register of systematic reviews (Greenwell, Sereda, Coulson, El Refaie, & Hoare, 2014). Reporting was guided by the preferred reporting items for systematic reviews and meta-analyses (PRISMA) statement (Moher, Liberati, Tetzlaff, Altman, & The PRISMA Group, 2009).

3.3.1. Inclusion and exclusion criteria

The inclusion criteria, with reference to Participants, Intervention, Control, Outcomes, Study design (PICOS), were as follows:

1. Participants - Adults (aged 16+ years) with chronic tinnitus;
2. Intervention - Self-help interventions that aim to reduce tinnitus handicap and are delivered without health professional contact. Interventions had to be implemented from a standardised manual that can be followed independently by people with tinnitus. Health professionals could refer people to the self-help interventions but must not be involved in their delivery.
3. Control - Passive (no treatment group, usual care, waiting-list control) and active (self-help interventions delivered in different formats or health professional- or therapist-led interventions) controls;
4. Outcomes - Questionnaire measures of tinnitus distress, functional management, depression, anxiety or quality of life;
5. Study design - Prospective controlled trials, including RCTs and non-randomised controlled trials (NRCTs).

Studies were included if they were published in peer-reviewed journals and written in English. Studies were excluded if the intervention group received any form of treatment or therapy alongside the self-help intervention.

3.3.2. Search strategy

Searches were carried out in January 2014 and then updated in March 2015 using the following electronic databases: OVID (MEDLINE, EMBASE, PsycINFO), ESBCOhost (CINAHL), Cochrane Library and Proquest (ASSIA), using the search terms tinnitus AND self-help OR self-manag* OR self-care OR self-treatment OR self- therapy OR self-direct* OR self-act* OR self-admin* OR unguid* OR self-guid* OR bibliotherapy OR internet OR online OR computer OR web OR ‘‘minimal contact’’ OR ‘‘short-term therapy’’ OR training OR education. An example search strategy is provided in Appendix 3.

This initial search was complemented by searching reference lists from relevant systematic reviews, the included primary studies, citation searching of the same studies using Web of Science, and hand searching the last six months of key audiology, ear, nose and throat, and psychology journals. Clinicaltrials.gov and the World Health Organization trial search were searched to identify potentially relevant ongoing or unpublished studies.

3.3.3. Study selection

The titles and abstracts of 2077 articles were screened independently by the author and another researcher for potential inclusion using the PICOS inclusion criteria outlined in Section 3.3.1. Full text articles were retrieved where the study appeared suitable for inclusion or where there was insufficient information in the title or abstract to exclude

the study. Forty-eight full text articles were retrieved and were independently assessed for inclusion by the two researchers (Figure 3.1).

3.3.4. Data extraction

The data extraction, and risk of bias and quality assessments were each carried out independently by at least two members of the review team and any disagreements resolved with discussion or consultation with additional team members. Data for each study were extracted using a data extraction form, which was piloted before use.

3.3.5. Quality assessment

Downs and Black's (1998) quality checklist was used to measure the quality of all studies. This checklist describes 27 quality criteria and is scored according to responses options of 'yes/no' (criteria 1–4, 6–10), 'yes/partially/no' (criteria 5), 'yes/no/unable to determine' (criteria 11–26), 0–5 (criterion 27). Criterion 27 is normally scored according to the power (i.e. sufficient sample size) of the study to detect a clinically meaningful change. As there is no defined or universally agreed clinically significant change score for many tinnitus questionnaires (Fackrell, Hall, Barry, & Hoare, 2014), the responses were modified to simply signify whether or not a power calculation was carried out (scored 'yes/no/unable to determine').

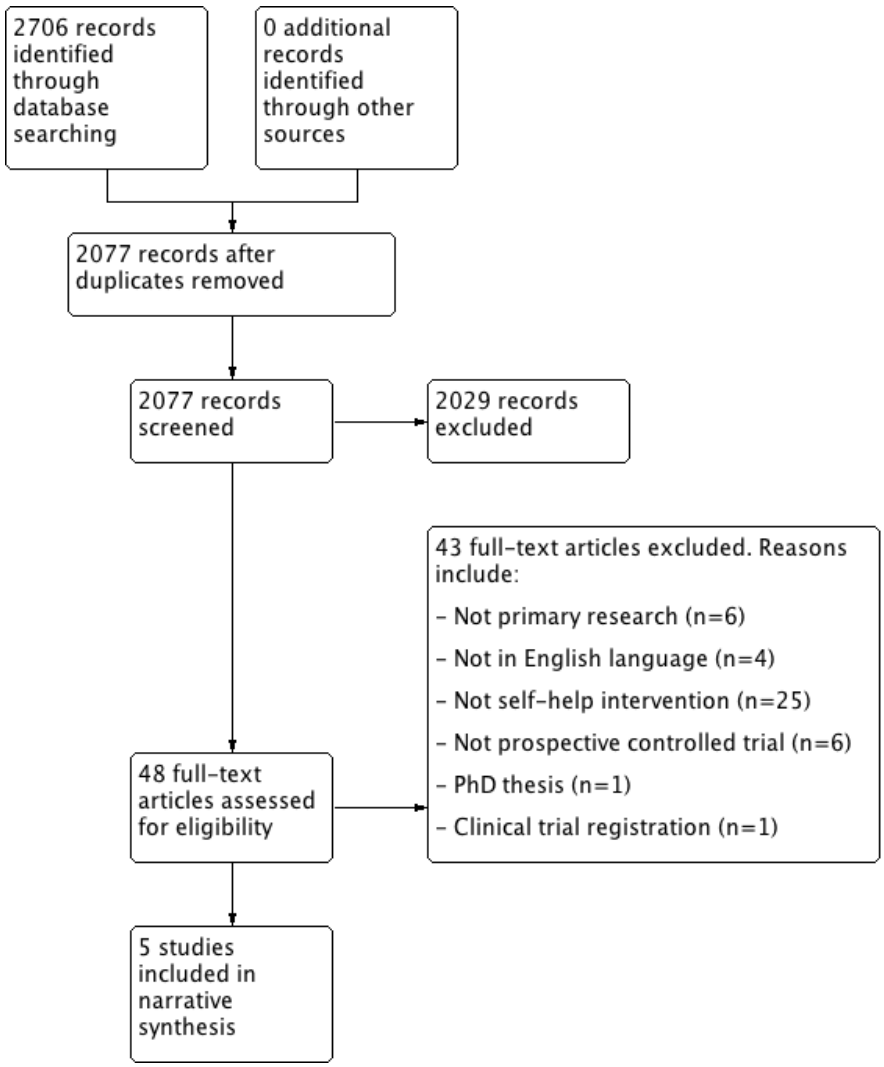

Figure 3.1 PRISMA flow chart of study selection process (Adapted from Greenwell, Sereda, Coulson, El Refaie, & Hoare (2016)

3.3.6. Risk of bias

The Cochrane collaboration risk of bias tool (Higgins & Green, 2011) was used to assess the risk of bias in the included RCT studies. Bias was judged as 'high risk', 'low risk' or 'unclear' across seven domains (Figure 3.2) using the criteria for judgements provided in the Cochrane Handbook (Higgins & Green, 2011).

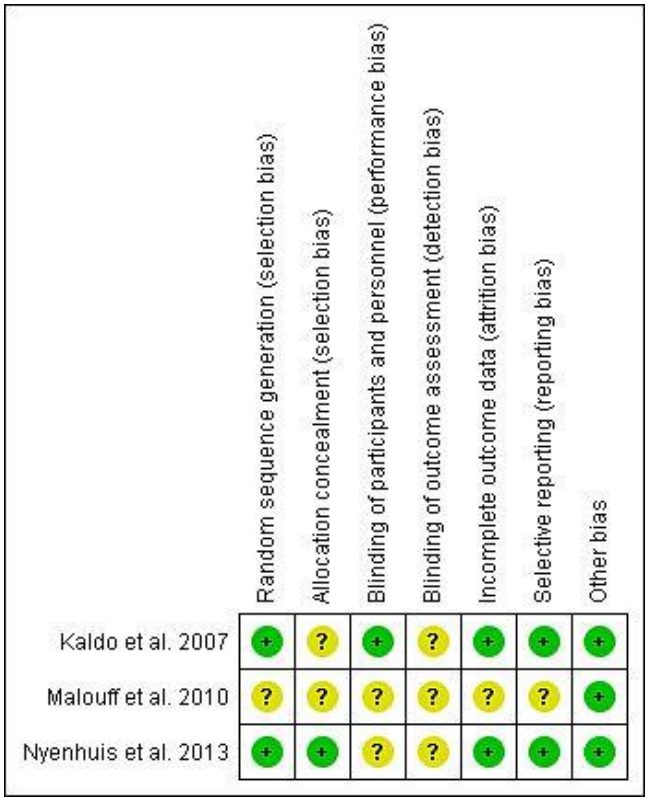

Figure 3.2 Cochrane risk of bias summary table including risk of bias judgements across studies for each criterion.
Key: ? unclear risk of bias; +low risk (Taken from Greenwell, Sereda, Coulson, El Refaie, et al., 2016)

3.3.7. Data synthesis

Data were synthesised using a narrative approach. It was not possible to perform meta-analyses as the interventions, control groups, and outcome measures of the three RCT studies were not sufficiently similar to meaningfully combine the results. Only the results from intention-to-treat analyses were reported unless the results from the complete case analysis differed significantly.

3.3.8. Intervention coding

Intervention taxonomies were used to identify and describe the 'active ingredients' of the interventions. In the absence of a well-established self-help taxonomy, Michie et al.'s (2013) BCTv1 was used to code intervention content into intervention techniques from a list of 93 items.

The focus on behaviour change seemed appropriate given that behaviour change is a key component of CBT, which most mental health and tinnitus self-help interventions are based on. As the BCTv1 was not designed with self-help interventions in mind, it was predicted that this taxonomy would not identify all techniques present in the included interventions. For example, some intervention techniques, such as cognitive restructuring, were used to improve psychological outcomes, rather than promote behaviour change. Narrative synthesis was used to summarise the additional techniques unique to self-help interventions or those used for purposes other than behaviour change.

The practical review of self-management support (PRISMS) taxonomy of self-management components (Taylor et al., 2014) was used to provide a framework for this synthesis. This taxonomy lists 14 self-management components directed at patients and/or carers, five indirect components aimed at health or social care professionals, and five components directed at the organisational level. These self-management components are broader than the techniques used in the BCTv1 and could comprise several techniques. For example, 'training/rehearsal for psychological strategies' could include practicing or rehearsing the psychological strategy, providing

instructions on how to perform the strategy, and goal setting for this strategy. The PRISMS taxonomy was chosen as it is not restricted to one particular intervention outcome, addresses some of the broader forms of self-management techniques, and is designed for use in systematic reviews. Taylor et al. (2004) recommended that both the PRISMS and BCTv1 should be used in systematic reviews.

Intervention content was coded using the intervention descriptions in the publication. The intervention protocol or original self-help material from the study authors was requested if insufficient information was available in the publication. The original self-help material was available for four studies in this review (Kaldo, Cars, Rahnert, Larsen, & Andersson, 2007; Loumidis, Hallam, & Cadge, 1991; Malouff, Noble, Schutte, & Bhullar, 2010; Nyenhuis, Zastrutzki, Weise, et al., 2013) and the intervention protocol was available for the remaining study (Kaldo et al., 2013). One of the self-help manuals (Nyenhuis, Zastrutzki, Weise, et al., 2013) was available in German only and was translated into English by a member of the research team who is fluent in German. Kaldo et al. (2007) provided a translated version of their original Swedish manual.

3.4. RESULTS

3.4.1. Study characteristics

The key study characteristics of the five included studies are provided in Table 3.1.

Table 3.1 Study characteristics and quality assessment for included studies (Taken from Greenwell, Sereda, Coulson, El Refaie, et al., 2016)

Reference	Country	Sample Size	Study Design; Trial type	Intervention	Control	Assessment Points			Outcome Measures		Quality Assessment
						BL	P-I	FU	Primary	Other	
Loumidis et al (1991)	UK	33[a]	NRCT; Parallel	Information Leaflet	Waiting list*	×	1 month	×	TEQ	–	13
Kaldo et al (2007)	Sweden	72	RCT; Parallel, cross-over	Self-help book	Therapist-guided self-help book**	✓	6 weeks	1 year	TRQ	THI, HADS, ISI	17
Malouff et al (2010)	Australia	162	RCT; Parallel, cross-over	Self-help book	Waiting list*	✓	2 months	***	TRQ[b]	GHQ-12	14
Nyenhuis et al (2013)	Germany	304	RCT; Parallel	Self-help book; Internet intervention	Information leaflet*; Group therapy**	✓	3 months	1 year	TQ	PHQ-D	19
Kaldo et al (2013)	Sweden	374	NRCT; Effectiveness trial	Internet intervention	Therapist-guided internet intervention**	✓	ns	×	TRQ	–	13

Note: Quality assessment was carried out using Downs and Black's (1998) quality checklist. The reported score is out of a total score of 27.

Key: [a]Only post-intervention sample size was given; [b]Primary outcome not stated; *Passive Control; **Active Control; ***Only within-group comparisons made at follow-up; RCT – Randomised Controlled Trial; NRCT – Non-randomised Controlled Trial; BL – Baseline; P-I – Post-intervention; FU – Follow-up; ns = not specified; TEQ – Tinnitus Effects Questionnaire (Hallam, Rachman, & Hinchcliffe, 1988); TRQ – Tinnitus Reaction Questionnaire (Wilson, Henry, Bowen, & Haralambous, 1991); TQ – Tinnitus Questionnaire (German version; Goebel & Hiller, 1998); THI – Tinnitus Handicap Inventory (C. W. Newman et al., 1996); HADS – Hospital Anxiety and Depression Scale (Zigmond & Snaith, 1983); ISI – Insomnia Severity Index (Bastien, Vallières, & Morin, 2001); GHQ-12 – General Health Questionnaire (Goldberg & Williams, 1988); PHQ-D - Patient Health Questionnaire (Gräfe, Zipfel, Herzog, & Löwe, 2004).

The self-help interventions assessed in the included studies were delivered via books (n=3), the Internet (n=2), or an information leaflet (n=1). Duration of interventions ranged from one to three months. All interventions, except the information leaflet (Loumidis et al., 1991), were based on a CBT approach, focusing on helping individuals to change their negative thoughts about their tinnitus and adopt new behaviours to reduce tinnitus distress. All five studies recruited from ENT and audiology departments and three studies also recruited from community samples where participants were approached via media releases (i.e. newspapers, internet, radio) and tinnitus support groups (Kaldo et al., 2007; Malouff et al., 2010; Nyenhuis, Zastrutzki, Weise, et al., 2013).

3.4.2. Quality assessment

Scores on the Downs and Black checklist ranged from 13 to 19 (out of 27) for the five studies (Table 3.1), which suggests a low-to-moderate level of quality. There are several common items responsible for the lower quality ratings across studies. None of the studies attempted to blind participants to the intervention they received. Only one of the five studies (Nyenhuis, Zastrutzki, Weise, et al., 2013) reported carrying out a power calculation to determine sample size, but this study did not meet its estimate at post-assessment or follow-up due to a high drop-out rate (39%). The external validity of the included studies was questionable. The samples were generally not representative of the target or source population or generalisability of findings could not be determined due to limited reporting. This was mainly due to limitations of the recruitment methods used, that is, participants were self-selected from a community or medical population or consecutive medical patients.

3.4.3. Risk of bias

A risk of bias summary is provided in Figure 3.2. None of the studies were rated as being at high risk of bias on any of the seven criteria. Risk of bias was unclear in all three RCTs for one criterion (blinding of outcome assessment).

3.4.4. Attrition

Attrition rates for the intervention group at post-assessment ranged from 34–37%. However, rates were clearly reported for only three studies. Attrition at post-assessment for the passive controls ranged from 10–25% (n=2), and 9–37% for the active controls (n=3). At one-year follow-up, attrition was 42–48% (n=2) for self-help interventions, 36% for passive controls (n=1), and 12–34% for active controls (n=2).

3.4.5. Effects of self-help interventions

3.4.5.1 Self-help interventions vs passive controls

Studies comparing the effects of self-help interventions compared to passive controls allow the unique effects of self-help interventions to be assessed. Two RCTs (Malouff et al., 2010; Nyenhuis, Zastrutzki, Weise, et al., 2013) and one NRCT (Loumidis et al., 1991), using two waiting list controls and one information-only control as passive controls, were included in this comparison (Table 3.2).

Table 3.2 Presence of between group effects for studies comparing levels of tinnitus distress and depression between self-help interventions and passive controls (Taken from Greenwell, Sereda, Coulson, El Refaie, et al., 2016)

Reference	Intervention	Control	Tinnitus Distress		Depression	
			P-I	FU	P-I	FU
Loumidis et al (1991)	Information Leaflet	Waiting list	No effect[a]	–	–	–
Malouff et al (2010)	Self-help book	Waiting list	No effect[b]	–	Effect[c]	–
Nyenhuis et al (2013)	Self-help book	Information leaflet	No effect	Effect[b]	No effect	No effect
	Internet intervention		Effect	Effect[b]	No effect	No effect

Key: P-I – Post-intervention; FU – Follow-up; [a]Only post-intervention scores compared between groups. No pre-intervention scores collected; [b]These results should be interpreted with caution as complete case analysis showed opposite effect; [c]Complete case analysis. Intention-to-treat not reported.

Tinnitus distress

Only one study found a significant between-group effect for their self-help intervention at post-intervention. Nyenhuis, Zastrutzki, Weise, et al. (2013) demonstrated that tinnitus distress was significantly lower at post-intervention in the internet self-help intervention group, compared to the information-only control group. However, using the same control group, there was no significant effect of the self-help book at post- intervention. At one-year follow-up, those in the internet and book self-help intervention conditions demonstrated a significantly lower tinnitus distress. For their internet self-help intervention, between group effect sizes were large at post-intervention (d=1.04) and medium at follow-up (d=0.66). Between group effect sizes for the self-help book were small at post-intervention (d=0.24) and follow-up (d=0.39).

Malouff et al (2010) found no significant between-group effects for their self-help book at post- intervention, when compared to a waiting list control. However, when complete case analysis was used, a small (*d*=0.28) but significant between-group effect was observed. There was a large amount of missing data present in this study, so it is possible that an effect may have been found if more complete data was collected. Loumidis et al. (1991) found no significant difference in tinnitus distress between their leaflet intervention and their waiting list control at post-intervention. However, this study had poor quality rating (13), a small sample size (n=33), and did not collect and account for the participants' pre-intervention scores, so the findings should be interpreted with caution.

Two studies explored the number of people in the self-help intervention groups reaching a clinically significant change in tinnitus distress, but results were mixed. Compared to the information-only control, Nyenhuis, Zastrutzki, Weise, et al (2013) demonstrated that more people in both their internet and book intervention groups reported a clinically significant improvement in tinnitus distress (defined as a reduction in tinnitus distress score of at least 50%) at both post-intervention and follow-up. In contrast, Malouff et al (2010) found no significant difference in the percentage of people reaching a clinically significant reduction in tinnitus distress between the self-help book intervention (17%) or control groups (13%) at post-intervention.

Only Nyenhuis, Zastrutzki, Weise, et al (2013) explored potentially negative effects of self-help interventions by measuring the number of participants demonstrating a

clinically significant worsening of tinnitus distress scores. Fewer people in the self-help interventions (n=0) and group therapy (n=1) groups had deteriorated at post-intervention, compared to the information-only group (n=2). None of the participants in the intervention and active control groups had deteriorated at follow-up. Two people had deteriorated in both the internet self-help intervention group and the information-only control group.

Depression

Malouff et al (2010) found a small but significant between-group difference in general psychological distress post-intervention (*d*=0.26), in favour of using a self-help book over a waiting list control. The authors used complete case data only; different results may have been produced with intention-to-treat analyses. Nyenhuis, Zastrutzki, Weise, et al (2013) found no significant effects on depressive symptoms for their internet or book interventions at post-intervention or follow-up, when compared to their information-only control.

Functional management, anxiety, and quality of life

None of the included studies assessed quality of life, anxiety, or functional management.

3.4.5.2 Self-help interventions vs active controls

Studies comparing the effects of self-help interventions to active controls allow us to assess whether the effects of self-help interventions differ significantly to psychological interventions that are therapist-led. Two RCTs (Kaldo et al., 2007; Nyenhuis, Zastrutzki, Weise, et al., 2013) compared self-help interventions to active controls, including group therapy or a therapist-guided self-help book. One NRCT (Kaldo et al., 2013) evaluated the effects of an unguided and therapist-guided internet intervention. Table 3.3 provides a summary of these intervention effects.

Tinnitus distress

Only Kaldo et al (2007) carried out a between-group comparison of self-help interventions and active controls. They found no significant difference in tinnitus distress between groups who used a self-help book, with (active control) or without (intervention) therapist guidance, at post-intervention or one-year follow-up.

However, when tinnitus distress was measured using the THI (Newman et al., 1996), they did observe a greater reduction in the therapist-guided group, but that difference was not maintained at one-year follow-up. Kaldo et al (2007) found no significant differences in the percentage of people reaching a clinically significant reduction in tinnitus reactions questionnaire (TRQ; Wilson et al, 1991) scores for the self-help intervention or active control group at post-intervention (28%; 32%, respectively) or at one-year follow-up (29%; 26%, respectively).

Table 3.3 Presence of between group effects for studies comparing levels of tinnitus distress, depression, anxiety and sleep quality between self-help interventions and active controls (Taken from Greenwell, Sereda, Coulson, El Refaie, et al., 2016)

Reference	Intervention	Control	Tinnitus Distress[a]		Depression		Anxiety		Sleep quality	
			P-I	FU	P-I	FU	P-I	FU	P-I	FU
Kaldo et al (2007)	Self-help book	Therapist-guided self-help book	No effect	No effect	No effect	No effect	Effect	No effect	No effect	No effect

Key: P-I – Post-intervention; FU – Follow-up; [a]Only effects for primary outcome measure of tinnitus distress are reported.

Nyenhuis, Zastrutzki, Weise, et al (2013) did not carry out analysis to compare self-help interventions with an active control, but they did include both self-help interventions (internet and book) and an active control (group therapy) in a four-arm trial that allowed the within group effects to be compared. Within group effect size for the internet intervention at post-intervention was slightly larger (*d*=1.04) than that for the active control (*d*=0.89). Conversely, the within group effect size of the internet intervention at follow-up (*d*=0.66) was slightly smaller than that for the active control (*d*=0.74). Comparatively, the self-help book intervention within group effect sizes at post-intervention (*d*=0.24) and follow-up (*d*=0.39) were small.

Kaldo et al (2013) assessed the effects of both unguided (intervention) and therapist-led (active control) internet interventions but no between-group comparisons were performed. Tinnitus distress significantly reduced for those in the internet self-help intervention group at post-intervention. This within-group effect size was smaller (*d*=0.1) than that of the active control (*d*=0.32), suggesting that therapist presence may be an important mediator of intervention outcome. However, the lack of between-group comparison makes it difficult to draw firm conclusions.

Depression and anxiety

Kaldo et al.'s (2007) therapist-guided self-help book led to a significant greater reduction in anxiety (but not depression), compared to their unguided self-help book. However, these between-group differences were not maintained at one-year follow-up.

Functional management and quality of life

Kaldo et al (2007) found no significant between-group differences in levels of sleep quality at post-intervention or one-year follow-up. Quality of life was not measured by any of the studies in this comparison.

3.4.6. Secondary review aim: Identifying intervention techniques used

Table 3.4 lists the BCTs and self-management components identified across studies. Only the four CBT-based interventions (Kaldo et al., 2013, 2007; Malouff et al., 2010) contained any BCTs. Generally, these techniques were targeted at the psychological strategies, mainly relaxation behaviour. Most techniques functioned to encourage enablement (i.e. increase an individuals' capability or opportunity for performing behaviour) or to impart behavioural skills through training (Michie, Atkins, et al., 2014). The most popular enablement techniques included 'action planning' (n=4), 'goal setting (behaviour)' (n=3), and 'self-monitoring of behaviour' (n=3). Regularly used skills training techniques included 'instruction on how to perform the behaviour' (n=4) and 'behavioural practice/rehearsal' (n=4).

The PRISMS self-management components taxonomy described some of the additional self-help specific intervention content that was not directed specifically at behaviour change. 'Education about condition [tinnitus] and management' was the only component used consistently across all five self-help interventions.

Table 3.4 Number of self-management components and behaviour change techniques across studies (Taken from Greenwell, Sereda, Coulson, El Refaie, et al., 2016)

Behaviour Change Techniques Taxonomy	Number of studies
1.4. Action planning	4[b-e]
4.1. Instruction on how to perform the behaviour	4[b-e]
8.1. Behavioural practice/rehearsal	4[b-e]
1.1 Goal setting (behaviour)	3[b,c,e]
2.3. Self-monitoring of behaviour	3[b-d]
2.4. Self-monitoring of outcome(s) of behaviour	2[b,c]
3.2. Social support (practical)	2[b,c]
5.6. Information about emotional consequences	2[b,c]
12.5. Adding objects to the environment	2[b,e]
1.2. Problem solving	1[b]
1.5. Review behaviour goal(s)	1[c]
7.1. Prompt/cues	1[b]
8.3. Habit formation	1[b]
8.6. Generalisation of target behaviour	1[b]
8.7. Graded tasks	1[b]
PRISMS Self-Management Components Taxonomy	**Number of studies**
Education about condition and management	5[a-e]
Training/rehearsal for psychological strategies	4[b-e]
Lifestyle advice and support	4[b-e]
Information about available resources	3[a,c,e]
Provision of/agreement on specific action plans and/or rescue medication	2[b,d]
Monitoring of condition with feedback to the patient	1[c]
Practical support with adherence (medication or behavioural)	1[b]
Provision of equipment	1[e]

Key: [a]Loumidis (1991); [b]Kaldo et al, (2007); [c]Malouff et al, (2010); [d]Kaldo et al, (2013); [e]Nyenhuis, Zastrutzki, Weise, et al, (2013)
Note: Only those techniques and components identified in this review are listed.

The four CBT-based interventions provided 'training/rehearsal for psychological strategies' and 'lifestyle advice and support'. To check material comprehension, Nyenhuis, Zastrutzki, Weise, et al. (2013) intervention included knowledge self-assessments throughout. The training/rehearsal in various psychological strategies provided in the interventions included: (1) applied relaxation or positive imagery; (2)

cognitive restructuring to identify, examine and challenge negative thoughts; (3) behavioural activation, which encourages individuals to re-introduce or increase pleasant activities that may have previously avoided as a result of tinnitus; (4) action planning; (5) goal setting; (6) problem solving; (7) sound enrichment; (8) attention control, which utilises positive imagery or focus exercises to increase one's ability to control their attention; (9) exposure to tinnitus where individuals actively and repeatedly focus on their tinnitus in a controlled and gradual way to improve their tolerance to it; and (10) self-instructions in which people internally give themselves instructions to motivate themselves and change how they respond to tinnitus (e.g. 'Do not panic. I can handle my tinnitus.').

Lifestyle advice and support was either general (e.g. sleep management, concentration management, handling life stressors, physical activity) or tinnitus-specific (e.g. hearing strategies). This intervention content tended to be passive in nature, offering advice regarding specific self-management behaviours (e.g. avoid caffeine before bed), without any supporting BCTs. None of the interventions provided social support components. Practical social support as a behaviour change technique was used by two studies. However, this technique was brief and limited to providing advice on how social support can be used to facilitate behaviour (e.g. 'ask someone to read the relaxation script for you') rather than being explicitly provided as part of the intervention.

3.5. LIMITATIONS

There are several limitations that should be considered when interpreting the review findings. First, this review identified only five studies that met the inclusion criteria and they all used different intervention delivery methods, outcomes, assessment methods, and comparators. Therefore, it was not possible to carry out a meta-analysis.

Second, the quality assessment demonstrated that the studies were only low-to-moderate quality. Several areas of poor quality and factors that left the studies open to risk of bias were identified. Specifically, none of the studies attempted to blind participants to the intervention they received. However, the chosen study comparisons (i.e. waiting list, active control) often meant it was infeasible to do so.

Third, included studies were limited to those published in peer-reviewed journals and written in English. Unpublished studies may have been missed, thus introducing a publication bias, which occurs when the results of published studies are systematically different to those that are unpublished (Song, Hooper, & Loke, 2012). This happens because journals are more likely to publish studies with positive or significant results than studies with negative or non-significant results. Choosing only studies published in English may have also introduced a language bias. Language bias may occur if non-English speaking authors are more likely to publish in an international English-language journal if the results are positive (Higgins & Green, 2011). However, the research examining the impact of language bias on trial results is conflicting and inconclusive (Jüni, Holenstein, Sterne, Bartlett, & Egger, 2002; Moher, Pham, Lawson, & Klassen, 2003).

Finally, the taxonomies that were used were not specifically designed for use in self-help interventions, thus limiting the process by which the intervention techniques were identified and reported. The BCTv1 is one of the most well-established taxonomies, but it was designed specifically for identifying techniques targeted at changing behaviour. Therefore, it did not capture some self-help techniques, such as cognitive restructuring that was aimed at reducing emotional distress, rather than behaviour change. To some extent, the PRISMS taxonomy was able to identify some of these other techniques, however, this taxonomy is limited in that it only identifies the broad components of the interventions (e.g. training/rehearsal for psychological strategies), rather than the more specific and smaller techniques, which would be useful to understand. Moreover, recent attempts to assess whether the BCTv1 improves the clarity and replicability of written reports of observed behaviour change interventions have demonstrated mixed findings (Wood et al., 2016). Better reporting and categorisation of self-help intervention techniques is needed for study replication and furthering our understanding of the processes by which these components and techniques mediate any changes in outcomes.

3.6. SUMMARY

Primary aim - Effects of self-help interventions on levels of tinnitus distress, functional management, depression, anxiety, or quality of life of adults with chronic tinnitus:

- Only five studies, including three RCTs, were identified that assessed the effects of self-help interventions delivered via the internet, books, and an information leaflet.

- Only two studies evaluated unguided self-help interventions via the internet and, only one study used an approach other than CBT (i.e. information only) and evaluated the intervention with a UK population.
- The narrative synthesis found mixed results for the effect of self-help interventions on tinnitus distress when compared to passive controls.
- Only one of the three studies exploring this comparison found a significant between group effect for their self-help intervention, which was delivered via the internet.
- The findings for the effects of self-help on psychological distress were also mixed and limited.
- Firm conclusions could not be drawn regarding whether self-help interventions can provide comparable benefit to traditional face-to-face therapies or therapist-guided self-help interventions. Only one study carried out a between groups comparison of self-help interventions with active controls.
- There was a considerable variability regarding outcome measures, with different tinnitus questionnaires being used across the studies, which can make comparisons between studies difficult.

Secondary aim - Identify what intervention techniques are used within these self-help interventions:

- Even without therapist contact, these interventions were still able to provide many techniques and components traditionally used in face-to-face therapy (e.g. training in psychological strategies, education about tinnitus, goal setting, action planning).

- Many of the intervention techniques identified in this review functioned to provide education and skills training and promote enablement.
- Processes relating to knowledge gain, changes in cognitions (i.e. attitudes, beliefs), self-efficacy, and skills building may be worth further investigation.
- There was an explicit lack of social support components in these interventions, which has been identified as a key part of self-management interventions for long-term conditions (Taylor et al., 2014).

3.7. CONTRIBUTION OF THE FINDINGS TO THE EVALUATION AND OPTIMISATION OF THE TINNITUS E-PROGRAMME 1.0

- This review highlighted a lack of evaluation work into unguided digital interventions for tinnitus.
- This review identified the most commonly used behaviour change techniques and self-management components used in self-help interventions for tinnitus.
- The findings of this work was used to identify any additional BCTs or self-management components that could be included in the Tinnitus E-Programme 2.0 or future iterations of the intervention (Section 6.4.2).

CHAPTER 4. DESCRIPTION OF THE TINNITUS E-PROGRAMME 1.0 AND ITS POTENTIAL CAUSAL MECHANISMS

4.1. INTRODUCTION

The aim of the Tinnitus E-Programme 1.0 is to reduce tinnitus distress, however, the precise mechanisms by which this change occurs has yet to be established. A first step to achieving this is to develop a full description of the intervention (Moore et al., 2014). In this Chapter, established taxonomies are used to systematically describe the components, techniques, and mode of delivery used in the Tinnitus E-Programme 1.0. The application of such methodology will provide reliable reporting to facilitate evaluation replication and develop an understanding of the intervention's potential mechanisms of change (i.e. the underlying psychological processes that bring about changes in outcome) (Craig et al., 2008; Michie & Abraham, 2004). This is the first reported use of this methodology with audiology digital interventions. The intervention description will be used to guide future intervention optimisation and evaluation work on the Tinnitus E-Programme.

4.2. AIM

To systematically describe the Tinnitus E-Programme 1.0 and its potential causal mechanisms.

4.3. METHOD

A description of the Tinnitus E-Programme 1.0 was developed through: (1) analysis of website content; (2) discussions with the intervention developer; and (3) the application of established taxonomies to identify the intervention's components, techniques, and mode of delivery. The intervention's components (i.e. self-management strategies) were coded using the PRISMS taxonomy of self-management components (Taylor et al., 2014). Any components associated with behaviour change were coded using Michie et al.'s (2013) BCTv1. Finally, the intervention's mode of delivery was coded using Webb et al.'s (2010) coding scheme for mode of delivery of internet-based health interventions. Webb et al. developed this coding scheme for use in their meta-analysis of internet-based health interventions. Specifically, it was used to identify the most effective modes of delivery by linking different modes to the effect sizes observed in the identified studies. These taxonomies and their development are described in more detail in Table 4.1.

Coding was carried out by the author and the intervention developer (Debbie Featherstone) independently and disagreements resolved by discussion with a third member of the research team. The findings are discussed in the context of the wider evidence-base, and potential causal mechanisms are identified.

Table 4.1 Features and development of the taxonomies used to describe the Tinnitus E-Programme 1.0

Taxonomy	Features	Development
PRISMS taxonomy of self-management (Taylor et al., 2014)	• 14 self-management components delivered directly to patients with long-term conditions and/or carers; • 5 indirect components delivered to individual health or social care professionals; • 5 indirect components delivered at an organisational level.	• Literature review, including national/international clinical guidelines; • Survey and consensus workshop with expert advisory group.
Behaviour Change Techniques Taxonomy (BCTv1; Michie et al., 2013)	• 93 behaviour change techniques, clustered into 16 groups relating to different 'active ingredients' (e.g. 'social support', 'feedback and monitoring').	• Literature review; • Online Delphi exercises[2], reliability testing (i.e. inter-rater agreement for the coding of intervention descriptions), and an open-sort grouping task to agree on overarching groups with international behaviour change experts.
Webb et al.'s (2010) coding scheme for mode of delivery of internet-based health interventions	• 11 modes of delivery divided into three groups: automated functions (e.g. 'automated follow-up messages'); communicative functions (e.g. 'access to an advisor to request advice'); and use of supplementary modes (e.g. 'email').	• Developed by the authors for use in a meta-analysis of internet-based behaviour change interventions. • No development detail given in publication.

[2] The Delphi exercise involved repetitively circulating lists of potential BCTs to the experts online and asking for their opinion on these BCTs. The goal was to arrive at something that is close to a consensus about which BCTs should be included in the taxonomy.

4.4. RESULTS

4.4.1. Self-management components

Five intervention components were identified using the PRISMS taxonomy: (1) Education about condition and management; (2) Information about available resources; (3) Training/rehearsal for psychological strategies; (4) Social support; and (5) Monitoring of condition with feedback to the patient.

4.4.1.1 Education about condition and management

The intervention provides several electronic information resources across first six weeks of the intervention. The GPG (Department of Health, 2009) recommends information provision and reassurance as a first line form of self-management support, and education about tinnitus and its management is recommended in clinical practice guideline for tinnitus (Tunkel et al., 2014). Through developing an understanding of their tinnitus, individuals can learn how to manage and cope with their illness. In their systematic review, Hoare et al. (2011) found that directive counselling (i.e. education/information giving), through providing a self-help book or therapist-led educational sessions, has significant benefits for people with tinnitus when compared to no intervention or unguided self-help groups. Moreover, education about tinnitus and its management was included as a component in all five self-help interventions identified in the systematic review (Chapter 3), and has been identified as a key part of self-management interventions for chronic conditions (Taylor et al, 2014).

One way in which education provision exerts its effect is by modifying, or correcting, an individual's beliefs about their illness (Dennison, Moss-Morris, & Chalder, 2009; Vollmann, Kalkouskaya, Langguth, & Scharloo, 2012), a determinant which has been proposed to play a key role in adjustment to tinnitus (McKenna et al., 2014). A minority of studies have assessed the associations between illness perceptions and tinnitus outcomes. Cross-sectional questionnaire studies with people who have tinnitus found that illness perceptions were associated with tinnitus distress. Specifically, evidence has been found for the role of illness identity (the symptoms people attribute to their tinnitus) (Vollmann et al., 2012), consequences (beliefs about the negative consequences of tinnitus) (Reynolds, Gardner, & Lee, 2004; Vollmann et al., 2012; Vollmann, Scharloo, Langguth, Kalkouskaya, & Salewski, 2013), coherence (sense of understanding), emotional representations (emotional responses) (Vollmann et al., 2012, 2013), treatment control (extent to which tinnitus can be controlled by treatment), and internal causes (beliefs in the internal causes of tinnitus, such as stress or your own behaviour) (Vollmann et al., 2013).

Several studies have successfully modified illness perceptions of people with chronic conditions and somatic symptoms through educational and CBT interventions (Christensen, Frostholm, Ørnbøl, & Schröder, 2015; Petrie, Cameron, Ellis, Buick, & Weinman, 2002; Yardley, Joseph, et al., 2010), but this has not yet been attempted for tinnitus. Dispelling misconceptions about tinnitus was also recently identified as a key component to be delivered in audiologist-delivered psychological interventions (D.M Thompson et al., 2016).

4.4.1.2 Information about available resources

As well as providing educational resources, the intervention also signposts users to other helpful resources using book references and website links.

4.4.1.3 Training/rehearsal for psychological strategies

Relaxation skills training is provided through written instructions and digital audio (MP3s) of guided relaxation exercises. Relaxation is believed to reduce physiological arousal, a factor which is hypothesised to be associated with tinnitus distress (McKenna et al., 2004). It been demonstrated that physiological arousal (e.g. elevated cortisol levels) and muscle tension is greater in those with tinnitus, and in particular, those with bothersome tinnitus (Andersson, Lyttkens, & Larsen, 1999; Hébert & Lupien, 2007; Hébert, Paiement, & Lupien, 2004; Rief, Sander, Gunther, & Nanke, 2004). Relaxation therapy is a tinnitus management strategy recommended in the GPG and is a commonly used psychological strategy in self-help interventions for tinnitus (Section 3.4.6). However, the evidence for its effect on tinnitus outcomes is mixed and inconclusive, and its use in English audiology departments is limited (Hoare et al., 2011, 2012). Relaxation therapy is a key component of CBT, which aims to tackle people's cognitive processes, as well as behaviour, and has demonstrated to be effective for tinnitus (Hoare et al., 2011; Martinez-Devesa et al., 2010). McKenna et al. (2014) argues that relaxation therapy may not be successful unless adequate consideration is also given to an individuals' cognitive processes. The specific behaviour change techniques used to facilitate relaxation behaviour are described in Section 4.4.2.

The intervention also includes brief cognitive skills training, through the use of cognitive restructuring, whereby information is provided on how to identify and change negative thoughts. Negative cognitions (e.g. despair, persecution, hopelessness, loss of enjoyment) and emotional distress (e.g. depression, anxiety) are believed to play a key role in adjustment to tinnitus distress (McKenna et al., 2014). Negative cognitions have been shown to be associated with tinnitus distress (Wilson et al., 1991) and more problematic tinnitus (Handscomb, Hall, Shorter, & Hoare, 2017). CBT interventions, including cognitive restructuring, have been shown to reduce negative cognitions (Cima et al., 2012), tinnitus distress (Hoare et al., 2011; Martinez-Devesa et al., 2010), and depression (Martinez-Devesa et al., 2010).

Although this is the most commonly used technique for developing effective and adaptive ways of thinking and feeling in tinnitus (Section 3.4.6), other cognitive skills techniques have also been suggested to be helpful. Cognitive defusion is used primarily in ACT therapy and, consistent with this therapy, involves reducing distress from thoughts by training the user to rethink their relationship to their thoughts (Hayes, Strosahl, & Wilson., 2012). Unlike cognitive restructuring, cognitive defusion does not try to change or control unwanted thoughts. Instead, it teaches individuals to view their thoughts as just thoughts, which do not have a literal meaning, and avoid the temptation to challenge or act upon the content of these thoughts. Techniques to identify and increase positive thoughts, such as gratitude diaries, have also been used to reduce emotional distress (e.g. worry, body dissatisfaction) (Geraghty et al., 2010a; Geraghty, Wood, & Hyland, 2010b; D.M Thompson et al., 2016). Gratitude diaries involve the user writing down a list of things they are grateful for. The intention is that thinking about the positive things in life, detracts people from their negative thoughts.

With regards to tinnitus, there is little conclusive evidence regarding the most appropriate technique for targeting negative thinking. Hesser et al., (2012) compared the efficacy of two internet-based interventions for tinnitus – a CBT intervention that included cognitive restructuring techniques, and an ACT intervention that included cognitive defusion. They demonstrated that there was no significant difference in their primary outcome (tinnitus distress) between the ACT and CBT conditions. This suggests that the techniques underlying each approach are equivalent in terms of efficacy. Other studies have carried out experimental studies to compare the use of cognitive defusion and cognitive restructuring techniques in clinical (Barrera, Szafranski, Ratcliff, Garnaat, & Norton, 2016; Deacon, Fawzy, Lickel, & Wolitzky-Taylor, 2011) and non-clinical (Larsson, Hooper, Osborne, Bennett, & McHugh, 2016; Yovel, Mor, & Shakarov, 2014) populations. These studies found that these techniques were equally effective for managing negative thoughts, reducing discomfort related to negative thoughts and improving symptomology (e.g. body image concerns, positive affect, depression, mood), and users' ratings of credibility and treatment expectancy between the techniques were comparable.

4.4.1.4 Social Support: Online support group

Tinnitus E-Programme 1.0 users are asked to join a professional- and lay-moderated online support forum at the beginning of the intervention to communicate with other users. The forum is hosted on an external website and joining the group must be approved by the moderators. Online support forums can provide several benefits to people with chronic conditions, such as the sharing of useful information and provision of emotional and social support to others with shared experiences (Mo & Coulson,

2013). P Thompson, Pryce, & El Refaie (2011) demonstrated that the peer support provided in group therapy can facilitate coping with tinnitus through information exchange, validation of experience, and social comparison. On their own, online support forums are shown to produce small effect sizes for tinnitus (Jasper et al., 2014), but they may be beneficial as part of a multi-faceted intervention. The GPG also recommends support groups for people with tinnitus.

Social support has been identified as a key part of self-management interventions for chronic conditions (Taylor et al, 2014). The relationship between social support and tinnitus outcomes has been explored, but with mixed findings (Erlandsson & Hallberg, 2000; Erlandsson, Hallberg, & Axelsson, 1992; Murphy, 2012). In the systematic review (Section 3.4.6), none of the unguided self-help interventions had explicitly provided social support.

4.4.1.5 Monitoring of condition with feedback to the patient

Users are asked to complete and self-score the THI (C. W. Newman et al., 1996) at the beginning and end of the intervention to monitor any changes in their levels of tinnitus distress. Based on their scores, users can obtain a tinnitus severity rating (i.e. 0-16 = 'no problem with tinnitus'; 18-36 = 'mild'; 38-56 = 'moderate'; 58-100 = 'severe'). These scores and tinnitus severity ratings provide users with feedback on their current tinnitus severity and, when measured again after ten weeks, how this has changed throughout the intervention. They are also encouraged to submit their THI scores to the intervention developer for evaluation purposes. Through self-monitoring and feedback, users can track their progress through the intervention, evaluate its success,

and gain insight into how their tinnitus affects them personally. All of these processes are believed to be essential components of psychological therapy (D.M Thompson et al., 2016), however, the exact mechanisms by which this component exerts its effects for people with tinnitus is unknown. Although use of the THI is recommended in the GPG, it's generally used in practice for diagnostic or outcome assessment (Hoare et al., 2012), rather than a self-management tool for people with tinnitus. This component was only used by one study in the systematic review (Section 3.4.6). The Tinnitus E-Programme 1.0 is the only unguided tinnitus intervention to use a validated questionnaire for the purposes of self-monitoring and feedback, with other intervention studies using such questionnaires for evaluation purposes only.

4.4.2. Behaviour change techniques

Practicing relaxation was identified as a behaviour change outcome of the intervention. Using the BCT taxonomy, five techniques to promote relaxation behaviour were identified. The identified techniques are provided in parentheses below. Users are provided with downloadable written instructions and digital audio recordings of guided relaxation exercises to develop their relaxation skills and to practice and rehearse relaxation behaviour (Code 4.1: Instruction on how to perform the behaviour; Code 8.1: Behavioural practice/rehearsal). The digital audio recordings provide users with new resources to facilitate relaxation behaviour (Code 12.5: Adding objects into the environment). The intervention also sets several daily relaxation goals to encourage users to practice relaxation in their everyday lives (Code 1.1: Goal setting [behaviour]; Code 1.4: Action planning). For example, from Week 1, users are encouraged to practice a breathing exercise at least three times a day.

These techniques cover four of the five most commonly-used (defined as those techniques in three or more studies) BCTs identified in the review of self-help interventions for tinnitus (3.4.6). Similar to the techniques identified in the review, most techniques functioned to encourage enablement (i.e. increase an individuals' capability or opportunity for performing behaviour; techniques 1.1 and 1.4) or to impart behavioural skills through training (techniques 4.1 and 8.1) (Michie, Atkins, et al., 2014). One technique (12.5) served to restructure an individual's environment to increase an individual's opportunity to practice (Michie, Atkins, et al., 2014).

4.4.3. Mode of delivery

Three internet delivery modes were identified using Webb et al. (2010)'s coding scheme. The intervention is delivered using automated functions, including 'the use of an enriched information environment' (i.e. supplementary content and links, testimonials, audio) and communicative functions, including 'access to an advisor to request advice' (i.e. professional- and lay-moderated support forums; contact details for the therapist) and 'peer-to-peer access' (i.e. peer-to-peer support forums). Optional CBT workbooks are also available to users to purchase and users can email the therapist if they have queries, but these delivery modes were not coded as they were not deemed to be a mandatory aspect of the intervention.

4.5. SUMMARY

- The three taxonomies provided a reliable method for reporting Internet-delivered self-help interventions.

- The intervention consists of five self-management intervention components, five BCTs, and three modes of internet delivery, which aim to promote relaxation behaviour and reduce tinnitus distress.
- This work also identified potential causal mechanisms by which it may exert its effect. The theoretical modelling suggests that the intervention may reduce tinnitus distress by modifying illness beliefs, reducing negative cognitions, physiological arousal, and emotional distress and facilitating behaviour change and social support.
- It is proposed that relaxation behaviour is promoted thorough encouraging enablement, imparting behavioural skills, and restructuring the user's environment.

4.6. CONTRIBUTION OF THE FINDINGS TO THE EVALUATION AND OPTIMISATION OF THE TINNITUS E-PROGRAMME 1.0

- This description identified some of the potential causal mechanisms by which the intervention could exert its effect on tinnitus distress. However, we currently do not know whether these components are acceptable to their target users; people with tinnitus.
- It identified the key self-management components that should be explored in the process evaluation that will explore users' views of these components.
- It will allow us to explore the acceptability of components that have been underutilised in self-help interventions for tinnitus, mainly 'social support' (online support forum) and 'monitoring of condition with feedback to the patient' (THI).

- It also identified potential determinants of tinnitus distress, which will contribute towards the theoretical modelling that will be carried out as part of the optimisation of the Tinnitus E-Programme 1.0.

CHAPTER 5. A MIXED METHODS PROCESS EVALUATION OF THE TINNITUS E-PROGRAMME 1.0

5.1. INTRODUCTION

As discussed in Section 1.9, the evaluation of the Tinnitus E-Programme 1.0 is guided by the MRC's guidance on developing and evaluating complex interventions (Craig et al., 2008). These guidelines emphasise the importance of carrying out adequate pilot and feasibility work prior to a definitive RCT. Interventions should be tested using a phased approach whereby a series of pilot and exploratory studies address any key uncertainties in the intervention design. So far, we know that self-help interventions for tinnitus, such as the Tinnitus E-Programme 1.0, have the potential to reduce tinnitus distress in people with tinnitus (Chapter 3). Theoretical modelling has also described the key intervention components, techniques, and mode of delivery and the key determinants of tinnitus distress that the components and techniques attempt to modify (Chapter 4). The systematic review also highlighted that the Tinnitus E-Programme 1.0 incorporates a unique component – an online support forum – which has not been previously explored in other unguided internet-based interventions for tinnitus. However, we still have little understanding of how the Tinnitus E-Programme 1.0 is used, how it works, the circumstances in which it works best, and whom it works best for.

A useful first step when evaluating developed interventions is to carry out a mixed methods process evaluation. This can provide information on the: (1) implementation

(what is delivered in practice and the structures and resources required for successful implementation); (2) mechanisms of impact (how the intervention components, and a user's interactions with them, lead to the desired changes in outcome); and (3) contextual factors (how external factors may strengthen or impede the delivery and functioning of the intervention) that influence the delivery and outcome of the intervention (Moore et al., 2014). Across the audiology and tinnitus literature, there is a lack of research on these three components of process evaluation with most research focusing on the efficacy of internet-based interventions. Specifically, the person-based approach to intervention development (Yardley, Morrison, Bradbury, & Muller, 2015) recommends that interventions should be grounded in an in-depth understanding of the users' perspective, gained through iterative qualitative research.

This chapter details a process evaluation of the Tinnitus E-Programme 1.0 that will further our understanding of the intervention's mechanisms of impact and identify any implementation or contextual factors that strengthen or impede its delivery and functioning. Most process evaluations of digital interventions have been carried out with people who were recruited offline and were using the intervention for the first time as part of a research study. This reduced the findings' external validity and relevance to real-world practice (Bennett & Glasgow, 2009; Glasgow, 2007; Glasgow, Lichtenstein, & Marcus, 2003). This study recruited users of the live intervention, as well as people with tinnitus who have not used the intervention previously. The findings informed the intervention optimisation (Chapter 6) and will inform future evaluations of the intervention, as well as the development of other similar internet-based self-management interventions.

5.2. AIM

To carry out a process evaluation to explore past, current, and new users' views and usage of the Tinnitus E-Programme 1.0 and develop an understanding of the intervention's mechanisms of impact, outcomes and identify any implementation or contextual factors that strengthen or impede its delivery and functioning.

5.3. METHODS

The reporting of the overall mixed methods study is guided by the Good Reporting of A Mixed Methods Study (GRAMMS) guidelines (O'Cathain, Murphy, & Nicholl, 2008). The GRAMMS provides guidance on the aspects of reporting that are specific to mixed methods (e.g. provide justification for mixed methods, describe insights gained from mixing methods), but does not provide detailed guidance on reporting the individual qualitative and quantitative data collection methods used in the study. Therefore, other reporting guidelines for the data collection methods were followed, where appropriate. This research has ethical approval from the University of Nottingham Research Ethics Committee (Reference Number: Q11122014 SoM NIHR RHA QEST), and was sponsored by the University of Nottingham. The protocol for this research has been published in Greenwell, Sereda, Coulson, El Refaie, et al. (2016).

5.3.1. Overarching design

Consistent with a pragmatic paradigm (Section 2.5), two parallel mixed methods studies were carried out with two different populations: (1) current or past users of the Tinnitus E-Programme 1.0; and (2) new users of the same intervention. This design allowed us to compare and contrast users' perspectives across two different intervention contexts (real-word use vs use in a research context). The use of both qualitative and quantitative research methods and more than one study population was chosen to develop a more complete, in-depth, and valid understanding of the intervention than if only one method or population was used (Creswell & Plano Clark, 2011; Torrance, 2012). Mixed methods have been used successfully for process evaluations (Moore et al., 2014) and evaluations of digital interventions (Morrison et al., 2014; Yardley et al., 2011). Study 1 used an online survey to explore the views of past and current users of the intervention. Study 2 recruited people who have not used the intervention previously, asked them to complete the intervention, and explored their views and usage of the intervention using retrospective semi-structured interviews and relaxation logs. The findings of the two mixed methods studies were triangulated in an overall interpretation (Section 5.3.4). A diagrammatical representation of the overall study design can be found in Figure 5.1.

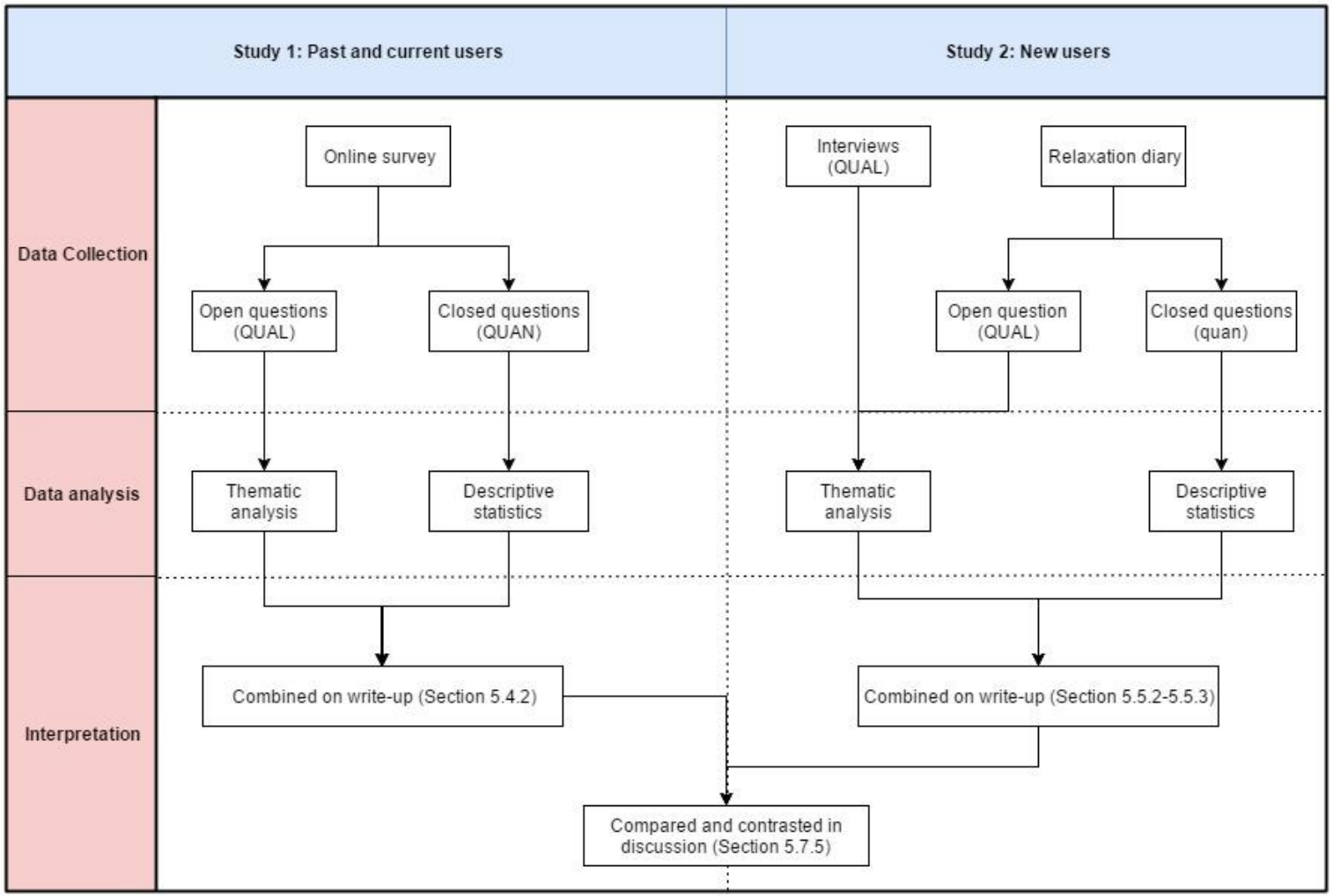

Figure 5.1 Data collection, analysis, and interpretation for Study 1 and 2

Key: QUAN = quantitative data; QUAL = qualitative data; quan = quantitative data that is secondary to the qualitative data

5.3.2. Study 1: Online survey with current and past users

5.3.2.1 Objectives

1. To explore past and current users' satisfaction with the intervention design and its components;
2. To assess past and current users' usage of the intervention and its components;
3. To explore past and current users' reasons for using, or not using, the intervention and reasons for not using the online support forum;
4. To explore potential intervention benefits gained by past and current users.

5.3.2.2 Design

Study 1 explored past and current users' views and usage of the intervention in the real world, outside of a research context. Due to technical limitations of the intervention, it was not possible to accurately monitor intervention usage. Therefore, an online survey was used to elicit self-reports of how users used the intervention, as well as users' views of the intervention. A convergent parallel mixed methods design (Creswell & Plano Clark, 2011) was used in which qualitative and quantitative methods were implemented simultaneously and given equal weight, but the data analysed separately. The simultaneous collection of qualitative and quantitative data in the same study made this an efficient design. Specifically, a data-validation variant of this mixed methods design was adopted (Creswell & Plano Clark, 2011) in which both open (i.e., qualitative) and closed (i.e., quantitative) questions were used in a

survey, and then the qualitative data used to validate and elaborate on the quantitative data.

5.3.2.3 Reporting

The reporting of this study follows the checklist for reporting results of internet e-surveys (CHERRIES; Eysenbach, 2004), which is a 30-item checklist. CHERRIES is the only reporting guidelines specific to online surveys and is endorsed by the EQUATOR network (Equator Network, 2015), an international initiative that aims to promote transparent and accurate reporting of published health research literature, and the Journal of Medical Internet Research (JMIR Publications, 2016).

5.3.2.4 Recruitment and participants

Participants in Study 1 self-selected, based on their own judgements of whether they met the following inclusion criteria: (1) adults aged 18 years and over, (2) ability to read English, (3) access and ability to use the Internet, and (4) had visited the Tinnitus E-Programme 1.0 website or used the intervention. Participants may have accessed the intervention anytime since it was launched in 2009. There were no exclusions regarding length of time since starting the intervention, tinnitus duration, severity, or co-morbidities.

Past and current intervention users were invited to take part in an online survey hosted on SurveyMonkey©. Advertisements and the participant information sheet were

posted on the Tinnitus E-Programme 1.0 website and online support forum. Advertisements included a direct link to the online survey or a dedicated page on the Tinnitus E-Programme 1.0 website. The information sheet detailed the purpose of the study, the length of time required to complete the survey, who the investigator and the supervision team were, and which data were stored, where, and for how long. The survey was also advertised via social media and national charities in an attempt to reach those who no longer interacted with the intervention or website. Email invitations and the participant information sheet were sent to the 97 unique email addresses that had been registered with the intervention website or online support forum at the time of recruitment. Twelve of the email addresses were found to no longer be valid. Reminder emails were sent to those with valid email addresses two months later.

Sample sizes for similar descriptive online survey studies have been between 50-249 individuals (Buchanan & Coulson, 2007; Coulson, 2013; Coulson & Knibb, 2007; Holbrey & Coulson, 2013; Malik & Coulson, 2008). Therefore, a sample size of 50 was deemed acceptable. From the statistics provided in Table 5.1, recruitment to this target was judged as achievable. The survey was launched in February 2015 and closed in June 2016, once 50 participants were recruited. No incentives were offered to complete the survey.

Table 5.1: Intervention statistics provided by the website host for the one-month period between 01/08/2014 – 31/08/14

Variable	Statistic
Total page views	1362
Visitors	1025
Average visit length	1 hour 40 minutes
No. of course materials page views	105
No. of downloads of intervention materials	46
Amount of relaxation music plays	7
No. of members in the discussion forum as of 01/09/2014	144
No. of members who have registered their email addresses with the intervention or discussion forum since its inception	185

5.3.2.5 Online survey: Development, piloting and administration

The initial survey design was informed by the study rationale, relevant literature, and the comprehensive intervention description developed previously (Greenwell et al., 2015). The survey focused on the information resources (i.e., education about condition and management, information about available resources; training/rehearsal for psychological strategies), relaxation exercises (i.e., training/rehearsal for psychological strategies), THI (i.e., monitoring of condition with feedback to the patient), and online support forum (i.e., social support).

The survey used a mix of closed and open questions concerned with: (1) reasons for participating or not participating in the intervention; (2) how the intervention was used; (3) satisfaction with the intervention; (4) acceptability of the individual intervention components; and (5) benefits derived from the intervention and its impact on tinnitus management. Satisfaction with the Tinnitus E-Programme 1.0 was assessed by user ratings of its usability, trustworthiness and aesthetic appeal, and user perceptions on

how achievable the required time was. Demographic data were also collected on gender, age, country of residence, whether English was their first language, presence of tinnitus, tinnitus duration, and tinnitus management strategies used.

Adaptive questioning[3] was used so that participants only viewed the questions that were relevant to them. Depending on their answers, participants were presented with between 7-18 pages of questions on the online survey. There were between 1-5 questions per page and questions with rating scales had no more than 7 items to avoid excessive page scrolling and encourage survey completion.

To assess the acceptability and face validity of the survey, an initial set of survey questions was reviewed by a public and patient involvement (PPI) panel assembled for the purposes of this study. The panel included four people with tinnitus and/or hearing loss who were recruited from an established National Institute for Health Research Nottingham Hearing Biomedical Research Unit (NIHR Nottingham Hearing BRU) PPI panel, based on their availability and previous experience of reviewing research materials. One voluntary sector representative from the British Tinnitus Association who had experience in writing communication materials for people with tinnitus was also recruited. A focus group was carried out with these PPI members to gather initial feedback on a paper version of the draft survey. The focus group was co-facilitated by the PPI manager at NIHR Nottingham Hearing BRU and an external facilitator who was not involved in the study but was familiar with issues relevant to hearing research.

[3] Adaptive questioning is where survey questions are conditionally displayed, depending on how previous questions were answered.

Panel feedback focused on the relevance and ordering of the questions, language used, and appropriateness of question type (i.e. closed or open). Following the focus group, a revised survey was uploaded onto SurveyMonkey© and this online version was circulated to the PPI panel via email for additional comments. The panel was satisfied with the online version and no further amendments were made.

The online survey was subsequently piloted with three Tinnitus E-Programme 1.0 users recruited from the intervention's online support forum. These participants completed the online survey and answered four additional questions about the survey length and relevance of the questions and closed-question answers. Informed consent was gained from these pilot participants who were told that their answers may or may not be used in the final analysis, depending on the outcome of the pilot. All three participants reported that the survey took less than 30 minutes and "*just the right amount of time*" to complete. One participant suggested that it would be helpful to add a free-text comments box next to some of the closed questions to allow people to clarify their answers. The same participant also suggested adding a "*cannot remember*" option for the questions regarding intervention usage (e.g. did you use the online support forum?) for those who used the intervention a long time ago. Both of these changes were made yielding the final survey (Appendix 4). As these amendments were minor and the questions did not change, the pilot data were included in the final analysis.

The online survey was anonymous (i.e. no personal data or IP addresses were collected) to encourage participation. Initially, the online survey was open to anyone who accessed the publically available survey link and it was restricted so that only one

submission per computer was allowed. However, it became clear that some participants were reaching the survey before they had made the decision to engage with the intervention, which was not anticipated. The survey was subsequently modified to include a disqualifier question to identify those who have not yet used the intervention, but intended to do so in the future. These participants were asked to return to the survey once they had completed the intervention and use the same security word so they could be identified as a duplicate participant on their return.

Participant responses were saved as they progressed through the survey so incomplete data could be accessed. Previous answers could be modified by clicking on the back button. View rate (number of unique survey visitors) was not recorded. Participants were given a 14-day period in which they could request to have their survey responses deleted. After this period, their responses were downloaded onto university servers and could not be deleted. Participants were asked to provide a security word as part of the survey and recite this for data identification purposes should they wish to withdraw their data from the study.

5.3.2.6 Analysis

Answers to closed questions were analysed in IBM's SPSS Statistics 22 (IBM Corp. Released, 2011) using descriptive statistics, including frequencies and percentages, and each statistic carried out on complete data only. To be defined as complete data, participants needed to respond to question 11, which asked if they had used the intervention. Future users, that is, those who indicated that they had not used the intervention but intended to do so in the future, were excluded from the analysis.

Answers to the open questions were analysed separately using inductive thematic analysis (Braun & Clarke, 2006) and QSR's NVivo 10 (QSR International Pty Ltd., 2014) qualitative data analysis software. Analysis was informed by guidelines for establishing validity in qualitative research (Krefting, 1991; Yardley, 2007), which recommends providing audit trails, comparing researchers' coding, ensuring rigor, and actively looking for data that contradicts your initial assumptions. Three coders (including the author) familiarised themselves with the data through repeated reading of the survey answers. The author then utilized line-by-line coding, a technique from grounded theory (Charmaz, 2006), in which each line of a transcript is coded. This ensured the coder remained open to the data and that subtle nuances in it were not missed.

The author developed a coding manual that listed all codes, including descriptions and example quotes from the text (Joffe & Yardley, 2004). The coding manual improved the rigor of the research, while also providing an audit trail for analysis decisions. At least one other coder independently applied the coding manual to all transcripts to clarify ambiguous codes, remove duplicate codes, and identify data that did not fit the coding scheme. Coding was compared and discussed between coders and subsequent modifications made to the coding manual. Coders collectively organised these codes into overarching themes and the coding manual was updated accordingly. The constant comparison method (Glaser & Strauss, 1967) was used to compare codes across different participants, contexts, and situations. Disconfirming case analysis (Yardley, 2007), in which coders actively sought out data that did not fit with the identified themes was used. These two techniques were used to ensure the analysis was carried out with rigor. The final interpretations were reviewed and agreed by the author and

three other coders. Participant comments (written exactly as they appeared in the survey) were used in the final write-up to illustrate the themes and pseudonyms used to refer to these participants.

Consistent with a data-validation variant of the convergent parallel mixed methods design (Creswell & Plano Clark, 2011), the qualitative findings were used to validate and elaborate on the quantitative data. The qualitative and quantitative results were merged in the results section using a side-by-side comparison (Creswell & Plano Clark, 2011). This integration was carried out by the author and then reviewed and agreed by the other coders.

5.3.3. Study 2: Retrospective interviews and relaxation log with new users

5.3.3.1 Objectives

1. To explore new users' expectations of the intervention;
2. To explore new users' views on the intervention and its individual components;
3. To explore new users' usage of the intervention and reasons for non-usage;
4. To explore potential intervention benefits gained by new users;
5. To assess new users' enactment with the relaxation goals and identify any barriers to reaching these goals.

5.3.3.2 Design

Study 2 recruited a cohort of individuals with tinnitus who have not previously used the intervention. Participants completed the intervention for the first time and took part in a semi-structured interview. Participants also completed a relaxation log to explore the extent to which they enacted the relaxation skills learned in the intervention and any barriers to doing so.

Qualitative findings were given priority over quantitative findings. This is consistent with the person-based approach, which focuses on developing an in-depth understanding the users' perspective through qualitative methods. An adapted version of an embedded mixed methods design was used (Creswell & Plano Clark, 2011) in which both the qualitative interview and quantitative relaxation log data collection and analysis were embedded within an overall qualitative research design. As such, relaxation log data were secondary to the qualitative data and served to enhance understanding of the qualitative interview findings.

5.3.3.3 Reporting

The interviews study is reported following the consolidated criteria for reporting qualitative research (COREQ; Tong, Sainsbury, & Craig, 2007), which is a 32-item checklist for interviews and focus groups. The COREQ checklist is the only guidelines specifically aimed at the reporting of interview studies and is recommended by the Equator Network (Equator Network, 2015).

5.3.3.4 Participants

Participants in Study 2 self-selected, based on their judgement of whether they met the following inclusion criteria: (1) adults aged 18 years and over, (2) ability to read English, (3) access and ability to use the Internet, (4) have self-reported tinnitus, (5) reside in the United Kingdom, and (6) have not previously used the Tinnitus E-Programme 1.0. Again, as the intervention is meant to be suitable for all tinnitus users, participants were not excluded based on any tinnitus-related characteristics.

5.3.3.5 Recruitment and procedure

A purposive sample of people was chosen from the NIHR Nottingham Hearing BRU research database, which includes approximately 900 UK residents with tinnitus who have agreed to be contacted about research. Maximum variation sampling (Polkinghorne, 2005) was used to ensure that a diverse sample with different demographics (e.g., gender, age) was recruited. As recruitment progressed, targeting became more specific as participants with certain characteristics (e.g., hearing loss, short tinnitus duration, younger age) were actively sought out to fill any demographic gaps in the current sample. An email invitation, together with a participant information sheet, was sent to a total of 42 database members by a member of the research team. On completion of all research activities, participants were given a free copy of the three CBT workbooks that were available to purchase on the Tinnitus E-Programme 1.0 website.

The procedure for Study 2 is illustrated in Figure 5.2. Once participants expressed an interest in the research, the researcher gained their informed consent using a paper or electronic consent form. Recruited participants were then sent the hyperlink to the Tinnitus E-Programme 1.0 and asked to notify the researcher once they started using the intervention. An interview was organised for six to eight weeks after their start date to explore how acceptable the six-week timeline was and to ensure maximum recall of intervention experiences. During this time, participants had sufficient time to complete the first six sections of the intervention and progress into the maintenance phase (Appendix 2). One week before their interview date, participants were emailed a set of sample interview questions, a hyperlink to their online relaxation log, and instructions on how to complete the log. Participants were sent a set of sample interview questions to encourage transparency with the interview process and improve recall by giving them time to think about the different topic areas and revisit the website if needed (Coulson, 2015).

Participants were asked to complete a daily relaxation log on paper or online during the four-week maintenance phase. Participants completed the relaxation log after their interviews so that their views and usage of the intervention were not influenced by this research activity. Email reminders were sent to those who had not yet started the intervention, organised an interview date, or completed their relaxation log. Recruitment ceased once data saturation was reached for the interviews; that is, when no new themes emerged (Patton, 1990).

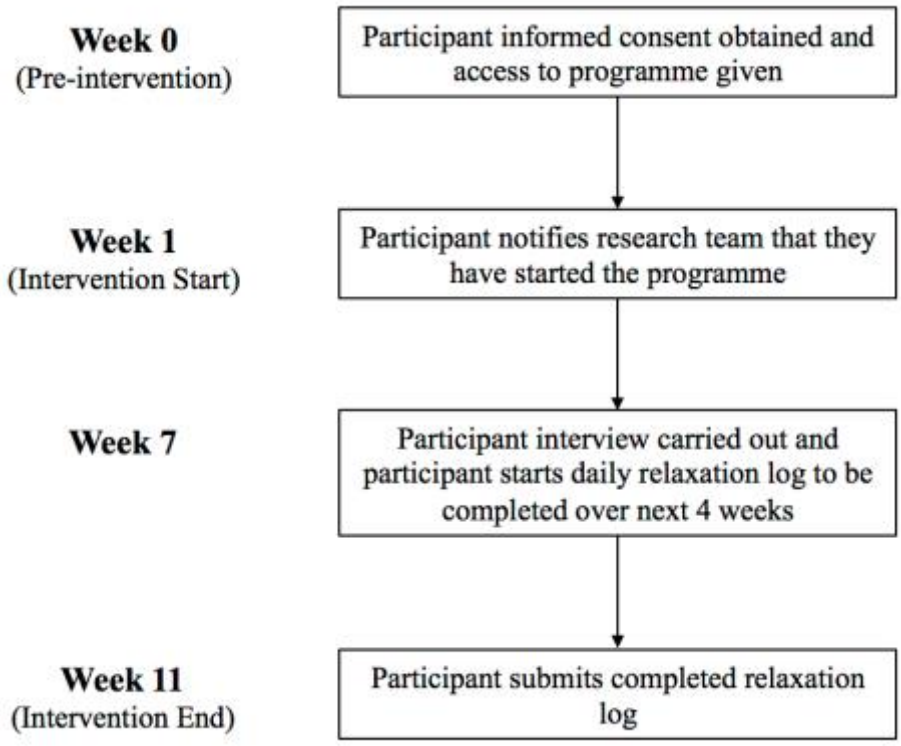

Figure 5.2 Flow chart showing the procedure for Study 2 (Taken from Greenwell, Sereda, Coulson, & Hoare, 2016).
Participants are asked to complete the intervention between weeks 1-10. Intervention content is delivered between weeks 1-6 and weeks 7-10 is the maintenance period during which time participants are asked to practice the relaxation skills they learned during the first six weeks.

5.3.3.6 Interviews

An interview guide was developed that was informed by the literature, intervention coding, and study rationale. Specifically, the interview questions were concerned with how people used the intervention; reasons for any non-usage; experiences of using the intervention; expectations of the intervention; usability and acceptability of the intervention, as well as its individual components; benefits derived from the intervention; and suggested improvements to the intervention. The interview guide can be found in Appendix 5. The interview guide was reviewed by the NIHR Nottingham Hearing BRU PPI panel and piloted with a previous user of the Tinnitus E-Programme 1.0. No modifications resulted from this process.

Demographic data, including gender, age, ethnicity, and tinnitus duration, were recorded. Interviews were carried out by the author, a female health psychologist and PhD student experienced in qualitative interviewing who was not involved in the Tinnitus E-Programme 1.0's development. Participants were aware that the study was part of the interviewer's PhD and that the aim of the study was to improve the Tinnitus E-Programme 1.0 for future users. None of the participants were known to the interviewer prior to recruitment. Only the interviewer and participant were present during the interviews. Interviews were carried out between April and November 2015 and lasted 26-81 minutes each.

Participants were given the choice of being interviewed in person at the research department, over the phone, or via video chat. Those with severe or profound hearing loss were offered the option to be interviewed using text communication methods (e.g. instant messaging or email). Five interviews were carried out over the phone, three in person at the research department, three via video chat, one at a participants' place of work, and one via email. The audio from the interviews was recorded using a digital dictaphone and transcribed by a professional transcriber using strict verbatim (i.e. including umms, laughter and hesitations). A transcription key can be found in Appendix 6. The text from the textual communication methods was saved electronically.

5.3.3.7 Relaxation log

The relaxation log assessed users' enactment of the relaxation goals set by the intervention during the four-week maintenance period. Users were set two daily goals;

one for each relaxation exercise. An online relaxation log was created for each participant using Google Sheets, an Internet-based spreadsheet. Google Sheets were hosted on the NIHR Google Hub, a secure online file storage system. The relaxation log was in tabular format with four columns and 28 rows representing each day of the four-week period. Users were required to answer the following three questions each day:

1. Did you practice the mind calming breathing exercise 3 or more times today? (Goal 1)
2. Did you practice any of the 30-minute relaxation exercises today? (Goal 2)
3. Did you use any other parts of the Tinnitus E-Programme today? If yes, please write which parts. If no, please write "no."

There was also a free-text comments box to write any other comments for each day. At the end of week 10, participants were asked to answer one final open question: "Did you practice the recommended relaxation exercises every day? If not, could you tell us about some of the things that made it difficult to do so?".

Users had the option of either accessing and completing their online log each day or printing and completing a paper copy. The completed paper copy could be posted or transferred onto the online log. Participants were provided with instructions for completing their online relaxation log. Each participant was given a unique hyperlink to access their personal log, and only the participant and researcher had access to this hyperlink. Relaxation logs were saved anonymously and participants were identified by a unique participant identification code. It was necessary that the author knew the

identity of the participants completing the log so that the author could send out emails to participants about their log.

5.3.3.8 Analysis

Interview data and open-question responses from the relaxation logs were analysed together using the same inductive thematic analysis strategy outlined in Study 1 (Section 5.3.2.6). The first coder was the same person who carried out the interviews. Line-by-line coding began during data collection to help the first coder reflect and learn from previous interviews and refocus future interviews (Charmaz, 2006). Reflections from the interviewer regarding the interviews and data analysis were provided (Section 5.5.4) to consider how the role of the interviewer may have influenced the findings (Krefting, 1991; Yardley, 2007). Similar to Study 1, participants were given pseudonyms.

Quantitative relaxation log data were analysed as frequencies and percentages. This data provided a secondary and supportive role to the qualitative data and was used to enhance the qualitative accounts. Consistent with an embedded mixed methods design, results from the relaxation logs are reported alongside the qualitative themes. This integration was carried out by the author and then reviewed and agreed by three other coders.

5.3.4. Summary and triangulation of Study 1 and 2 findings

The findings from the Study 1 and 2 were summarised and triangulated (i.e., compared and contrasted) to produce an in-depth understanding of the intervention's mechanisms of impact and identify any implementation or contextual factors that strengthen or impede its delivery and functioning (Section 5.7). The GRAMMS guidelines specify that reports of mixed methods studies should describe any insights gained, specifically from mixing methods. In the context of this study, this description will also be extended to include any insights gained from mixing the findings from two different populations.

5.4. RESULTS: STUDY 1 (ONLINE SURVEY WITH CURRENT AND PAST USERS)

5.4.1. Participant characteristics

Fifty people consented to the survey. Of these, 13 were excluded because they identified themselves as future users (rather than as users or non-users) and 10 were excluded because they provided incomplete data. Analysis was carried out on the remaining 27 participants (completion rate of 73%). Participants were from 14 different countries, with 48% (n = 13) living in the UK. Two participants did not have tinnitus; rather they were health professionals who provided services to people with tinnitus. Participant characteristics are provided in Table 5.2. Twenty-one participants provided answers to the open questions. Eighteen had used at least some of the intervention and one participant had used the forum only. The characteristics of these participants are outlined in Table 5.3.

Table 5.2 Participant characteristics for Study 1 quantitative

Variable	*n* (%)
Age (n=27)	
18-24	1 (3.7)
25-34	5 (18.5)
35-44	3 (11.1)
45-54	5 (18.5)
55-64	8 (29.6)
65-74	5 (18.5)
Gender (n=27)	
Female	14 (51.9)
Male	13 (48.1)
Country (n=27)	
Argentina	1 (3.7)
Australia	1 (3.7)
Austria	1 (3.7)
Canada	1 (3.7)
Czech Republic	1 (3.7)
Finland	1 (3.7)
India	1 (3.7)
Ireland	1 (3.7)
New Zealand	2 (7.4)
Portugal	1 (3.7)
Slovenia	1 (3.7)
Spain	1 (3.7)
United Kingdom	13 (48.1)
United States	1 (3.7)
English as first language (n=27)	
Yes	20 (74.1)
No	7 (25.9)
Do you have tinnitus? (n=27)	
Yes	25 (92.6)
No, I have never had tinnitus	2 (7.4)
Tinnitus Duration (n=25)	
< 6 months	4 (16.0)
1-5 years	9 (36.0)
5-10 years	5 (20.0)
10+ years	7 (28.0)
What have you used to help you manage your tinnitus? (n=25)	
Sound therapy	16 (64.0)
Relaxation	19 (76.0)
Counselling or other psychological therapy	9 (36.0)
Tinnitus retraining therapy	5 (20.0)
Medication	11 (44.0)
Seeking out information about tinnitus:	
• from health professionals	17 (68.0)
• online	23 (92.0)
• from books	10 (40.0)
• from other people with tinnitus	16 (64.0)
Taking part in face-to-face tinnitus support groups	2 (8.0)
Taking part in online tinnitus support groups	16 (64.0)
Contacting a charity or non-profit organisation	10 (40.0)
Other[a]	2 (8.0)

Key: [a]Included changing diet (i.e. cutting out caffeine), hyperbaric oxygen therapy, and dietary supplements (e.g. ginkgo biloba)

Notes: Percentages for each variable are reported using one decimal point so may not always add up to 100%. Only the variables with responses are reported.

Table 5.3 Participant characteristics for Study 1 qualitative data

Pseudonym	Gender	Age range	Country	English as first language?	PwT/ HP	Forum user?	Intervention user?	Self-reported benefit gained from intervention/forum?
Anna	Female	55-64	Australia	Yes	PwT	Yes	Yes (all)	Yes
Jayne	Female	55-64	UK	Yes	PwT	Yes	No	Yes (forum)
Alice	Female	55-64	New Zealand	Yes	PwT	Yes	Yes (all)	Yes
James	Male	45-54	USA	Yes	PwT	Yes	Yes (all)	Yes
Silvia	Female	65-74	Spain	Yes	PwT	No	Yes (some)	Yes
Gavin	Male	35-44	UK	Yes	PwT	No	Yes (some)	Yes
Katharina	Female	55-64	Austria	Yes	PwT	Cannot remember	Yes (all)	Yes
Sandra	Female	45-54	UK	Yes	PwT	Yes	Yes (all)	Yes
Nora	Female	65-74	Ireland	Yes	PwT	Yes	Yes (all)	Yes
Oliver	Male	45-54	New Zealand	Yes	PwT	Yes	Yes (some)	No
Jim	Male	65-74	UK	Yes	PwT	Cannot remember	Yes (some)	No
Isabella	Female	55-64	Canada	Yes	PwT	No	Yes (all)	Yes
Dave	Male	55-64	UK	Yes	PwT	Cannot remember	Yes (all)	Yes
Klara	Female	35-44	Czech Republic	No	PwT	Cannot remember	Yes (some)	Yes
Jeremy	Male	65-74	UK	Yes	PwT	Cannot remember	Yes (some)	Yes
Laura	Female	25-34	UK	Yes	PwT	Yes	Yes (some)	Yes
Alma	Female	45-54	Argentina	No	HP	Not Applicable	Yes (some)	Yes
Martim	Male	25-34	Portugal	No	PwT	No	No	-
Cathy	Female	45-54	UK	Yes	HP	Not Applicable	Yes (some)	Yes
Aditya	Male	25-34	India	No	PwT	Cannot remember	Yes (all)	Yes
Matias	Male	25-34	Finland	No	PwT	No	No	-

Key: PwT= person with tinnitus; HP = Health professional

5.4.2. Themes

There were six themes identified across the quantitative and qualitative data: (1) How participants used the intervention; (2) Satisfaction with the intervention; (3) Acceptability of the intervention and its components; (4) Motivations for engaging with the intervention; (5) Barriers and facilitators to engagement; and (6) Gaining benefit. Four of these themes (Themes 3-6) were identified in the thematic analysis. Where appropriate, relevant quantitative findings were discussed alongside these themes to allow direct comparisons of the qualitative and quantitative findings (Themes 3 and 6).

The remaining quantitative findings that did not fit under the four qualitative themes were reported under two other themes (Theme 1 and 2), which were created for the purpose of reporting. Where appropriate, qualitative findings were used to support, challenge, or enrich understanding of the quantitative findings (Theme 2). Table 5.4 provides a description of the six themes identified in this study and outlines how the qualitative and quantitative findings were reported across these themes.

5.4.2.1 Theme 1: How participants used the Tinnitus E-Programme 1.0

Table 5.5 outlines participants' responses to the closed questions on how they used, and continued to use, the Tinnitus E-Programme 1.0. Most people found out about the intervention via an internet search engine. Forty-one percent of participants reported using *all* of the intervention (*n*=11), 37% (*n*=10) used *some* of the intervention, and 22% percent (*n*=6) did not use the intervention at all.

Table 5.4 How qualitative and quantitative findings were reported across the six themes identified in Study 1

Theme	Type of research data	Description
1. How participants used the intervention	Quantitative	Describes how much of the intervention the participants used, how long ago they used it, which components they used, and how they use the intervention now.
2. Satisfaction with the intervention	Mixed	Assesses users' satisfaction with the intervention in terms of its usability, aesthetics, trustworthiness and clarity of instructions and describes users' views on these aspects.
3. Acceptability of the intervention components*	Mixed	Assesses users' satisfaction with, and usefulness of, the four self-management components contained in the intervention and describes users' views on these aspects.
4. Motivations for engaging with the intervention*	Qualitative	Describes users' motivations for engaging with the intervention.
5. Barriers and facilitators to engagement*	Qualitative	Describes users' views on the factors that discouraged or motivated them to engage with the intervention.
6. Gaining benefit*	Mixed	Assesses the extent to which users benefitted from the intervention and describes users' views on any benefits they gained from the intervention.

Key: *Themes identified in the qualitative thematic analysis

All participants who reported using some of the intervention indicated using at least some of the information leaflets and relaxation exercises, and all but two users (75%; *n*=6) reported completing the THI (the remaining users could not recall whether they had used it). Almost half of users (48%; *n*=10) reported joining the online support forum and reading the posts of others and only half of forum users had posted on the forum themselves. Most forum users (70%; *n*=7) indicated that they no longer use the forum.

Table 5.5 Participants' interactions with the Tinnitus E-Programme 1.0

Variable	*n* (%)
How did you find out about the website? (n=27)	
Internet search engine	19 (70.4)
Health professional	2 (7.4)
Word of mouth	2 (7.4)
Other[a]	4 (14.8)
Did you use the TEP? (n=27)	
Yes, all of it	11 (40.7)
Yes, some of it	10 (37.0)
No	6 (22.2)
How do you use the programme now? (n=18)	
I have not used it since the first time I used it	8 (44.4)
I still use at least some of the programme regularly	6 (33.3)
I still use at least some of the programme occasionally	4 (22.2)
When was the last time you used any part of the programme? (n=18)	
In the last 6 months	7 (38.9)
7 months-1 year ago	2 (11.1)
More than 1 year ago	9 (50.0)
Do you think you will use the programme again in the future? (n=8)	
Yes	3 (37.5)
No	5 (62.5)
Did you read the information leaflets? (n=8)	
Yes, all weeks	3 (37.5)
Yes, but only some of the leaflets	5 (62.5)
Did you do any of the relaxation exercises? (n=8)	
Yes, all relaxation exercises	1 (12.5)
Yes, but only some of the exercises	7 (87.5)
Did you complete the THI? (n=8)	
Yes, at the beginning of the programme	3 (37.5)
Yes, at the beginning AND end of the programme	3 (37.5)
Cannot remember	2 (25.0)
Did you join the Yahoo! support forum? (n=21)	
Yes	10 (47.6)
No	5 (23.8)
Cannot remember	6 (28.6)
Did you read the posts of others? (n=10)	
Yes	10 (100)
Did you post anything yourself? (n=10)	
Yes	5 (50)
No	3 (30)
Cannot remember	2 (20)
How do you use the forum now? (n=10)	
I do not use it anymore	7 (70)
I use it occasionally	3 (30)
Did the programme help you? (n=20)	
Yes	18 (90.0)
No	2 (10.0)
Did the forum help you? (n=1)[b]	
Yes	1 (100)

Key: [a]Including tinnitus online support forum, contact with the therapist, and searching online; [b]This question was available only to those who used the forum and not the main programme. All other users were asked 'Did the programme help you?'
Notes: Percentages for each variable are reported using one decimal point so may not always add up to 100%. Only the variables with responses are reported.

Approximately half of users (56%; *n*=10) reported still using the intervention at least occasionally. Of those who had not used the intervention since first use of it, most (63%; *n*=5) reported that they would not use the programme again in the future. Fifty percent of users *(n*=9) had used the intervention more than one year before the end of the survey.

5.4.2.2 Theme 2: Satisfaction with the intervention

Table 5.6 outlines users' quantitative ratings of satisfaction with the intervention. Regarding its usability, all users (*n*=18) reported that the website was easy to use. Users reported that it was clear how much time they needed to spend on the intervention (100%; *n*=18), which intervention tasks they had to complete (94%; *n*=17), the order in which they needed to complete the intervention tasks (100%; *n*=18), and that the intervention's time requirement was achievable (94%; *n*=17). Ninety-four percent of users (*n*=17) indicated that the intervention was a trustworthy source of support for tinnitus.

The poorest satisfaction ratings were given for the intervention's aesthetics, with one third of users (*n*=12) disagreeing with the statement that the intervention website was visually attractive. The qualitative data from the open survey questions provided further support regarding the importance of the intervention's aesthetics and presentation. Matias (non-user with tinnitus, Finland) explained why he chose not to use the intervention: "*The website design was not too inviting. I thought it looked a little unprofessional and uninteresting"*.

Table 5.6 Users' ratings of satisfaction with the intervention (n=18)

Variable	Strongly Agree, n (%)	Agree, n (%)	Disagree, n (%)
The website was easy to use	8 (44.4)	10 (55.6)	0
The website was visually attractive	2 (11.1)	10 (55.6)	6 (33.3)
The programme was a trustworthy source of support for tinnitus	11 (61.1)	6 (33.3)	1 (5.6)
It was clear from the website which tasks I had to complete	11 (61.1)	6 (33.3)	1 (5.6)
It was clear how much of my time I needed to spend on the programme	10 (55.6)	8 (44.4)	0
The amount of time I needed to spend on the programme was achievable	8 (44.4)	9 (50.0)	1 (5.6)
The order in which I needed to complete the tasks was clear	9 (50.0)	9 (50.0)	0

Note: Only the variables with responses are reported

For one user, the language used was also an important part of the intervention's presentation: "*The use of 'my patients' was irritating to me"* (Jim, user with tinnitus, UK). In addition to the aspects of satisfaction assessed by the closed survey questions, the qualitative data also revealed that some users liked that it was a stepped programme that introduced different intervention components gradually.

5.4.2.3 Theme 3: Acceptability of the intervention components

All users (*n*=18) rated the information resources easy to understand. The qualitative data revealed that users felt the information was better than most explanations they had previously come across and they particularly valued the explanation of the tinnitus cycle and scientific nature of the content. All but one user (*n*=17) reported that the information leaflets were relevant to them and were helpful. Despite these generally positive views, the qualitative data revealed that there were some users, including the two users who did not gain benefit from the intervention, who perceived the

information resources less positively. Specifically, users commented that they already knew a lot of the information, found it was not *"authoritative",* and lacked essential information: *"The [tinnitus] E programme made very little mention of habituation and the processes involved"* (Oliver, user with tinnitus, New Zealand). One user commented that, as she has profound sensorineural hearing loss and hyperacusis, some of the information was not as relevant to her.

All but one user (*n*=17) reported that the relaxation exercises were helpful. The qualitative data provided further support for these positive views: *"The relaxation exercises were the key for me to move on with my life"* (Anna, user with tinnitus, Australia). One user who found the relaxation helpful was disappointed that it did not also help her to manage her hyperacusis (sensitivity to sound), which was also problematic for her. One user commented how she practiced the intervention's relaxation exercises regularly at one time but has since *"moved on to mindfulness",* which she finds *"generally more helpful"*.

Seventy-eight percent of users (*n*=14) of the relaxation exercises reported that the relaxation goals were achievable. Further to this, the qualitative data suggested that some users might be more motivated than others to meet these goals:

> *30 mins sounds long, so I was too lazy to do it [the relaxation]. Maybe provide shorter versions [of the exercises] too e.g. 5-10 mins? (Laura, user with tinnitus, UK)*

> *I had to conciously [sic] commit to spending the time but I was so desperate that I would have fitted in hours if it would have helped* (Anna, user with tinnitus, Australia)

Most users (81%; *n*=13) who reported using the THI found it helpful. One user who reported that she did not find the THI helpful explained that this was because she was already aware of how tinnitus impacts on her life but appreciated that it may be helpful for the intervention developers to be able to measure the effectiveness of the intervention and improve it accordingly. One user was disappointed that he did not get an acknowledgement of receipt when he submitted his completed THI to the therapist.

Views on the online support forum were mixed; with just over a half of forum users (60%; *n*=6) reporting that they found it helpful. Only one user provided an explanation of why she found the forum helpful:

> *Tinnitus can be a very isolating and frightening condition. The support forum is a positive environment in which help can be provided and sufferers do not feel so alone. Some of the mainstream online forums are full of frightening scare stories, the [Tinnitus] e-programme is a much safer, kinder and more positive environment* (Jayne, forum user with tinnitus, UK)

Several users did not join the forum or stopped using it because they perceived the forum posts to be negative or believed it would, or did, have a negative impact on their tinnitus. In the quotes below, Anna and Nora explained why they no longer used the forum. It was not that they did not find online support forums useful, rather, it was the

negative experiences they encountered on this particular forum that caused them to disengage from it. Despite these experiences, Anna still rated the intervention forum as helpful and was able to report some benefit she gained from it and Nora went on to join another forum:

> *I dont [sic] use the [Tinnitus E-Programme 1.0] forum now as it is mostly people who are in the acute distress who post there and I find reading such posts now increases my own tinnitus for a day or so. At the time it helped me feel that I wasnt [sic] alone and others were finding ways to live with the horror that I felt this affliction to be at the time* (Anna, user with tinnitus, UK)

> *At first I found it very frightening because many of the people posting were just as desperate as myself. I would become more anxious reading about their despair. I didn't find enough positive experiences however I found another online group and met a lady who became my lifeline* (Nora, user with tinnitus, Ireland)

Two users expressed a dislike for the platform that hosts the forum with one noting that it takes over their computer. Another user commented that they received too many emails from the forum. Other users explained that they did not join the Tinnitus E-Programme 1.0 forum because they were already members of other online forums, including the Tinnitus Talk support forum and Action on Hearing Loss forum. One user had used the Tinnitus E-Programme 1.0 forum but found it less helpful than other forums she had tried.

5.4.2.4 Theme 4: Motivations for engaging with the intervention

Users outlined several motivations for using the intervention. First, users accessed the intervention because of desperation when they were experiencing high levels of tinnitus distress or were struggling to manage their tinnitus:

> *[I used the intervention because] at the time I was very very desperate to do something to relieve myself from the incessant ringing. I could not read a book watch TV or a film or use a computer. I cried often that this had happened to me and I felt it was my fault* (Anna, user with tinnitus, Australia)

> *[I used the intervention] because the tinnitus seemed to get worse. I couldn't self-help like I did the first time* (Laura, user with tinnitus, UK)

Second, users wanted to gain support in managing their tinnitus or provide support to others with tinnitus. Users spoke about how they were motivated by a perceived lack of support from health professionals and the inadequacies of the health services in their country:

> *[I used the intervention] because in my country there is very limited help for tinnitus sufferers. There are literally no support groups, no hearing therapists, and ENT specialists have no time to dwell on a problem they do not know how to treat* (Klara, female user with tinnitus, Czech Republic)

> *I live in N.Ireland [Northern Ireland] and there was one person responsible for tinnitus in the whole country and she was on long term sick leave at the*

> *time I developed tinnitus. When you develop tinnitus you need help immediately not to be put on a waiting list for 6 months* (Nora, user with tinnitus, Ireland)

One user had used the forum so she could provide advice and support for those who were severely distressed by their tinnitus.

Finally, health professional users spoke about how they used the intervention to extend, or complement, the health services they provide. One health professional from Argentina reported using the intervention to organise the goals of her therapeutic work and recommended a similar approach to her patients, at regular clinic appointments:

> *In my country even many doctors say their patients ""you have tinnitus, there is nothing to be done, you will have to get used to them [sic]"". This is not true! Because of this I read, study and seek new horizons on the internet* (Alma, health professional user, Argentina)

A health professional user from the UK used the intervention for what she called *"progressive self management"* with her patients and directed her patients to the intervention. However, she emphasised that the intervention should not be used without health professional support: *"clients reported that the programme supported the face to face clinical supprt [sic] but did not replace it"*.

Users with tinnitus also mentioned how they used the intervention following a referral from their health professional or as part of the service that the intervention therapist

provided in her private practice: *"I was seeing [the intervention therapist] so I got to work with the author. We used it throughout our sessions and it was a useful supporting tool that I could refer to between visits"* (Dave, user with tinnitus, UK).

5.4.2.5 Theme 5: Barriers and facilitators to engagement with the intervention

The qualitative analysis of the open question responses identified several barriers and facilitators to intervention engagement. Facilitators to engagement included the accessibility of the intervention, the provision of therapist support, and user perceptions of the interventions' credibility. Regarding the intervention's accessibility, users valued that the intervention was easy to access, provided free of charge, and could be started immediately:

> *As a long term tinnitus sufferer, who has spent tons of time and money in an attempt to find a relief, I appreciate an attempt on behalf of professionals to provide FREE help and support to anyone, anywhere and at any time* (Klara, female user with tinnitus, Czech Republic)

Users who had contact with the intervention therapist spoke extremely highly of her and the additional counselling services she provided, thus highlighting a perceived benefit of therapist support:

> *[The intervention therapist] provides an essential service to those who have problems with tinnitus . . . She has great experience of the issues that tinnitus sufferers face and this is reflected in the [Tinnitus] e programme. For those who are unable to visit her in person, the [Tinnitus] e programme is an*

> *extension of her expertise and provides support and care in a wholly appropriate way, allowing the user to self help in a controlled manner* (Dave, user with tinnitus, UK)

> *Her counselling and the exercises in the program helped me regain control of my life. I'm truly grateful to [the intervention therapist]* (Aditya, user with tinnitus, India)

Consistent with the quantitative findings in Section 5.4.2.2, qualitative comments implied that users generally perceived the intervention as trustworthy. Users commented how there are so many companies trying to make money from people with tinnitus by offering dubious treatments. They valued that this intervention was not-for-profit, had worked for others, and delivered the essential elements of professional tinnitus therapy. One user mentioned how she trusted the intervention as it had been recommended by her health professional. Users' perceptions of credibility were also influenced by their, generally positive, evaluations of the intervention developer's expertise and experience as a therapist. Discussions of the intervention and the intervention developer were often intertwined, with the intervention perceived to be an *"extension of her expertise"*. For one user, the intervention developer's personal expertise as someone living with tinnitus would have been a useful addition: *"I seem to remember that the facilitator [intervention developer] was also a sufferer and it would have been helpful to have had a full history of her experience"* (Jim, user with tinnitus, UK). Some users mentioned how they valued the intervention developer's attempts to further improve the intervention.

Barriers included concerns about the intervention's credibility and lack of time and ability to practice relaxation. In contrast to those users who perceived the intervention credible, some users also identified factors that negatively influenced their perceptions of the intervention's credibility, mainly concerns that the intervention was still live, its *"confrontational"* style, unengaging appearance, and lack of novelty:

> *I was a bit worried that the Tinnitue [sic] E-Programme was still live as the web site only had old comments on it* (Jeremy, user with tinnitus, UK)

> *Recently I have stopped directing people to the site as the first page seems a little confrontational and implies the site is so longer supported* (Cathy, health professional user, UK)

> *It was useful in that it brought together a lot of material I had already seen. However it felt like a DIY package and a little bit 'institutionalised' in its approach* (Jim, user with tinnitus, UK)

Users identified factors that made it difficult to meet the relaxation goals, mainly being able to find the time to practice the relaxation, especially for those who are in employment. One user found the relaxation difficult, claiming that they are *"not very good at relaxation"*.

5.4.2.6 Theme 6: Gaining benefit

The majority of intervention users (90%; *n*=18) reported that the intervention had helped them and the one forum only user indicated that the forum had helped them. Users claimed that the Tinnitus E-Programme 1.0 was *"absolutely essential"*, *"a lifesaver"* and, for one user from the USA, it was his *"salvation"*. One user made the following plea: *"The Tinnitus E-Programme should be given all possible help, so that it can reach those in need in all corners of the world"* (Aditya, user with tinnitus, India).

Users reported that the intervention helped them gain control over their tinnitus and their lives. Specifically, accounts focused on how the intervention led to reductions in the intrusiveness of tinnitus, that is, how much they noticed their tinnitus or the extent to which it interfered with their lives:

> *I stopped focusing on the noise so much. It changed my perception of it. I felt power over it. It was like I could lower the volume, even though I really can't. Now I know that if it seems louder it's only because I'm stressed out over something else in my life. Or the room I'm in is just quiet. Either way, the moment will pass* (Laura, user with tinnitus, UK)

> *Before the programme, I spent every waking moment dwelling on my tinnitus . . . I thought my life as I knew it was going to end. It took a while, but by rigorously practicting [sic] the exercises, I re-trained my brain to no longer be as alarmed at my tinnitus. I still have it - but I no longer think about it all the time. It's just something that's there - sometimes it raises its head and makes*

my quite miserable, but the exercises help me get my thoughts back under control (James, user with tinnitus, USA)

Users also reported that the intervention helped them to deal with the emotional impact of tinnitus, specifically, the worry, distress and upset caused by tinnitus:

The most important thing it teaches you to NOT panic. Previously I have reacted very badly when my tinnitus was bad (Jeremy, user with tinnitus, UK)

The relaxation exercises helped me get out of the state of constant anxiety and let me focus on things other than tinnitus . . . The [Tinnitus] e-Programme drove away the fear of T [Tinnitus] and that helped me recuperate (Aditya, user with tinnitus, India)

Users explained how the intervention provided them with hope that their tinnitus will get better, that there is help available and that they will be able to cope with or manage their tinnitus:

I cant speak highly enough about how this programme helped me. it took me from upset and distressed about tinnitus to, 'okay I can cope'. Its not a major (Alice, user with tinnitus, New Zealand)

It took a while for the relaxtion [sic] exercises to become effective, but I'll never forget the first day I went nearly the whole day without being aware of tinnitus all the time. From that day forward, I knew I could live with tinnitus, thanks

to what I learned from the [Tinnitus] E-Programme (James, user with tinnitus, USA)

In the short term the relaxation and breathing gave me something to focus on and some hope that I would be able to manage with the tinnitus (Sandra, user with tinnitus, UK)

Users highlighted how the intervention reduced the feelings of isolation they experience with tinnitus. Users valued knowing that there were others out there with tinnitus. A forum user explained how the forum can help overcome the isolation and fear associated with tinnitus by providing a positive environment in which help can be provided and people with tinnitus do not feel alone. For some, the relaxation exercises helped users to overcome difficulties with sleep. One user passed the relaxation exercises to her son to help him sleep when he was experiencing anxiety due to his exams. The information resources and the support forum also helped some users to learn about tinnitus and learn from others about what they do to manage their tinnitus.

Although the majority of users reported benefit, two users indicated that the intervention had not helped them. The users' reasons for this centred on the intervention's poor presentation and inability to offer any long-term relief from tinnitus, and a perceived lack of credibility and specificity: *"Too generic and not specific enough to my particular issue - which is what to be expected on an on-line resource"* (Oliver, user with tinnitus, New Zealand). Jim also commented that *"CBT*

and mindfulness is the way to go", suggesting that these preferred components were lacking from the current intervention.

5.5. RESULTS: STUDY 2 (RETROSPECTIVE INTERVIEWS AND RELAXATION LOG WITH NEW USERS)

5.5.1. Participant characteristics

Twenty-four people consented to take part in the study. Ten of these people were recruited from the research database and three people found out about the study through the intervention website or word of mouth. Six consenting participants dropped out before they started the programme and five dropped out after starting the programme. Reported reasons included personal or family illness, an increased tinnitus severity, lack of available time, and technical problems (e.g. their computer was not working). Thirteen people completed the interview, including 7 males and 6 females. Ages ranged from 22-79 years, with a mean age of 54 years. Most participants had tinnitus for more than ten years; all were White British. Nine participants submitted their relaxation log. Gail started the intervention, but decided to drop-out due to competing time commitments. It was agreed that she would still take part in the interview but not the relaxation log. The participant characteristics are detailed in Table 5.7.

Table 5.7 Study 2 participant characteristics

Pseudonym	Gender	Age	Ethnicity	Tinnitus Duration
Karen*	Female	70	White British	10+ years
Margaret	Female	70	White British	10+ years
Phillip*	Male	64	White British	10+ years
Michael	Male	40	White British	10+ years
William*	Male	79	White British	10+ years
Jackie*	Female	47	White British	10+ years
David*	Male	73	White British	10+ years
Jack	Male	33	White British	2-5 years
Gail	Female	36	White British	6 months - 1 year
Becky*	Female	22	White British	6 months - 1 year
Thomas*	Male	68	White British	10+ years
Patrick*	Male	65	White British	10+ years
Caroline*	Female	40	White British	2-5 years

Key: *Participants who returned their completed relaxation logs.

5.5.2. Relaxation log

The findings from the relaxation logs gave insights into users' abilities to meet the daily relaxation goals. The percentages of relaxation goals met for each user who submitted their completed relaxation log are provided in Table 5.8. On average, these users met just under half of the daily relaxation goals (Mean = 42.46%), suggesting that, overall, users demonstrated poor adherence to the relaxation goals.

Table 5.8 Percentage of relaxation goals met for each user

Pseudonym	Goal 1: Breathing exercise goals met (%)	Goal 2: Guided relaxation goals met (%)	Total goals met (%)
Karen	50	21.43	35.71
Phillip	100	85.71	92.86
William	0	0	0
Jackie	75	0	37.5
David	32.14	35.71	33.93
Becky	7.14	85.71	46.43
Thomas	89.29	78.57	83.93
Patrick	0	0	0
Caroline	64.29	39.29	51.79
Mean	**46.43**	**38.49**	**42.46**

Note: Percentages for the breathing exercises and guided relaxation are calculated by dividing the number of daily goals each user met over the 28 days by the total number of daily goals set by the intervention for each exercise (i.e. 28). The total goals met by each user was calculated by dividing the number of daily goals each user met over the 28 days by the total number of daily goals set by the intervention (i.e. 56, 2 goals each day).

5.5.3. Themes

Thematic analysis identified six themes from the data: (1) Intervention expectations and motivations; (2) Acceptability of self-management components; (3) Acceptability of design features; (4) Barriers and facilitators to engagement with the intervention; (5) Barriers and facilitators to enactment of relaxation skills; and (6) Gaining benefit. The six themes are described in Table 5.9.

5.5.3.1 Theme 1: Intervention expectations and motivations

Users discussed their expectations of the intervention and their motivations for completing the intervention. In the intervention, it was explained that the Tinnitus E-Programme 1.0 was not a cure for tinnitus, nor a ‘quick-fix’.

Table 5.9 Description of six themes identified in the thematic analysis

Themes	Description
1. Intervention expectations and motivations	Describes users' expectations towards the intervention and their motivations for engaging with it.
2. Acceptability of self-management components	Describes users' views on the four self-management components contained in the intervention. The self-management components include the intervention content that is aimed at supporting people to better manage their tinnitus.
3. Acceptability of design features	Describes users' views on four design features of the intervention. The design features describe ways in which the self-management components are delivered.
4. Barriers and facilitators to engagement with the intervention	Describes users' views on the factors that discouraged or motivated them to engage with the intervention.
5. Barriers and facilitators to enactment of relaxation skills	Describes users' views on the factors that discouraged or motivated them to practice the relaxation outside of the intervention.
6. Gaining benefit	Describes users' views on any benefits they gained from the intervention.

The aim of the intervention was to reduce tinnitus distress, and users' expectations regarding the outcomes of the intervention were generally in line with this aims and users did not expect it to cure their tinnitus. Some users expected that the programme would lead to a reduction in the intrusiveness of their tinnitus. Users hoped to be able to ignore their tinnitus better or notice it less, gain relief from their tinnitus, or for the tinnitus to become a *"much less part"* of their lives.Although most did not expect a *"physical improvement"* following the intervention, some did, however, hope that the

intervention would alter the sensation of their tinnitus. They expected that their tinnitus would reduce or improve, or that they would *"notice a difference in the tinnitus"*.

Some expected to learn how to manage their tinnitus, this would involve them learning a new technique or way to deal with their tinnitus. Users also had expectations that were linked to the intervention's components, that is, the intervention would help them relax and/or better understand tinnitus, specifically, why they have tinnitus and how it is created. None of the users stated that they expected the intervention to reduce any emotional or tinnitus-related distress. Users were also aware that the intervention would require a personal commitment to engage with the intervention and its techniques. Patrick mentioned how he expected to give a far larger time commitment than was actually required:

> *There was nothing to do . . . I was quite disappointed actually . . . to take part in research, you feel as if you're going to be stretched a little bit or, you know, that you're going to have to just do a little bit of work* (Patrick, 65, had tinnitus for 10+ years)

Some users were motivated to take part for altruistic reasons, that is, to help out with the research that would ultimately help others with tinnitus. Users were also motivated by interest and curiosity about the intervention.

5.5.3.2 Theme 2: Acceptability of self-management components

Users discussed the four self-management components of the Tinnitus E-Programme 1.0: (1) education about tinnitus and its management (information leaflets); (2) Training/rehearsal for psychological strategies (Relaxation & brief cognitive restructuring); (3) Monitoring of condition and feedback to the patient (THI); and (4) Social support (Online support forum).

<u>Self-management component 1: Education about tinnitus and its management (Information leaflets)</u>

This component was highly acceptable to users who valued the information provided about tinnitus and its management. Generally, users perceived the information to be informative, clear, and easy to read and understand. Specifically, they liked the technical and scientific nature of the information, which they found enjoyable and interesting. However, some users found that the description of the human function curve was complex and difficult to understand.

Some users who had tinnitus for a long time explained how they already knew a lot of the information and perceived some of the information as basic or common-sense. David highlighted an example of such information:

> *The British Tinnitus Association leaflet on taming tinnitus . . . as an example: . . . "If you have difficulty getting off to sleep, it may be the, that the shift from a relatively noisy daytime environment to the quietness of the bedroom makes the tinnitus noises more noticeable." I would say, well, of course it does. You*

> *go into the quiet of anywhere, the tinnitus is much more relevant, and in your, in your head* (David, 73, had tinnitus for 10+ years)

Caroline did not read any of the information resources, but kept them as a reference to read at a later date. She explained her reasons for this. She felt she already had a good understanding of tinnitus, found that reading in general was *"boring"* and preferred to be doing something practical, and disliked reading as she finds that quiet environments make her tinnitus worse.

Most users felt they could relate to the information. However, Jackie felt uncertain about what she called the intervention's *"theories"* of tinnitus. Mainly, she disagreed with the proposal that people's experience of tinnitus is influenced by how they perceive and react to it:

> *Jonathan Hazell and his theory that the tinnitus is perceived as a threat by the brain and therefore we concentrate on it...find this one more difficult to accept. It's a loud noise to me, but not sure I find it as an alert-type noise, hence a threat etc. Sounds do not sound like something negative going on.* (Jackie, 47, had tinnitus for 10+ years, email interview)

> *You get the impression after a while [from the intervention] that it is our responses that is making it [the tinnitus] loud, when I think mine is linked to cochlear hair damage and not entirely the brain itself* (Jackie, 47, had tinnitus for 10+ years, email interview)

A few users also felt that some of the advice in the British Tinnitus Association's Taming Tinnitus leaflet was impractical and unhelpful. Specifically, users explained how they would find it difficult to whisper a nonsense word to block out intrusive thoughts or worries, going into another room if you are lying awake for more than 20 minutes and struggling to sleep, and avoiding taking 'cat naps' throughout the day (one user found cat naps beneficial).

Users made several suggestions of additional information topics that they would find helpful, including information about the benefits of distraction and further background to tinnitus (e.g. the prevalence of tinnitus). Users were particularly keen to find out about research into tinnitus and any progress that has been made towards understanding tinnitus and finding a cure, which they would find reassuring and encouraging. A few users were keen to understand how their tinnitus and individual experiences of tinnitus compares to that of others with tinnitus. One user was surprised that there was no mention of old analogue hearing aids being a cause of constant noise but acknowledged that the intervention was not created specifically for people with hearing loss.

<u>Self-management component 2: Training/rehearsal for psychological strategies (Relaxation skills training & brief cognitive restructuring)</u>

The relaxation skills component was widely used and valued by most users: *"I did it for the first week and it was fantastic. And I've, I really did, in fact I was nearly falling asleep when I was listening to it [Laughter], you know, and it was lovely."* (Margaret,

70, had tinnitus for 10+ years). Most users had experience with practicing relaxation and understood the relevance of it to tinnitus.

Users' preferences regarding individual relaxation exercises varied widely. Most users valued the breathing exercises as they were brief, easy to do, and could be practiced anywhere (e.g. when travelling, watching TV, at work) and without anyone noticing: *"Oh the breathing exercises I find they are absolutely brilliant. I can do it at work, I am out and about quite a lot and if I have got five minutes"* (Jack, 33, had tinnitus for 2-5 years). Some liked the physiological relaxation exercise as they could feel the immediate benefits, allowing them to relax their body, as well as their mind. Whereas, other users found the exercise took too long or were too brief to be effective. Generally, people liked the guided relaxation exercises but, as they were considerably longer, they were more difficult to do on a daily basis. Despite this, this difficulty did not necessarily translate into poor adherence, as the mean percentage of daily relaxation goals met across all users was similar for the breathing exercise (46.43%) and the guided relaxation (38.49%; Table 5.8). Margaret explained why she particularly liked the verbal instructions:

> *It makes you do it. It makes you listen. It disciplines you. It disciplines you to do it, whereas if you were trying to do it yourself . . . because you haven't got the tape and the man telling you what to do- You only do it for, like, 10 minutes instead of 30 minutes. Whereas when you're- Listening to the tape . . . you do do it for that- 30 minutes* (Margaret, 70, had tinnitus for 10+ years)

In contrast, a few users found the guided relaxations monotonous and the voice distracting and frustrating. Those who expressed negative views about the guided relaxation typically exhibited poorer adherence for the guided relaxation, compared to the breathing exercises (see Caroline and Karen in Table 5.8)

Some users preferred alternative types of relaxation exercises or ways of relaxing over those provided in the intervention, including meditation, positive imagery (i.e. visualising an image), playing a musical instrument, or engaging in physical activity:

> *If the aim of the exercise is to become more relaxed then I, kind of, tended to do things that I know relax me rather than necessarily sticking rigidly to what was said there* (Michael, 40, had tinnitus for 10+ years)

> *I hadn't got half an hour to sit around and, and listen [to the guided relaxation] . . . I'd rather practice the piano* (Patrick, 65, had tinnitus for 10+ years)

William did not meet any of the relaxation goals (Table 5.8). He explained that this was because he already had his own relaxation practice and preferred to continue with that, rather than the practice outlined in the programme. Michael and Patrick were generally less positive about the relaxation component, which did not appeal to them. Both users spoke about lacking the time or patience to practice relaxation. Michael also explained how, although he understood that relaxation was important, it felt too general and was not specific to his tinnitus. Patrick did not gain any benefit from the relaxation exercises, explaining that he was *"not a great believer in relaxation therapy"* and that *"his lifestyle does not promote or lend itself to periods of quiet*

reflection/relaxation". This view was reflected in his relaxation log data (Table 5.8), as Patrick did not meet any of the relaxation goals. These two users also wanted to know why it is important to stick to the 30-minute relaxation goals and whether the relaxation is for everyone or only certain sub-types of people with tinnitus.

Users varied regarding their ability to meet the daily relaxation goals. Some reported being able to easily meet the relaxation goals, while others found it difficult to practice the relaxation every day or for the required amount of times per day. Most users felt that, although they were not always able to meet the daily relaxation goals, they were achievable and realistic:

> *[My work schedule] is just ridiculous at the moment. But never at one point is it [the relaxation goals] unachievable. It is more than achievable. Half an hour a day it seems ridiculous to say that you can't find half an hour a day just to relax* (Jack, 33, had tinnitus for 2-5 years)

However, a minority of users did suggest reducing the duration or frequency of the relaxation goals. One person felt that having to do relaxation for a certain length of time makes her feel pressured.

Several users found the brief cognitive restructuring helpful and understood the relevance of negative thinking to tinnitus: *"I found it very useful really because I could, I could relate to a lot of it and agree with a lot of it. Particularly, as I say, I keep saying about the negative thoughts. I think that's me all over"* (Karen, 70, had tinnitus for 10+ years). Thomas had not previously heard about CBT and he spoke

about how the intervention had encouraged him to find out more: *"If I see any new books out associated with, you know, behaviour or changing [negative thoughts], I'll be more inclined to, you know, to go and pick one up"*. In contrast, Patrick reported that he had a great deal of experience with CBT and believed that the negative thoughts component in the intervention was limited and *"fairly superficial"*, especially for those experiencing high levels of tinnitus distress:

> *Well, I don't think there was enough explanation about the CBT side of it . . . . it's just introduced [in the intervention] . . . I would've hoped for perhaps, erm, some more practical examples of how to deal with it or perhaps some little tests that you can do.* (Patrick, 65, had tinnitus for 10+ years)

<u>Self-management component 3: Monitoring of condition and feedback to the patient (THI)</u>

Some users reported that they did not complete the THI. Most of these users did not make an active decision not to do so; rather they were not aware it was there or could not find it. Some reported that they had used a similar questionnaire before with their clinicians or when taking part in research. Some felt it was easy to complete, while others found the rating scale, the item responses, and some of the questions difficult to use or interpret:

> *I have no idea, you see, when it [the THI] says severe, 58 to 100, whatever it is- I, I have no idea what that might involve- bells, whistles, drums banging. I've- well, I don't know. What is severe tinnitus? What does it sound like? . . . does it send you screaming mad?* (Patrick, 65, had tinnitus for 10+ years)

> *Sometimes it was difficult to, you know, [decide], is it a 'yes' or is it a 'sometimes'? I mean, erm- 'sometimes' is a bit of a grey area* (Thomas, 68, had tinnitus for 10+ years)

> *I tend to disagree on some of the questions yet again. Erm, let's read one to you, if I can . . . "Because of your tinnitus, do you feel you have a terrible disease?" It, it isn't a disease. It is, it's a, it's a physical problem, that's created by your brain, and it's not a disease that you can eradicate. So it's just a question I think is irrelevant* (David, 73, had tinnitus for 10+ years)

One user was disappointed that he was not instructed to compare his pre- and post-intervention scores and was not told what his results were. Several users were surprised with their final scores, which were higher or lower than expected: *"I was a bit surprised that I was only classed as moderate . . . But I class, I class meself as a bit worse than that"* (Phillip, 64, had tinnitus for 10+ years). David felt his tinnitus was severe and was surprised that his scores classified him as 'moderate'. He explained how he thought that the scoring system was *"wrong"* and *"biased"* in a way that forces those who have had tinnitus for a long time score lower than it should be. Despite considering his tinnitus to be loud, he found himself always responding 'no' to the questions. He explained that this was because he had adapted to his tinnitus over time so a lot of the tinnitus-related issues were not problematic for him. This can be interpreted that David was confused regarding the purpose of the aim of the THI and had interpreted his scores to mean that he had moderate level tinnitus loudness, rather than moderate levels of tinnitus distress.

Both users and non-users of the THI discussed the potential benefits of using questionnaires or other methods, including a progress log, face-to-face interview, or keeping a journal. Specifically, such design features would allow users to gain feedback on their progress towards their personal goals, providing them with a sense of achievement and confidence that the intervention techniques are having benefit:

> *Maybe if there was, I don't know, the use of a tablet, or something where you can sort of measure your progress along the way . . . maybe you could see which things had really helped you out or whether there was any change or anything like that . . . When it is put into numbers, it makes it a bit more real maybe and you can actually see it having a difference or whether you are just convincing yourself it has [made a difference]* (Becky, 22, had tinnitus for 6 months – 1 year)

> *I wanted to see . . . what progress I would have made over ten weeks, if I was still feeling the effects of, "Are you stressed? Is your tinnitus worse?"* (Jack, 33, had tinnitus for 2-5 years)

Some users questioned whether the THI was intended for them. Rather they believed it served to benefit the intervention developers only: *"When time is precious, then . . . part of the motivation is, 'Am I doing this for, for my benefit or, for the benefit of the programme?' . . . It felt like it was more for [the intervention developer's] benefit"* (Michael, 40, had tinnitus for 10+ years).

Self-management component 4: Social support (Online support forum)

Approximately one third of users reported joining the forum and none of the users reported posting on the forum. Users reported concerns regarding internet safety, doubts about the trustworthiness of the information provided in the posts, difficulty of use, and forgetting to use it:

> *I seem to be getting a few [emails] where it's got 'Tinnitus E-Programme' as a subject header but then it just says 'hello' and it's got a link underneath it. And when I see that I, I think, "Hang on, is this a scam?" So, to be honest, it's stopped me from, from using that bit of it* (Thomas, 68, had tinnitus for 10+ years)

> *You have to sort of take that kind of thing [the forum] with a little bit of caution . . . when you're looking through the computer there's all sorts of forums for things, isn't there? . . . then you read [a post] a bit further down by somebody that's put something on that's a, an expert in that particular field and they say, "Don't listen to this, it's rubbish." . . . some people [on forums] exaggerate as well, don't they?* (Margaret, 70, had tinnitus for 10+ years)

> *I looked at it and then I think I got to a page where I was having to have a Yahoo email address, which put me off 'cause I've got, like, two or three different emails and I, So I haven't joined it, for that reason* (Caroline, 40, had tinnitus for 2-5 years)

Most users spoke about their unwillingness to talk to other people with tinnitus. This was either because talking about their tinnitus made it worse (also see Section 5.5.3.4), they did not like talking about themselves to others, or they perceived the posts to be too negative:

> *I think my only concerns were because I have done another relaxation group before and my reasons why I pulled out of that was about talking about it with other people, I didn't really feel comfortable with that . . . when you discuss it [tinnitus], because you are talking about it, it gets worse . . . yes I have got it [tinnitus], it is a pain in the arse, but I want to just be my own person and be able to deal with it on my own and not let it take control of my life. If I continue talking about it with people then it is sort of controlling my life a little bit* (Jack, 33, had tinnitus for 2-5 years)

> *I don't like anything like that [online forums] . . it didn't appeal to me to, to talk about meself to other people who I, who I couldn't see or wasn't there, you know what I mean?* (Phillip, 64, had tinnitus for 10+ years)

> *The support forum – am afraid I avoid interacting with other people about tinnitus experiences as I find just talking to other people who find it a very negative experience can easily make mine go loud! So I do prefer not to seek out sharing experiences though I am sure some people might find it very supportive. It does the opposite for me by reinforcing the negativeness others perceive about it* (Jackie, 47, had tinnitus for 10+ years, email interview)

5.5.3.3 Theme 3: Acceptability of design features

Users discussed three specific design features of the Tinnitus E-Programme 1.0: (1) the ten-week structure; (2) the ability to use intervention materials online and offline; (3) the user autonomy provided by the self-guided nature of the intervention; and (4) the perceived credibility of the intervention.

Feature 1: Ten-week structure

When discussing the ten-week structure, users discussed how intervention content was distributed across the ten weeks, the duration and intensity of the intervention, whether they would continue aspects of the intervention after they completed the ten weeks; and the flexibility regarding intervention timings (i.e. when each week could be started). Generally, users liked the ten-week structure. They liked that the content was broken down into different stages, which made the intervention well-structured, manageable and methodical. It gave users a sense of progression and helped them be disciplined in their use. Margaret explained what she liked about the structure: *"It gives you the, all the information that you need, as foundation, and then you move onto doing something about it. Y'know, move onto the, the exercises and things"*.

Views were mixed regarding the duration and intensity of the intervention. Some felt the length was reasonable, while others would have preferred that the duration be decreased and/or intensity of the intervention increased. Caroline felt that the intervention was too long, which she believed could make some users lose interest. She would have preferred for the intervention to be shorter but more intense: *"Like a*

four-week programme, two or three times a day, maybe with a shorter, sort of, like a 30-minute morning and evening but with a shorter meditation or some sort of something or other in the daytime". Caroline also explained how a short time period would make it easier to judge whether the intervention had led to any improvements. David felt that the ten-week duration was ample, but felt that the intervention could be condensed. Specifically, he suggested that the first two weeks could be combined, as week one contained only the breathing exercises and a single information sheet. Patrick felt that there was not enough content to justify a ten-week time period: *"Why it takes ten weeks, I've no idea. I could've done that in a week. I could've done it in a day actually".*

In contrast, Becky felt that the intervention could have been made longer and the content better spaced out across the weeks to reduce the weekly intensity. She explained that:

> *Sometimes having a week between each one didn't seem quite as long enough to get used to whatever it was asking or to properly take it in and then it was the next week and then you felt like you weren't really on top of it* (Becky, 22, had tinnitus for 6 months – 1 year)

Becky also disliked how the intervention's intensity differed between weeks: *"There was quite a big jump from doing nothing to doing [the relaxation], sort of, three times a day"*. When starting the intervention, Phillip initially feared that it might take up too much of his time, but, once he got into a routine with the intervention, he realised that the time commitment was manageable. Most participants reported that they would

continue to use the programme past the ten weeks, mainly the relaxation exercises. William explained why he would not continue with any aspect of the intervention: *"Once you've got the explanation and the interesting bit that's there anyway, you don't need to do that again"*.

Although there was a ten-week structure, there were no restrictions on intervention content and users were free to access materials from any of the weeks. As such, users did not necessarily follow the consecutive weekly structure. Some users liked how you could do the intervention in your own time and like the intervention's flexibility. In contrast, Michael had mixed feeling towards the intervention's flexibility. On the one hand, he spoke about how, as he was not as interested in the relaxation component, he found the intervention slow initially and was tempted to skip onto the content which he perceived as more interesting (e.g. educational content). On the other hand, he highlighted that, if the relaxation has been shown to be beneficial, the weekly structure does provide less incentive to skip this material.

Feature 2: Online vs. offline use

The intervention was designed to be used primarily online, however, users could use parts of the intervention offline. Users could download and print the information sheets and relaxation instructions (in pdf format), and download the guided relaxation MP3s to be used on computer or transferred onto CD or MP3 player. Users chose to use the intervention in different ways. The majority of users printed the information sheets or saved the pdfs on their computer, tablet or smartphone, so that they were all in one place and could access the materials without being online. There were several reasons

why users chose to do this. Some found it easier to read and understand printed text over text printed on a screen. Moreover, printed information could be accessed easily without turning on a computer and being online.

By transferring the audio to CD or portable MP3 player, users were able to practice the relaxation at a comfortable and convenient location (lying on bed, going for walk), which made their practice easier. One user explained how she printed the information materials to overcome problems she was experiencing with navigating the website, as she found the intervention easier to follow this way. In contrast, some users chose to access the intervention and its materials solely online, using a computer, laptop, or tablet. A minority of users were reluctant to access the materials offline:

> *I have an immediate antipathy towards, erm, downloading stuff. Put it, put it on a CD? I'm not gonna do that* (Patrick, 65, had tinnitus for 10+ years)

> *I looked at them on the computer . . . Yeah, couldn't see the point of printing them off 'cause you can always go back again . . . And it costs you money to print* (William, 79, had tinnitus for 10+ years)

Feature 3: User autonomy

Users identified several advantages and disadvantages of the self-guided nature of the intervention. Some spoke about previous experiences they had with group relaxation therapy and preferred the self-guided approach, as it was more convenient and less pressured:

I didn't feel under any pressure [doing relaxation in the intervention]. You know, before it [relaxation therapy] was in a group, and this one [in the intervention], I could do it when I wanted and how I wanted and, and it was sort of it was self-management really, being in control. I like to be in control really (Karen, 70, had tinnitus for 10+ years)

Jack also spoke about how the programme allowed him to avoid talking about his tinnitus and the negative social encounters he had at previous relaxation therapy groups:

I pulled out of that [relaxation group] . . . I didn't want to go to the classes, because to be totally honest quite a lot of them [people at the group] – it [tinnitus] was really hard for them to deal with and it was quite depressing to be honest on these groups (Jack, 33, had tinnitus for 2-5 years)

I could do it [the Tinnitus E-Programme] in my own time and it looked more personal . . . I didn't have to talk about it [tinnitus], because I talk to my wife about it and that, but I could just do it in my own time and progress. And that is what I preferred really, instead of talking about it (Jack, 33, had tinnitus for 2-5 years)

Michael spoke about the advantages and disadvantages of the lack of therapist contact:

On the one hand, by being checked up on, then it, erm, it increases your likelihood of, of following the process and doing it properly. Erm, the downside

to it is that as it- it feels a bit like, kind of, teacher's watching you (Michael, 40, had tinnitus for 10+ years)

A few users would have liked further contact from the intervention or a person, suggesting introducing either contact from a therapist or automatic reminder emails to remind you what week you are on and provide encouragement, or having a face-to-face interview with someone to explore how you are feeling about your tinnitus at the beginning and end of the intervention. Although the intervention was self-guided, users had the option of contacting a therapist if required. None of the users reported doing so and some did not know they could do this.

Feature 4: Credibility

Users' perceptions of the intervention's credibility were influenced by users' evaluations of the website's professional presentation, trustworthiness of the intervention, and the extent to which the intervention was able to convince users that it and its various components would be beneficial. Regarding the presentation of the intervention, some felt the intervention was professional, while others felt the opposite. Several people suggested improvements to the visual appearance of the website or noticed spelling mistakes. Some users noticed that the intervention had not been updated since 2009 and one user felt this was *"a bit complacent"*. Both Caroline and David wanted *"fresh material"* to be introduced after the ten weeks to maintain their engagement.

Some users trusted the intervention because it mentioned the NHS and came from a reliable source (NIHR Nottingham Hearing BRU). As the intervention was developed by a health professional in private practice, credibility was also influenced by the expertise and motivations of the intervention developer. Michael specifically appreciated the passion that had gone into the intervention and also liked the altruistic motivations of the intervention developer and that she had experience in tinnitus. He explains how he assessed the credibility of the intervention, which was influenced by the developer's motivations and the effort put into the intervention:

> *I clicked through the link which then went onto . . . her paid service that she provides . . . to see, kind of, I suppose what her motivation for doing it was, whether it was something that was, was just a, an altruistic, thing to, to help people or whether there was some kind of, what her motivation was whether it was a way of being able to encourage people to then go and use her, use her service or, or pay for her services . . . And I think she was doing it, she is doing it for the right reasons . . . she, kind of, had this brainwave and then within a week generated this programme, which then led you to think a little bit if it's been done that quickly, again, what's the evidence base behind it?* (Michael, 40, had tinnitus for 10+ years)

Two users felt that the intervention was too simplistic or did not offer anything new:

> *My first impression was, "Is that it?" It didn't seem particularly profound or, or extensive. It was just a very bare couple of pages to read, and that, that was that* (Patrick, 65, had tinnitus for 10+ years)

> *You think - "Oh, good this is something that could help my tinnitus", and then I'm like - "Oh actually I've done it all." You kind of get that bit of a come down* (Gail, 36, had tinnitus for 6 months – 1 year)

Patrick was disappointed that he could have completed the intervention in two hours, explaining that spending more time on the intervention would have made it more meaningful.

It was important for users to understand the rationale and evidence-base behind the various components of the intervention: "*[The information helps] you understand . . . how the stuff that you are doing is going to make a difference"* (Becky, 22, had tinnitus for 6 months – 1 year). Michael discussed the role that the intervention could play in convincing users of its value:

> *As you started to read through it, there was, I suppose, an element of cynicism as to - is this really going to make much of a difference or not? . . . I think once the evaluation has been done, putting that kind of information into it will be a really powerful thing to make you want to do it, make you want to invest the time in it, and feel like it's going to make a difference* (Michael, 40, had tinnitus for 10+ years)

Patrick felt that the intervention did not provide *"enough explanation as to why the things help"*. Michael suggested it would be helpful to have videos from health professionals explaining *"what they found helps or how it demonstrates that what she's [the intervention developer] suggesting has helped and does work"*.

Some users discussed the value of personalisation. Caroline liked that it was designed specifically for people with tinnitus, however, Patrick felt the intervention took a *"one size fits all"* approach and expected the intervention to be more personal to his own tinnitus:

> *I expected to answer, or be asked, far more about my own personal tinnitus experience, if you like. Far more about the personal effect . . . Far more detail about the specific problem and then, or should I say, about the problem in general and then more about how it specifically affects me* (Patrick, 65, had tinnitus for 10+ years)

5.5.3.4 Theme 4: Barriers and facilitators to engagement with the intervention

Users shared their views on the factors that discouraged (barriers) or motivated (facilitators) them to engage with the intervention, including: (1) usability and accessibility; (2) perceived need; (3) beliefs regarding the intervention's negative impact on tinnitus; and (4) external barriers.

<u>Usability & accessibility</u>

There were mixed views regarding the intervention's usability. Some found the intervention easy to use and follow, user-friendly, and clear. Users liked that they could easily return to the materials as they were all in same place and one user liked that once they clicked on a hyperlink it changed colour so could see what parts of the intervention they had done. These aspects of usability are potential facilitators to user engagement.

On the other hand, usability was a barrier for most, as users encountered issues that made the intervention difficult to use or prevented them from using certain components. Specifically, users found the intervention confusing, complicated, and difficult to navigate, with one user stating that she would have not continued with the intervention had she not been part of the research. As discussed in Section 5.5.3.2, several users did not complete the THI as they were not aware it was there. One user who chose to use the intervention on a tablet noted that the THI could not be completed electronically, which prevented him from using it. Several users had difficulties downloading the MP3s to put them on a CD and recommended having instructions on how to do this.

Poor accessibility was also a barrier, as two users were unable to use the audio materials due to their hearing loss:

> *[I] did feel quite excluded from a large part of it . . . I can imagine for someone who is severely to profoundly deaf (especially those with acquired deafness and tinnitus) really wanting to gain more might find it a disappointing set back to find they cannot access it* (Jackie, 47, had tinnitus for 10+ years, email interview)

> *Relaxation, because it's a voice activated thing and being deaf I struggle . . . I have to concentrate on the voice telling me what to do I can't relax . . . I could not use those relaxation exercises . . . If it'd have been come up with the written word it probably would've the same thing because . . . I'd had to concentrate on that* (William, 79, had tinnitus for 10+ years)

This barrier was significant enough to prevent these users from achieving their relaxation goals. As you can see from Table 5.8, William was unable to meet any of the relaxation goals and Jackie could not meet any of the guided relaxation goals. These users suggested introducing visual relaxation such as music with calming imagery, breathing exercises, or visualisation relaxations (e.g. focusing on an image). Patrick, who didn't meet any of the relaxation goals, explained that one reason for this was due to his lack of computer skills and poor access to the required computer equipment.

Perceived need

Users' perceptions of need for the intervention influenced their motivation to engage with the intervention or the individual components. Specifically, a low perceived need for the intervention acted as a barrier to engagement. For some users, their low tinnitus severity and ability to relax meant that their need was not great enough. These users implied that they would not have engaged with the intervention, had it not been for the research:

> *[The intervention] is something which was interesting, but not, not for me, or didn't do anything really. It's more for people who I think suffer more* (Patrick, 65, had tinnitus for 10+ years)

> *I was just participating to help others I thought . . . I didn't feel that I had to do anything about mine [my tinnitus]* (William, 79, had tinnitus for 10+ years)

> *Am doing the relaxation exercises but do not generally have any problems with relaxing . . . But happy to do it for the programme* (Jackie, 47, had tinnitus for 10+ years, email interview)

Interesting, these users were the only users who explicitly stated that they did not gain any benefits from the intervention, which may suggest that this factor is also important for the intervention's efficacy, as well as user engagement. Likewise, experiencing improvement from the intervention also led to people disengage from the intervention, as they no longer felt a personal need to use the intervention. Margaret explained how she temporarily stopped using the intervention when she was starting to feel better.

For the above users, a low tinnitus severity acted as a barrier to engagement by reducing users' perceived need for the intervention. Conversely, a tinnitus severity that was too high also served as a barrier. Some users withdrew from the research or delayed their start date because their tinnitus was too severe: *"Well, at the time, you will remember, possibly, that I was going through a pretty severe tinnitus moment and I didn't start it [the intervention] on the correct date"* (David, 73, had tinnitus for 10+ years).

On the other hand, a high perceived need for the intervention, mainly due to severe tinnitus and a tendency for feeling stressed, acted as a facilitator to engagement:

> *I think the relaxation part is, you know, for me is important. Because I, it does help to relax me because I, I do suffer from a bit of anxiety to start with* (Phillip, 64, had tinnitus for 10+ years)

I thought it [the intervention] looked really good. Yeah, I thought, "This, this is what I'm looking for." Because at that time, my tinnitus was incredibly bad (Margaret, 70, had tinnitus for 10+ years)

Users also highlighted how they would be more likely to commit to the intervention and engage with its components if their tinnitus severity, and therefore their perceived need, increased:

If it got really bad, like worse, then I probably would join . . . a forum and just engage with more people about it (Caroline, 40, had tinnitus for 2-5 years)

I think I would have more capability to find that time [to use the intervention] if it was in a time that it [tinnitus] was very bad (Gail, 36, had tinnitus for 6 months – 1 year)

<u>Beliefs regarding the intervention's negative impact on tinnitus</u>

A belief that the intervention would negatively impact on their tinnitus was also a barrier to engagement. As discussed in Section 5.5.3.2, some people did not engage with the support forum due to a belief that it would make their tinnitus worse. This concern also applied to the intervention as a whole, reading the provided information, or practicing relaxation in quiet environments:

I'm sure it's on this programme [the Tinnitus E-Programme] that I've [heard] that the more you focus on it [tinnitus] the worse it is. So reading the

> *[information] material to me is focusing on it too much . . . So I don't* (Caroline, 40, had tinnitus for 2-5 years)

> *For me, kind of, doing some sort of relaxation in quiet environments isn't possible because I will start drifting off and focusing on my tinnitus* (Gail, 36, had tinnitus for 6 months – 1 year)

Gail spoke about how she avoided doing things that were specifically aimed at helping her tinnitus as this can become *"tinnitus-related activity"* that can make you focus on your tinnitus.

External barriers

Users also identified several external barriers that prevented them from engaging with the intervention, including lack of time and illness unrelated to tinnitus.

5.5.3.5 Theme 5: Barriers and facilitators to enactment of relaxation skills

In addition to those barriers and facilitators reported in Section 5.5.3.4, users also reported factors that were specifically influenced users' enactment of the relaxation skills learnt in the intervention. One facilitator to enactment was the availability of a suitable environment in which to practice their relaxation. Users preferred to practice relaxation on their own, in a comfortable (e.g. lying down on the bed) and quiet environment, and away from interruptions or distractions (e.g. their children).

Fatigue was a factor that influenced whether they practiced relaxation and the benefits they received from it. On the one hand, fatigue acted as a barrier to enactment, with some users finding it more difficult to meet the daily relaxation goals when they were tired:

> *As I am my mother's main carer - she is 92 with vascular dementia - some days I am so busy taking her for gp and hospital appointments . . . I also clean, cook, launder, garden, transport, administer medication etc., that by the end of the day I am so exhausted or frustrated that I really cannot include relaxation exercises* (Karen, 70, had tinnitus for 10+ years)

Some users found that they would fall asleep during their relaxation. For some, this would be helpful as they often had difficulties sleeping, whereas others were frustrated by this interruption as it would prevent them from feeling the full effects of the relaxation. In this context, fatigue was a barrier to enactment by limiting a user's ability to practice relaxation successfully:

> *I did the listening exercises every day, but as they make me fall asleep, this would always be at bed time, and I'm not sure if they had the desired effect due to me never making it to the end of one of the recordings* (Becky, 22, had tinnitus for 6 months – 1 year)

In contrast, fatigue also acted as a facilitator to enactment. Some users explained how they were more likely to practice their relaxation when they were tired or had a busy day, as this was when their tinnitus was worse.

Although the relaxation goals were generally perceived as achievable (Section 5.5.3.2), users frequently reported that it was difficult to find the time to fit the relaxation goals into their busy lives, thus identifying another barrier to enactment. The final barrier that users' identified was forgetting to practice relaxation every day. Becky, who was only able to meet 7% of the relaxation goals for the breathing exercises, explained: "*I would forget to do the breathing exercises, then it is hard to cram three exercises into the five minutes before bed*". Although not part of the intervention, several users believed that the study's relaxation log was useful for remembering to practice the relaxation. One user set an alarm on his phone to remind him to practice his relaxation.

5.5.3.6 Theme 6: Gaining benefit

Users reported gaining a range of benefits from the programme: (1) Learning about tinnitus and its management; (2) Improved ability to relax and sleep; (3) Reduced intrusiveness of tinnitus; (4) Normalising and accepting tinnitus; and (5) Gaining confidence in ability to manage, and cope with, tinnitus.

<u>Learning about tinnitus and its management</u>

Users reported learning new things about tinnitus and gaining new ideas on what they could do to help themselves. In doing so, they developed a better understanding of tinnitus and its management:

> *I had never sort of had that information before even at the hospital and stuff like that. I had never been told some of the stuff that I read about. So it is always*

> *good to know like a bit more about it [tinnitus]* (Becky, 22, had tinnitus for 6 months – 1 year)

> *[The intervention affected] my understanding of what can help and, and also what can make it worse, so things like, for example, the, the negative thoughts or stress and that kind of thing* (Michael, 40, had tinnitus for 10+ years)

Even if users already knew the information, they still found it helpful for confirming what they already knew to be correct: *"It does no harm to know that, what you think [about tinnitus], and what you've heard [about tinnitus], and what you've understood [about tinnitus] from health professionals, is where the evidence lies"* (Michael, 40, had tinnitus for 10+ years). William explained how the hearing aids he used helped his tinnitus and how the information he read in the intervention provided him with an understanding of why they helped:

> *So hearing aids are a fantastic cure, for me, for tinnitus . . . I didn't realise why that was until I read that article which said that tinnitus is a sound . . . your mind tries to find out what it is because that's how sound wo- hearing works. And I suddenly realised that's what I was doing. When I can't hear, I'm trying to pick up every sound* (William, 79, had tinnitus for 10+ years)

Users also spoke about how online support groups may provide opportunities to learn about what others are doing to help themselves and to benefit from other people's experiences. However, this was not reported as an actual benefit of the intervention as very few people had used the intervention's forum.

Improved ability to relax and sleep

Most users reported that the intervention, through the use of the relaxation therapy, improved their ability to relax. Users reported feeling calm, focused, and energised following the relaxation, which, in turn, helped them deal with their tinnitus:

> *I don't think I am as uptight . . . in the last six weeks. I know I can re-focus my mind by doing the breathing exercises for a couple of minutes. Yes, I think it [the intervention] has benefited me a hell of a lot to be honest* (Jack, 33, had tinnitus for 2-5 years)

> *I started doing my breathing exercises . . . and that really helped. Because it calms you down. And you think, "Hang on. It's not, don't let yourself get carried away here." And, and it, it, it definitely does work* (Thomas, 68, had tinnitus for 10+ years)

Some users reported that they also found the relaxation helpful for dealing with general life stress and anxiety unrelated to tinnitus: *"[The intervention] has helped with the tinnitus, don't get me wrong, but it has just helped certainly in my life in general, just helped me to be a little bit more relaxed, not to worry about so many things"* (Jack, 33, had tinnitus for 2-5 years). Some users found that the intervention also helped them sleep, which is something they had previously struggled with:

> *I have usually had to put the television on and go to sleep watching television . . . But since starting this relaxation programme, I have found that by going to bed earlier and doing the programme, I am sleeping better . . . Without the*

television on, without the noise as a background (Karen, 70, had tinnitus for 10+ years)

Now, if it's [sic] beginning to think, "Oh it's loud" I will then listen to a relaxation tape. And I found, I find that very helpful then to help me go off to sleep (Phillip, 64, had tinnitus for 10+ years)

However, as discussed in Section 5.5.3.5, falling asleep during relaxation was not always perceived as a helpful outcome of the relaxation as it could potentially limit the benefit gained from the relaxation.

Reduced intrusiveness of tinnitus

In line with their expectations of the intervention (Section 5.5.3.1), none of the users reported any differences in the loudness of their tinnitus: *"I can't say that it's dramatically changed the- my tinnitus or the way that I hear it"* (Michael). However, many users reported that the intervention reduced the intrusiveness of their tinnitus, that is, it reduced how much they noticed, or were bothered by, their tinnitus, or improved their tolerance to it. This benefit was mainly attributed to the relaxation therapy, which acted as a distraction, masked the tinnitus sound, or reduced the amount they thought about their tinnitus:

I don't think I notice it [tinnitus] half as much as I did before, sort of, just, like, in the day. And when I do notice it, it doesn't bother me as much as it did in the past (Becky, 2, had tinnitus for 6 months – 1 year)

So it was more just re-focusing but just getting my own whole body relaxed and my whole mind relaxed and just getting away, losing the thought of the tinnitus and how it changes (Jack, 33, had tinnitus for 2-5 years)

Normalising and accepting tinnitus

Users reported how the intervention helped them to normalise and accept their tinnitus. Many found it comforting to know that there are other people with tinnitus, which normalised it and made them feel less alone. Such accounts derived mainly from discussions of the intervention's online support forum or other forums users had used previously:

It [the intervention] helps you feel as though you're not quite on your own, y'know, you're not as isolated. There is a lot of people that have got the same things. Same problem. So that in itself makes you feel better, really. Because when you've got something wrong with you, you think you're the only person that's got it . . . it does help (Margaret, 70, had tinnitus for 10+ years)

One of the things what I did find interesting reading the forum, was the amount of people what's very, very similar to meself. I found that interesting that, you know, I, I mean I know I'm not on me own . . . it just gives you that bit of reassurance that, "Oh yeah, that used to happen to me" and, "Oh yeah, that really annoys me that bit as well." And it, it made you think that you're not, that you're more normal than, you know what I mean, as normal is (Phillip, 64, had tinnitus for 10+ years)

Several users who completed the THI found it helpful for gaining feedback on their tinnitus severity category, which made them realise that their tinnitus was not as bad as they sometimes thought it was, or confirmed that their tinnitus was not particularly problematic. On the other hand, there may also be potential risks associated with knowing your tinnitus severity. Thomas explained how finding out that you have 'mild' tinnitus may make people worry about how much worse their tinnitus may get in the future.

Normalising and accepting tinnitus was a particularly salient theme for Margaret. Specifically, she found that the THI questions themselves helped to normalise her tinnitus experience:

> *I suppose in a way it did [help me to fill in the THI], in as much as the questions that they asked were, quite well related to how you feel when you've got tinnitus. So they were the right questions. But I think it also made me think, well, I'm not the only person here that's suffering like this . . . Because it's a question that you've, you know, you think, "Yeah, that's definitely how I feel." Then obviously other, a lot of other people feel it, at the same, the same . . ."That's obviously how a lot of people feel, it's not just me."* (Margaret, 40, had tinnitus for 10+ years)

She also explained how the information, although she already knew a lot of it, helped her to accept and normalise her tinnitus:

> Margaret: Well, having had tinnitus for so long, I think probably I already knew [a lot of the information] [laughs]. But having said that,

although you've got the information stored up here, you don't always accept it [Laughter] . . .

Interviewer: Mmm. Can you tell me a bit more about what you were meaning by "you don't always accept the information"?

Margaret: I think when you're going through this, when you're going through the stage that I went through just after Christmas, with the tinnitus being really bad, you get, [it] doesn't matter how much you know about it, it's still very difficult to accept - that it's normal, and that it will get better or it will go away.

For a minority of users, part of this normalisation and acceptance process involved challenging their negative thoughts about tinnitus or adopting a more positive mind-set:

> *On week three, it mentions, "Why should tinnitus be a threat?", "What does this- what does this feelings of threat lead to," and so on, and you challenge yourself on "is it a threat?" It isn't* (David, 73, had tinnitus for 10+ years)

> *It's [the intervention has] made me more positive rather than negative about things* (Karen, 70, had tinnitus for 10+ years)

Gaining confidence in ability to manage, and cope with, tinnitus

Users reported that the intervention gave them the confidence and tools to be able to manage, and cope with, their tinnitus:

> *Going onto this programme made me think more positively of what I can do to help myself* (Karen, 70, had tinnitus for 10+ years)

> *The positive thing about this [intervention] is that it's something that you can help do yourself* (Michael, 40, had tinnitus for 10+ years)

One user reported that he gained reassurance from the intervention that he is already coping with his tinnitus well. Another user liked that he could come back to the intervention if he was finding it difficult to cope in the future.

5.5.4. Interviewer reflections on interviews

I felt reasonably comfortable carrying out these semi-structured interviews because, compared to the think aloud interviews carried out in Chapter 7, I had relatively more experience with this type of interview. As I had not been involved in the development of the Tinnitus E-Programme 1.0, I found it easier to adopt a more neutral position during the interviews. It was easier to discuss participants' critical feedback and I was less tempted to defend particular design choices. On the other hand, it was challenging to prevent your own views of the intervention from influencing the interviews. For example, if participants expressed negative views on aspects of the intervention you

liked, or vice versa. In these situations, I tried to stay open-minded and would ensure that my responses were neutral, not revealing to the participant what my true views were.

Some participants had not used all of the components of the intervention and it was sometimes difficult to ask people why they did not use these components without sounding critical. To overcome this, I would reassure participants that they were not alone, as others had used the intervention in a similar way. I also reiterated why an understanding of their reasons for not using certain components was important to the research, that is, to help the research team identify areas of the intervention that needed improving.

The interviews were carried out face-to-face, over the phone, via video chat, and by email. Through offering a range of options, I felt that I was able to better meet the needs of the participants. The email interview option enabled a participant with profound hearing loss to take part in the research, which she would not have been able to do otherwise. The video chat and phone options also enabled me to schedule interviews outside of office hours, which better suited those participants who worked during the day. This may explain why I was more successful at recruiting younger participants in this study, compared to the think aloud interview study (Chapter 7).

I found the video chat interviews particularly challenging because it was the first time I had used this method. On the one hand, the video allowed me to read the non-verbal cues of the participant, which, to some extent, simulated an in-person interview. Some

participants explained to me that they chose the video chat option because it was important for them to be able to see the face of the person they were speaking to. On the other hand, I initially found these interviews somewhat artificial and it took a while before I felt comfortable using the video chat. The participants and I had to look at the computer screen to be able to see each other. This meant that we were not looking at the web-cam, so you did not get that sense of eye contact, which I find helpful for building rapport, demonstrating active listening, and expressing empathy during interviews. You can also see your own face in a small window on the screen, which could be distracting at times.

5.6. LIMITATIONS

These studies have some limitations that need to be considered. As registration to the intervention is not mandatory and users can choose to complete it anonymously, there was no way of knowing how many people had previously used, or were currently using, the live intervention. This made it difficult to reliably estimate the sample size and accurately assess external validity for Study 1. It was also not possible to track past and current users who did not register, making this target group difficult to identify and reach. This limitation meant that convenience sampling was the only feasible sampling method, which may have introduced a self-selection bias. It also resulted in a small sample size (n=27), which will reduce the external validity of the findings, making them less generalisable to the wider target group.

The Tinnitus E-Programme 1.0 does not monitor actual intervention usage, which meant that it was not possible to validate whether participants actually used the

intervention and their self-reported usage. However, the focus of these exploratory studies was on the participants' accounts of their usage and reasons for usage or any non-usage.

Participants recruited to Study 1 were likely to represent a particularly motivated and satisfied group of users. Those who chose not to use the intervention, gained no benefit from the intervention, or no longer used the intervention were less likely to take part. Study 2 provided more diversity as it introduced a group of people to the dataset with different motivations (e.g. to support tinnitus research, looking to benefit from a novel intervention). Once recruited, Study 2 participants were encouraged to continue onto the interview, even if they did not complete or feel they had benefited from the intervention. In Study 1, there were no exclusions regarding length of time since completing the intervention to maximise recruitment for this very specific population. Most participants completed the intervention more than one year before the survey, which may have introduced a recall bias.

There were several limitations that may have led to an overinflated overall mean adherence to the relaxation goals. First, 69% of Study 2 participants completed their relaxation log after their interview which meant that relaxation data was not available for all of the participants. It may be that those who failed to submit their log did so because they had stopped using the intervention after the first six weeks. Second, researchers have claimed that the act of recording ones behaviour can act as a behaviour change technique that encourages that behaviour (Michie et al., 2013). Therefore, adherence may have been higher than would have been observed if the relaxation log had not been used. In fact, some users noted that the relaxation log had

motivated them to practice the relaxation and helped them to remember to do it. Finally, participants were asked to complete their relaxation log after their interview. This interview may have introduced a social desirability bias in which the participants may want to please the interviewer with whom they had built a rapport during their interview. However, as the adherence data was secondary to the qualitative data, this limitation should not influence the overall conclusions to a great extent.

Creswell and Plano Clark (2011) classify the use of both open and closed survey questions as a convergent design. However, it can be argued that, through using a predominantly quantitative data collection method (i.e. surveys) and recruitment method (i.e. convenience sampling), the qualitative and quantitative strands may not be entirely equal. Utilising more in-depth qualitative methods (e.g. interviews) and recruitment strategies (e.g. purposively sampling) may have improved the rigor of the qualitative strand, thus reducing this equality gap. On the other hand, using the same data collection method allowed a direct comparison of the qualitative and quantitative data from the same participant that would lead to a deeper understanding of the participants' experiences. Furthermore, analysing the qualitative and quantitative data separately ensured that equal priority was given to the findings from each strand.

5.7. SUMMARY AND TRIANGULATION OF STUDY 1 AND 2 FINDINGS

This section will first summarise the key findings of the two studies in terms of mechanisms of impact, implementation, contextual factors, and outcomes. Instances where the two studies were comparable or contrasting are highlighted. Consistent with

a mixed methods approach, the key contrasting findings between the two studies are highlighted and potential reasons for these disparities discussed (Section 5.7.5).

5.7.1. Mechanisms of impact: Acceptability, satisfaction, and intervention factors influencing user engagement

- Overall, users in both studies demonstrated high levels of acceptability and satisfaction with the intervention.
- Across both studies, user acceptability regarding the education about tinnitus and its management, and training/rehearsal for psychological strategies components was high.
- Generally, Study 2 users perceived the relaxation goals as achievable, with only a minority of users requesting that the goals were of a shorter duration or frequency. These findings mirror the quantitative findings in Study 1, where 78% of those who used the relaxation component reported that the goals were achievable.
- Study 2 users expressed some difficulties with the item responses, scoring system, and some of the questions of the THI (monitoring of condition with feedback to the patient). They perceived the THI (or an alternative method for monitoring tinnitus and providing feedback) as a valuable self-management component for two reasons:
    - It allows users to measure the benefit they gained from the intervention, which was important for convincing users of benefit and providing a sense of achievement.

    - It provided users with tinnitus severity rating, which was important for realising the benefit ‘normalising and accepting of tinnitus’.
- Across both studies, views on the online support forum were mixed. Users’ reasons for poor usage or disengagement from the forum included: negative views of the forum platform; users were already members of another forum that they preferred; perceived negativity of the forum posts; beliefs that the forum would make their tinnitus worse; concerns regarding internet safety; doubts about the trustworthiness of the information provided; and forgetting to use it.
- Study 2 users valued the intervention’s ten-week structure, however, some users commented that they would have preferred a different intensity and duration. Users also liked being able to use the intervention materials (e.g. relaxation audios) offline.
- In Study 1, users who had contacted the therapist highlighted how important this form of support was. However, in Study 2, users’ views regarding the self-guided nature of the intervention were mixed, with some users preferring the user autonomy provided by the unguided intervention.
- Users’ perceptions of the intervention’s usability, credibility and accessibility, and provision of therapist support influenced their engagement with the intervention.

5.7.2. Implementation: Intervention usage and user enactment

- In Study 1, intervention usage was mixed, with approximately one half of users using the full intervention and the remaining users using only some of it.

- On average, those Study 2 users who submitted their completed relaxation logs met just under half of the daily relaxation goals, suggesting that users' adherence to the relaxation goals was poor.
- Usage of the online support forum was lower in both studies, with only 60% of Study 1 users rating this component as helpful.

5.7.3. Contextual factors: Factors external to the intervention that may influence user engagement, enactment, and outcomes

- **User motivations** - Study 1 users outlined several motivations for using the intervention, including desperation, resulting from an increasingly severe tinnitus, a need to gain support in managing their tinnitus or a desire to provide this support to others with tinnitus, or to extend or complement the services that health professionals provide.
- **User expectations** - Study 2 users' expectations regarding the outcomes of the intervention were generally in line with the intervention aims. However, there were a minority of users who expected that the intervention would lead to a physical change or alter their sensation of their tinnitus.
- **Users' perceptions of need -** A low perceived need for the intervention acted as a barrier to engagement. Perceived need was influenced by users' perceptions of their tinnitus severity and ability to manage their tinnitus (i.e. relaxation ability).
- **Users' beliefs regarding the intervention's negative impact on tinnitus –** Users' beliefs that the intervention would negatively impact on their tinnitus was a barrier to engagement. Some people did not engage with the aspects of

the intervention because they believed that doing so would make their tinnitus worse.

- **Presence of hearing loss –** Some users reported that they were unable to use the guided relaxation audios because of their hearing loss.
- **External barriers –** External barriers, including lack of time and illness, influenced users' engagement with the intervention or enactment of the relaxation skills.
- **Relaxation environment** - One facilitator to user enactment was the availability of a suitable environment in which to practice relaxation. Users preferred to practice relaxation on their own, in a comfortable and quiet environment, and away from interruptions or distractions.
- **Fatigue -** On the one hand, fatigue acted as a barrier to enactment, with some users finding it more difficult to practice relaxation goals when they were tired. In contrast, fatigue also acted as a facilitator to enactment, as some users were more likely to practice relaxation when they were tired or had a busy day (this was when their tinnitus was worse).
- **Forgetting** – One barrier to enactment of the relaxation skills was users forgetting to practice relaxation every day.

5.7.4. Outcomes: Benefits gained from the intervention

- In Study 1, 90% percent of users reported that the intervention had helped them. However, as discussed in Section 5.6, the sample in this study was small (n=27) and is likely to represent a particularly motivated and satisfied group of users.

- Users in both studies identified several actual and potential benefits gained from the intervention. These benefits could be broadly grouped into three areas: functional (i.e. sleep, relaxation, intrusiveness) and emotional management; self-efficacy for managing, and coping with, tinnitus, understanding of tinnitus and its management; social support; and acceptance of tinnitus.

5.7.5. Key contrasting findings between Study 1 and 2

Usage of the THI ('monitoring of condition and feedback to the patient' component) varied between studies. Usage appeared lower in the Study 2 users, compared to users in Study 1. There are some potential reasons for this difference. It is likely that Study 1 users received therapist support during the intervention and the therapist may have directed them to the THI and provided encouragement and support to use it. Without this additional therapist guidance, users in Study 2 often encountered usability issues that caused them to overlook the link to this component. Moreover, Study 1 users who encountered major usability issues may have possibly been less likely to respond to the online survey.

In Study 1, usability was rated highly, with all users agreeing that the intervention was easy to use. In contrast, Study 2 participants generally found the intervention's usability to be poor with many finding it difficult to navigate. Again, this difference may be explained by the provision of therapist guidance and a reduced reliance on the intervention materials for Study 1 users. For example, one user mentioned how the therapist sent her a CD of the relaxation audios when she was unable to transfer the

MP3s onto a CD herself. Hence the therapist was helping Study 1 participants overcome a usability issue they encountered. Another explanation is that those completing the survey in Study 1 were likely to be highly motivated users who had a positive experience of the programme.

The theme ‘gaining benefit’ was identified across both studies, but there were some similarities and differences between studies regarding the actual benefits reported by users. Table 5.10 provides a comparison of the benefits identified in each study. Some benefits were identical (Comparison 6 in Table 5.10) between studies. Other benefits were identified in both studies, but they were defined differently due to the different ways the qualitative data was organised during the thematic analysis across the studies. For example, the benefit ‘reduced feelings of isolation’ identified in Study 1 was also identified in Study 2, however, it was grouped under a broader benefit termed ‘normalising and accepting tinnitus’ (Comparison 4 in Table 5.10). Generally, the benefits identified in Study 2 were less specific than those identified in Study 1. One explanation for these differences may be a result of the more in-depth qualitative methods used in Study 2, which provided richer and more detailed accounts of users’ experiences.

There were some other subtle differences between the identified benefits that are worthy of note. First, in comparison 1 (Table 5.10), the benefits identified in both studies incorporated a reduction in the intrusiveness of tinnitus. However, Study 1 extended this concept to ‘gaining control over your tinnitus and your life’.

Table 5.10 Comparison of 'gaining benefit' sub-themes between studies

Comparison No.	Benefits identified in Study 1	Benefits identified in Study 2
1	Gaining control over your tinnitus and your life	Reduced intrusiveness of tinnitus
2	Dealing with the emotional impact of tinnitus	
3	Providing hope	Gaining confidence in ability to manage, and cope with, tinnitus
4	Reducing feelings of isolation	Normalising and accepting tinnitus
5	Improved sleep	Improved ability to relax and sleep
6	Learning about tinnitus and its management	Learning about tinnitus and its management

Second, Study 1 categorised discussions about tinnitus management as 'providing hope', whereas this was categorised as 'gaining confidence in ability to manage, and cope with, tinnitus' in Study 2 (Comparison 1). Finally, the benefit 'dealing with the emotional impact of tinnitus' in Comparison 3 was identified in Study 1, but not in Study 2.

These differences between the identified benefits may be explained by the characteristics of the different target populations. That is, many of the users in Study 1 had turned to the intervention in desperation, following a particularly bad tinnitus experience. For them, the resulting reduction in intrusiveness was more about re-gaining some control they may have lost to their tinnitus. Moreover, the provision of management techniques went beyond merely supporting Study 1 users to better manage their condition, helping restore their sense of hope regarding tinnitus. It is also possible that many Study 1 users had higher pre-intervention levels of tinnitus distress; if so, this would explain why 'dealing with emotional distress' emerged as a prominent benefit in this study only. In contrast, the majority of Study 2 users did not seem to be

highly distressed by their tinnitus and, as they completed the intervention as part of a research project, they may have been less motivated and to engage with the intervention. In relation to comparison 4, as those in Study 2 were generally not as distressed by their tinnitus, they may have been more prepared to start normalising and accepting it.

5.8. CONTRIBUTION OF THE FINDINGS TO THE EVALUATION AND OPTIMISATION OF THE TINNITUS E-PROGRAMME

- This study explored the extent to which the intervention components and design features were well-used and acceptable to users. This informed decisions regarding which components and features should be retained for use in the Tinnitus E-Programme 2.0.
- Potential short- and long-term outcomes of the intervention were identified. This understanding contributed towards the development of a logic model that explains how the intervention leads to changes in outcomes.
- This study also identified barriers and facilitators to engagement and enactment. This knowledge helped decide which additional behaviour change techniques or design features should be added to the Tinnitus E-Programme 2.0 to improve user engagement and enactment.

CHAPTER 6. OPTIMISATION OF THE TINNITUS E-PROGRAMME

6.1. INTRODUCTION

The previous chapter used mixed methods research to develop an in-depth understanding of users' views and usage of the Tinnitus E-Programme 1.0. It demonstrated that the Tinnitus E-Programme 1.0 was generally acceptable to its target group and users reported gaining several benefits from using the intervention. However, there were several implementation and contextual issues that influenced users' engagement with the intervention. It is important that these issues are addressed to maximise user engagement and subsequent adherence before further evaluation is carried out. This chapter details the development of the Tinnitus E-Programme 2.0, an optimised version of the Tinnitus E-Programme 1.0. This new intervention was developed systematically and drew upon person-, theory-, and evidence-based approaches to intervention development to maximise its acceptability and efficacy, and successful implementation. This is the first time this methodology has been systematically applied to the development of internet-based interventions for tinnitus. The intervention development process is reported in detail to enable replication by other researchers and intervention developers.

6.2. AIM

To comprehensively describe the development of the Tinnitus E-Programme 2.0, an optimised version of the Tinnitus E-Programme 1.0.

6.3. METHODS

This research will combine evidence-, theory-, and person-based approaches to develop the Tinnitus E-Programme 2.0, using a similar methodology to Band et al. (2017; Section 2.1.4). As part of the intervention planning process for the Tinnitus E-Programme 2.0, evidence was collected and synthesised through literature review (Chapter 1 and 4; evidence-based approach), systematic review (Chapter 3; evidence-based approach), and primary mixed methods research (Chapter 5; person-based approach). Similar to Band et al. (2017), this planning work informed intervention design, which was carried out through: (1) the creation of a set of guiding principles (person-based approach); (2) behavioural analysis (theory-based and evidence-based approach); and (3) logic modelling (theory-based and evidence-based approach). These three streams of work were carried out iteratively and in parallel, with all aspects contributing to one another.

The majority of the intervention design was carried out by the author, however, the author also consulted with experts, including the three members of the research team, who have expertise in tinnitus and health psychology, the original developer of the Tinnitus E-Programme 1.0, and experts in digital intervention development at the University of Southampton. The research team and original developer of the Tinnitus E-Programme 1.0 approved the final intervention, and the research team reviewed and agreed the final guiding principles, behavioural analysis, and logic modelling. The intervention was developed using LifeGuide, an open-source software platform for developing digital health interventions (S Williams, Yardley, Weal, & Wills, 2010).

6.3.1. Guiding principles

Before creating the guiding principles, the person-based approach recommends describing the 'context' of the intervention. There are three stages to doing this:

1. Stating the intervention objectives, in terms of behaviour and outcomes.
2. Briefly describing the key characteristics of the intervention's target users, in terms of their psychosocial characteristics and the behavioural context in which they will be using the intervention.
3. Identifying the key behavioural issues, needs or challenges the intervention must address.

The description of the intervention context was informed by previous literature (Chapter 1) and findings from the mixed methods process evaluation (Chapter 5). A set of guiding principles were created that consisted of intervention design objectives and the key intervention features that will achieve these objectives. The intervention context and the relevant evidence-base was consulted throughout the creation of these principles. Only the self-management components from the Tinnitus E-Programme 1.0 (i.e. education about tinnitus and its management; monitoring of condition with feedback to the patient, training/rehearsal for psychological strategies, social support) were considered for inclusion in the Tinnitus E-Programme 2.0 to make best use of the time available.

In addition to the intervention-specific guiding principles, the three common guiding principles from the person-based approach (Yardley, Morrison, Bradbury, & Muller, 2015) were also added to ensure the Tinnitus E-Programme 2.0 was consistent with these best practice guidelines for intervention design. These common principles were:

(1) to promote user autonomy; (2) to promote user competence; and (3) to promote a positive emotional experience and sense of relatedness (Section 2.1.3). Key design features specific to the Tinnitus E-Programme 2.0 were identified to address these common guiding principles.

6.3.2. Behavioural analysis

To complement the guiding principles, a comprehensive behavioural analysis was carried out to systematically describe and identify the intervention's potential mechanisms of impact. Behavioural analysis involves comprehensively mapping out all of the elements of an intervention. Specifically, it identifies and links each of the intervention's target behaviours (e.g. engaging with the relaxation skills training); the determinants of these behaviours (i.e. factors that influence behaviour); and appropriate intervention content to addresses these determinants. Following the methodology outlined by Band et al. (2017), each stage of the analysis was incorporated into a set of tables.

First, using the findings from the mixed methods evaluation of the Tinnitus E-Programme 1.0 (Chapter 5), the target user behaviours for the Tinnitus E-Programme 1.0 and the barriers (e.g. finding the time) and facilitators (e.g. achievable goals) for each of these behaviours were identified. Design features that addressed each of these barriers and facilitators were then selected. Target user behaviours and additional design features that were not included in the Tinnitus E-Programme 2.0 were still included in the analysis so that they can be incorporated into future iterations of the intervention.

Second, where possible, the contents of the behavioural analysis tables were mapped onto two evidence-based frameworks and taxonomies, that is, the BCTv1 (Michie et al., 2013; Section 2.1.2.2) and Morrison et al.'s (2012) framework of design features for e-health interventions. While other frameworks have identified design features that are important in digital intervention development (Mohr, Schueller, Montague, Burns, & Rashidi, 2014; Ritterband et al., 2009; Yardley, Morrison, Bradbury, & Muller, 2015), Morrison's framework was chosen because it is the only one to provide a comprehensive description of design features. It used systematic methodology (i.e. critical interpretative synthesis) to identify design features that may mediate and moderate the effects of intervention design on outcomes. The 11 design features and their conceptual definitions are provided in Table 6.1.

Third, the findings from the systematic review (Section 3.4.6) were used to identify any additional BCTs that should be included in the intervention. Fourth, each of the key behaviours, the new BCTs identified by the behavioural analysis, and the original BCTs taken from the Tinnitus E-Programme 1.0 were mapped onto the BCW (Michie, Atkins, et al., 2014; Michie et al., 2015; Section 2.1.2.1). This involved mapping either individual, or sets of, BCTs to their corresponding intervention function (i.e. ways by which an intervention can change behaviour, such as education or training; Table 6.2), theoretical domain (i.e. a group of theoretical constructs) from the theoretical domains framework (e.g. knowledge, skills; Table 6.3), and source of behaviour from the COM-B model (i.e. capability, opportunity, or motivation).

Table 6.1 Conceptual definitions for the 11 design features (Taken from Morrison et al., 2012)

Design feature	Conceptual definition
Social context and support[a]	Facilitate perceptions of social context, human or human-like interaction, and social support
Contacts with intervention[a]	Provide direct or mediated contact with the intervention, or individuals responsible for the intervention
Tailoring and targeting[a]	Provide optimally relevant information matched to individual users (tailoring) or groups of user (targeting)
Self-management[a]	Use of personal information for reflective self-management and monitoring of health behaviour
Entertainment[b]	Provide content-based entertainment activities
Aesthetics[b]	Provide an aesthetically pleasing or engaging intervention
Updated information[b]	Provide regularly updated information throughout the intervention period
Usability[b]	Facilitate users' ability to successfully navigate the intervention
Credibility[b]	Provide information or services to facilitate perceptions of credibility
Information architecture[b]	Access to information and navigation through the intervention
Program exposure[b]	The length of time a user is entitled to engage with the intervention

Key: [a]Design features proposed to mediate the effects of intervention design on outcomes
[b]Design features proposed to moderate the effects of intervention design on outcomes

The intervention was not mapped onto the political outer layer of the wheel, which details the seven types of policy that can be used to deliver the intervention function, as policy considerations were outside of the scope of this research.

6.3.3. Logic model

The MRC guidelines for process evaluations recommends creating a logic model, which provides a diagrammatical method for explaining how a complex intervention works (Moore et al., 2014).

Table 6.2 Definitions of the nine intervention functions of the Behaviour Change Wheel (Taken from Michie et al., 2015)

Intervention function	Definition
Education	Increasing knowledge or understanding
Persuasion	Using communication to induce positive or negative feelings or stimulate action
Incentivisation	Creating expectation of reward
Coercion	Creating expectation of punishment or cost
Training	Imparting skills
Restriction	Using rules to reduce the opportunity to engage in the target behaviour (or to increase the target behaviour by reducing the opportunity to engage in competing behaviours)
Environmental restructuring	Changing the physical or social context
Modelling	Providing an example for people to aspire to or imitate
Enablement	Increasing means/reducing barriers to increase capability (beyond education and training) or opportunity (beyond environmental restructuring)

It outlines the intervention's hypothesised mechanisms of change by which the intervention exerts changes in outcome. A logic model was created for the Tinnitus E-Programme 2.0, informed by the evidence on the determinants of tinnitus-related quality of life (Chapter 1 and 4) and the findings from the behavioural analysis (Section 6.4.2). This logic model describes a set of causal assumptions that can be tested, or elaborated on, in future development and evaluation work.

6.3.4. Implications for future optimisation work

As mentioned previously, modifications were limited to the intervention components present in the Tinnitus E-Programme 1.0 to make best use of the time available.

Table 6.3 Descriptions of the 14 theoretical domains from the Theoretical Domains Framework (Summarised from Cane et al., 2012)

Theoretical Domain	Definition
Knowledge	An awareness of the existence of something
Skills	An ability or proficiency acquired through practice
Memory, attention, and decision processes	The ability to retain information, focus selectively on aspects of the environment and choose between two or more alternatives
Behavioural regulation	Anything aimed at managing or changing objectively observed or measured actions
Social/professional role and identity	A coherent set of behaviours and displayed personal qualities of an individual in a social or work setting
Beliefs about capabilities	Acceptance of the truth, reality, or validity about an ability, talent, or facility that a person can put to constructive use
Optimism	The confidence that things will happen for the best or that desired goals will be attained
Beliefs about consequences	Acceptance of the truth, reality, or validity about outcomes of a behaviour in a given situation
Intentions	A conscious decision to perform a behaviour or a resolve to act in a certain way
Goals	Mental representations of outcomes or end states that an individual wants to achieve
Reinforcement	Increasing the probability of a response by arranging a dependent relationship, or contingency, between the response and a given stimulus
Emotion	A complex reaction pattern, involving experiential, behavioural, and physiological elements, by which the individual attempts to deal with a personally significant matter or event
Environmental context and resources	Any circumstance of a person's situation or environment that discourages or encourages the development of skills and abilities, independence, social competence, and adaptive behaviour
Social influences	Those interpersonal processes that can cause individuals to change their thoughts, feelings, or behaviours

The findings of the systematic review (Section 3.4.6) were used to highlight additional intervention self-management components that should be considered for inclusion in future optimisation work.

6.4. RESULTS

6.4.1. Guiding principles

The description of the context of the Tinnitus E-Programme 2.0 is presented in Box 6.1 and the intervention-specific guiding principles are presented in Table 6.4. The intervention objective of the Tinnitus E-Programme 2.0 was to provide cost-effective support to people with tinnitus to improve their tinnitus-related quality of life by supporting their self-management. Achieving this objective required support for people with tinnitus to develop realistic illness beliefs; effective and adaptive ways of thinking and feeling; and relaxation skills and a regular relaxation practice to reduce their physiological arousal. These three design objectives were informed by the evidence-base which identified illness beliefs, negative thinking, emotional distress and physiological arousal as key determinants of tinnitus-related quality of life (Section 4.4.1).

Due to the resource challenges facing tinnitus services in the UK (Section 1.4.2), the intervention also had to be delivered at a low-cost. This meant that the intervention could not require extensive time or resource commitment from health professionals.

Box 6.1 Context of the Tinnitus E-Programme 2.0

Intervention objective:

To provide cost-effective support to people with tinnitus to improve their tinnitus-related quality of life by supporting their self-management.

Key characteristics of the intervention's target users:

As there is no cure for tinnitus, management aims to improve quality of life of people with tinnitus, mainly through reducing the associated emotional distress. Psychological therapies are acknowledged as beneficial to people with tinnitus; however, such therapies are not always readily accessible. Not everyone with tinnitus seeks medical attention, so they may not be under a clinical service.

Key behavioural issues, needs, or challenges the intervention must address:

- People with tinnitus need better access to self-management support.
- Providing therapist support or guidance may be beneficial for some but is not possible at all tinnitus clinics and is not always preferable to users.
- There is limited time and resources for intervention development (approximately 2-3 months) and little long-term support for the intervention.
- The online support forum was not acceptable or well-used by users and, on a practical level, its maintenance would be time and resource intensive.
- Users encountered difficulties with the THI, specifically its response scale, and the scoring and feedback system were confusing, and some of the items were difficult to use or interpret. This raises concerns regarding the acceptability of this tool as it stands. Identifying or creating a new, more acceptable tool would be time-consuming and therefore outside the scope of this project.
- Adherence to relaxation goals was poor. Users encountered several barriers that prevented them from enacting the relaxation goals, including accessibility of relaxation audio, finding a suitable environment, finding the time to practice, fatigue, and forgetting.
- There were several important factors that influenced users' engagement with the intervention, such as the acceptability of the components, users' perceived need for the intervention, and the usability, accessibility, and aesthetics of the intervention.

Table 6.4 Intervention-specific guiding principles for the Tinnitus E-Programme 2.0

Intervention design objectives ***[module name]***	**Key features of the Tinnitus E-Programme 2.0**
1. To support people to develop realistic illness beliefs *[Introduction to tinnitus; Mechanism of tinnitus]*	• Providing information that targets specific illness cognitions[1]. • Interesting and lay-friendly explanations of tinnitus mechanisms, drawing upon the signal filter[2] and somatosensory amplification[3] theories of medically unexplained symptoms
2. To support people to develop effective and adaptive ways of thinking and feeling *[Managing your thoughts]*	• Provide training in cognitive techniques to manage the emotional distress, including cognitive restructuring, cognitive defusion, gratitude diary, monitoring thoughts, and thought record techniques. • Education about the association between their thoughts, emotions and behaviour and how negative thinking can lead to increased perceptions of tinnitus and emotional distress. • Behaviour change techniques to maximise capability, opportunity, and motivation to practice cognitive techniques (see behavioural analysis).
3. To support people to develop relaxation skills and a regular relaxation practice to reduce their physiological arousal *[Relaxation therapy]*	• Provide a variety of relaxation techniques to manage the physiological arousal and emotional distress and achievable relaxation goals. • Behaviour change techniques to maximise capability, opportunity, and motivation to practice relaxation (see behavioural analysis; Section 6.4.2).
4. To deliver the intervention at a low cost	• Therapist support should be optional, depending on user preferences or resource availability (e.g. lack of trained therapists).

Note: [1]Illness cognitions include: identity (e.g. reassuring users that is it normal for their tinnitus to fluctuate and allaying fears that tinnitus is a sign of a worse illness), causes (e.g. not everyone is able to identify what caused their tinnitus), timeline (e.g. reassuring users that most people find their tinnitus gets better with time), consequences (e.g. highlighting high prevalence of tinnitus in the population and that only a minority of people find that tinnitus significantly affects their lives), curability or controllability (e.g. reassure people that there are things they can do to prevent tinnitus significantly affecting their lives) (Leventhal, Meyer, & Nerenz, 1980); [2]Signal filter theory suggests that, in healthy people, the brain successfully blocks any 'sensory noise' (i.e. tinnitus signals). However, people with medically unexplained symptoms have 'faulty filtering' that allows this noise to pass through (i.e. tinnitus is experienced)(van Ravenzwaaij et al., 2010); [3]Somatosensory amplification theory suggests that when patients experience a physical sensation (i.e. tinnitus), they focus their attention on it. This can lead them to attribute certain beliefs or thoughts to this sensation, which can subsequently lead to an amplification of people's perception of the physical signals (i.e. a vicious cycle) (van Ravenzwaaij et al., 2010).

Therefore, the intervention was unguided, but designed in a way that optional therapist support could be provided, depending on user preferences and resource availability (e.g. trained therapists). Table 6.5 outlines the key intervention design features addressing the three common guiding principles identified by Yardley, Morrison, Bradbury, and Muller (2015). Features primarily focused on providing users with choice where possible, ensuring the intervention is easy to use and navigate, promoting credibility, and providing acceptable and relatable content.

In response to the mixed usage and acceptability of the THI and online support forum identified in the mixed methods process evaluation (Chapter 5), these components were not included in the Tinnitus E-Programme 2.0 (See Section 6.4.2.4 for further discussion). Therefore, modifications were limited to the intervention components present in the Tinnitus E-Programme 1.0: Education about tinnitus and its management; and training/rehearsal for psychological strategies (cognitive and relaxation skills training). Potential future optimisation work for the THI and online support forum is highlighted in the behavioural analysis (Section 6.4.4).

In the Tinnitus E-Programme 1.0, the cognitive restructuring component was brief. Although this is the most commonly used technique for developing effective and adaptive ways of thinking and feeling in tinnitus (Section 3.4.6 and 4.4.1.3), other cognitive skills techniques, such as cognitive defusion and gratitude diaries, have also been suggested to be helpful (Section 4.4.1.3). There is little evidence regarding the most effective technique for reducing negative thoughts in tinnitus (Section 4.4.1.3).

Table 6.5 How the common guiding principles of the person-based approach were addressed in the Tinnitus E-Programme 2.0

Common guiding principles	Key features of the Tinnitus E-Programme 2.0
To promote user autonomy	• Recommended course structure given but users are able to choose which modules to use and when to start each module. • Choice of different cognitive and relaxation techniques that people can choose depending on preference, available time, accessibility needs, and context [e.g. at work]. • Relaxation audios and written information or instructions can be used online and offline (i.e. printed or downloaded) • Optional 'find out more' pages with non-essential information for those who prefer more detailed information.
To promote user competence	• Provide clear structure, guidance and instructions, and relatable examples when describing tinnitus mechanisms. • Minimise lifestyle disruption by asking for an achievable time commitment, providing realistic relaxation goals and breaking content down into manageable chunks. • Option to use materials offline.
To promote a positive experience and relatedness	• Including only self-management components that are acceptable to users. • Content written in an informal, non-directive, relatable, empathetic, and positive manner. • Acknowledging users' concerns, drawing upon some of the concerns or barriers to engagement identified in the mixed methods research (Chapter 5). • Following best practice to maximize accessibility, usability, and credibility (British Dyslexia Association, 2016; Krug, 2014; University of Southampton, 2016; Yardley, Morrison, Bradbury, & Muller, 2015). • User testimonials and quotes. • Scientific evidence and rationale behind each module and/or technique. • Background to the intervention and meet the team section.

Consistent with Yardley, Morrison, Bradbury, and Muller's (2015) common guiding principles, users should ideally be offered a choice of different techniques. This recommendation was also substantiated by the findings on the acceptability of relaxation from the mixed methods process evaluation (Chapter 5.5.3.2) that highlighted that users differ in their preferred relaxation techniques.

Given the lack of conclusive evidence about the most effective cognitive skills techniques, it was decided that all three cognitive techniques would be offered in the Tinnitus E-Programme 2.0, including a cognitive restructuring task from the Tinnitus E-Programme 1.0 and cognitive defusion and positive thinking techniques that were created for the Tinnitus E-Programme 2.0. Specifically, the intervention included the cognitive defusion technique 'leaves on a stream', which asks users to imagine placing their thoughts on a leaf on a stream and then watching it drift away (Hayes et al., 2012). This technique encourages users to perceive thoughts as just thoughts, and refrain from trying to change or respond to these thoughts. Two additional techniques were included to help people become more aware of their thoughts and the link between thoughts and feelings: 'monitoring your thoughts' and a 'thought record'. Screenshots of the final intervention can be seen in Figures 6.1 and 6.2. A summary of the final intervention is provided in Table 6.6 and additional screenshots are provided in Appendix 7.

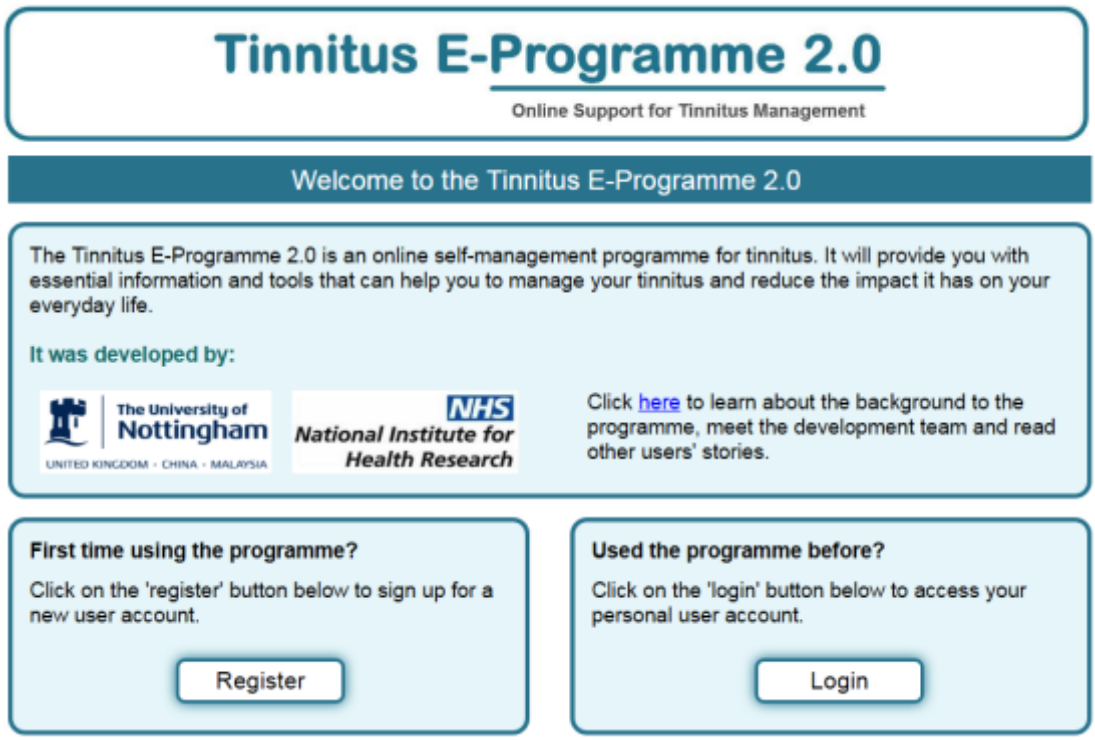

Figure 6.1 Screenshot of the Tinnitus E-Programme 2.0 login screen

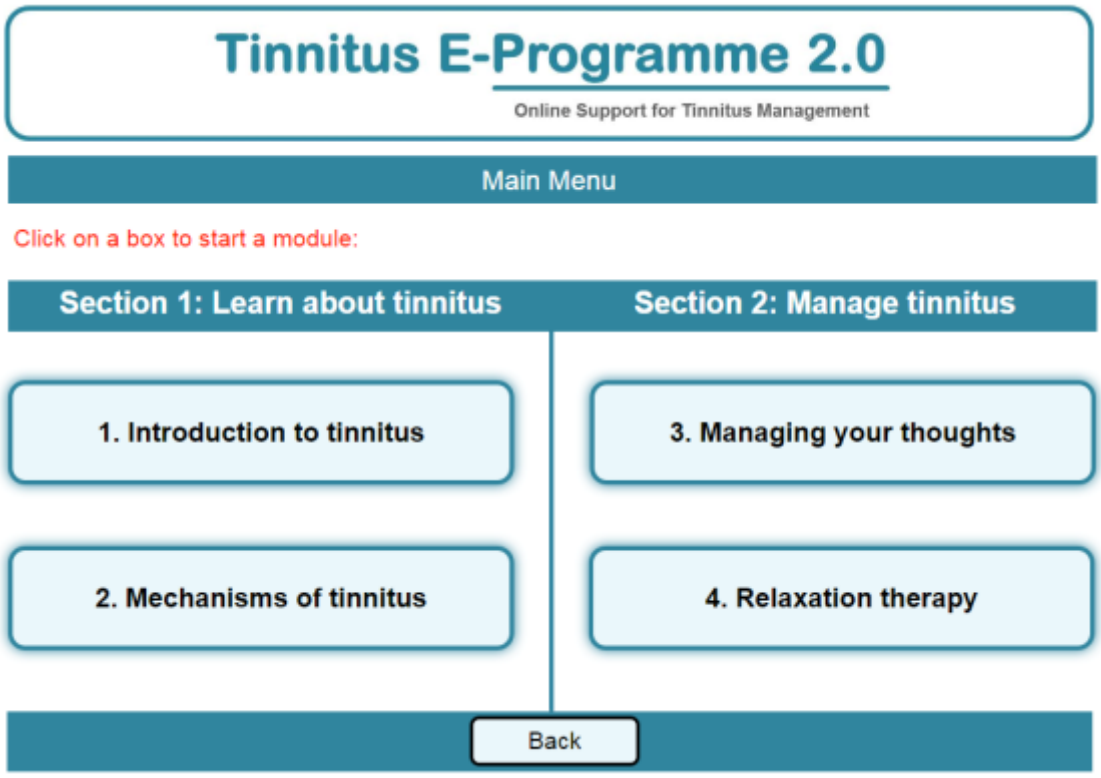

Figure 6.2 Screenshot of the Tinnitus E-Programme menu screen

Table 6.6 Outline of intervention content, including intervention aims, self-management components, module names, and individual techniques

Intervention aims presented to users	Self-management component	Module name presented to users	Individual techniques presented to users [type of technique]
To support people to manage their tinnitus and reduce the impact it has on their everyday lives	-		
To support people to better understand their tinnitus [guiding principle 1]	Education about tinnitus	• Introduction to tinnitus • Mechanisms of tinnitus	
To support people to become more aware of, and manage, unhelpful helpful thoughts [guiding principle2]	Cognitive skills training	• Managing your thoughts	• Monitoring thoughts • Thought record • Letting your thoughts go [cognitive defusion] • Challenging your thoughts [cognitive restructuring]* • Challenging your beliefs [cognitive restructuring]* • Positive thinking [Gratitude diary]
To support people to learn and practice relaxation skills [guiding principle 3]	Relaxation skills training	• Relaxation therapy	• Breathing exercise* • Muscle relaxation* • Guided relaxation* • Relaxation challenge

Key: *Techniques included in the Tinnitus E-Programme 1.0

6.4.2. Behavioural analysis

6.4.2.1 Behaviours and BCTs identified by the behavioural analysis

Six user target behaviours were identified from the Tinnitus E-Programme 1.0: engagement with the overall intervention; engagement with the education about tinnitus; practicing cognitive skills techniques; practicing regular relaxation; engagement with the THI; and engagement with the online support forum. Table 6.7 outlines the key issues and barriers and facilitators for each of these six behaviours that were identified by the mixed methods research (Chapter 5), and the design features that were used to address these. From this work, nine additional BCTs were introduced into the Tinnitus E-Programme 2.0, alongside the original five that were already present in the Tinnitus E-Programme 1.0 (Section 4.4.2). The BCTs and design features that were present in the Tinnitus E-Programme 1.0 are marked with an asterisk (*) in Table 6.7.

6.4.2.2 Additional BCTs identified by the systematic review

When deciding on the final list of BCT, the list of commonly used behaviour change techniques that were identified in the systematic review (Section 3.4.6) was also consulted (Table 6.8).

Table 6.7 Behavioural analysis for the Tinnitus E-Programme 2.0 using Morrison's 11 design features for e-health interventions and Michie et al.'s Behaviour Change Techniques Taxonomy

Implementation issue [Thesis section]	Facilitators/Barriers to the target behaviour identified	Tinnitus E-Programme 2.0 design feature addressing this issue	Design features (MF)	Behaviour Change Techniques (BCTv1)
Target behaviour: Engagement with the overall intervention				
Credibility [5.4.2.5; 5.5.3.3]	**Facilitators:** Rationale behind components provided; Intervention coming from a credible source; Positive evaluations of developers who have expertise in tinnitus and altruistic motivations; Demonstrating the benefit that others have gained from the intervention **Barriers:** Perceived simplicity; Concerns about lack of updating and ongoing maintenance; Spelling mistakes; Lack of novelty	• Scientific evidence and rationale behind each module and/or technique • Meet the team section outlines developers' credentials and expertise in tinnitus • Background to the intervention outlines how intervention has been improved and updated over time • User quotes and testimonials* demonstrating how the intervention had helped them • Correct and check for spelling mistakes • Intervention offered free of charge to highlight altruistic motivations* • Update content • *Explain how this intervention is different to other forms of available support* • *Inclusion of evaluation results*	Credibility; Updated information; Social context and support	5.1. Information about health consequences 5.6. Information about emotional consequences 6.3. Information about others' approval 9.1. Credible sources

Implementation issue (cont.)	Facilitators/Barriers (cont.)	Tinnitus E-Programme 2.0 design feature addressing this issue (cont.)	Design features (cont.)	Behaviour Change Techniques (cont.)
Aesthetics [5.4.2.2]	**Facilitators:** Intervention looks professional and visually attractive	• Improving presentation using LifeGuide • Introduction of engaging images and diagrams • Language addressing people with tinnitus not health professionals	Aesthetics	[Could not be matched]
	Barriers: Uninviting and uninteresting presentation; non patient-friendly language (e.g. 'my patients); confrontational or clinical appearance			
Accessibility [5.4.2.5]	**Facilitators:** Free to use; ability to start immediately	• Intervention offered free of charge* • Users can self-register and gain access immediately*	[Could not be matched]	[Could not be matched]
Usability [5.4.2.2; 5.5.3.2; 5.5.3.3; 5.5.3.4]	**Facilitators:** Clarity of instructions for using intervention; ease of use; being able to access material online and offline	• Improving usability by using LifeGuide and following usability guidelines (Krug, 2014; University of Southampton, 2016) • Written scripts of the guided relaxation audio exercises for those unable to access the audio exercises • Continue to allow users to use the relaxation audios and written information or instructions online and offline (i.e. printed or downloaded)* • Instructions on how to use relaxation audio offline provided	Usability	[Could not be matched]
	Barriers: Difficult and confusing to navigate; Unclear/hidden links to essential content (e.g. THI); People with hearing loss unable to access audio materials; Difficulties downloading materials			

Implementation issue (cont.)	**Facilitators/Barriers to the target behaviour identified (cont.)**	**Tinnitus E-Programme 2.0 design feature addressing this issue (cont.)**	**Design features (cont.)**	**Behaviour Change Techniques (cont.)**
Acceptability of ten-week structure [5.4.2.2; 5.5.3.3; 5.5.3.4]	**Facilitators:** Achievable time commitment; Content broken down into stages; Flexibility; Introduction of new material after ten weeks **Barriers:** Preference for different intervention intensity and duration; Finding the time to engage with the intervention	• Recommended course structure given* • Users able to choose which modules to use and when to start each module to fit around their other commitments* • Recommended course structure reduced from 10 to 7 weeks • Content broken down into four modules • *Provide links to additional sources of information and support that can be used after the ten-weeks**	Program exposure; Information architecture	[Could not be matched]
Perceived need [5.5.3.4]	**Barrier:** Low perceived need	• Scientific evidence and rationale behind each module and/or technique • Users can choose which modules to use* • *Tailoring the content of the intervention depending on individual need (e.g. the presence of negative thinking)* • *Diagnostic assessment to help users and clinicians decide whether the intervention would be relevant*	*Tailoring/ targeting*	[Could not be matched]

Implementation issue (cont.)	Facilitators/Barriers to the target behaviour identified (cont.)	Tinnitus E-Programme 2.0 design feature addressing this issue (cont.)	Design features (cont.)	Behaviour Change Techniques (cont.)
User autonomy/ Therapist guidance [5.4.2.5; 5.5.3.3]	**Facilitators:** Additional counselling and guidance provided by therapist; Convenience and flexibility of delivery medium; Email reminders or prompts	• *Therapist support should be optional, depending on user preferences or if there are resource limitations (e.g. lack of trained therapists)** • *Additional email reminders or prompts*	*Contacts with intervention*	*3.1. Social support (unspecified)* *3.3. Social support (emotional)*
	Barriers: Feeling pressured or checked up on; Concerns that talking about tinnitus would make it worse; Negative social encounters			
Beliefs regarding impact of intervention on tinnitus [5.4.2.3; 5.5.3.2; 5.5.3.4]	**Barriers:** Concerns about intervention components making tinnitus worse	• Reassure users that it is completely normal for tinnitus to fluctuate and nothing to worry about • Reassure users that a temporary increase in perceived loudness is normal when practicing relaxation and will improve with practice • State and remind people that the aim of the relaxation is to reduce tinnitus distress • Keep the educational modules brief and break down content into small chunks* and across two modules	Program exposure	5.1. Information about health consequences 5.6. Information about emotional consequences

Implementation issue (cont.)	Facilitators/Barriers to the target behaviour identified (cont.)	Tinnitus E-Programme 2.0 design feature addressing this issue (cont.)	Design features (cont.)	Behaviour Change Techniques (cont.)
Target behaviour: Engagement with the education about tinnitus				
Acceptability of information [5.4.2.3; 5.5.3.2]	**Facilitators:** Ease of understanding; interesting content **Barriers:** Impractical advice given in British Tinnitus Association (BTA) leaflet	• Include additional interesting and scientific content • Remove BTA leaflet	Aesthetics; Credibility	[Could not be matched]
Target behaviour: Practicing cognitive skills techniques				
Acceptability of brief cognitive restructuring 5.5.3.2]	**Facilitator:** Relating to the content **Barrier:** Not convinced that negative thinking information will be beneficial because 'too brief'	• Provide instructions on how to perform several different cognitive skills techniques* • Information about the association between thoughts, emotions and behaviour and how negative thinking can lead to increased perceptions of tinnitus and emotional distress • User quotes on the role of negative thinking in tinnitus	Credibility; Social context and support	4.1. Instruction on how to perform the behaviour# 5.1. Information about health consequences 5.6. Information about emotional consequences 6.3. Information about others' approval 9.1. Credible sources

Implementation issue (cont.)	Facilitators/Barriers to the target behaviour identified (cont.)	Tinnitus E-Programme 2.0 design feature addressing this issue (cont.)	Design features (cont.)	Behaviour Change Techniques (cont.)
Target behaviour: Practicing regular relaxation				
Acceptability of relaxation [5.4.2.3; 5.5.3.2]	**Facilitators:** Choice of different relaxation exercises; Ease of use; Experiencing benefit **Barriers:** Formal relaxation exercises not appealing and preference for alternative methods of relaxing; Not convinced that formal relaxation will be beneficial	• Continue to offer users a choice of different relaxation exercises • Continue to provide instructions on how to perform the relaxation techniques • Encourage users to practice the relaxation exercises to experience the benefit for themselves • Provide information on how relaxation will help • User quotes saying how much the relaxation helped them • *Explain why it is important to use formal relaxation exercises or provide alterative stress-management techniques*	Credibility; Social context and support	4.1. Instruction on how to perform the behaviour* 5.1. Information about health consequences 5.6. Information about emotional consequences 6.3. Information about others' approval 8.1. Behavioural practice/rehearsal* 9.1. Credible sources
Enactment of relaxation [5.4.2.3; 5.4.2.5; 5.5.3.5]	**Facilitator:** Achievable goals **Barrier:** Finding the time	• Remove daily breathing exercise goals to reduce the duration and intensity of daily goals (one 30 minute session or two 15 minute sessions per day) • Encouraging people to make time and plan when they will do their relaxation	[Could not be matched]	1.1. Goal setting (behaviour)* 1.4. Action planning* 8.1. Behavioural practice/rehearsal*

Implementation issue (cont.)	Facilitators/Barriers to the target behaviour identified (cont.)	Tinnitus E-Programme 2.0 design feature addressing this issue (cont.)	Design features (cont.)	Behaviour Change Techniques (cont.)
Enactment of relaxation [5.4.2.3; 5.5.3.5] (cont.)	**Facilitators:** Relaxation log; Setting an alarm as a reminder **Barrier:** Forgetting	• Encourage habit formation by suggesting people do relaxation at the same time each day • Provide relaxation diary so users can log their daily relaxation practice • Suggest asking a friend or family member to remind them to practice • Suggest setting an alarm as a reminder to practice • Suggest putting a marker, post-it or sticky spot somewhere eye catching to remind them to practice	Self-management	2.3. Self-monitoring of behaviour 3.2. Social support (practical) 7.1. Prompts/cues 8.3. Habit formation 12.5. Adding objects to the environment*
	Barrier: Fatigue	• Provide advice on how to avoid falling asleep while practicing relaxation • Reassurance that developing a new skill takes a while and its ok if relaxation is not perfect	[Could not be matched]	4.1. Instruction on how to perform the behaviour*
	Facilitators: Availability of a comfortable and quiet environment **Barrier:** Distractions/interruptions	• Provide advice on how to make your environment conducive to relaxation practice (e.g. avoid distractions, creating a comfortable environment)	[Could not be matched]	12.1. Restructuring the physical environment

Implementation issue (cont.)	Facilitators/Barriers to the target behaviour identified (cont.)	Tinnitus E-Programme 2.0 design feature addressing this issue (cont.)	Design features (cont.)	Behaviour Change Techniques (cont.)
Target behaviour: Engagement with the THI				
Acceptability of THI [5.4.2.3; 5.5.3.2]	**Facilitators:** Ease of completion; Perceived benefit **Barriers:** Difficulties with using or interpreting the rating scale, item responses, and some of the questions; Lack of agreement with final tinnitus rating	• *Choosing a more user-friendly methods for measuring progress* • *Providing helpful feedback on the meaning of the tinnitus severity scores and the extent to which these scores changed*	*Self-management*	[Could not be matched]
Target behaviour: Engagement with the online support forum				
Acceptability of online support forum [5.4.2.3; 5.5.3.2]	**Barriers:** Concerns regarding forum making tinnitus worse, negativity of posts, and internet safety; Dislike of forum platform; Forgetting; Low perceived need as already using another forum	• *Address concerns about using forums* • *Move forum to more user-friendly platform or provide links to established and more active forum and add as an optional component*	*Social context and support*	[Could not be matched]

Notes: This table includes the seven target behaviours identified from the behavioural analysis of the Tinnitus E-Programme 1.0. Target behaviours not transferred to the Tinnitus E-Programme 2.0 are italicised. The implementation issues identified by the mixed methods research (Chapter 5) are listed in the first column and the associated barriers and facilitators to engaging in the seven target behaviours associated with the Tinnitus E-Programme 1.0 are listed in the second columns. Design features that were included in the Tinnitus E-Programme 2.0 to overcome these implementation issues are listed in the third column. The fourth and fifth columns map the design features from the third column onto two theoretical frameworks to describe the BCTs and design featured used. Recommended BCTs and design features that should be considered for future optimisation work are italicised.

Key: *BCTs and design features that were present in the Tinnitus E-Programme 1.0. #BCTs that were present in the Tinnitus E-Programme 1.0 but were targeting a different behaviour in the Tinnitus E-Programme 2.0 (e.g. practicing cognitive skills techniques instead of regular relaxation); MF = Morrison et al.'s (2012) framework; BCTv1 = BCT taxonomy version 1

Table 6.8 Presence of commonly used behaviour change techniques identified from the systematic review of five self-help interventions for tinnitus (Section 3.4.6)

Behaviour Change Techniques (BCTv1)	Number of studies (out of 5)	Presence in the Tinnitus E-Programme 2.0
1.4. Action planning	4	✓
4.1. Instruction on how to perform the behaviour	4	✓
8.1. Behavioural practice/rehearsal	4	✓
1.1 Goal setting (behaviour)	3	✓
2.3. Self-monitoring of behaviour	3	✓
2.4. Self-monitoring of outcome(s) of behaviour	2	×
3.2. Social support (practical)	2	✓
5.6. Information about emotional consequences	2	✓
12.5. Adding objects to the environment	2	✓
1.2. Problem solving	1	×
1.5. Review behaviour goal(s)	1	×
7.1. Prompt/cues	1	✓
8.3. Habit formation	1	✓
8.6. Generalisation of target behaviour	1	×
8.7. Graded tasks	1	×

The Tinnitus E-Programme 2.0 includes all of the commonly used (i.e. if included in 3 or more studies in the systematic review) BCTs. It also includes five of the remaining ten BCTs that were used less frequently. One additional BCT, 'self-monitoring of outcome(s) of behaviour', was introduced into the intervention from the BCTs identified in the systematic review. In addition to asking users to record their relaxation practice, users were also asked to record their levels of tension before and after practicing relaxation. This should help to facilitate users' beliefs in the benefits of relaxation and their perceptions of the intervention's credibility, which was identified as important factors for improving user engagement. The remaining BCTs were used

only once across the five self-help interventions so were not deemed essential to this intervention.

6.4.2.3 Additional design features identified in Morrison et al.'s framework

The behavioural analysis revealed that eight of Morrison et al.'s (2012) 11 design features were addressed in the Tinnitus E-Programme 2.0. Two of the remaining design features - 'contacts with intervention' and 'tailoring and targeting' – were highlighted as potentially important features (Table 6.7) that should be considered for future iterations of the Tinnitus E-Programme 2.0. 'Entertainment' was not addressed by the intervention or highlighted as an important feature in the behavioural analysis. Future work should consider providing content-based entertainment activities (e.g. quizzes), providing direct or mediated contact with the intervention (e.g. motivational or reminder emails) or a therapist, and tailoring the intervention to the users' needs to improve user engagement.

6.4.2.4 Removal of the THI and online support forum

The mixed methods research demonstrated that THI is a potentially valuable tool that would allow users to normalise their tinnitus and measure the benefit they gained from the intervention. Despite these perceived benefits, users encountered some difficulties with the THI, specifically they found its response scale and scoring and feedback system confusing, and some of the items were difficult to use or interpret. The THI was initially developed as a diagnostic and screening tool, rather than an outcome measure (C. W. Newman et al., 1996), and has been criticised for its lack of sensitivity

to change (Fackrell et al., 2014). This calls into question whether the THI is the most appropriate tool for monitoring changes in users' levels of tinnitus distress. There is currently a lack of agreement in the field of tinnitus regarding the most appropriate questionnaire for measuring outcomes for psychological interventions. However, international work is presently underway to establish a core set of outcome measures that should be used for evaluating different types of interventions (Hall et al., 2015; Section 8.2.1). The problems users encountered with the THI, and the lack of an obvious alternative outcome measure, meant that the THI was not included in the Tinnitus E-Programme 2.0.

The online support forum was also removed due to its low usage and poor acceptability among users. The Tinnitus E-Programme 2.0 did, however, include information about other users in the form of user stories and testimonials. It has been suggested that this design feature may facilitate users perceptions of social context and support (Morrison et al., 2012). Future optimisation work for these two self-management components will be discussed in more detail in Section 8.2.2.

6.4.2.5 Mapping intervention techniques onto the behaviour change wheel

After removing the THI and online support forum, the final list of target behaviours was reduced to three and included: engagement with the intervention and its individual modules; practicing cognitive skills techniques; and practicing regular relaxation. Table 6.9 details these behaviours, the intervention ingredients that addressed these behaviours, and the corresponding components of the TDF and BCW.

Table 6.9 Behavioural analysis of Tinnitus E-Programme using the Behaviour Change Wheel and Behaviour Change Techniques Taxonomy v1

Target Behaviour	Intervention techniques targeting behaviour	Behaviour source (BCW)	Theoretical domain (TDF)	Intervention function (BCW)	Behaviour Change Techniques (BCTv1)
Engagement with the intervention and its individual modules	• User testimonials demonstrating how the intervention had helped them • Scientific evidence and rationale behind each module and/or technique	Reflective motivation	Beliefs about consequences	Education; Persuasion	5.1. Information about health consequences 5.6. Information about emotional consequences 6.3. Information about others' approval 9.1. Credible sources
Practicing cognitive skills techniques	• Provide instructions on how to perform several cognitive skills techniques	Psychological capability	Skills	Training	4.1. Instruction on how to perform the behaviour
	• Provide guided audio exercises that can be used offline	Physical opportunity	Environmental context and resources	Environment restructuring	12.5. Adding objects to the environment
	• Information about the association between thoughts, emotions and behaviour and how negative thinking can lead to increased perceptions of tinnitus and emotional distress • User quotes on the role of negative thinking in tinnitus	Reflective motivation	Beliefs about consequences	Education; Persuasion	5.1. Information about health consequences 5.6. Information about emotional consequences 6.3. Information about others' approval 9.1. Credible sources

Target Behaviour	Intervention techniques targeting behaviour	Behaviour source (BCW)	Theoretical domain (TDF)	Intervention function (BCW)	Behaviour Change Techniques (BCTv1)
Practicing regular relaxation	• Relaxation diary to record levels of tinnitus distress before and after practicing • Encourage users to practice the relaxation exercises to experience the benefit for themselves • Provide information on how relaxation will help • User quotes saying how much the relaxation helped them • State and remind people that the aim of the relaxation is to reduce tinnitus distress • Reassure users that a temporary increase in perceived loudness is normal when practicing relaxation and will improve with practice	Reflective motivation	Beliefs about consequences	Education; Persuasion	2.4. Self-monitoring of outcome(s) of behaviour 5.1. Information about health consequences 5.6. Information about emotional consequences 6.3. Information about others' approval 8.1. Behavioural practice/rehearsal* 9.1. Credible sources
	• Provide instructions on how to perform the relaxation techniques • Provide advice on how to avoid falling asleep while practicing relaxation • Set daily goals to provide opportunities to practice and rehearse relaxation	Psychological capability	Skills	Training	4.1. Instruction on how to perform the behaviour* 8.1. Behavioural practice/rehearsal*

Target Behaviour	Intervention techniques targeting behaviour	Behaviour source (BCW)	Theoretical domain (TDF)	Intervention function (BCW)	Behaviour Change Techniques (BCTv1)
Practicing regular relaxation (cont.)	• Set daily goals and encourage people to do relaxation at same time each day. • Encouraging people to make time and plan when they will do their relaxation	Reflective motivation	Goals	Enablement	1.1. Goal setting (behaviour)* 1.4. Action planning* 8.1. Behavioural practice/rehearsal*
	• Provide advice on how to make your environment conducive to relaxation practice • Provide relaxation diary so users can log their daily relaxation practice • Suggest asking a friend or family member to remind them to practice • Suggest setting an alarm as a reminder to practice • Suggest putting a marker, post-it or sticky spot somewhere eye catching to remind them to practice	Physical opportunity	Environmental context and resources	Environment restructuring	2.3. Self-monitoring of behaviour 3.2. Social support (practical) 7.1. Prompts/cues 12.1. Restructuring the physical environment 12.5. Adding objects to the environment*
	• Encourage habit formation by suggesting people do relaxation at the same time each day	Automatic motivation	Reinforcement	Training	8.3. Habit formation

Key: *BCTs present in the Tinnitus E-Programme 1.0.

The 15 BCTs identified in Table 6.7 were mapped onto all three constructs of the COM-B model, five theoretical domains (beliefs about consequences, skills, environmental context and resources, goals, and reinforcement), and five intervention functions (education, persuasion, training, environmental restructuring, and enablement).

6.4.3. Logic model

The Tinnitus E-Programme 2.0 logic model is presented in Figure 6.3. It represents the hypothesised links between the intervention processes (e.g. engaging with the relaxation skills training module, user motivation to practice relaxation), proposed mediating variables (e.g. improving self-efficacy), and intervention outcomes (e.g. improved tinnitus-related quality of life, reduced emotional distress). Consistent with the intervention objective, the long-term outcome was 'tinnitus-related quality of life'. This outcome was made up of several factors of tinnitus-related quality of life that were identified from the user benefits reported in the mixed methods research; these were intrusiveness, physiological arousal, emotional distress, and sleep.

Proposed mediating variables, in the form of cognitive and behavioural mediators, were also identified. Two of the cognitive mediators ('modifying illness beliefs' and 'minimising the occurrence [of effect of] negative thinking') were identified from the literature review (Chapter 3). Two additional cognitive mediators ('facilitating acceptance' and 'improving self-efficacy/sense of control') were also taken from the reported benefits identified in the mixed methods research ('normalising and accepting tinnitus', 'gaining confidence in ability to manage, and cope with, tinnitus).

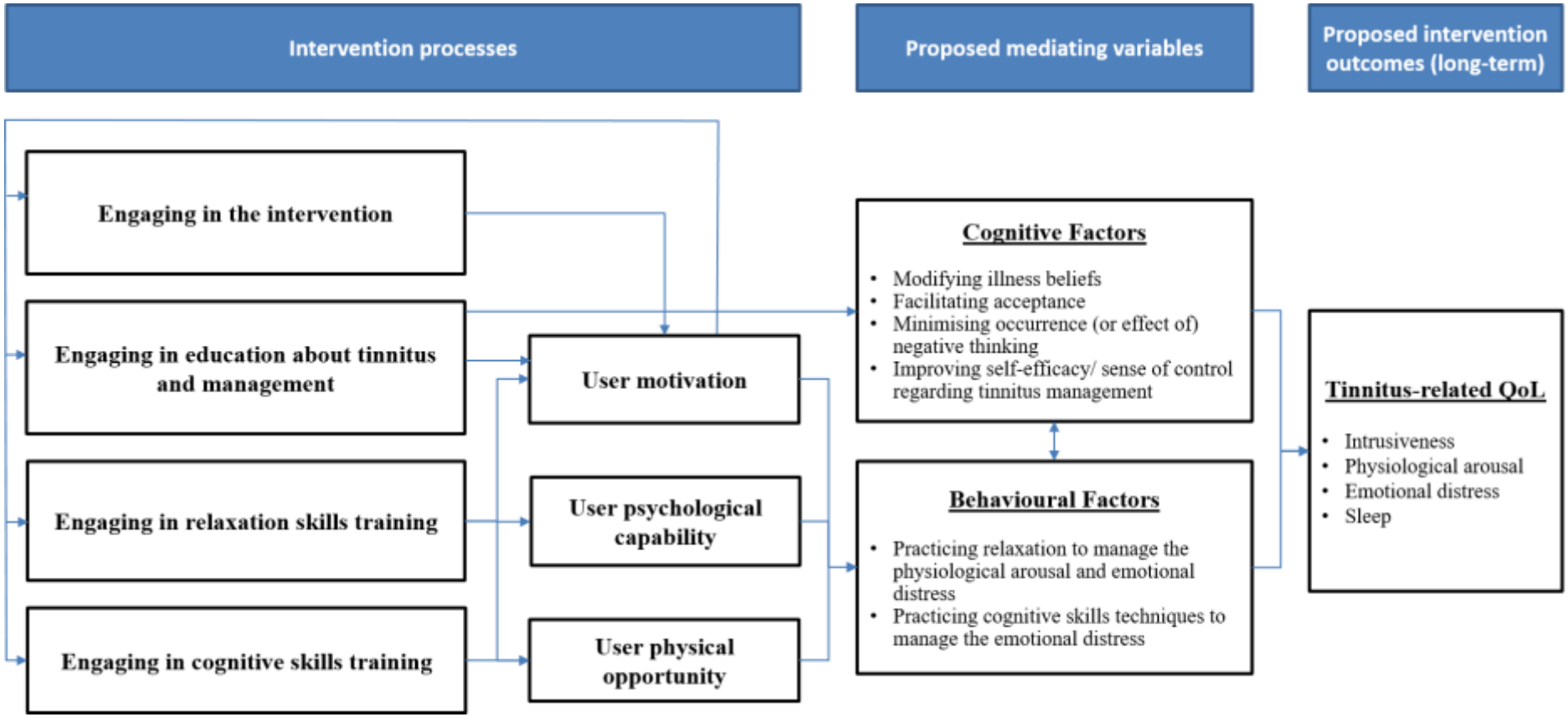

Figure 6.3 The Tinnitus E-Programme 2.0 logic model

6.4.4. Implications for future optimisation work

Referring back to the findings of the systematic review (Table 6.10), it can be seen that the Tinnitus E-Programme 2.0 incorporates two of the four self-management components that were most commonly used in the identified self-help interventions (education about tinnitus and its management and training/rehearsal for psychological strategies). Additional BCTs were introduced into the Tinnitus E-Programme 2.0 to improve users' motivation and opportunity to practice daily relaxation. Due to this explicit attempt to improve users' adherence to the relaxation goals, it was decided that the component 'practical support with adherence (medication or behavioural)' (a component that was used in one study included in the systematic review) was also present in the Tinnitus E-Programme 2.0. 'Information about available resources' was included in the Tinnitus E-Programme 1.0 but was not included in the Tinnitus E-Programme 2.0. This was because the work that would be needed to update the list of additional available resources was not possible within the time restraints. However, it is recommended that this component should be included in future iterations. Moreover, 'lifestyle advice and support' (i.e. provision of advice and support around health and lifestyle) was another commonly used self-management component that was not included in the Tinnitus E-Programme 2.0. This component should also be considered for inclusion in future iterations of the intervention.

Table 6.10 Presence of commonly used self-management components identified from the systematic review (Section 3.4.6)

PRISMS Self-Management Components Taxonomy	Number of studies (out of 5)	Presence in the Tinnitus E-Programme 2.0
Education about condition and management	5	✓
Training/rehearsal for psychological strategies	4	✓
Lifestyle advice and support	4	×
Information about available resources	3	×
Provision of/agreement on specific action plans and/or rescue medication	2	×
Monitoring of condition with feedback to the patient	1	×
Practical support with adherence (medication or behavioural)	1	✓
Provision of equipment	1	×

6.5. LIMITATIONS

First, compared to other published intervention development work (Band et al., 2017), the intervention planning and design process drew upon a limited evidence-base, including a brief literature review, a systematic review of five studies, and one primary research study. This is because there is limited available evidence from the wider research literature on the most effective intervention components and design features for internet-based interventions for tinnitus. However, Band et al. (2017) stated that a 'light-touch' and rapid evidence collection and theoretical modelling is still appropriate, as additional evidence could always be integrated into the intervention as it becomes available. The logic model in this research generated a set of hypothesised mechanisms of impact that can be tested in future evaluative work.

Second, not all of the self-management components, BCTs, and design features that were highlighted by the behavioural analysis were included in the Tinnitus E-Programme 2.0 to make best use of the time available. Intervention development is, however, an iterative process and this intervention content should be considered in future optimisation work.

Third, the behavioural analysis was carried out mainly by the author. Although the final analysis was reviewed and agreed by the research team, independent analysis may have produced more reliable results.

Finally, the behavioural analysis was limited by a lack of taxonomies for self-help or internet-based interventions. The BCTv1 and Morrison's (2012) framework provided a common language to describe the techniques and design features included in the Tinnitus E-Programme 2.0. However, as they were not designed specifically for use with self-help interventions, there were some techniques and design features that could not be mapped onto this taxonomy and framework. This methodological issue will be discussed in more detail in Section 8.3.

6.6. SUMMARY AND FUTURE DEVELOPMENT WORK

- Consistent with a person-based approach, mixed methods research was used to understand and accommodate the users' perspective on the intervention and to create a set of guiding principles that outlined the key design objectives and features of the Tinnitus E-Programme 2.0, and ensured a coherent focus.

- Evidence-based approaches integrated the findings from the literature review (Chapter 1 and 4) and systematic review (Chapter 3) to ensure that the intervention contained the key intervention components and techniques and addressed the key determinants of tinnitus distress.
- The literature review and mixed methods research also helped to identify potential short- and long-term outcomes of the intervention.
- Theory-based approaches (behavioural analysis and logic modelling) helped to systematically describe and identify the intervention processes and potential mediating variables to explain how the intervention works.

The intervention development process also identified some potentially fruitful directions for future optimisation work:

- Explore the possibility of replacing the THI that was included in the Tinnitus E-Programme 1.0 with a more user-friendly tool for measuring users' progress throughout the intervention and benefits gained.
- The Tinnitus E-Programme 2.0 provided information about other users in the form of user stories and testimonials, as an alternative to the online support forum included in the Tinnitus E-Programme 1.0. Users' reactions to this design feature are explored in more detail in Chapter 7.
- Several intervention design features should be considered for inclusion in future iterations of the Tinnitus E-Programme, including providing contact with the intervention (e.g. emails) or a therapist, tailoring the content of the intervention depending on individual need (e.g. the presence of negative thinking), and the provision of content-based entertainment activities to improve user engagement.

- The systematic review of self-help interventions for tinnitus (Section 3.4.6) identified two intervention components that were commonly used in these interventions - information about available resources and lifestyle advice and support. These components may be worth considering for future iterations of the Tinnitus E-Programme 2.0.

CHAPTER 7. EVALUATING THE TINNITUS E-PROGRAMME 2.0: A THINK ALOUD INTERVIEW STUDY

7.1. INTRODUCTION

In the previous Chapter, the development of the Tinnitus E-Programme 2.0, an optimised version of the Tinnitus E-Programme 1.0 was described. This development work was informed by a mixed methods evaluation of the Tinnitus E-Programme 1.0, the current evidence-base, and theoretical approaches to intervention development. The Tinnitus E-Programme 2.0 is yet to undergo any formal evaluation. As discussed in Section 2.1.3, the person-based approach proposes that intervention development is an iterative process (Yardley, Morrison, Bradbury, & Muller, 2015). It recommends that, with every new version of the intervention, all additional intervention features should be evaluated in detail and further optimised from the user perspective. This chapter will describe a think aloud study that aimed to evaluate the Tinnitus E-Programme 2.0.

The mixed methods study developed an understanding of users' acceptability of the three individual self-management components contained in both the Tinnitus E-Programme 1.0 and 2.0, that is education about tinnitus and its management, relaxation skills training, and cognitive skills training. It also explored users' experiences of using these self-management components in the real-world and identified barriers and facilitators that influenced users' engagement with these components. This think aloud study will complement the mixed methods study by exploring users' immediate reactions and interactions with the intervention, allowing the intervention content to be evaluated in detail. Such an understanding is helpful for ensuring that the

intervention is engaging, easy to use and the content is relatable and easy to understand. Another advantage of think aloud interviews is that users are observed using the intervention which makes it easier to identify navigational or clarity problems. Think aloud, rather than think after, interviews (Section 2.3.4) were chosen because it was the most time-efficient option for both participant and researcher, and would maximise participant recall of their immediate reactions and thought processes. As the Tinnitus E-Programme 2.0 included new content (e.g. cognitive therapy techniques) and has a different presentation than the original, it was important to further explore users' reactions to these new features. Therefore, it was decided that the think aloud protocol would enable a greater focus on understanding users' reactions and their behavioural barriers and facilitators than problem identification. Think aloud interviews have not been used previously to evaluate internet-based interventions for tinnitus, so this study will provide a unique insight into users' perspectives of these interventions.

So far, this PhD research has developed an understanding of the active ingredients of the Tinnitus E-Programme 2.0 and the mechanisms by which the intervention exerts its effect. However, there is still little understanding regarding the circumstances in which the intervention works best, and whom it works best for. Such an understanding of these contextual factors is important for identifying sub-populations of people with tinnitus who will benefit most from the intervention. To explore these contextual factors in more detail, semi-structured interviews were carried out after the think aloud interviews.

7.2. AIMS

This research aimed to evaluate the Tinnitus E-Programme 2.0 to develop an understanding of the intervention's mechanisms of impact and identify any implementation or contextual factors that may strengthen or impede its delivery. The objectives are to explore:

1. Users' reactions and interactions with the Tinnitus E-Programme 2.0
2. Users' views on the times when the Tinnitus E-Programme 2.0 will be most helpful

7.3. METHODS

This study is reported following the COREQ checklist (Tong, Sainsbury, & Craig, 2007), which was also used to report the qualitative research in the mixed methods study (see Section 5.3.3.3). This research has ethical approval from the University of Nottingham Research Ethics Committee (Reference Number: Q11122014 SoM NIHR RHA QEST).

7.3.1. Sampling and recruitment

Adults (aged 18 years and over) were chosen from the NIHR Nottingham Hearing BRU research database if they had self-reported tinnitus and resided in the UK. Participants self-selected, based on their judgement of whether they met the following criteria: (1) ability to read English; (2) ability to use a computer; and (3) have not previously used the Tinnitus E-Programme 1.0. To further explore any contextual

factors that may influence intervention delivery, participants were not excluded based on any tinnitus-related characteristics (e.g. tinnitus duration or severity).

Maximum variation sampling (Polkinghorne, 2005) was used to recruit participants covering a wide range of ages and tinnitus durations, and similar amount of males and females. Three rounds of email invitations, together with a participant information sheet, were sent to selected database members by a member of the research team. In the first round, a small number of people (n=48) were contacted, targeting mainly those at the older and younger ends of the age range. Everyone who volunteered at this stage was recruited (n=9). For the remaining two rounds, only volunteers with characteristics that filled specific demographic gaps in the current sample were invited and recruited. In the second round of emails (n=25), mainly females were targeted as most of the volunteers from the previous round of emails were male. Priority was given to females who were at the younger or older ends of the age range or had a different type of tinnitus from those participants already recruited (e.g. pulsatile tinnitus, tinnitus caused by an acoustic neuroma).

The final round of emails was sent to a larger amount of people (n=157), specifically requesting individuals who have experienced tinnitus for less than five years, as most of those recruited so far had tinnitus durations greater than 10 years. Volunteers from this final round of emails were chosen if they were distinctly different from those who had already taken part (e.g. younger, had objective tinnitus). Participants were recruited until data saturation (Patton, 1990) was met (i.e. no new themes were emerging) and each page of the intervention was viewed by at least three participants. Data saturation was met after 15 interviews, but there was still some intervention pages

that had not been viewed by at least three people. An additional four interviews were carried out until this criteria was met. On average, five participants viewed each of the intervention pages and 5-10 participants viewed each module. Participants were paid £10 for taking part and local travel expenses were paid up to the amount of £15.

7.3.2. Procedure

The author carried out the interviews between March and May 2016. More information on the credentials, occupation, and experience of the author is provided in Section 5.3.3. Generally, the interviewer did not know the participants, however, two of the participants were known to the researcher as they had previously been involved in the PPI activities for the mixed methods study (Section 5.3.2.5). These participants will not be identified for confidentiality reasons. Participants were aware that the interviewer had been involved in the development of the intervention and that the research was part of the interviewer's PhD. Participants were encouraged to provide honest and critical feedback so that the intervention could be optimised for future users.

Single session think aloud interviews were carried out at the NIHR Nottingham Hearing BRU. Participants were seated directly in front of the computer and the interviewer sat next to the participant. To minimise participant burden, participants were asked to complete only one or two modules. The interviewer introduced the task by explaining that participants should say whatever they are thinking as they went through the intervention pages. Non-judgemental prompts were used to clarify the meaning of users' statements, understand why users made certain navigational

decisions, and encourage the user to continue to comment when they were silent. Consistent with a person-based approach, the interviewer also asked a minimal amount of evaluative (e.g. 'what do you think of this page?') questions and explored users' views on the intervention aims and components (e.g. 'what are your thoughts on the intervention goals?') throughout the think aloud interview.

Following the think aloud interview, some semi-structured interview questions were asked about the intervention as a whole to further explore satisfaction and usability and explore the times when the intervention would be most and least helpful to people with tinnitus. The think aloud interview procedure was piloted with a member of research staff not involved in the project to test the computer setup and interview timings. The interview topic guide was not piloted but feedback on the topic guide was gained from the first participant. This participant did not suggest any changes. A copy of the interview topic guide can be found in Appendix 8.

Interviews lasted between 67-96 minutes, were audio recorded, and then transcribed verbatim by an external transcription company. The researcher occasionally made observational field notes throughout to capture any non-verbal information (e.g. buttons clicked on) that would be absent from the audio recording. To provide an aide memoir during data analysis, the author used her field notes and recollection of the interviews to note on the transcriptions what intervention page the participants were on. Sometimes participants read the intervention content aloud. This dialogue was italicised in the transcription. One participant (Ian) provided additional comments via email which were, with his permission, included in the analysis. The audio for one of the interviews (Edward) was not available due to a technical error. The interviewer

created a summary of the key points made by this participant and asked them to check the notes for accuracy. The participant agreed that the summary was an accurate representation of the interview and had no further comments to add. Transcriptions were not sent to participants to review as it was felt that this task would be difficult for participants to do purely based on their recall of the intervention.

Table 6.6 outlines the intervention content, including its intervention aims, self-management components, and individual techniques. To make best use of the time available, modifications to the intervention would only be made during interviews to resolve serious navigational issues that prevented all participants from using the intervention effectively, or to correct minor problems that could be resolved quickly (e.g. spelling or typographical errors). There was one incidence where a participant became upset when reading some of the intervention content. Following this interview, this intervention page was discussed with the research team and it was decided that, as no other participants had raised any issues with this content so far, the content would not be changed, and additional participants would be asked to review this content. No other participants reported feeling upset by this content. This issue is discussed in more detail in the results. Recommendations regarding improvements to the intervention and the need for additional think aloud interviews are made in Section 8.4.

7.3.3. Qualitative analysis

The transcripts were analysed using inductive thematic analysis (Braun & Clarke, 2006) and QSR's NVivo 10 (QSR International Pty Ltd., 2014) qualitative data analysis software. In a person-based approach think aloud protocol, there is not a clear

distinction between the think aloud data (i.e. discourse that arose in response to viewing the intervention content) and semi-structured interview data (i.e. discourse in response to direct questioning from the interviewer). This is because the person-based approach perceives engagement with the intervention and engagement with the wider behavioural goals of the intervention as closely linked (Yardley et al., 2016). Consistent with this, these two sets of qualitative data are analysed together, rather than separately (Anthierens et al., 2012; Essery et al., 2015; Morrison et al., 2009; Rowsell et al., 2015; Yardley et al., 2011, 2013; Yardley, Morrison, Bradbury, Muller, & Band, 2015) . This analytic approach will be adopted in this study.

This analysis was informed by guidelines for establishing validity in qualitative research (Krefting, 1991; Yardley, 2007), which recommends providing audit trails, comparing researchers' coding, using reflexivity, ensuring rigor, and actively looking for data that contradicts your initial assumptions. First, the author familiarised herself with the data through repeated reading of the transcripts. Second, the author generated initial codes from the data and developed a coding manual that listed all codes, including descriptions and example quotes from the text (Joffe & Yardley, 2004). Third, at least one other coder (MS, DH) independently applied the coding manual to approximately 50% sample of transcripts (ten transcripts) to clarify ambiguous codes, remove duplicate codes, and identify data that did not fit the coding scheme. Coding was compared and discussed between coders and subsequent modifications made to the coding manual.

Fourth, coders collectively organised these codes into overarching themes and the coding manual was updated accordingly. Each version of the coding manual and

NVivo analysis was saved to provide an audit trail, demonstrating how the findings emerged (Yardley, 2007). The constant comparison method (Glaser & Strauss, 1967), a grounded theory technique, was used to compare codes across different participants, contexts, and situations. Disconfirming case analysis (Yardley, 2007) was used to actively identify data that did not fit with the identified themes. These two techniques were used to ensure the analysis was carried out with rigor. Reflections from the interviewer regarding the interviews and data analysis were provided (Section 7.5) to consider how the role of the interviewer may have influenced the findings. Participant quotes were used in the final write-up to illustrate the themes and pseudonyms used to refer to these participants.

Writing up the results section of this chapter led to further re-organisation to the thematic structure. For example, the author identified that there were some common issues that cut across the initial themes and sub-themes, which led to some repetitive results. This content was subsequently combined and the four themes were reduced to three themes that addressed these crosscutting issues. Furthermore, there were some sub-themes that had a large amount of qualitative data coded under them. However, once written up, these sub-theme sections were relatively short and did not warrant their own section of the results. This led to some minor sub-themes being combined to create larger and more salient ones. For example, sub-themes ‘design of intervention pages’ and ‘information architecture’ were combined to create Sub-theme 2.5: ‘Design of intervention pages and information architecture’. The final interpretations in the results section were reviewed and agreed by four coders.

7.4. RESULTS

7.4.1. Participants

From the 45 people who volunteered to take part, 26 did not take part. Three participants agreed to do the research but later dropped out due to competing work commitments and personal and family illness. Twenty-three participants were not recruited as they were too similar to those in the current sample or contacted the author once the interviews had finished. The final sample included 19 people: 10 males and 9 females. The age range was 42-73 years (Mean = 58 years) and the tinnitus duration was 1-25 years (Mean = 9 years). Most participants had high levels of education and used computers and the Internet daily. Participant characteristics are detailed in Table 7.1.

7.4.2. Themes

Three themes were identified from the thematic analysis: (1) Reactions to the intervention content; (2) Reactions to the intervention delivery method and design features; and (3) Right people, right time. These themes and are detailed in Table 7.2.

7.4.2.1 Theme 1: Reactions to the intervention content

Reactions to the intervention content addressed users' views on the intervention content that aimed to help people to manage their tinnitus. Specifically, this content refers to the intervention aims, self-management components, and individual techniques (Table 6.6).

Table 7.1 Participant characteristics for the think aloud interview study

Pseudonym	Gender	Age	Ethnic Group	Tinnitus duration (years)	Management strategies used	Computer use	Internet use	Work status	Education Level	Additional information disclosed in interview
Graeme	Male	71	WB	22	HP;OL;BK;ST;MED	Daily	Daily	Retired	3	
Alan	Male	73	WB	6	HP;OL;BK;ST;CO;MED	Daily	Daily	Retired	4+	
Ron	Male	58	WB	25	HP;OL;OTH;ST	Daily	Daily	Employed FT	4+	
Richard	Male	49	WB	20	OL	Daily	Daily	Employed PT; Self-employed PT	3	
Janice	Female	61	WB	4	HP;OL;OTH; ST;REL;MED;SGO	Weekly	Daily	Retired	4+	Has cochlear hydrops[a]
Anne	Female	59	WB	3.5	HP;OL;REL;SGF	Daily	Daily	Retired	4+	
Ben	Male	47	WB	23	HP;OL;REL	Daily	Daily	Employed FT	4+	Hearing aid user
Helen	Female	47	WB	8	-	Daily	Daily	Employed FT	1	
Sally	Female	60	WB	4	HP;OL;OTH;ST;REL;SGF	Daily	Daily	Retired	2	
Avril	Female	63	WB	10	OTH;ST	Weekly	Weekly	Retired	4+	Hearing loss
Dorothy	Female	53	WB	2.5	OTH;ST	Daily	Daily	Self-Employed FT	4+	Has acoustic neuroma[b]
Lisa	Female	58	BB	1.5	HP;OL;ST	Occasionally	Daily	Unemployed due to illness	4+	
Ian	Male	53	WB	4	HP;OL;OTH; REL;SGF	Daily	Daily	Self-Employed FT	4+	
Edward	Male	70	WB	3	HP;OL	Daily	Daily	Retired	3	
Andrew	Male	61	WB	4	HP;OL	Daily	Daily	Employed FT	4+	
Brenda	Female	63	WB	3	OL;ST	Daily	Daily	Retired	1	Pulsatile tinnitus[c]
Brian	Male	59	WB	2	ST	Daily	Daily	Employed FT	4+	
Nick	Male	46	WB	1	HP;OL;ST; Other	Daily	Daily	Employed FT	4+	Hearing loss
Joanne	Female	42	WB	23	HP;BK;ST; MED	Daily	Daily	Employed FT	4+	Hearing loss; Hearing aid user

Key: WB = White British; BB = Black British; HP = Seeking out information from a health professional; OL = Seeking out information online; BK = Seeking out information from books; OTH = Seeking out information from other people with tinnitus; ST = Sound therapy (e.g. hearing aids, sound therapy system, combination devices, noise generators); REL = Relaxation; CO = Counselling or other psychological therapy; MED = Medication (e.g. sleeping tablets, antidepressants); SGF = Participating in face-to-face tinnitus support groups; SGO = Participating in online tinnitus support groups; FT = Full-time; PT = Part-time; Education level 1 = 1-4 O-Levels, GCSE's grade D-G, Foundation Diploma, Foundation Learning or equivalent; 2 = GCSE's grades A*-C, Higher Diploma, BTEC First Diploma or equivalent.; 3 = A & AS Level, Advanced/Progressive Diploma, Advanced Apprenticeship, BTEC National Diploma or equivalent.; 4+ = BTEC level 4, HNC, Certificate of Higher Education, Professional qualification, Foundation Degree, NVQ Level 4-5, Honours Degree (BA, BSc), Higher Degree (MA, PhD, PGCE) or equivalent.

Notes: [a]Cochlear hydrops is a condition that accompanies tinnitus and affects the balance system in the ear; [b]An acoustic neuroma is a non-cancerous tumour on one of the nerves connecting the inner ear to the brain and causes tinnitus; [c]Pulsatile tinnitus is a rhythmic tinnitus noise. A medical cause is more likely with this form of tinnitus.

Table 7.2 Descriptions of three themes

Themes	Description
Theme 1: Reactions to the intervention content	Describes users' reactions to the intervention content that was targeting at helping users to manage their tinnitus. Users discussed how much the intervention self-management components and individual techniques appealed to them and how satisfied they were with this content; their beliefs regarding whether the intervention aims and its associated self-management components would lead to a personal benefit; and the extent to which users related to, or agreed with the educational content and advice.
Theme 2: Reactions to the intervention delivery method and design features	Describes users' reactions to the way that the above intervention content is *delivered*. This includes the delivery method (i.e. a self-guided internet-based intervention) and specific design features (e.g. usability, design of intervention pages, clarity of written content).
Theme 3: Right people, right time	Describes users' views on the characteristics of the users who will benefit most from the intervention (right people) and the most appropriate times to deliver the intervention to people with tinnitus (right time). When defining the right people for the intervention, users also discussed how relevant the intervention, its aims, and its self-management components are to them.

This theme comprised three sub-themes. The *'appeal of the content'* sub-theme incorporates users' views on how much the intervention content, specifically the self-management components and individual techniques, appealed to them. The *'expectations of benefit'* sub-theme describes users' beliefs regarding whether the

intervention aims and its associated self-management components would lead to a personal benefit. The *'relating to the educational content and advice'* sub-theme addressed the extent to which users related to, or agreed with the educational content and advice.

Sub-theme 1.1: Appeal of the content

This sub-theme discusses users' views on how much the self-management components (i.e. education about tinnitus and its management; relaxation skills training; and cognitive therapy) and techniques contained within these components, appealed to them. Generally, users expressed positive views about the intervention content. Specifically, the educational component was highly appealing to users, who had a strong desire for information: *"knowledge is key, information is key"* (Lisa, tinnitus for 1.5 years). On the other hand, users' views about relaxation and cognitive therapy components were more mixed. Some users expressed positive views about these components and their associated techniques:

> *I think even just looking at that [the thought record] and making you think about it is very positive because it does make you think. A lot of things happen where my tinnitus isn't involved or I do a lot of nice things or have a lot of nice thoughts and it is not all negative* (Avril, tinnitus for 10 years)

> *Relaxation is top of my agenda . . . I think it's a real way to go forward with tinnitus* (Sally, tinnitus for 4 years)

In contrast, other users held more negative views about these components. Some users associated practicing formal relaxation techniques and the cognitive defusion technique with other calming complementary therapy activities that did not appeal to them, such as pilates, massage, and meditation. Users acknowledged the value of relaxation, but preferred more traditional ways of relaxing, such as having a bath or watching TV:

> *I'm a standard bloke, you know, I watch sport on television and that relaxes me. Erm, but I know there are other people who . . . find, erm, meditation relaxing. Erm, I personally don't.* (Richard, tinnitus for 20 years)

> *I've not really been one for relaxation . . . it's just not me . . . I don't go in for massages or anything like that . . . but that's just how I am . . . you see I quite like my bath that relaxes me and- sit and read a book or watch the telly, switch off* (Helen, tinnitus for 8 years)

> *I'm not a big fan of sort of, new age, crystal therapy, and stuff like that, you know . . . I'm more a, I'm more of a practical, this heals this, type person, rather than "Sit and think about your breathing", all that, you know. It probably works, I'm just saying, initially, to me, I just start to think, "What a load of cock"* (Brian, tinnitus for 2 years)

It can be argued that such negative views represented a pre-existing lack of openness to these type of techniques (e.g. "that's just how I am"), rather than a dissatisfaction with the specific techniques included in the intervention. Other factors influenced the

appeal of the individual cognitive therapy techniques for users, including how well the techniques fit with their personality (e.g. optimistic) or current way of thinking (e.g. positive thinker), and the familiarity or novelty of the technique:

> *[The technique that] would appeal to me it is my somewhere between letting my thoughts go [cognitive defusion] and positive thinking [gratitude diaries]. We already know I am positive thinking, so I will go to letting my thoughts go and see what that says . . . letting my thoughts go is better than challenging negative thoughts because I don't have a lot of negative thoughts* (Avril, tinnitus for 10 years)

> *Well I think, erm, it [the monitoring your thoughts technique] can be quite helpful . . . I've started to engage with that, having done the mindfulness course* (Ron, tinnitus for 25 years)

One user disliked the 'challenging your unhelpful beliefs' technique, as it did not directly address her tinnitus. She was confused by the explanation of unhelpful beliefs, which related them to 'superstitions' and questioned whether 'beliefs' could be changed:

> *Superstitions . . . are nothing to do with tinnitus, 'cause I didn't know there was any superstitions or anything . . . but that's irrelevant to me, totally. Can't see the reason for that* (Brenda, pulsatile tinnitus for 3 years)

What beliefs? I mean, do I believe in God? Yeah. Has God got anything to do with tinnitus? No. Erm... Do I believe if the black cat crosses your path? No. (Brenda, pulsatile tinnitus for 3 years)

But I don't see why it's [the concept of 'long-standing beliefs'] so relevant, because you can't change who you are (Brenda, pulsatile tinnitus for 3 years)

Across all of the self-management components, users specifically liked content that normalised tinnitus (e.g. knowing there are others with tinnitus), made them feel less isolated (e.g. user quotes), and portrayed a positive image of tinnitus self-management (i.e. there are things that you can do that will help you to manage your tinnitus). In particular, the user quotes and stories served this purpose:

Well, certainly, erm, I've always found people's own journeys through tinnitus very helpful and inspiring, sort of on two levels. One is to know that you're not alone. And the second is to- just sometimes they've got helpful tips, that you can think, "Oh yeah, that happened to me" or, "Oh, yeah, I might try that" you know. So, erm, so it, that, that's [user quotes] nice (Anne, tinnitus for 3.5 years)

[The user quotes] can be quite erm, helpful maybe er, in knowing that there are other people out there thinking er, kind of er, about ways of, of coping with this condition and having the condition themselves, you know, erm, you're not on your own (Ron, tinnitus for 25 years)

Ben explained the key message he took away from the introduction to tinnitus module:

> *That there are, that there are actual sort of- there are things you can do. Erm, it's not just sort of, er, you know, "You've got tinnitus, live with it" . . . There are things you can maybe, changes you can make in your life, and things you can do to help you live with it* (Ben, tinnitus for 23 years)

In contrast, users disliked content that reminded them how bad their tinnitus was or disrupted their positive mind-set. Two users explained why they did not want to look at the 'unhelpful thoughts' intervention content:

> *I would rather not be reminded of what isn't good and I would rather go straight for the things that are helpful so I can deal with it. Unhelpful thoughts are negative* (Avril, tinnitus for 10 years)

> *If I'm engaged in something like this I want it, I want to think and head positively. Erm, and I know the negative situations, I've lived with them and I do live with them, you know, with regards to tinnitus* (Ron, tinnitus for 25 years)

One user, Janice, particularly struggled with some aspects of the intervention content. Although she felt comforted by the fact that there are lots of people with tinnitus, this fact also highlighted how she may not coping as well as others: *"I look . . . and I think, 'Well, all these people have tinnitus but they're just getting on with life, and you're the only one who's, sort of, erm, freaking out about it.'"* (Janice, tinnitus for 4 years). Furthermore, Janice later became upset when reading through the content on 'who is

affected by tinnitus', which stated: 'Interestingly, most people with tinnitus do not find that it bothers them. However, for some people, tinnitus can be distressing and greatly affect their everyday lives'. She explained that this was because this content highlighted how much tinnitus did affect her life: *"I don't want to be reminded that I'm in despair"*. Five other users viewed this intervention page, but no-one else had a similar negative reaction to this page. However, it may be that these users were considerably less distressed by their tinnitus. Janice explains that it may not be helpful for those who have severe tinnitus:

> *I did wonder whether, because there is quite a lot, a psychological aspect to tinnitus, whether actually being confronted with a, a programme like this would be helpful and actually, you know, I have kind of found this screen a bit of a, an upsetting screen . . . I've got quite bad tinnitus and, er, maybe that [screen] wouldn't be so helpful.*

When discussing the appeal of the current intervention content, users also made suggestions for additional content that would be appealing to them. Specifically, information about the latest medical research (e.g. drug treatments for tinnitus), additional helpful hints on managing tinnitus, case studies of people who have had a positive experience of tinnitus (e.g. they have changed their lives for the better or found effective ways of managing their tinnitus), and other useful sources of support (e.g. websites, meditation classes). Two users also explained how they recently took part in, and read the findings of, a survey of people with tinnitus and how they found this information helpful for normalising tinnitus: *"It can be very easy to think that you're the only person in the world with this thing. And it's quite good to know that there are lots of other people. And theirs [tinnitus] is similar to yours."* (Janice, tinnitus for 4

years). Ian suggested how such a survey could be used to categorise people's tinnitus symptoms better and then provide recommendations regarding the most appropriate techniques for each individual.

Sub-theme 1.2: Expectations of benefit

This sub-theme addresses users' beliefs regarding whether the intervention aims and its associated self-management components would lead to a benefit. Users' views on the intervention design features that aimed to facilitate users' perceptions of credibility are detailed in Sub-theme 2.2.

Generally, users expressed positive views about the intervention aims and commented that they were the kind of aims they would have expected from such an intervention, considering that there is not a cure for tinnitus. However, other users questioned whether the aims would be personally beneficial. Alan explained how he did not have high expectations of the intervention because he had not found anything helpful so far:

> *I feel sceptical because nobody so far has come up with anything that helps me . . . and I feel that people have rejected me . . . only, er, two months ago . . . [I] was told "Go away and learn to live with it"* (Alan, tinnitus for 6 years)

Dorothy explained that the intervention aims were of little value to her unless they were changing her tinnitus in some way: *"Because my tinnitus is there anyway, so it doesn't matter what I think about it I can't change it"* (Dorothy, tinnitus for 2.5 years, acoustic neuroma).

In fact, a few users questioned whether tinnitus should be 'managed' at all or just 'ignored'. These users were concerned that the act of focusing on their tinnitus, specifically through reading about tinnitus, would be counter-intuitive. Janice (tinnitus for 4 years) discussed these concerns, but explained how she found that ignoring her tinnitus was not that easy to do when it was bad:

> Janice: Yes. Some people say that you shouldn't really focus on your tinnitus much and actually doing this [the intervention] may be a bad thing . . . By kind of managing it. The best thing maybe is to forget about it and keep busy.
>
> Interviewer: Mhm. And how do you feel about that advice?
>
> Janice: Well I, I mean well at the moment it's, it's [tinnitus] quite bad and I seem to be, I can't help myself. I want to find out everything that I can find out about it.

Users also shared their expectations of the benefits they may gain from the individual self-management components, specifically, the education about tinnitus and cognitive skills training. Generally, users believed that education about tinnitus was beneficial. By understanding tinnitus, they were better able to deal with, and take control of, their tinnitus; normalise, or making sense of, their tinnitus; and overcome any fear or panic when the tinnitus appears:

> *Well, for me, understanding the science and what's happening to generate the noise, that to me is empowering, because if- I just, I like to understand things*

and I like to know what's happening and then I feel I've somehow got more control of it (Joanne, tinnitus for 23 years)

I think that knowing about it [tinnitus] is helpful . . . Because when it [tinnitus] comes you're not, you don't go into panic mode. I mean I think, "Oh yes, hello again that sound" and all I need to do is lie in this position or lie in that position or walk round the garden and then it'll change (Janice, tinnitus for 4 years)

However, there was one user who questioned whether understanding tinnitus helped him to manage his tinnitus. Although information was helpful to him, Alan (tinnitus for 6 years) explained how his desire for information was more for his own interest and to reassure him that tinnitus is not a life-threatening condition: *"I like to understand things better; but I don't think it will help me to manage it and take control . . . If there's no cure, I don't see why just understanding it helps"*.

Some users were sceptical about aspects of the cognitive skills training. Specifically, users questioned the value of techniques that encouraged people to become more aware of, or deal with, their negative thoughts, with some believing this to be counter-intuitive. Users were concerned that these techniques might make them dwell on their negative thoughts or become more aware of their tinnitus, which is what they tried to avoid:

My worry would be that if you're a person who typically thinks negatively, you'd be writing all these things down and you'd be left in a bit of a low mood,

> *or feeling low, because you've written negative things down . . . and there's nobody there to challenge those negative thoughts . . . and, in a way, it emphasises them . . . they weren't just in your head, they're now on paper, and they're real, and they're looking back at you, and they're negative* (Anne, tinnitus for 3.5 years)

> *I don't know that it [the 'thought record' technique] would [be helpful], because I think it would make me, erm, become more aware of it [tinnitus], and, the, the less I think about it [tinnitus], the less I'm made conscious of it [tinnitus], then the, the better off I am* (Graeme, tinnitus for 22 years)

Some users were confused as to the purpose of the 'monitoring thoughts' and 'thought record' techniques, which were aimed at increasing users' awareness of their thoughts: *"I think I might start something like that [the monitoring thoughts technique] and then start feeling daft . . . What's the purpose of this? Where's the good that's gonna come out of this?"* (Ian, tinnitus for 4 years).

Sub-theme 1.3: Relating to the educational content and advice

This sub-theme addressed the extent to which users related to, or agreed with the educational content and advice. Although this sub-theme is, to some extent, addressing the relevance of this content, it was decided that it was distinctly separate from the *right people* sub-theme in Theme 3. This is because it focuses on how users reacted to the actual educational content, rather than how relevant the educational self-

management component is for them. Discussions regarding the relevance of this educational content for users, in terms of their need to develop a better understanding of tinnitus, are detailed in sub-theme 3.1. This sub-theme was included under theme 1 because it is referred to *what* content is delivered, not *how* this content is delivered. Users views on the clarity of this explanation, language used and level of detail provided is discussed in sub-theme 2.4.

Generally, users related to, or agreed with, the educational content and advice provided in the intervention: *"I liked the explanations . . . I think it's good"* (Ben, tinnitus for 23 years). Users related to the description of tinnitus, including the typical sounds associated with tinnitus (e.g. buzzing, ringing), the possible locations of the sound (i.e. one ear, both ears), and the nature of the tinnitus (i.e. constant or intermittent). The majority of users were able to identify with at least one of the possible risk factors of tinnitus (e.g. loud noise exposure) or related to the statement that it may not be possible to identify what triggered the tinnitus. Dorothy, whose tinnitus was caused by an acoustic neuroma, highlighted that the cause of her tinnitus was not in the list of risk factors or causes. Users also tended to agree with the advice that was provided in the relaxation therapy module.

In contrast, there were some sections of intervention content that some users did not fully relate to, or agree with, including: (1) the explanation of signal filter theory of tinnitus; and (2) the explanation of the somatosensory amplification theory of tinnitus. These two sections of intervention content, as well as other examples of problematic intervention content, will be discussed in turn.

The explanation of the signal filter theory

The intervention provides an explanation of how tinnitus is created and maintained in the brain. This explanation was based on the signal filter theory (van Ravenzwaaij et al., 2010), which suggests that, in healthy people, the brain successfully blocks any 'sensory noise' (i.e. tinnitus signals). This theory argues that people with tinnitus have 'faulty filtering' that allows this noise to pass through (i.e. tinnitus is experienced). Most of the eight users who viewed the mechanisms of tinnitus were satisfied with this explanation, however, two users commented how it was different to what they believed or had been told previously by an audiologist. These users believed that their tinnitus was caused by damage to their hearing system. Dorothy (acoustic neuroma, tinnitus for 23 years) offered the explanation that was provided by her audiologist, which can be identified as the homeostatic plasticity model of tinnitus (Schaette & Kempter, 2006; 2012; Noreña, 2011; Section 1.3.1). She also struggled with the conceptualisation of tinnitus as a collection of 'random signals'. This was because, to her, her tinnitus was not 'random', it was caused by her acoustic neuroma.

The explanation of the somatosensory amplification theory

The educational modules also provided an explanation of the tinnitus cycle and autonomic response to explain how tinnitus can become bothersome. This explanation is based on the somatosensory amplification theory of tinnitus. This theory suggests that when patients experience a physical sensation (i.e. tinnitus), they perceive it as a threat, and subsequently focus their attention on it (van Ravenzwaaij et al., 2010). This can lead them to attribute certain beliefs or thoughts to this sensation, which can subsequently lead to an amplification of people's perception of the physical signals,

thus setting up a vicious (or 'tinnitus') cycle. This explanation also included a description of the 'autonomic response' to explain how our bodies physiologically react to potential threats in our environment. Views on the relevance of this explanation of tinnitus were mixed among the eight users who viewed the mechanisms of tinnitus module. Most users were satisfied with this explanation and could relate to aspects of the tinnitus cycle. For example, they had personally experienced an amplification of their tinnitus in response to stress or when they focused on their tinnitus:

> *I relate to that very much (Laughter) because . . . the more stress you get, the louder it gets, the more stressed you become . . . It's difficult to, er, get yourself out of that cycle sometimes* (Ben, tinnitus for 23 years)

> *It does make sense that . . . about six weeks [after first experiencing tinnitus] I was in that perpetual cycle there all the time, even at work, even at home, it never got any easier* (Nick, tinnitus for 1 year)

In contrast, other users did not relate to aspects of this explanation. Some users did not perceive a link between their tinnitus and feelings of stress or emotions. That is, they were not aware that their tinnitus became worse when they were stressed or they did not perceive their tinnitus as a threat:

> *I don't understand why it would want to attach an emotional label to a high-pitched whine. I don't feel the slightest bit emotionally connected to mine [Laughter]. Some, emotions never come into it* (Brian, tinnitus for 2 years)

> *I just think of it [tinnitus] as annoyance . . . And I wish it'd stop. Yes, so I don't see it as a threat, but I see it as a very substantial discomfort that is ruining my life* (Alan, tinnitus for 6 years)

Although Alan did not perceive his tinnitus as a threat, the above quote demonstrates that he still perceived his tinnitus negatively. Therefore, it may be that it is the extreme language, rather than meaning behind the world 'threat', that prevented him from relating to the explanation of the tinnitus cycle. Two users disagreed that the tinnitus cycle was never-ending and that tinnitus becomes louder over time:

> *The implication there though is that it [tinnitus] carries on getting worse and worse . . . It doesn't, it is a plateau. You don't carry on getting more and more stressed is what I am saying . . . It was there and it just stayed loud, it didn't get any louder* (Dorothy, acoustic neuroma, tinnitus for 2.5 years)

Other problematic sections of intervention content

There were other sections of the intervention content that some users did not relate to or agree with. About half of the users who viewed the introduction to tinnitus commented that they could not relate to the statement that 'most people find that their tinnitus gradually gets better with time'. This is because their tinnitus had either got worse or stayed the same since they first experienced it. A few users found some of the examples that were used to describe physiological and psychological processes difficult to relate to. For example, two examples were used in the cognitive skills training module to explain how your thoughts and feelings can influence your behaviour. The analogy of being chased by a dangerous animal was used to explain

how our thoughts (e.g. 'this animal could kill me') help us to make the correct response (i.e. run away from the animal). Some users found this example too abstract. Additionally, gardening was used as an example of a quiet environment that could lead people to experience negative thoughts about their tinnitus. However, some people commented how the garden was not always a silent environment (e.g. hearing birds) and did not make their tinnitus worse. In fact, for some users, gardening was an enjoyable hobby that provided a distraction from their tinnitus. Moreover, not all users were able to relate to the negative thoughts, such as 'I can't cope'. This was generally because these users did not have negative thoughts about tinnitus in general, rather than the example being particularly bad example of a negative thought. Several users did not like the example situation of getting lost when walking in the woods that was used to explain the autonomic response. Users found it complicated, too abstract, and that it provided irrelevant detail. Brian suggested using a different example or removing it completely.

7.4.2.2 Theme 2: Reactions to the intervention delivery method and design features

Theme 2 describes users' reactions to the way that this content is *delivered* within the intervention. This specifically includes users reactions to the delivery method (i.e. the internet as a delivery medium and the self-guided nature of the intervention) and several design features: (1) Content that facilitates users' perceptions of credibility (e.g. scientific evidence behind each module); (2) Intervention exposure – the length of time the overall intervention and each module should take to complete; (3) Clarity, language, and level of detail; (4) Design of the intervention pages (e.g. layout) and

information architecture (i.e. the way the content is organised and structured); and (5) Usability.

Sub-theme 2.1: Delivery method

During the think aloud interview, some users highlighted potential advantages and disadvantages of the intervention's delivery method. Specifically, users shared their views on the internet as a delivery medium and the self-guided nature of the intervention. Generally, users were positive about the internet: *"there's quite a lot of good stuff out there"* (Alan). Some users commented how internet-based interventions may provide a viable alternative to support groups for those who may dislike, do not have the time to attend, or do not have access to, support groups. They hoped that the intervention could provide people with tinnitus this missing help and support:

> *It is a good thought 'cause . . . at least you're trying to set up a programme to help people with tinnitus because it is a lonely thing when you have tinnitus. It's just like nobody's really understanding [what it's like]* (Lisa, tinnitus for 1.5 years)

> *I do think it's nice to have- this is a good tool, and especially if you've called it tinnitus. So people with tinnitus might think it's been developed especially for them, so you've developed, they think "Oh this is going to be good for me" . . . Because people with tinnitus want to know there's something out there for them. They feel a bit isolated because there's not a lot out there* (Sally, tinnitus for 4 years)

In contrast, a few people expressed concerns about the internet as a delivery medium, mainly that the internet may not be accessible to those living in rural areas and older people, and that not everyone would be willing to spend lots of time on the computer. A minority of users also highlighted concerns about the self-guided nature of the intervention, specifically, the lack of contact with health professionals. Joanne explained how she disliked the trend in healthcare towards technology and was concerned that the internet was trying to replace the face-to-face services provided by health professionals. In the below extract, Joanne shares her initial thoughts on the intervention:

> *[I was thinking] that, erm, perhaps this has been developed online to cut costs of running programmes . . . I think it's a shame . . . I think you can't beat having someone to interact with and talk to and ask questions . . . it all seems to be going electronic and I'm not personally sold on it. I think it's a cost-cutting exercise* (Joanne, tinnitus for 23 years)

Some users commented how they would prefer to attend a support group, instead of starting an internet-based intervention. They stressed the importance of being able to talk to someone, especially people with tinnitus that are more likely to understand what you are going through:

> *I think you need to start a [support] group . . . Not a programme [internet-based intervention], because I think people need to talk about it . . . Not just listen to a programme. I think you need to get a group together . . . I'd love to talk to somebody else, with the same [condition] as me. But not online, in person. I'd love to do that . . . Because I think the more you talk about things,*

the less of a load you've got to carry yourself (Brenda, pulsatile tinnitus for 3 years)

When discussing the relaxation diary, Sally suggested that users could show their completed diaries to a health professional at tinnitus clinics or discussing it with other people with tinnitus as part of a group. She explained that this would be helpful because knowing that someone is going to review it *"would make you do it"*. Ian suggested that the intervention should not be a stand-alone resource and should be embedded within a broader support framework, such as an established tinnitus charity or university website.

Sub-theme 2.2: Content that facilitates perceptions of credibility

This sub-theme describes users' views on the specific intervention features that aimed to facilitate users' perceptions of credibility. These features include: (1) the 'scientific evidence' sections, which provided a lay-person summary of the evidence supporting the role of understanding tinnitus, negative thinking, and stress in tinnitus management; (2) the 'meet the team' section, which provides the credentials and expertise of the development team; (3) the 'user stories', which are testimonials from previous users; (4) the 'user quotes', which provide quotes from other users highlighting the role of negative thinking and how much relaxation can help; (5) the 'relaxation diary' that allows users to measure the immediate benefit they gained from practicing relaxation.

Generally, users held positive views about the four design features. They believed that they added credibility to the intervention by improving users' confidence in the intervention and its individual techniques and facilitating an understanding of why the techniques are important:

> *[The scientific evidence] adds comp- a feeling of competence to the programme* (Alan, tinnitus for 6 years)

> *[The user quotes] makes you think about why you're doing it as well as just doing it, doesn't it? . . . No point just doing it if you're not understanding why you're doing it* (Helen, tinnitus for 8 years)

> *All of the perceptions [from the user stories] seem to be positive so . . . It puts you in a positive frame of mind before you do it* (Nick, tinnitus for 1 year)

> *Well it [the relaxation diary] would prove to yourself, wouldn't it, that relaxing and doing this technique actually makes it better, makes it more tolerable* (Sally, tinnitus for 4 years)

For Brian (tinnitus for 2 years), the user stories held more authority over a recommendation from a health professional: *"It's alright a professional telling you something, but if you've got a normal person saying they've had exactly the same thing as you, they've done what this says, and it's worked"*. Users who used the 'meet the team' section liked that the developers had a wide range of backgrounds and

experience and that they have all got an interest in tinnitus. In contrast, Brian did not find this section useful and felt it was important that this content was optional: *"I'm not interested in all those six people, to be perfectly honest . . . Because it's not going to actually make any difference, knowing them, to what's going to come next on the thing"* (Brian, tinnitus for 2 years). A few users commented how they appreciated the "*thinking*" and research that had gone into the intervention: *"I get some confidence with this scheme [intervention], because it looks well set up and obviously the exercises have been thought through there. Somebody, you know, professional has put a lot of time into it and I'm thinking, 'Yeah, you know, it's worth a go trying it'"* (Andrew, tinnitus for 4 years).

Users suggested improvements to these design features that would further facilitate perceptions of credibility. When assessing the authenticity of the user quotes and stories, many users wanted more detail on who the users were. Specifically, it was important that the user quotes and stories came from real users: *"It's whether you believe they're genuine accounts or whether the author of the programme's just written them to sell their programme"* (Joanne, tinnitus for 23 years). Some people, wanted to know more about the characteristics (e.g. tinnitus duration, age) of the users behind the testimonials and quotes so they can identify with these users: *"If I recognise myself in there somewhere I'll say, 'Ah, it's helped a person sort of quite like me'"* (Andrew, tinnitus for 4 years). Other suggested improvements included adding in information about how many previous users found the intervention to be beneficial and more information on the credentials of the authors of the scientific studies. Nick (tinnitus for 1 year) also highlighted the importance of managing expectations of

benefit, explaining how, if the intervention does not work, people with tinnitus may feel deflated and even worse than they did when they started.

Sub-theme 2.3: Intervention exposure

This sub-theme details users' views regarding the length of time the overall intervention and each module should take to complete. Generally, users felt that the seven-week time-commitment was manageable. However, several users commented that they would like further detail about the precise weekly time commitment that would be involved: "*If it's ten minutes a day for three weeks, not a problem. If it's two hours a day for three weeks, I would say, probably I wouldn't do it.*" (Andrew, tinnitus for 4 years).

Generally, users found the relaxation goals in the 'relaxation challenge' achievable. Several users commented that users' views on the intervention's duration could be influenced by their expectations of tinnitus management. Users commented that those who are desperate to find something that will help or for those who are still searching for a cure may perceived the seven week duration as too long:

> *People with tinnitus have a real urgency to find something that will help them to improve the quality of their life. And seven weeks feels too long to wait for some improvement* (Anne, tinnitus for 3.5 years)

> *I suppose for the more anxious of us, I sort of think "Well, why have I gotta go at that pace?" . . . it's just, Christ, I mean, it's gonna be sort of seven weeks before I feel any better* (Ian, tinnitus for 4 years)

Some users were concerned that it might be difficult to fit the intervention in during the working week. However, these users felt that the time commitment would be manageable because the weekly content was broken down in stages and could be completed flexibly at times that suit, rather than seven consecutive weeks: "*Having some[thing] that's flexible takes off the pressure and creates less stress so you can work it around yourself*" (Nick, tinnitus for 1 year). Other users commented that they would be willing to commit the time, if they were confident that it would benefit them. Two users wanted to know what happens after the seven weeks of the intervention or two-week relaxation challenge have been completed: *"For people less able to deal with their, er, situation, of tinnitus, then, erm, you know, they might start panicking, 'What happens after seven weeks?'"* (Richard, tinnitus for 20 years).

Sub-theme 2.4: Clarity, language and level of detail

This sub-theme details users' view on the clarity of the information and instructions provided, language used, and level of detail provided within the educational content. Overall, users found the intervention content and instructions for the various self-management techniques to be clear, concise, and easy to understand: *"It's clear, it's, it's in layman's terms, which is, erm, always helpful"* (Graeme, tinnitus for 22 years).

There were a few sections of content that some users found unclear or confusing. Generally, such issues were mentioned by only one user, however, there were a few issues that were identified by more than one user. For example, the terms 'autonomic response', 'managing your unhelpful thoughts', and 'mechanisms of tinnitus' were difficult for some. Two people found the term 'relaxation exercise' confusing, as they associated exercise with physical activity, not relaxation. Some users experienced difficulties with the instructions for the relaxation techniques. For example, some users were unable to follow certain steps of the relaxation (e.g. clenching your knee and tensing your lower arm); wanted more detail about the ideal times (e.g. morning, afternoon, when tinnitus is bad) and place (e.g. at home) to practice relaxation; found the instructions for the muscle relaxation long and complicated; and were unclear how to use the tension rating in the relaxation diary, and what to do with the relaxation diary once completed. Some users preferred that all of the intervention content was tinnitus-specific. For example, the cognitive skills training module included examples of negative thoughts that were both tinnitus-specific (e.g. 'I'll never be able to forget my tinnitus') and general (e.g. 'I am not good enough'). This inconsistency was confusing to some who tried to relate the general negative thoughts to their experience of tinnitus.

Regarding the level of detail provided for the educational content, some users wanted more detail on the physiological mechanisms and scientific evidence behind the intervention content (e.g. causes of tinnitus, scientific evidence). For example, they wanted to know more about the parts of the brain that are involved, where the electric signals causing tinnitus come from, and what causes the filter that blocks these signals to fail in people with tinnitus. Some would have liked to read the original journal

articles behind the claims made in the intervention (e.g. risk factors, role of stress in tinnitus). Several of these users, some of whom had academic backgrounds, recognised that not all users would have the same desires for this additional information, and suggested that this content could be optional. They acknowledged that this information was more for their own interest and was not necessarily essential to the intervention. Dorothy (acoustic neuroma, tinnitus for 2.5 years) felt that the explanations provided in the programme were basic and suggested that the level of detail was more appropriate to those who have just been diagnosed.

Sub-theme 2.5: Design of intervention pages and information architecture

This sub-theme describes users' reactions to the design of the intervention pages (e.g. layout) and the intervention's information architecture, that is, how the content is organised and structured. When discussing the design of the intervention pages, users commented on the diagrams and images, text layout and font colour and size, page layout and design. Generally, users were positive about the page layout and design and liked that there was not too much information on each page:

> *I actually like the layout . . . Because I am dyslexic I often get befuddled by screens and because everything is in boxes I can just look at a box before I go onto the next box it is not just one big blur. I like that I can learn. At the top it tells me what it is I am on and then I have got a bit that tells me what I am going to do and then a bit that says, 'Press this and you will go somewhere.' . . . I like that. I like the layout of it* (Avril, tinnitus for 10 years)

> *The screen is, is, is quite relaxing to look at, and there are no garish colours, or anything. It, it seemed, it wants, it draws you in to, to be involved* (Graeme, tinnitus for 22 years)

Some users identified some minor design issues, including pages that were cluttered, wordy, or confusing; and content that was inconsistent (e.g. the fact that user quotes are on some pages but not others). Ian felt that the blue colour and boxes made the intervention look "*clinical*" and made him feel medicalised. He suggested adding more pictures of scenery or friendly people with tinnitus who looked like they were leading a happy life. A few users commented that the design was basic and plain and would have liked it to have more engaging aesthetics. Two users commented on the fact that the intervention page did not expand to the full size of the computer screen, with one user finding that the white space around the intervention content led to some glare.

Some suggested introducing more interactive features, such as audio-visual features, the option to complete the thought record electronically, and a progress bar to illustrate how much of the intervention was remaining. It was also suggested that the intervention should be available via smartphones and tablets. Users' differed regarding whether they preferred to listen to audio (e.g. relaxation MP3s), read content on the screen or print and read content. This provides further support for the need to offer users different formats.

Users particularly liked the use of pictures and the diagrams that supported the intervention text. Users liked the positive images, such as the nature images, which

were calm and relaxing. Images that were liked to a lesser extent were those that were abstract, unclear what they were depicting, used more than once, unrelated to the intervention text, or did not portray a positive image of tinnitus. For example, several users disliked the image of a brain containing cogs that was used to portray 'mechanisms of tinnitus'. To them, this image looked like a *"confused brain"* which they associated with the negative experience of having tinnitus: *"that's what my brain feels like"* (Lisa). Some users liked the font size and colour, however, a few users would have preferred the font size to be bigger. Many users found the bolded blue text confusing, as they mistook it for a hyperlink. Users liked when the blocks of text was broken down into bullet points and some suggested using this formatting style more often.

Generally, users believed the intervention content to be well structured and organised in a logical manner. The minority of negative comments about the information architecture focused on repetitive content, lack of detail about what to expect when following certain links, the excessive time it takes to get to the main content within a module, and not explaining what the intervention involves upfront. Users expressed mixed views regarding the role of choice in the intervention. A few users were concerned that making content optional and giving users the choice regarding which modules they completed and in what order would encourage users to skip or miss essential content, which may make the intervention less effective. In contrast, others preferred having the choice:

> *That sentence is sort of confusing. "We recommend you start with section one, as it will help you understand section two." . . . just tell them . . . Not*

recommend . . . it's sort of a bit wishy-washy . . . Why, why give them the choice? (Brian, tinnitus for 2 years)

Give them a choice . . . I think no-one wants to be told what to do, especially when you get to a certain age (Sally, tinnitus for 4 years)

If it's choice just for the sake of choice, erm, it can be possibly worthless. If it's choice through design and somebody's you know, done the research and found three different ways that a particular thing can work, then yeah, that's great (Ron, tinnitus for 25 years)

Sub-theme 2.6: Usability

Generally, users were positive about the usability of the intervention, which was very easy to use, intuitive, and flowed well. Specifically, users liked being able to move backwards and forwards through the material and the intervention function that marked modules as 'done' once completed. However, some minor usability and navigation issues were identified, either by the user themselves or by the interviewer when observing the user interact with the intervention. The main difficulties users experienced focused on knowing how to use internet browser functions (i.e. close the pop-up windows to return to the main intervention, scrolling down the page), lack of clarity over what aspects of the intervention page can or cannot be clicked on, confusion regarding which techniques or modules users have already completed, not realising that context was clickable, and uncertainty regarding where hyperlinks will

lead. One user, who was an experienced computer user, expressed concerns that those who were less knowledgeable about computers may not be able to follow the instructions on how to put the MP3 files on a CD.

7.4.2.3 Theme 3: Right people, right time

Right people, right time had two sub-themes. In the sub-theme *right people*, users discussed how relevant the intervention, its aims, and its self-management components are to them, and outlined the characteristic of the users who they believed would benefit most from the intervention. In the sub-theme *right time*, users discussed the most appropriate times to deliver the intervention to people with tinnitus.

Sub-theme 3.1: Right people

When assessing the personal relevance of the intervention, users considered how well they were already managing their tinnitus or how much their tinnitus currently impacted their everyday lives. Those users who felt that the intervention held little relevance for them believed that the intervention was more suitable for those who had more severe tinnitus or were less able to cope with their tinnitus:

> *With such a mild base level as I call it . . . I don't feel I need to go and search out a cure or searching out a management technique. But with, for people with, erm, much higher levels of discomfort, then absolutely this, this should be very early on in their recognition that they've . . . got a problem* (Richard, tinnitus for 20 years)

> *I think it would help people who were fragile minded, and, and, and, and felt a real need for it, erm, people depressed, I suppose, erm, yeah, people temperamentally not as, not as strong as, as obviously I am* (Graeme, tinnitus for 22 years).

Users also considered the specific effects of tinnitus and their current ability to manage their tinnitus when assessing the relevance of the individual self-management components or aims of the intervention. Specifically, users reflected on the extent to which they experienced high levels of stress (relaxation skills training) and negative thoughts (cognitive skills training), as well as how well they already understood tinnitus (education about tinnitus) and were aware of, and able to manage, their negative thoughts (cognitive skills training):

> *I don't know actually, whether they [the aims] would be [helpful], because I'm pretty much like that anyway, I'm sort of fairly chilled out, I don't have unhelpful thoughts, I'm quite relaxed . . . it doesn't sort of, erm, you know, impact on me life very much* (Brian, tinnitus for 2 years)

> *[Learning relaxation skills] to me would be a bonus. Because I don't relax* (Nick, tinnitus for 1 year)

> *I'm thinking most people already know this, who've got tinnitus, they already know how to manage their thoughts* (Brenda, pulsatile tinnitus for 3 years)

Janice explained how her tinnitus was currently severe. After getting upset when reading some of the intervention content (see Sub-theme 1.1 for further discussion), she did question whether the intervention would be too upsetting for people like her. When progressing though the 'managing your thoughts' module, users explained how they already practiced some version of the cognitive skills training techniques, that is, they already made thought records in their head (thought record), challenged their thoughts (cognitive restructuring), let their thoughts go (cognitive defusion), or thought positively (gratitude diary). For some users, doing these techniques was "automatic" and they did not necessarily see it as a technique.

Some of those users who found the intervention less relevant were still keen to access the intervention in the hope that it contained new content that would help them to manage their tinnitus even better. Some users found it difficult to assess whether aspects of the intervention were relevant to them. Specifically, they were unsure whether tinnitus affected their lives and if they had negative thoughts. One user was concerned that the intervention may not be suitable for those with poor literacy skills.

Sub-theme 3.2: Right time

Users generally believed that the best time to access the intervention would be at times of crisis, that is, when tinnitus is causing distress or they are struggling to cope. Users explained how they would be more likely to engage with, and commit time to the intervention and its individual modules if, or when, their tinnitus became more of a problem: *"I might need to do something like this [relaxation skills training] at some stage [but] not now"* (Andrew, tinnitus for 4 years).

In contrast, there were other users who felt that the intervention would not be appropriate at times of crisis. Some users stressed that, although people with tinnitus may be more in need of support at times of crisis, they may not necessarily be willing to engage with the intervention during this time. Specifically, when in crisis, people with tinnitus are looking for an immediate solution, which the intervention did not provide:

> *[The intervention would not be helpful] when . . . it's [tinnitus is] very acute for me . . . in troublesome times, you need something that offers you a bit more kind of immediate relief . . . I wouldn't come to a written programme, I don't think, in those times. Because, erm, because the anxiety around it makes it difficult to concentrate on something* (Avril, tinnitus for 10 years)

Ian explained how he would have been less willing to engage with the intervention during the early stages of tinnitus, when he was still looking for a cure and had not yet accepted his tinnitus:

> *At the very inception of getting tinnitus, I'd have thought, "Oh God, have I gotta do this [the cognitive skills training module]?" . . . where's this [module] going? . . . You've almost got to appreciate that maybe for the first couple of months . . . of having the thing [tinnitus], you're fighting. You're resisting what you've got to the point where you're not accepting it . . . I wouldn't have used it, at that time, I'd still be fighting against it and still be in denial* (Ian, tinnitus for 4 years)

Janice initially explained that she was currently highly motivated to seek any form of help and support because her tinnitus was quite severe: *"At the moment it's, it's [tinnitus is] quite bad and I seem to be, I can't help myself. I want to find out everything that I can find out about it"* (Janice, tinnitus for 4 years).

In contrast to those who felt that the intervention is most useful at times of crisis, many users believed that the intervention, in particular the educational components, should be offered early on. This is to provide support during this worrying, confusing, and lonely period and before tinnitus becomes a problem:

> *I think it's important to do something at the very beginning . . . I think it would put some positivity, if you did the right programme, it, it might make your, your thoughts more positive than negative, if they can actually get to you at the beginning* (Brenda, pulsatile tinnitus for 3 years)

> *When I was diagnosed, it was, there was nothing . . . you're just told what it is, and get on with it, and deal with it . . . someone young, who is diagnosed- or becomes, you know, realises they have a problem with tinnitus, it'd be nice if they could get to this sort of information early on, to help them understand . . . 'cause it can be quite a scary thing* (Ben, tinnitus for 23 years)

Others felt the intervention should be offered once tinnitus has become permanent and or a diagnosis has been given to avoid the intervention being given incorrectly or unnecessarily (i.e. if the tinnitus is temporary). Some users believed that the intervention could be helpful at any time, even if you have had tinnitus for a

considerable time, because you may learn something new or it may refresh your current knowledge: *"To be perfectly honest I'm finding it helpful today, you know, 20 years in"* (Richard, tinnitus for 20 years). In contrast, others users felt it would be less helpful for those who have had tinnitus for a long time, as it is likely these people have already learned to manage their tinnitus.

7.5. INTERVIEWER REFLECTIONS ON INTERVIEWS AND QUALITATIVE ANALYSIS

Generally, I found that participants were very good at articulating their thoughts and relating the content to their own situation. When using prompts, it was challenging to strike the balance between encouraging participants to think aloud and ensuring that the participants stayed on topic and were able to view a suitable amount of the intervention content. In contrast to Study 2 in Chapter 5, I found it more difficult to remain neutral when conducting the interviews because I developed the intervention. Participants were aware of my involvement and often asked me questions about the content (e.g. what is this technique trying to do? Is this statement really true?). If this happened, I would first ask participants what they thought the answer to their question might be and then tried to ascertain why the answer to this question was important to them. For example, were they asking for more information because it was essential to their understanding or effective use of the intervention, or were they asking because they were curious and thought I might know the answer? I would generally avoid explaining development decisions to participants to prevent coming across as defensive. However, it was sometimes necessary to provide a brief explanation when an issue was preventing the participant from proceeding (e.g. if an explanation or instructions were not clear). I would try to follow my explanations with questions such

as, ‘now I have explained that to you, how well did the intervention explain that same issue?’

As I was present while the participants used the intervention, participants would often ask me what they needed to click on next or look to me for guidance if they were encountering difficulties. At times like these, I would suggest that they use the intervention in the same way they would if I were not here, unless I needed them to do something specific (e.g. start a specific module). In an attempt to better understand participants’ reasons for clicking or not clicking on certain buttons, I would often ask users why they chose to make certain navigational decisions. This was helpful as I could ascertain whether it was because they were not interested in the intervention content linked associated with that button or because they were not aware of its presence. However, such questioning would lead some users to click on the same button on similar pages because they assumed this is what I wanted them to do. This suggests that their usage may have been influenced by my presence and they were not using the intervention as they might do normally, thus demonstrating a conflict between acceptability and usability research.

When users would encounter content that was less relevant to them, some users would try to put themselves in the shoes of other potential users and explain how they might react to the intervention (e.g. ‘others might find that off-putting’), rather than share their own experiences. When this happened, I asked for their own thoughts on the intervention content, which was sometimes different to their perceptions of what others may think. In this situation, it was difficult to know what users’ true reactions were.

Were they explaining the views of others to minimise the impact of negative feedback or to avoid admitting that they did not understand something (e.g. 'some people might find this difficult to understand')? Or were they merely trying to put themselves in the shoes of others? Interestingly, the two users who were more likely to do this were the two users who were also PPI panel members. These panel members also advised on the mixed-methods studies in Chapter 5. On one hand, their feedback was valuable and well-informed as they were aware of the Tinnitus E-Programme 1.0 and the research context. However, I found that their interviews were more positive, which may be for two reasons. First, they met me previously so were perhaps more reluctant to provide negative feedback. Second, they had seen the Tinnitus E-Programme 1.0 and were therefore commenting on how much the intervention had been improved, rather than taking it on face value.

When analysing the data, I felt confident in my decision to analyse the qualitative data in its entirety. During the interview, users seamlessly changed between interacting with and responding to the intervention ('think aloud data'), and explaining their responses and responding to my open interview questions during and after the think aloud interview ('semi-structured data'). If I decided to analyses these two sets of data separately, it would have been difficult to know the points at which this data should have been split. Furthermore, topics derived from questions asked in the semi-structured exit interviews at the end were also naturally discussed in the preceding think aloud interviews by participants (e.g. Theme 3: Right people, right time). It is likely that there would have been some overlap across the two sets of analysis if this data were analysed separately.

There were often some disparities between how I coded the transcriptions and the coding of the other two coders, who were not as familiar with the intervention and were not present at the interviews. For example, one user mentioned how he found it difficult to relate to, and gain value from, the user testimonials, as he did not know what the intervention actually was at this stage. I coded this as 'information architecture' as I knew that it was mentioned later in the intervention, whereas, one of the other coders coded this as 'expectations/more information' as the participant perceived this information as missing at the time. I found the second coding extremely valuable for making sure that I did not over-interpret the data and its impact on intervention development, rather than analysing it on face value.

Although participants were being paid for the research, I got the impression that this was not the only motivation they had to take part. Many participants commented how they were curious about the research and wanted to see if the intervention could help them. Others explained how they appreciated being able to talk about their tinnitus as they found have previously had little opportunity to do so.

7.6. LIMITATIONS

First, unlike the mixed methods study (Chapter 5), the interviewer was involved in the development of the Tinnitus E-Programme 2.0. Although users were encouraged to provide critical feedback, it is possible that they may have been trying to please the interviewer, which may have led to a social desirability bias (Section 7.5). Second, as the focus was on exploring users' reactions to the intervention, the interviewer was reasonably involved in the think aloud process which may have influenced how they

interacted with the intervention (Section 7.5). This may have reduced the chances of detecting problems with the intervention. Third, although attempts were made to recruit a diverse sample, users were generally older, White British, highly educated, had tinnitus for an average of nine years, and regular computer and internet users. Furthermore, during the interviews, many participants disclosed that they did not experience high levels of tinnitus distress. This is consistent with the literature which states that tinnitus is bothersome for only 20% of those who experience it. Future work would benefit from testing the intervention with those who have moderate to high levels of distress. Especially in light of the findings of this research, which highlighted that this intervention may be most appropriate for those who may be experiencing distress because of their tinnitus.

7.7. SUMMARY

This chapter details a think aloud interview study that aimed to explore users' reactions and interactions with the newly developed Tinnitus E-Programme 2.0. A summary of the findings is given according to the three process evaluation components: mechanisms of impact; implementation; and context.

7.7.1. Mechanisms of impact: Acceptability, satisfaction, and intervention factors influencing user engagement

- Generally, users found the intervention to be acceptable and engaging and reactions to the intervention's content and design features were positive.
- Users found the intervention easy to use and understand.

- Users liked content that normalised tinnitus, made them feel less isolated, and portrayed a positive image of tinnitus self-management.
- Users disliked content that reminded them how bad their tinnitus was or focused on the negative aspects of tinnitus.
- Users highly valued education about tinnitus and related to, or agreed with, the educational content and advice provided in the intervention.
- Reactions to the relaxation therapy and cognitive therapy were more mixed.
- Some users questioned the value of cognitive skills training techniques that facilitated awareness and management of negative thoughts. They were concerned that this would be counter-intuitive by making them dwell on their negative thoughts, become more aware of their tinnitus, or disrupt their positive mind set.
- The majority of users found the intervention duration manageable and the relaxation goals achievable.
- Some users expressed concerns regarding the self-guided nature of the intervention and would have preferred a face-to-face service (e.g. support group, health professional-led service), liked to be able to talk to a health professional or other people with tinnitus, or use the intervention alongside a face-to-face intervention.

7.7.2. Implementation: Intervention usage and user enactment

- The intervention was relatively problem-free, however, some minor issues with usability, design and clarity of written content were identified that affected the quality of intervention's implementation.

7.7.3. Contextual factors: Factors external to the intervention that may influence user engagement, enactment, and outcomes

This study identified several contextual factors, external to the intervention, that may facilitate or impede its future implementation or effects. These factors included users' pre-existing attitudes, beliefs, and perceptions, the stage in their healthcare journey, and the nature of tinnitus:

- **Users' perceptions of their tinnitus severity and ability to manage their tinnitus** – users were more likely to engage in the intervention and its individual self-management components if their tinnitus was greatly affecting their lives or they were struggling to cope. In contrast, some users highlighted that they would be less willing to engage with the intervention when their tinnitus is particularly severe, during which time they are looking for a solution that is more immediate.
- **Users' readiness to engage in self-management -** some users explained how they would be less ready to engage with the intervention if they have not yet accepted the permanency of their tinnitus or received a permanent diagnosis of tinnitus.
- **Stage in healthcare journey** - Generally, users believed that the intervention should be offered early on when feelings of uncertainty are greatest and before their tinnitus became problematic. The intervention was deemed less appropriate once people have had tinnitus for a long time and had developed their own means of coping.
- **Users' willingness to engage in self-management –** A minority of users questioned whether tinnitus should be managed at all or just ignored. These

users were concerned that focusing on their tinnitus may make it worse or believed management was only helpful if it cured or changed the tinnitus in some way.

- **Users' openness to engage in relaxation therapy and mindfulness techniques** - Some users held negative views about the relaxation and mindfulness techniques. They either did not see the value of the techniques, did not like doing it, or preferred alternative ways of relaxing (e.g. having a bath, watching TV).
- **The heterogeneous nature of tinnitus** - A minority of users did not relate to some aspects of the explanations of how tinnitus develops either because it contradicted the explanations they had previously been given or was not congruent with their own experience of tinnitus. As explained in Chapter 1, there are several theories of tinnitus and not one provides conclusive support for the development and experience of everyone with tinnitus. Therefore, the heterogeneous nature of tinnitus means that there will be some people who do not fully relate to all aspects of the explanations given, no matter which theory is chosen. The range of available theories also mean that it is likely the person with tinnitus may come with their own pre-existing theories, especially if they have had tinnitus for a long time.

CHAPTER 8. DISCUSSION

8.1. INTRODUCTION

This PhD aimed to evaluate and optimise the Tinnitus E-Programme, an internet-based intervention to support tinnitus self-management that was developed in the UK. Although freely available online, there was little understanding of how the intervention is used, its active ingredients, how it works, the circumstances in which it works best, and whom it works best for. Such knowledge regarding the mechanisms of impact, implementation, and context of digital and self-management interventions for tinnitus was also limited.

This PhD research provided the first process evaluation of the Tinnitus E-Programme ('Tinnitus E-Programme 1.0') and offers insights into the users' perspective on internet-based interventions for tinnitus, which has previously received little attention. This research was also the first study to systematically apply person-based, evidence-based, and theory-based approaches to optimise an internet-based intervention for tinnitus ('Tinnitus E-Programme 2.0'). Taken together, the findings of this research improved our understanding of the Tinnitus E-Programme's (versions 1.0 and 2.0) mechanisms of impact and outcomes, and identified implementation or contextual factors that strengthened or impeded its delivery and functioning. The objectives of this PhD were:

1. To systematically review the current evidence-base to assess the effects of self-help interventions for tinnitus and identify the self-help techniques used;

2. To develop an understanding of the Tinnitus E-Programme's (1.0 and 2.0) mechanisms of impact, outcomes, and identify any implementation or contextual factors that strengthen or impede its delivery and functioning;
3. To develop the Tinnitus E-Programme 2.0, an optimised version of the Tinnitus E-Programme 1.0.

8.2. KEY FINDINGS AND IMPLICATIONS FOR FUTURE DEVELOPMENT, EVALUATION AND IMPLEMENTATION WORK

8.2.1. Firm conclusions cannot be drawn from the current evidence-base regarding the efficacy of unguided self-help interventions for tinnitus

A systematic review assessed the effects of self-help interventions for tinnitus on levels of tinnitus distress, functional management, depression, anxiety, or quality of life of adults with chronic tinnitus. Only five studies, including three RCTs, were identified that assessed the effects of self-help interventions delivered via the internet, books, and an information leaflet, and only one study was carried out on a UK population. Studies used different outcomes, assessment measures, controls, and intervention delivery mediums, making them unsuitable for meta-analysis. Instead, a narrative synthesis was carried out, which found mixed results for the effect of self-help interventions on tinnitus distress and psychological distress when compared to passive controls. Only one of the three studies exploring this comparison for tinnitus distress found a significant between group effect for their self-help intervention, which was delivered via the internet, although effect sizes for this study were large.

The findings of the review should be interpreted with caution as the included studies were of low-to-moderate quality and the risk of bias assessment highlighted several concerns. Mainly, none of the studies made attempts to blind participants to the intervention they received. However, this is not always possible when using active or passive controls. Future RCTs should use self-help interventions with fewer intervention techniques as controls, such as information-only interventions or online support groups. Participants could be blinded to which intervention arm they are in and this would partially control for any placebo/non-specific effects (e.g. time spent on self-management, knowledge gain).

There was also considerable differences between the studies identified in the review regarding outcome measures selected. Four tinnitus questionnaires were used across the studies, each with a different level of sensitivity to different aspects of tinnitus (Fackrell et al., 2014), which can make it difficult to compare findings between studies. Differences in outcome measures use is a commonly reported problem in tinnitus trials (Hoare & Hall, 2011; Hoare et al., 2011).Work is presently underway to agree a core set of outcome measures that should be used for evaluating different types of interventions (Hall et al., 2015). Once agreed, this core set should be used for future trials of self-help interventions for tinnitus.

In summary, findings on the efficacy of internet-based interventions are promising, however, the lack of high quality and homogenous studies mean that firm conclusions cannot be drawn. There is a need for high quality RCTs of unguided self-help interventions on a UK population. Ongoing international tinnitus trials focus primarily

on biomedical treatments (e.g. drugs, brain stimulation) and devices to reduce the tinnitus percept (e.g. tinnitus masking devices). However, there are some ongoing trials of self-help interventions. During this PhD, work was started in the UK to develop and trial an audiologist-supported internet-based CBT intervention (Beukes et al., 2016; Beukes, Manchaiah, Allen, Baguley, & Andersson, 2015). Internationally, there is an ongoing trial of an internet-based CBT intervention in the United States (Clinical trials ID: NCT02438891) and another evaluating Tinnitus Retraining Therapy delivered via the internet and smartphone application in Korea (Clinical trials ID: NCT01663467). However, there are no ongoing evaluations of unguided self-help interventions for tinnitus in the UK. The Tinnitus E-Programme 1.0 provided the opportunity for such an evaluation. As it had not yet undergone any formal evaluation, a process evaluation was needed first to ascertain and address uncertainties in its design and maximise its chances for success in a RCT.

8.2.2. The Tinnitus E-Programme 1.0 was acceptable to its target users, but some implementation factors that impeded its delivery were identified

A mixed methods process evaluation explored past, current, and new users' views on, and usage of, the Tinnitus E-Programme 1.0. It was found that, overall, the intervention was acceptable to its target users, with 90% of past and current users reporting that the Tinnitus E-Programme 1.0 had helped them. Intervention usage was mixed, with approximately one half of past and current users using the full intervention, and new users reported meeting under half of the daily relaxation goals. This indicates that users' adherence to the relaxation goals was poor. Some new users found the Tinnitus E-Programme 1.0 confusing and difficult to navigate, and these issues led some to miss

out key self-management components (i.e. THI). A few users were unable to use the audio recordings because of their hearing loss. These usability and accessibility problems limited user engagement and prevented the successful implementation of the intervention. Two components of the Tinnitus E-Programme 1.0 were not included in the Tinnitus E-Programme 2.0: THI (a questionnaire to measure tinnitus distress) and an online support forum (where users could receive social support through communicating with other users and people with tinnitus). Reasons for this decision and suggestions for future development work on these components will be discussed.

8.2.2.1 Monitoring of condition with feedback to the patient (THI)

In the Tinnitus E-Programme 1.0, users were asked to complete and self-score the THI at the beginning and end of the intervention to allow users to monitor changes in their levels of tinnitus distress between these two time points. In the mixed methods study, users perceived the THI (or a similar self-monitoring and feedback tool) as valuable for two reasons. It allowed users to gain feedback on their progress towards their goals, which was important for convincing users that the intervention was providing benefit and providing them with a sense of achievement. It also provided users with a tinnitus severity rating, which helped some users realise that their tinnitus was not as bad as they sometimes thought it was. Despite these perceived benefits, users encountered some difficulties with the THI, specifically they found its response scale and scoring and feedback system confusing, and some of the items were difficult to use or interpret. These user-reported problems with the THI, and the lack of an obvious alternative outcome measure, meant that the THI was not included in the Tinnitus E-Programme 2.0.

When considering future development work, one must also ask whether a validated outcome measure is the most effective tool for self-monitoring and providing users with feedback on progress. Validated measures provide the most reliable and valid way to capture changes in outcomes, however, this information may not always be helpful to an individual's adjustment to tinnitus if, for example, the outcome assessment demonstrated that the intervention led to an increase in a user's tinnitus distress or failed to measure any difference in outcome. Receiving such feedback, without a comprehensive explanation of why this change did or did not occur (as is the case in the Tinnitus E-Programme 1.0), could potentially have a detrimental effect on the person with tinnitus, who may already be feeling hopeless or questioning the value of self-management. It may be that positive changes did occur; it was just that these changes were too subtle for the outcome measure to detect, or the benefits achieved were not measured by the questionnaire used (e.g. improved understanding of tinnitus).

It may be more appropriate to provide more user-friendly tools that allow users to set and regularly review their own intervention goals (e.g. to learn more about tinnitus, to reduce the stress caused by tinnitus). The use of personally relevant goals would be specifically salient given the variety of outcomes that were reported in this intervention (Section 8.2.5). Such a tool would more likely capture subtle changes that may occur during the intervention and allow users to assess how beneficial the intervention has been for them. Such an approach has been used in other unguided interventions (e.g. Kaldo et al., 2007).

8.2.2.2 Social support (Online support forum)

The mixed methods study also found that users' views on the online support forum included in the Tinnitus E-Programme 1.0 were mixed and usage was low among new users. Some users' reasons for poor usage or disengagement from the forum were similar to those found in other evaluations of online support forums, including negative views of the forum platform; doubts about the trustworthiness of the information provided; perceived negativity of the forum posts; and concerns regarding internet safety (Coulson, Smedley, et al., 2016; Malik & Coulson, 2008). There was also one barrier to participation that was unique to this target group, that is, some users were concerned that participation in the forum would make their tinnitus worse by encouraging people to focus on it. Furthermore, two barriers were identified that applied specifically to the use of forums within the context of an internet-based intervention; some users were already members of another forum that they preferred; and some forgot to use it. These problems with the online support forum meant that this component was not included in the Tinnitus E-Programme 2.0.

Despite a lack of explicit social support in the Tinnitus E-Programme 2.0, users in the think aloud interviews still identified content in this version that normalised their tinnitus and made them feel less isolated. This suggests perceptions of social context may still be facilitated, even without any social contact. However, some users in the think aloud interview study still expressed a desire to connect with others with tinnitus. As this component is beneficial to some but not all users, it is recommended that users should be signposted to online or face-to-face support forums, as an optional component in future iterations of the Tinnitus E-Programme 2.0. These online support

forums should be active and moderated to minimise users' negative experiences when using the forum.

8.2.3. The Tinnitus E-Programme 2.0 and its components were acceptable to its target users, but some further development work would be beneficial

Once the Tinnitus E-Programme 2.0 was created, a think aloud interview study explored users' reactions and interactions with this optimised version. Generally, users found the intervention engaging and their views on the intervention's content and design features were positive. The usability and accessibility issues identified in the Tinnitus E-Programme 1.0 were addressed and users reported the Tinnitus E-Programme 2.0 was easy to use and navigate, and few problems were identified. Users particularly valued the education about tinnitus and its management and related to or agreed with the educational content and advice provided.

All but one (i.e. the information leaflet) of the unguided self-help interventions identified in the systematic review was based on CBT, so relied mainly on cognitive restructuring techniques for managing negative thoughts. The Tinnitus E-Programme 2.0 was unique because it offered users a choice of different techniques for managing negative thoughts, including techniques from CBT (i.e. cognitive restructuring), ACT (i.e. cognitive defusion), and positive psychology (i.e. gratitude diary). The decision to provide multiple techniques was informed by psychological theories on motivation that emphasise the importance of user autonomy, the finding from the mixed methods study that users had different preferences regarding the relaxation techniques, and a

lack of guidance on the most effective technique for managing negative thoughts in tinnitus.

The think aloud interview study found that users preferred some techniques over others. Users' preferences were influenced by how well the techniques fit with their personality (e.g. optimistic) or current way of thinking (e.g. positive thinker), and the familiarity or novelty of the technique. Moreover, some users disliked content such as the cognitive restructuring technique that focused on facilitating awareness and management of negative thoughts. Users feared it would be counter-intuitive, making them dwell on their negative thoughts and more aware of their tinnitus or disrupting their positive mind set. In the mixed methods study of the Tinnitus E-Programme 1.0, users' preferences regarding the individual relaxation exercises varied widely. Taken together, these findings highlight the importance of offering users a choice of different self-management techniques. There is evidence that matching an individual to their preferred psychological therapy improves treatment attrition and outcomes (Corrigan & Salzer, 2003; Swift & Callahan, 2009). The efficacy of this multi-technique approach to reducing negative thoughts in people with tinnitus is still to be tested.

The think aloud interview study found that some users expressed an apathy towards individual components contained in the Tinnitus E-Programme 2.0, specifically, the relaxation and mindfulness techniques. They either did not see the value of the techniques, did not like doing it, or preferred alternative ways of relaxing (e.g. having a bath, watching TV). It was argued that this apathy may be caused by a pre-existing lack of openness (e.g. "that's just how I am") or unfamiliarity with these type of

techniques, rather than a dissatisfaction with the specific techniques included in the intervention. Interestingly, the relaxation skills training component was well-used by users in the mixed methods study, and these users expressed more positive views about this component, compared to the users in the think aloud study.

This difference may be explained by the nature of the two qualitative studies. It is possible that those users in the mixed methods study expressed more positive views because, unlike the users in the think aloud interview study, they had the opportunity to experience the relaxation techniques for themselves and were therefore more likely to be aware of their potential benefit. In fact, behavioural practice or rehearsal has been identified as a behaviour change technique in its own right (Michie et al., 2013). This technique was included in the Tinnitus E-Programme 1.0 and 2.0. Users were asked to spend time trying the relaxation exercises and were encouraged to practice relaxation daily. Moreover, users in the mixed methods study had to commit to completing the intervention across a ten-week period, so were likely to be reasonably motivated to engage with the intervention. Whereas, the users in the think aloud study only had to commit to a single think aloud interview and most reported that they were already managing their tinnitus quite well. Therefore, it is likely that users' motivation to engage in the relaxation skills training is likely to be greater in those who are motivated to take part in the entire intervention and would improve once users become more familiar with this component.

In addition to the formal relaxation techniques in the Tinnitus E-Programme 2.0, future modifications of the intervention should also recommend alternative stress

management practices (e.g. exercise, taking a bath) for those who do not like formal relaxation. Advice on how to deal with particularly severe episodes of tinnitus should also be provided. Several additional behaviour change techniques were introduced into the Tinnitus E-Programme 2.0 to improve users' adherence to the relaxation goals and these techniques were found to be acceptable to users. Future evaluations of this intervention should re-assess whether these modifications led to improvements in users' adherence to the relaxation goals.

Although the online support forum was not included in the Tinnitus E-Programme 2.0, information about other users via user stories and quotes was provided. This is suggested to be an effective design feature for facilitating perceptions of social context and support (Morrison et al., 2012). This feature was generally acceptable to users, however, some users wanted more information to ascertain the credibility of the user information. Based on their findings from a critical interpretative synthesis, Morrison et al. (2012) hypothesised that only the provision of information from real, rather than hypothetical, users is likely to have a positive effect on intervention outcomes.

Andersson et al. (2009) recommends that internet-based interventions for tinnitus should be comprehensive, providing several self-management components that address all aspects of the tinnitus experience (e.g. physical, emotional, and daily effects). To make best use of the time available, only those self-management components (i.e. education about tinnitus and its management, training/rehearsal for psychological strategies, monitoring of condition with feedback to patient, and social support) and psychological strategies (i.e. relaxation and cognitive skills training)

included in the Tinnitus E-Programme 1.0 were considered for inclusion in the Tinnitus E-Programme 2.0. The systematic review identified two additional intervention components that may be worth considering for inclusion in future iterations of the Tinnitus E-Programme 2.0, that is, information about available resources (which may be addressed by the links to the optional online support forum discussed earlier) and lifestyle advice and support (e.g. sleep and concentration management). Specifically, providing advice on how to change the patient's environment (to increase or decrease situations in which tinnitus will be better) and sleep hygiene (habits and practices that are conducive to good sleep) are suggested to be two important aspects of this component for psychological interventions for tinnitus (D.M Thompson et al., 2016).

The systematic review also highlighted additional psychological strategies that could be included, including techniques related to sound enrichment, attention control, exposure to tinnitus, behavioural activation, problem solving, and self-instructions. However, an understanding of which of these strategies is most effective and acceptable to users is currently lacking. A useful way forward may be to focus on strategies that attempt to modify the two factors in McKenna's cognitive behavioural model of tinnitus (Figure 1.1; McKenna et al., 2014) that were not addressed by the Tinnitus E-Programme 2.0, that is, selective attention and monitoring, and safety behaviours. The addition of mindfulness and acceptance techniques and strategies for managing avoidance behaviours is recommended.

The behavioural analysis of the Tinnitus E-Programme 2.0 also highlighted some additional design features that should be considered for inclusion in future development work. These include content-based entertainment activities (e.g. quizzes), additional contacts with the intervention (e.g. therapist contact, motivational emails, or email reminders), and tailoring the intervention to the users' needs. Some users in the think aloud interview study also suggested introducing more interactive features, such as audio-visual features and content that can be modified electronically (e.g. thought record).

8.2.4. Users views on the need for therapist support or guidance were mixed and the evidence on the effectiveness of this component is inconclusive

Firm conclusions could not be drawn from the systematic review regarding whether tinnitus self-help interventions can provide comparable benefit to traditional face-to-face therapies or therapist-guided self-help interventions. Only one study carried out a between groups comparison between self-help interventions and active controls (e.g. face-to-face therapy or a therapist-guided self-help intervention). This study found no significant difference in tinnitus distress between groups who used a self-help book, with (active control) or without (intervention) therapist guidance, at post-intervention or one-year follow-up. Meta-analyses for other long-term conditions have found that effect sizes for unguided interventions are smaller than those for therapist-guided self-help interventions (Baumeister et al., 2014; Spek et al., 2007). However, a recent systematic review demonstrated that the findings regarding the added value of therapist-guidance in tinnitus self-help interventions are somewhat mixed. Nyenhuis, Golm, et al. (2013) found that the presence of therapeutic contact did not influence the

effect sizes for tinnitus distress and psychological distress, with one exception. The presence of therapeutic contact was demonstrated to be a predictor of larger effect sizes for depressiveness when comparing self-help interventions to passive controls. However, similar to the systematic review in this thesis (Chapter 3), their conclusions were based on a small number of studies.

The Tinnitus E-Programme 1.0 provided optional contact with a therapist and the Tinnitus E-Programme 2.0 provided no therapist contact at all. In the mixed methods study, current and past users of the Tinnitus E-Programme 1.0 who chose to contact the therapist highlighted how important this form of support was. On the other hand, the views of new users of the Tinnitus E-Programme 1.0 were mixed, with some users preferring the user autonomy and convenience provided by the unguided version of the intervention. None of these users reported contacting the intervention therapist. In the think aloud interview study of the Tinnitus E-Programme 2.0, some users expressed concerns regarding the unguided nature of the intervention and would have liked to be able to talk to a health professional. It is yet to be found whether therapist contact improves outcomes.

This research highlights that such contact may encourage user engagement. However, it is important that such contact preserves some of the key benefits of an unguided intervention, that is, it promotes a users' sense of autonomy and minimises any disruption to their everyday lives. Similar to Beukes et al. (2015, 2016), it may be more appropriate that delivery is supported by audiologists, rather than psychological therapists, to fit with a current service model for tinnitus. Future trials of the Tinnitus

E-Programme should assess the impact of therapist or audiologist support on the intervention's implementation and outcomes and additional qualitative studies should explore users' acceptability of this additional feature.

8.2.5. It is hypothesised that the Tinnitus E-Programme 2.0 will modify cognitive and behavioural factors and affect a variety of tinnitus-related outcome domains

An understanding of the likely Tinnitus E-Programme 2.0's mechanisms of change was developed through the use of theory-based (logic modelling, behavioural analysis), evidence-based (literature search), and person-based (mixed methods process evaluation of Tinnitus E-Programme 1.0) approaches to intervention development. Consistent with a cognitive-behavioural model of tinnitus, it is hypothesised that the Tinnitus E-Programme 2.0 exerts its effect by modifying cognitive and behavioural factors. Short-term cognitive outcomes included modifying illness beliefs, facilitating acceptance, minimising the occurrence (or effect of) negative thinking, and improving self-efficacy and a sense of control regarding tinnitus management. These factors are suggested as important for adjustment in people with tinnitus (Hesser et al., 2013; McKenna et al., 2014) and other long-term conditions (Moss-Morris, 2013).

This research also identified two short-term behavioural outcomes that may mediate the outcomes of the Tinnitus E-Programme 2.0: practicing relaxation and cognitive skills training to manage the physiological arousal and emotional distress associated with tinnitus. It is hypothesised that the intervention achieves these behavioural

outcomes through improving users' capability, opportunity and motivation to practice these self-management behaviours, thus addressing all three components of the COM-B model (Michie, Atkins, et al., 2014; Michie et al., 2015).

Ultimately, the long-term outcome of the Tinnitus E-Programme 2.0 is to improve the tinnitus-related quality of life of people with tinnitus. The findings of the mixed methods study also suggested that the intervention may lead to improvements in the following outcome domains: tinnitus intrusiveness, relaxation, emotional distress, and sleep. This research suggests that outcome measures that capture functional (e.g. intrusiveness, sleep, relaxation) and emotional (e.g. distress) domains of tinnitus may best capture changes resulting from self-help interventions. One tinnitus questionnaire that may be appropriate for measuring outcomes for self-help intervention is the Tinnitus Functional Index (Meikle et al., 2012), which includes sub-scales for each of the domains highlighted by this research. However, the responsiveness of this measure for psychological or self-help interventions has not been tested. As mentioned earlier, work is currently underway to define a core outcomes set (i.e. a list of the outcome domains that are essential to measure) for each type of intervention and agree the outcome measures that should be used (Hall et al., 2015).

The systematic review in this research found that measurement of generic quality of life is currently lacking across the evidence-base. Introducing such measures into RCTs for self-help interventions for tinnitus would allow comparisons of intervention effects to be made with other long-term conditions, which can be helpful when considering allocation of healthcare resources (Kennedy, Wilson, & Stephens, 2004).

8.2.6. The nature of tinnitus was identified as a contextual factor that influenced users' engagement with the intervention

Users' experiences and reactions to the intervention were influenced by their beliefs about tinnitus and the complex nature of tinnitus management. First, the think aloud interviews revealed that a minority of users did not relate to aspects of the explanation that was provided on how tinnitus is created and maintained provided in the educational module. This is perhaps an unavoidable issue for tinnitus interventions as it is unlikely that one explanation will accurately represent the experience of everyone with tinnitus. This is because tinnitus is heterogeneous in its aetiology and clinical characteristics, with the experience of tinnitus varying greatly between individuals (Baguley et al., 2013). Future modifications of the Tinnitus E-Programme 2.0 should reassure users that, although the tinnitus theories provided are based on the best available evidence, they may not explain everyone's experience. This will provide validation for users who do not relate to the theories, reassuring them that their experience is still normal.

Second, some users expressed an apathy or scepticism towards self-management in general. They questioned whether tinnitus should be managed at all or just ignored, or believed that management was only helpful if it cured or changed the tinnitus sensation in some way, which the Tinnitus E-Programme does not aim to do. Several design features were included in the Tinnitus E-Programme 2.0, such as scientific evidence sections, and user quotes and stories, to facilitate users' perceptions of credibility regarding the intervention. Generally, users held positive views about these design features. They believed that they added credibility to the intervention by improving

users' confidence in the intervention and its individual techniques and facilitating an understanding of why the techniques are important. Once the efficacy of the Tinnitus E-Programme 2.0 is determined, the findings of the outcome evaluation should be communicated to users in order to further facilitate perceptions of credibility. As discussed in Section 8.2.2.1, tools to help users to monitor and provide feedback on their progress may also raise users' awareness of any benefits they are gaining from the intervention.

Third, some users in both studies believed that the Tinnitus E-Programme 1.0 and 2.0, and self-management interventions in general, may negatively impact on their tinnitus. A belief that the intervention may make their tinnitus worse prevented some users from engaging in certain intervention components (e.g. online support forum). It also made some question whether engaging in self-management would be counter-intuitive, as it required them to focus on their tinnitus. This is an understandable belief, especially given the evidence regarding the role of attention in the experience of tinnitus (Rossiter, Stevens, & Walker, 2006; Stevens, Walker, Boyer, & Gallagher, 2007). However, this worsening of symptoms is likely to be temporary and is likely to be outweighed by the long-term benefits of self-management. Such concerns were acknowledged and addressed to some extent in the relaxation skills training component of the Tinnitus E-Programme 2.0. Future modifications to the intervention should address these concerns earlier on in the intervention.

8.2.7. The Tinnitus E-Programme 2.0 is likely to be most effective when delivered to the right person at the right time

The think aloud interview study provided insights into who will benefit most from the intervention and when it should be delivered. Users generally believed that the Tinnitus E-Programme 2.0 should be offered early in their tinnitus journey, when feelings of uncertainty are greatest and before their tinnitus became problematic. On the other hand, users explained how some people with tinnitus may not be ready to engage in self-management during this early stage. Specifically, they would be less ready to engage with the intervention if they have not yet accepted the permanency of their tinnitus (i.e. were still searching for a cure) or received a diagnosis of subjective tinnitus (i.e. were still undergoing diagnostic tests). Users acknowledged that the intervention may be less useful once people have had tinnitus for a long time and have developed their own means of coping.

Furthermore, users explained how they were more likely to engage in the intervention and its individual self-management components if their tinnitus was greatly affecting their lives or they were struggling to cope. That is, users were driven by a motivation to reduce their tinnitus severity or better manage their condition. However, this research also acknowledges that perceptions of tinnitus severity and ability to manage their tinnitus only motivates users to a certain point. Some users highlighted that they would be less willing to engage with the intervention when their tinnitus is particularly severe, during which time they are looking for a solution that is more immediate. Moreover, high tinnitus severity also served as a barrier to user engagement in the mixed methods study, with some users withdrawing from the research or delaying their

start date because their tinnitus was too severe. Taken together, these findings imply that the intervention is relevant to those with mild to moderate tinnitus severity. Future modifications to the Tinnitus E-Programme 2.0 should also include self-management techniques that can immediately alleviate tinnitus distress (e.g. rapid relaxation techniques that can be used at times of stress or when tinnitus distress is high).

These insights from users regarding who will benefit most from the Tinnitus E-Programme 2.0, and when it should be delivered, also suggest that users' motivations to engage with the intervention and perceived relevance and suitability of the intervention and its content, are important factors that influence users' engagement. These contextual factors are found to influence user engagement in face-to-face and internet-based psychological therapy for other long-term conditions (Bendelin et al., 2011; Dennison et al., 2013; Nicholas et al., 2010; Strecher et al., 2008).

A recent online survey study by the research team (Hoare et al., 2016) explored 124 tinnitus health professionals' perspectives on who will benefit most from self-help interventions and the current benefits and barriers to implementation of these interventions in practice. Consistent with the findings from this research, most health professionals believed that self-help interventions were most suitable for patients who are motivated and those with mild tinnitus or mental health difficulties and not suitable for those looking for a 'quick-fix'.

Taken together, the findings of this research suggests that the intervention should be offered early in people's tinnitus journey, so people with tinnitus have access to self-

management support during this confusing time. This is consistent with the tinnitus GPG which recommends self-management as the first line of support. Although the intervention should be available to everyone with tinnitus, the intervention is likely to be most beneficial for those with a mild to moderate level of tinnitus distress and those who are ready, willing, and motivated to engage in self-management. Consistent with guidelines for delivering self-help interventions for other conditions (NICE, 2009, 2011a, 2011b), the intervention is best delivered as part of a stepped care approach, in which those with the most complex needs are referred to more intensive specialist services, such as, face-to-face therapy.

8.3. METHODOLOGICAL DISCUSSION

This research was the first to systematically apply evidence-, theory- and person-based approaches to the development and evaluation of internet-based interventions for tinnitus. Specifically, it applied taxonomies to describe the techniques used in self-help interventions and carried out behavioural analysis and logic modelling to identify the causal mechanisms by which the Tinnitus E-Programme 2.0 may exert its effect. A search of the BCTv1 (Michie et al., 2013) interventions database (http://www.bct-taxonomy.com/interventions) revealed that this research is one of two research studies (Cook & Watkins, 2016) to use the BCTv1 to describe a self-help intervention and the only study to use it within a systematic review.

The use of the BCW and BCTv1 provided several benefits to this research. First, the use of the BCTv1 provided a common and specific language to communicate the techniques used in the Tinnitus E-Programme 1.0 and 2.0, which should facilitate the

understanding and future replication of the intervention. Second, the use of the BCTv1 as part of a systematic review provided a reproducible way of identifying the techniques used in self-help interventions for tinnitus and the frequency of their usage. Finally, I believe that the BCTv1 and BCW encouraged me to inspect and understand the self-help interventions identified in the systematic review and the different versions of the Tinnitus E-Programme in more detail than I would have done without the use of the taxonomy. The published intervention descriptions tend to broadly and vaguely describe the techniques used in self-help interventions, referring to the use of 'CBT techniques' or 'relaxation techniques'. The BCTv1 enabled me to break down these broad behavioural techniques into several smaller behaviour change techniques (e.g. 'instructions on how to perform the behaviour', 'goal setting'), which allowed me to develop a more detailed understanding of what techniques were contained in the Tinnitus E-Programme and other self-help interventions for tinnitus.

Moreover, by using the BCW to link the BCTs contained in the Tinnitus E-Programme 2.0 to the theoretical constructs used in behavioural science, I was able to identify additional mechanisms of impact (i.e. improving a users' capability, motivation, and opportunity to practice self-management behaviours) that may not have been identified if I had focused solely on the self-help literature, which tends to be written from a clinical psychology perspective.

On the other hand, the use of the BCT and BCW in this research also posed several challenges. The main challenge was that these tools were not designed specifically for use with self-help or internet-based interventions. When coding versions of the

Tinnitus E-Programme or the self-help interventions in the systematic review, some of the techniques listed in the BCTv1 were present, but were not coded because they were not targeting a specific behaviour. For example, the BCTv1 techniques 'body changes' (i.e. altering the body through relaxation) and 'framing/reframing' (i.e. cognitive restructuring) were present in the Tinnitus E-Programme 2.0, but for the purpose of reducing physiological arousal and emotional distress, rather than for facilitating behaviour change. Other self-help techniques were not included at all in the taxonomy (e.g. education about tinnitus and its management). The BCTv1 is therefore limited in its use for self-help interventions because behaviour change is only one component of these interventions.

Moreover, the BCTv1 and BCW do not currently address how these behaviour change techniques are delivered (e.g. face-to-face, written information, video). To some extent, the PRISMS taxonomy was able to identify some of the non-behaviour change techniques and Morrison et al.'s (2012) framework of design features for e-health interventions provided a common language for communicating the design features used in our internet-based intervention. However, these taxonomies are limited in that they only identify the broad components (e.g. training/rehearsal for psychological strategies) and design features (e.g. social support) of the interventions, rather than the more specific and smaller techniques and features, which would be useful to understand.

Another challenge with using a theoretical approach to intervention development for tinnitus is that work linking the BCTs and intervention components to their associated

theoretical mechanisms of impact is still in its infancy. Specifically, the evidence base on the predictors of tinnitus distress, behavioural determinants, and applicability of behaviour change theory in tinnitus is particularly lacking. Nevertheless, the need for a methodology that helps developers link theory and design has been acknowledged and such work is currently underway (Kok et al., 2016; Michie et al., 2016). Ongoing work is also being carried out to test models that explain the role of cognitive and behavioural factors in tinnitus distress (Handscomb et al., 2016). Despite their limitations, the use of the BCW and logic modelling in this research provided a useful starting point by identifying a number of hypothesised causal mechanisms that can be tested in future experimental research work.

8.4. FUTURE DIRECTIONS

The previous sections highlighted some future development work that needs to be carried out prior to a definitive outcome evaluation and implementation. This work includes introducing additional self-management components, psychological strategies, and design features; modifying components that were included in the Tinnitus E-Programme 1.0; and imparting advice to users to address their concerns and beliefs. These modifications should be tested using additional think aloud interviews with people with tinnitus. Few of the users in the think aloud interview study as part of this research reported high levels of tinnitus distress. Given that perceptions of tinnitus severity may influence users' engagement with the intervention, future think aloud interview studies should also attempt to recruit those with confirmed levels of moderate to high tinnitus distress. This will ensure that the findings are also transferable to those with higher levels of distress. Moreover, most users in the think

aloud interview study in this PhD research were highly educated and regular computer and internet users. It is recommended that future think aloud studies should also target those with lower educational levels and less frequent computer and internet users.

As well as considering how the Tinnitus E-Programme 2.0 could be modified to maximise intervention outcomes, additional development work also needs to consider the future implementation of the intervention. It is important to consider such issues at an early stage to ensure the developed intervention can be successfully implemented into current healthcare practice. In their survey of tinnitus health professionals, Hoare et al. (2016) found that the most commonly cited reason why health professionals did not refer people with tinnitus to self-help interventions, like the Tinnitus E-Programme 2.0, was because self-help interventions do not fit with their current service model. Additional reasons included a lack of knowledge regarding self-help interventions and a lack of confidence in the efficacy of the interventions that are currently available.

Implementation work should focus on how the intervention can best fit with current service models and improving health professionals' knowledge and confidence in self-help interventions. The normalisation process theory (May et al., 2009; May & Finch, 2009; Murray et al., 2010) identifies the factors that promote or inhibit the implementation of complex interventions into routine practice. This theory would provide a useful framework for exploring and addressing potential implementation issues that may face future iterations of the Tinnitus E-Programme and has been used to guide the development of internet-based interventions (Band et al., 2017).

This research has improved our understanding of the Tinnitus E-Programme 2.0's potential mechanisms of impact, and implementation and contextual factors that may strengthen or impede its delivery. However, there are still some final uncertainties that need to be addressed. A series of feasibility studies should test the acceptability and feasibility of trial procedures, estimate likely rates of recruitment and attrition of participants, and calculate appropriate sample sizes for subsequent randomised controlled trials. An additional process evaluation is needed to test the hypothesised causal mechanisms, and the contextual factors identified in this research. This work could be carried out as part of a pilot study or definitive outcome evaluation. Exploratory randomised controlled trials (e.g. Yardley, Joseph, et al., 2010) can be used to test whether the intervention leads to improvements in the hypothesised short-term outcomes, such as illness beliefs, or negative thinking. They can also be used to identify contextual factors that predict intervention outcomes (e.g. tinnitus severity and duration).

Exploration of the intervention usage statistics would develop an understanding of how intervention usage effects intervention outcomes and predictors of intervention usage (Arden-Close et al., 2015). Such exploratory work would confirm the sub-populations of people with tinnitus who would benefit most from the intervention and who might need additional self-management support. For example, those with poor outcomes or adherence may benefit from additional support of guidance from a health professional. Randomised controlled trials should also explore the added benefit of this additional health professional support on intervention outcomes and attrition.

8.5. CONCLUSION

This research presents the first process evaluation of the Tinnitus E-Programme 1.0, an internet-based self-management intervention for tinnitus that is currently available online. A mixed methods study of past, current, and new users of the intervention found that the intervention was acceptable to its target users. However, this study also highlighted that its implementation was limited by instances of poor usability, user engagement and adherence, and some components were less acceptable to users. Using evidence-based (i.e. systematic and literature reviews), theory-based (i.e. behavioural analysis and logic modelling), and person-based (i.e. the findings of the mixed methods study) approaches, the Tinnitus E-Programme 2.0 was developed. This new intervention was further evaluated using think aloud interviews with people with tinnitus. The findings of this study revealed that the Tinnitus E-Programme 2.0 was acceptable to its target users and some of the implementation issues identified in the Tinnitus E-Programme 1.0 had been resolved.

The two primary studies in this research identified potential mechanisms of impact by which the Tinnitus E-Programme 2.0 exerts its effect, contextual factors that may impede or strengthen its delivery and functioning, and outcomes of the intervention. Several cognitive (e.g. illness beliefs) and behavioural factors (e.g. practicing relaxation), and behavioural determinants (e.g. motivation to practice relaxation) were identified by users to explain how the changes in intervention outcomes may occur. This research also highlighted how users' pre-existing beliefs regarding tinnitus and self-management, their perceptions of relevance, and the nature of tinnitus can influence user's engagement with the Tinnitus E-Programme 2.0. These contextual

factors should be taken into account when designing, evaluating, and implementing internet-based interventions for tinnitus.

Intervention development and evaluation is an iterative and time-consuming process. This research has highlighted the need for additional development work that will introduce and evaluate additional content (e.g. lifestyle advice and support) and design features (e.g. additional health professional support or guidance) to the Tinnitus E-Programme 2.0, thus potentially maximising the intervention's outcomes. Development work should also consider how future iterations of the Tinnitus E-Programme 2.0 can fit into current service models for tinnitus to facilitate the intervention's adoption into routine practice. Future evaluation work is needed to test the Tinnitus E-Programme 2.0's mechanisms of impact and contextual factors and pilot the procedures for a randomised controlled trial. This work should inform the design of a high quality RCT that will assess the efficacy of the intervention. Better methods for reporting self-help intervention techniques, tools for guiding the development of self-help interventions, and an improved theoretical understanding of tinnitus distress is needed for improving the development of self-help interventions for tinnitus.

CHAPTER 9. APPENDICES

9.1. APPENDIX 1: SCREENSHOTS OF TINNITUS E-PROGRAMME COURSE MATERIALS PAGE

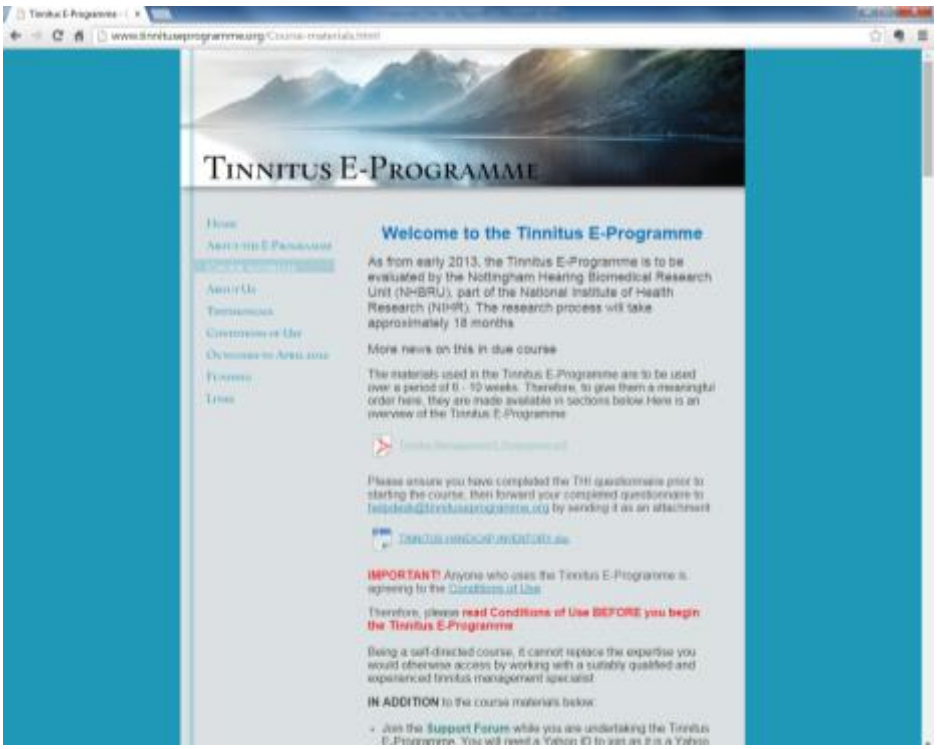

Figure 9.1 Screenshot of Tinnitus E-Programme 1.0 course materials page (1 of 2)

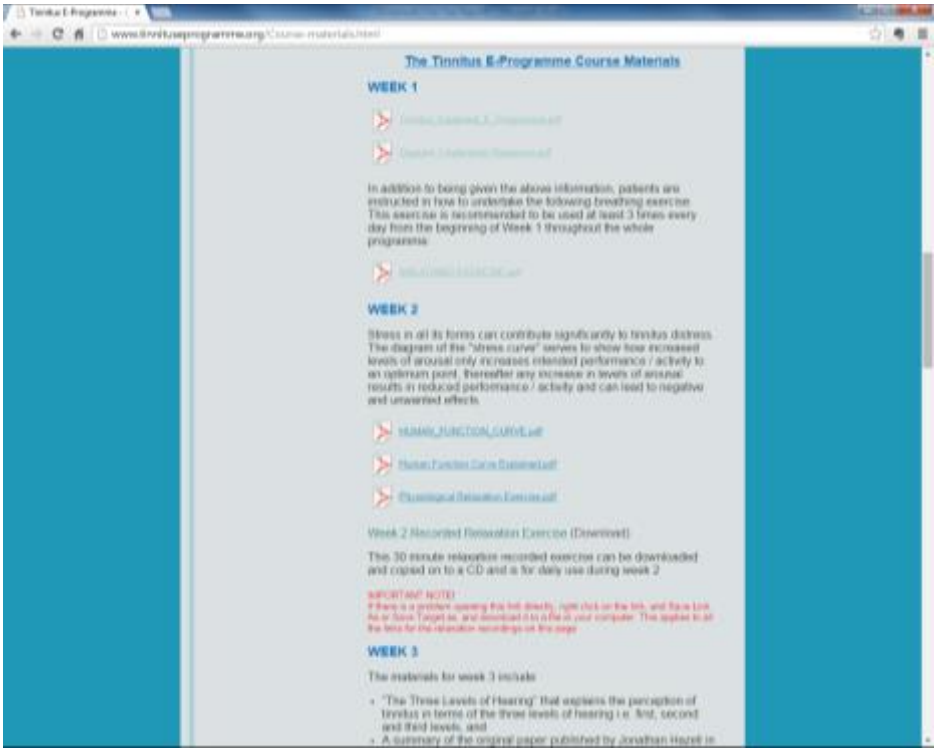

Figure 9.2 Screenshot of Tinnitus E-Programme 1.0 course materials page (2 of 2)

9.2. APPENDIX 2: CONTENT AND STRUCTURE OF THE TINNITUS E-PROGRAMME

Table 9.1 Intervention content across the 10-week Tinnitus E-Programme 1.0

	Intervention content
Week 1	• Completion and self-scoring of Tinnitus Handicap Inventory (THI; pdf questionnaire) • Mechanisms of tinnitus (pdf information) • Three main aspects to the effect management of tinnitus (written information) • Mind calming breathing exercise (pdf instructions) • Prompt users to join and participate in online support group (webpage) • Goal setting: Practice the mind calming breathing exercise at least 3 times a day throughout the 10-week course (webpage)
Week 2	• Effects of stress and how to manage it (pdf information) • Relationship between human performance and physiological arousal • Physiological relaxation exercise (pdf instructions) • Guided Relaxation 1 (MP3 audio) • Goal Setting: Practice 'Guided Relaxation 1' for 30 minutes every day during week 2 (webpage)
Week 3	• 'Three Levels of Hearing' and its relationship to tinnitus (pdf information) • Significance of Sound in relation to our behaviour towards tinnitus (pdf information) • Role of attention-focus and stress that relates to tinnitus distress (pdf information) • Guided Relaxation 2 (MP3 audio) • Goal Setting: Practice 'Guided Relaxation 2' for 30 minutes every day during week 3 (webpage)
Week 4	• Negative thinking and how it promotes intrusive distressing tinnitus (pdf information) • How to identify negative thoughts, challenge those thoughts through looking at the evidence for and against them and change negative thought into positive thought (pdf information) • Guided Relaxation 3 (MP3 audio) • Goal Setting: Practice 'Guided Relaxation 3' for 30 minutes every day during week 4 (webpage)
Week 5	• Behavioural techniques on how to manage tinnitus (British Tinnitus Association pdf information) • Guided Relaxation 4 (MP3 audio) • Goal Setting: Practice 'Guided Relaxation 4' for 30 minutes every day during week 5 (webpage)
Week 6	• Prompt users to review written information materials from week 1-5 (webpage) • Goal Setting: Continue practicing the mind-calming breathing exercise for a minimum of 3 times each day and practicing relaxation for 30 minutes (by choosing one of the 30 minute recordings from weeks 2-5) each day (webpage)
Week 7-10 (maintenance period)	• Continue Goal Setting as per week 6 (webpage) • Complete and self-score the THI at the end of Week 10 (pdf questionnaire)

9.3. APPENDIX 3: EXAMPLE SEARCH STRATEGY FROM EMBASE DATABASE

1. tinnitus.mp.
2. self-help.mp
3. self-manag*.mp.
4. self-care.mp.
5. self-treatment.mp.
6. self-therapy.mp.
7. self-direct*.mp.
8. self-act*.mp.
9. self-admin*.mp.
10. unguid*.mp.
11. self-guid*.mp.
12. bibliotherapy.mp.
13. internet.mp.
14. online.mp.
15. computer.mp.
16. web.mp.
17. "minimal contact".mp.
18. "short-term therapy".mp.
19. training.mp.
20. education.mp.
21. 2 or 3 or 4 or 5 or 6 or 7 or 8 or 9 or 10 or 11 or 12 or 13 or 14 or 15 or 16 or 17 or 18 or 19 or 20
22. 1 and 21
23. limit 22 to (english language and humans

9.4. APPENDIX 4: ONLINE SURVEY FOR STUDY 1

Questions are consecutive, unless a different next question is specified in the brackets (e.g. [GO TO Q7]). Questions marked with an asterisk (*) are mandatory

TELL US ABOUT YOURSELF

1. Which of the following describes how you think of yourself?*

- Male
- Female
- In another way (please say)

2. What is your age?*

- 18-24
- 25-34
- 35-44
- 45-54
- 55-64
- 65-74
- 75+

3. Which country do you live in?*

Drop-down box of countries

4. Is English your first language?*

- Yes
- No

5. Do you have tinnitus?*

- Yes [GO TO Q8]
- No, but I did have tinnitus previously [GO TO Q6]
- No, I have never had tinnitus [GO TO Q7]

6. Did you have tinnitus when you first visited the Tinnitus E-Programme website?*

- Yes [GO TO Q8]
- No [GO TO Q7]

7. What were your reasons for visiting the website?

Comments box [GO TO Q10]

8. Approximately how long is it since you first had tinnitus?*

- Less than 6 months
- 6 months - 1 year
- 2-5 years
- 6-9 years
- 10+ years

9. Which of the following ways have you used to help you to manage your tinnitus?*

You may be using these ways currently or have tried them previously but are no longer using them. Please select all that apply:

- Seeking out information about tinnitus:
  - online,
  - from books
  - from other people with tinnitus
  - from health professionals
- Sound therapy (e.g. hearing aids, sound therapy system, combination devices, noise generators)
- Relaxation
- Counselling or other psychological therapy (e.g. cognitive behavioural therapy)
- Tinnitus Retraining Therapy
- Medication (e.g. sleeping tablets, antidepressants)
- Taking part in **face-to-face** tinnitus support groups
- Taking part in **online** tinnitus support groups
- Contacting a charity or non-profit organisation (e.g. British Tinnitus Association, American Tinnitus Association)
- Other (please say)

WHAT ARE YOUR EXPERIENCES OF USING THE TINNITUS E-PROGRAMME WEBSITE?

10. How did you find out about the website?*

Select one only:

- Internet search engine (e.g. Google, bing)
- Health professional
- Word of mouth (e.g. someone with tinnitus)
- Researcher from NIHR Nottingham Hearing Biomedical Research Unit
- Other (please say)

11. Did you use the Tinnitus E-Programme?*

- Yes, all of it [GO TO Q12]
- Yes, some of it [GO TO Q12]
- No [GO TO Q13]

12. Why did you use the programme?

Comments box [GO TO Q14 if person with tinnitus OR Q17 if person without tinnitus]

13. Why did you not use the programme?

Comments box [GO TO Q37]

14. How do you use the programme now?*

Select which option best describes you:

- I have not used it since the first time I used it [GO TO Q15 then Q16]
- I still use at least some of the programme **regularly** [GO TO Q15 then Q18]
- I still use at least some of the programme **occasionally** [GO TO Q15 then Q18]

15. When was the last time you used any part of the programme?

- In the last 6 months
- 7 months - 1 year ago
- More than 1 year ago

16. Do you think you will use the programme again in the future?*

- Yes
- No [GO TO Q18]

[If person without tinnitus]

17. How did you use the programme?

Comments box [GO TO Q44]

Please click on the response that best describes you:	Strongly Agree	Agree	Disagree	Strongly Disagree
18. The website was easy to use*				
19. The website was visually attractive *				
20. The programme was a trustworthy source of support for tinnitus*				
21. It was clear from the website which tasks I had to complete*				
22. It was clear how much of my time I needed to spend on the programme*				
23. The amount of time I needed to spend on the programme was achievable*				
24. The order in which I needed to complete the tasks was clear*				

WHAT ARE YOUR EXPERIENCES OF USING THE INFORMATION LEAFLETS?
This section will ask about the **information leaflets** used in the programme.

[If used 'some of the programme']

25. Did you read the information leaflets?*

- Yes, all weeks [GO TO Q26]
- Yes, but only some of the leaflets [GO TO Q26]
- No, I did not read any of the information leaflets [GO TO Q30]
- Cannot remember [GO TO Q30]

Please click on the response that best describes you:	Strongly Agree	Agree	Disagree	Strongly Disagree	Did not use
26. The information leaflets were easy to understand*					
27. The information leaflets were relevant to me*					
28. The information leaflets were helpful*					

29. Any other comments?
Comments box

WHAT ARE YOUR EXPERIENCES OF USING THE RELAXATION EXERCISES?
This section will ask about the **relaxation exercises** used in the programme.

[If used 'some of the programme']

30. Did you do any of the relaxation exercises?*

- Yes, all weeks [GO TO Q32]
- Yes, but only some of the exercises [GO TO Q32]
- No, I did not do any of the relaxation exercises [GO TO Q34]
- Cannot remember [GO TO Q34]

31. The recommendation is to practice the **Week 1 mind calming breathing exercise at least three times every day** and complete a **Week 2-5 30 minute recorded relaxation exercise every day** throughout the programme.

Do you feel this is achievable?*

- Yes
- No

32. The relaxation exercises were helpful*

Please click on the response that best describes you:

- Strongly Agree
- Agree
- Disagree
- Strongly Disagree
- Did not use

33. Any other comments?
Comments box

WHAT ARE YOUR EXPERIENCES OF USING THE TINNITUS HANDICAP INVENTORY?
This section will ask about the **Tinnitus Handicap Inventory**, a questionnaire used in the programme to find out what kind of problems tinnitus might be giving you.

[If used 'some of the programme']

34. Did you complete the Tinnitus Handicap Inventory?*

- Yes, at the beginning of the programme [GO TO Q35]
- Yes, at the end of the programme [GO TO Q35]
- Yes, at the beginning AND end of the programme [GO TO Q35]
- No, I did not complete the Tinnitus Handicap Inventory [GO TO Q37]
- Cannot remember [GO TO Q37]

35. The Tinnitus Handicap Inventory was helpful*

Please click on the response that best describes you:

- Strongly Agree
- Agree
- Disagree
- Strongly Disagree
- Did not use

36. Any other comments?
Comments box

WHAT ARE YOUR EXPERIENCES OF USING THE YAHOO! SUPPORT FORUM?
This section will ask about the **Yahoo! Support Forum**.

37. Did you join the Yahoo! Support Forum?*

- Yes [GO TO Q38]
- No [GO TO Q43]
- Cannot remember [GO TO Q44]

38. Did you read the posts of others?*

- Yes
- No
- Cannot remember

39. Did you post anything yourself?*

- Yes
- No
- Cannot remember

40. How do you use the forum now?*

- I do not use it anymore
- I use it **occasionally**
- I use it **regularly**

41. The forum was helpful*

Please click on the response that best describes you:

- Strongly Agree
- Agree
- Disagree
- Strongly Disagree

42. Any other comments?
Comments box [Users of the programme GO TO Q44; Users of the forum only GO TO Q47]

43. Why did you not to join the forum?
Comments box [GO TO Q44]

WHAT EFFECT HAS THE TINNITUS E-PROGRAMME HAD ON YOU? This section will help us to understand the effect of the Tinnitus E-Programme on you. This includes the Yahoo! Support forum, if you used it.
44. Did the programme help you?* • Yes [GO TO Q45] • No [GO TO Q46]
45. Please tell us how the programme helped you? Comments box [GO TO Q50]
46. Please tell us why the programme did not help you? Comments box [GO TO Q50]
WHAT EFFECT HAS THE YAHOO! SUPPORT FORUM HAD ON YOU? This section will help us to understand the effect of the Yahoo! Support Forum on you.
47. Did the forum help you?* • Yes [GO TO Q48] • No [GO TO Q49]
48. Please tell us how the forum helped you? Comments box
49. Please tell us why the forum did not help you? Comments box
FINAL
50. Any other comments? Comments box

This appendix is taken from Greenwell, Sereda, Coulson, and Hoare (2016).

9.5. APPENDIX 5: INTERVIEW GUIDE FOR STUDY 2

1. What were your initial impressions of the Tinnitus E-programme website?
2. What was your understanding of what would be expected of you throughout the programme?
3. Thinking back to before you started the programme. What did you personally hope to get out of it?
4. Can you talk me through how you used the programme across the 6 weeks?
5. Can you tell me about your experiences of using the information resources/relaxation exercises/Tinnitus Handicap Inventory/online discussion forum?
6. What did you like/dislike about the programme? Why?
7. Which components of the programme were the most helpful? Why?
8. Were there any components of the programme which you found were not helpful? Why?
9. In your opinion, has participating in the programme made any difference to how you manage your tinnitus? If so, how?
10. Do you think you will continue to use any other aspects of the programme after the 10 weeks? Which parts? If not, why?
11. In your opinion, how do you think the programme could be improved for future users?

This appendix is taken from Greenwell, Sereda, Coulson, and Hoare (2016).

9.6. APPENDIX 6: TRANSCRIPTION KEY

. . .	Transcription text removed by the author
[tinnitus]	Additional text added by the author to clarify meaning
(I hope!)	As written by participant
[sic]	Transcribed exactly as participant wrote or spoke

9.7. APPENDIX 7: SCREENSHOTS OF TINNITUS E-PROGRAMME 2.0

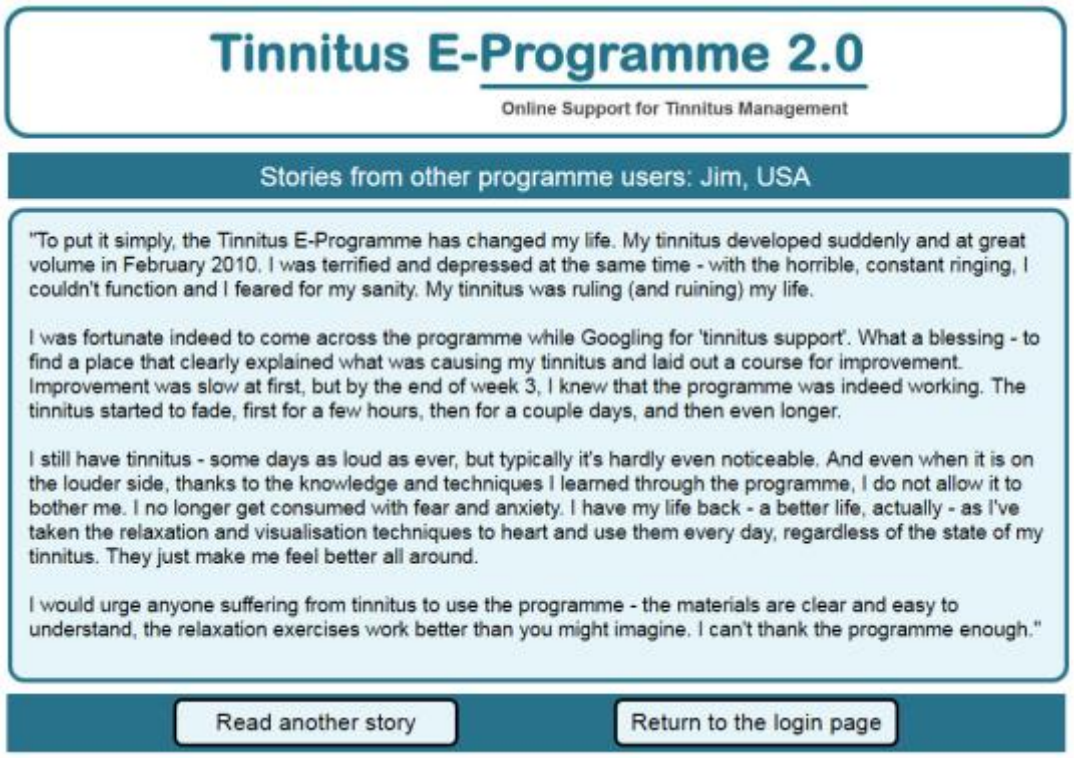

Figure 9.3 Screenshot of example user testimonial



Figure 9.4 Screenshot of aims of the Tinnitus E-Programme 2.0 page

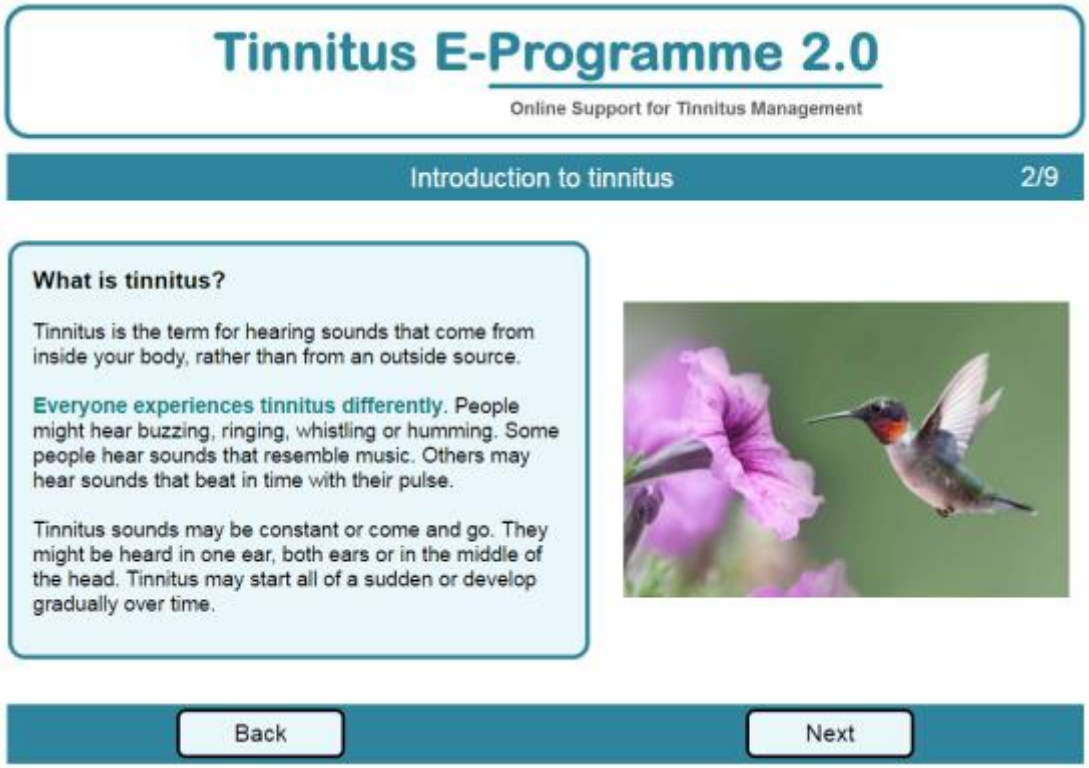

Figure 9.5 Screenshot of example page from the 'introduction to tinnitus' module

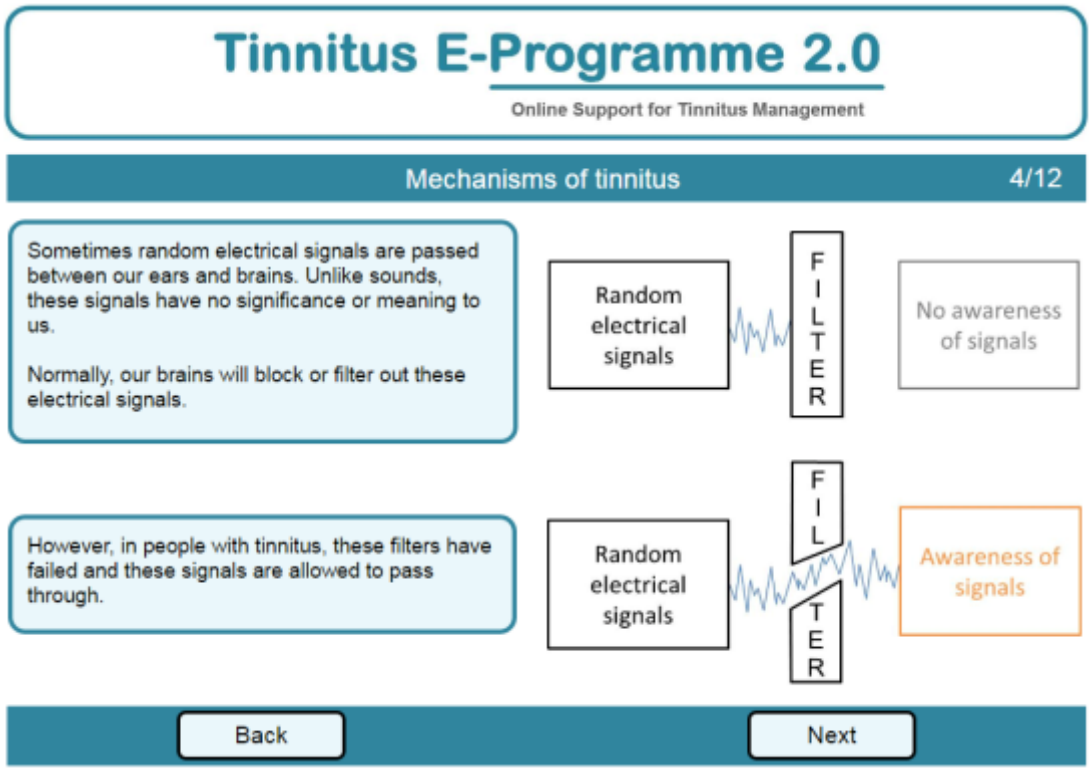

Figure 9.6 Screenshot of example page from the 'mechanisms of tinnitus' module

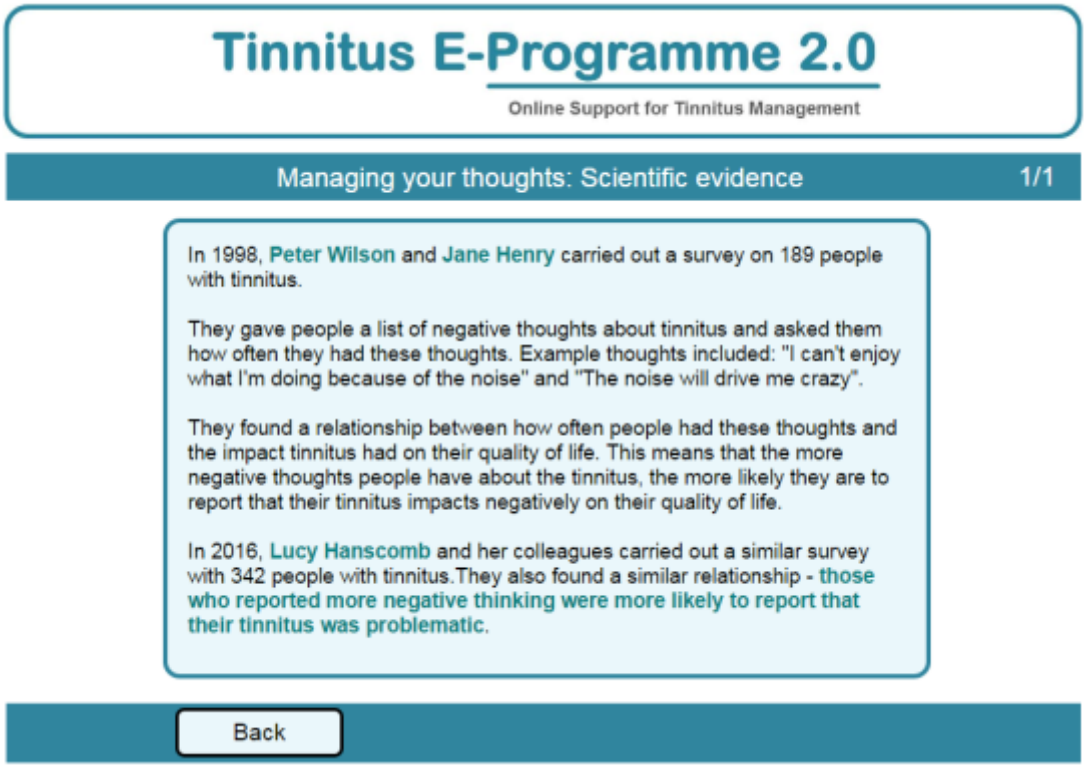

Figure 9.7 Screenshot of example scientific evidence page

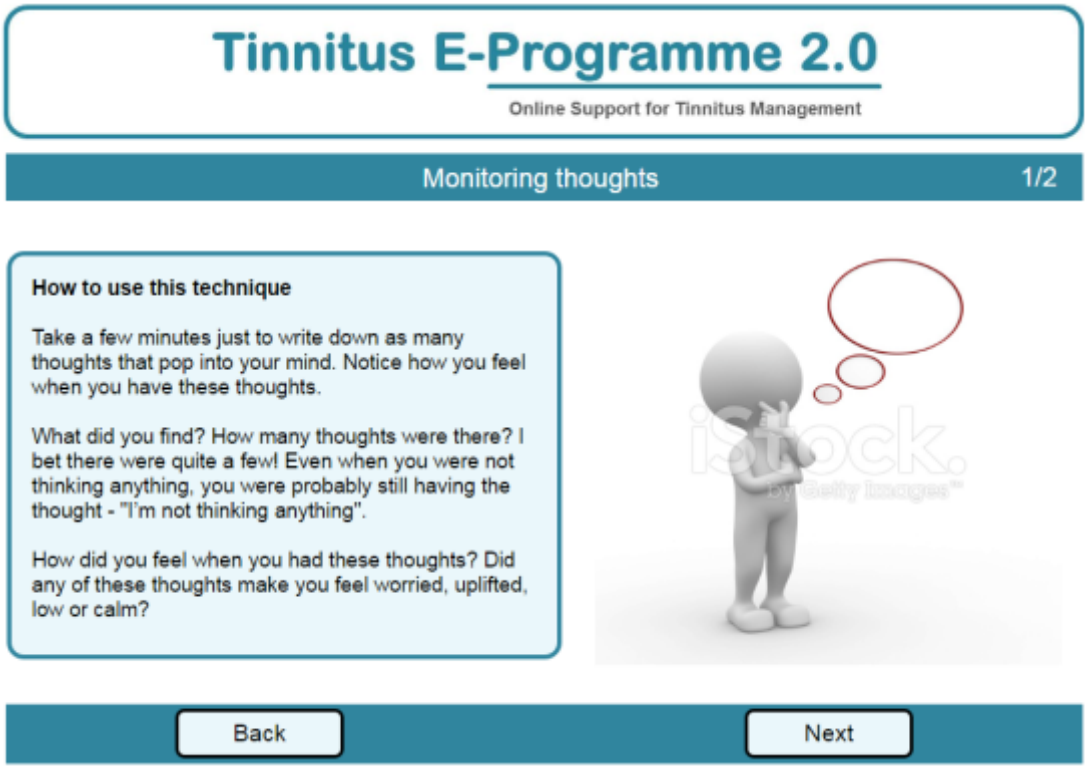

Figure 9.8 Screenshot of monitoring thoughts technique page from managing your thoughts module

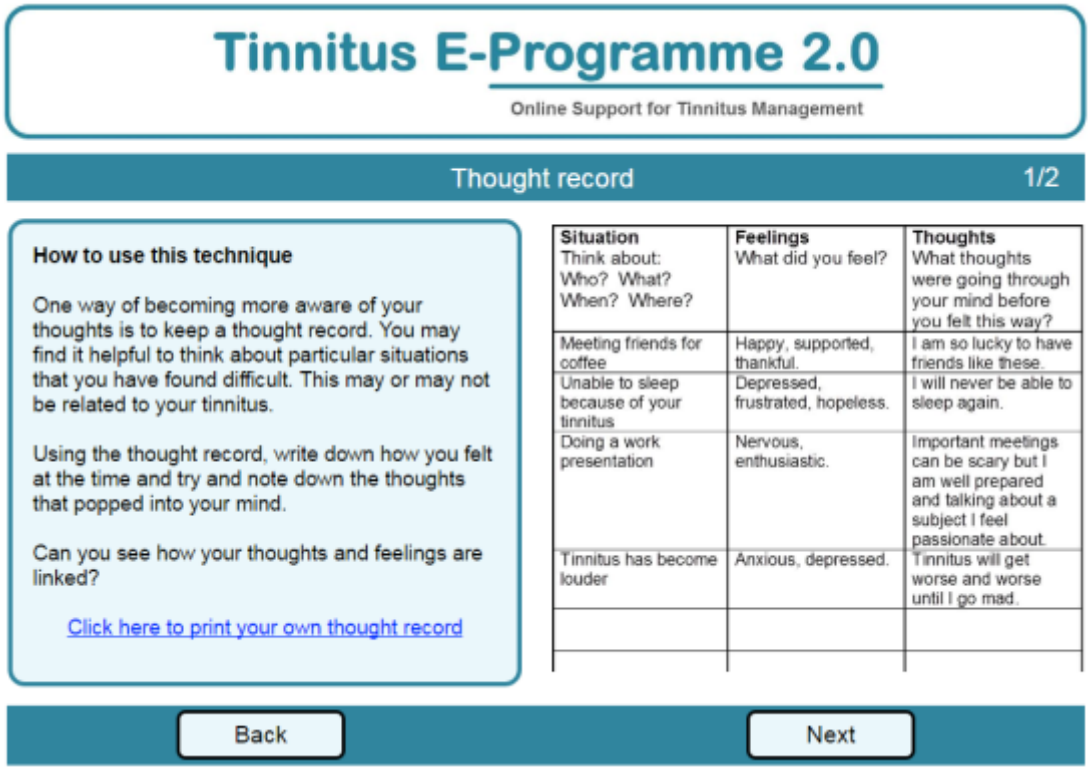

Figure 9.9 Screenshot of the thought record technique page from managing your thoughts module

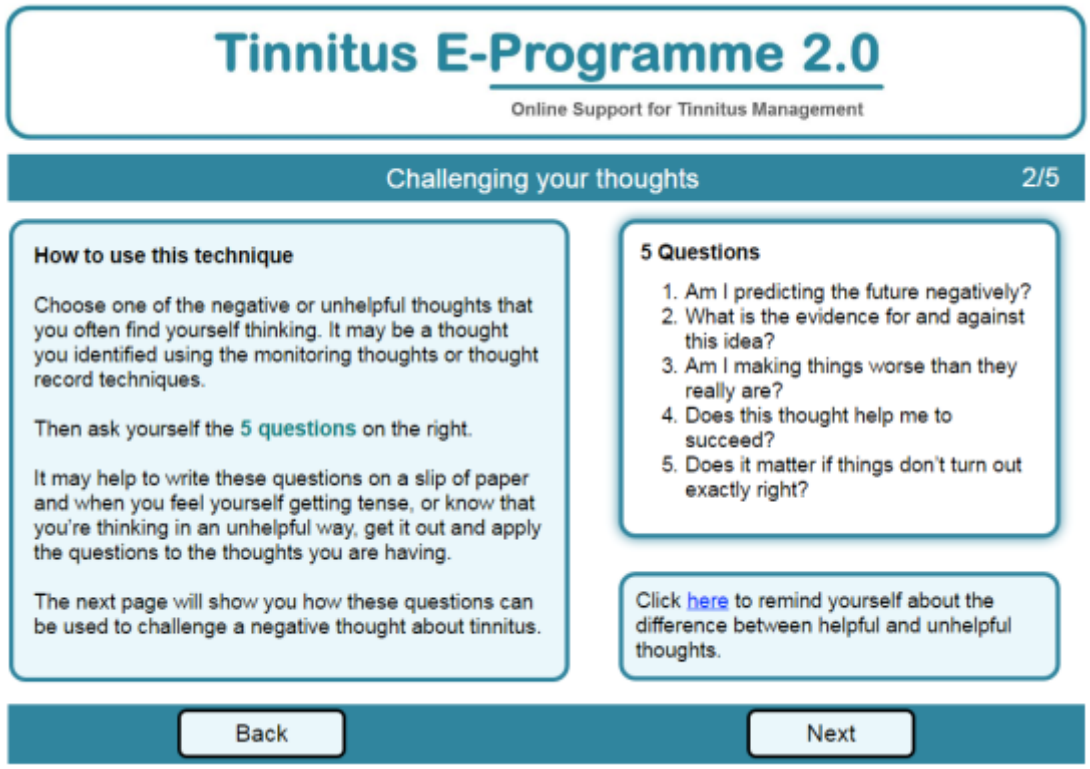

Figure 9.10 Screenshot of challenging your thoughts technique page from managing your thoughts module



Figure 9.11 Screenshot of letting your thoughts go technique page from managing your thoughts module

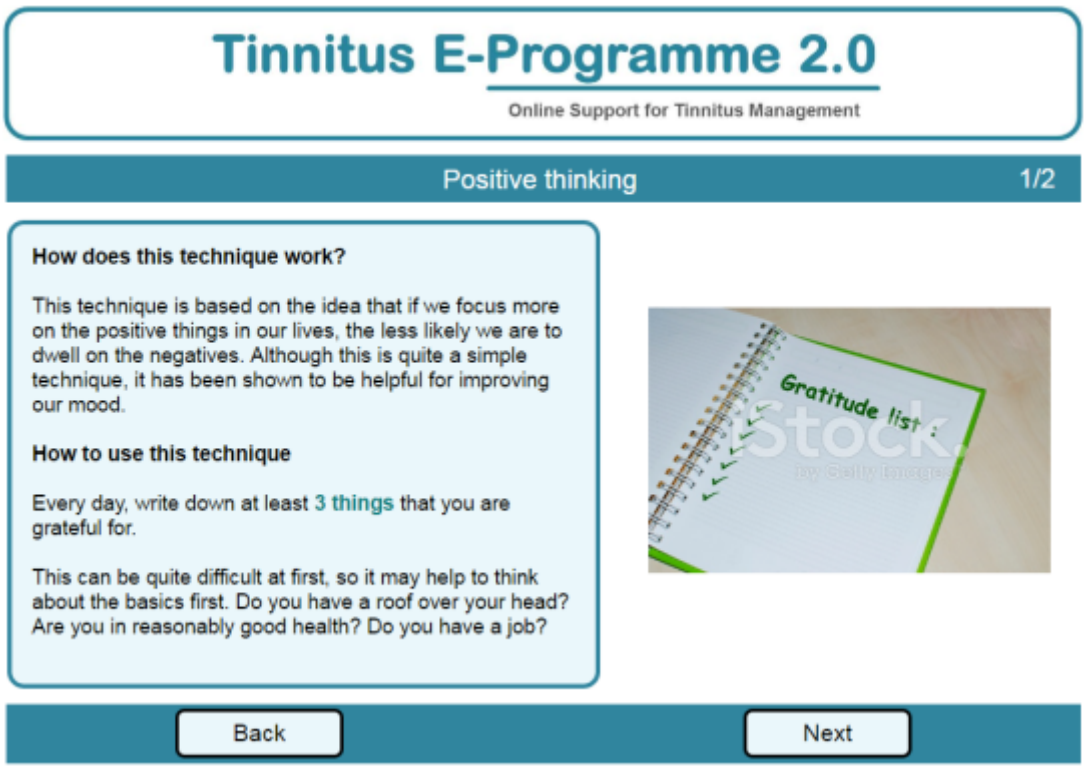

Figure 9.12 Screenshot of gratitude diaries technique page from managing your thoughts module

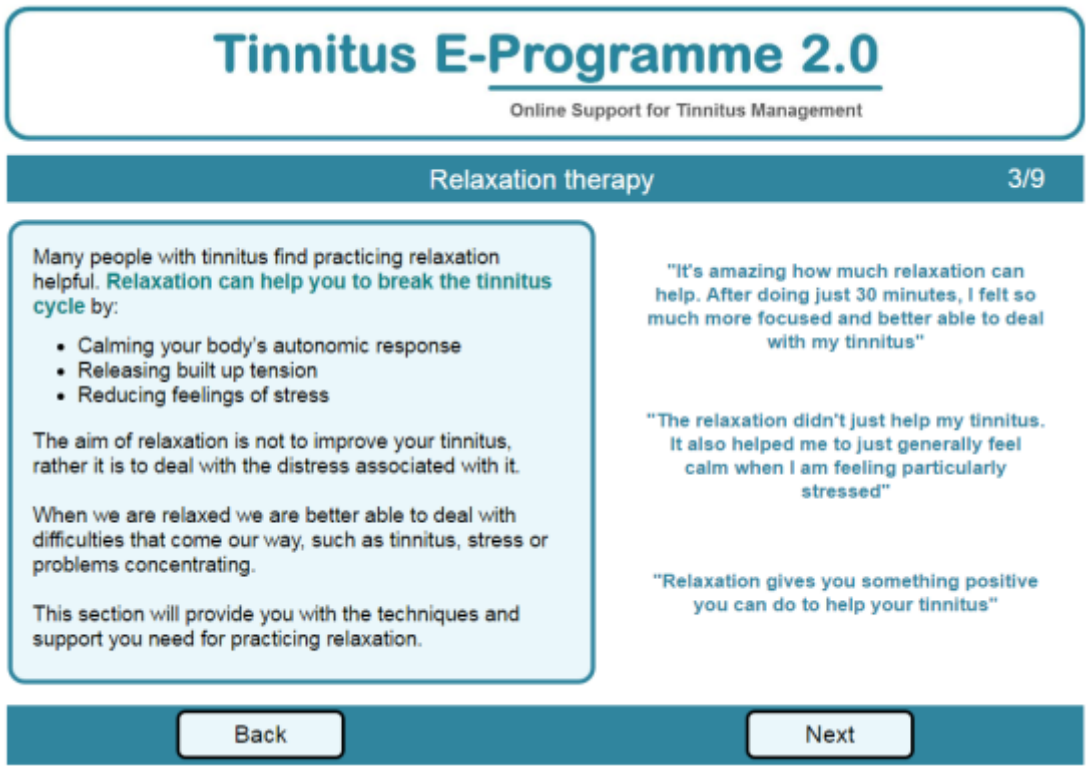

Figure 9.13 Screenshot of page from relaxation therapy module with user quotes

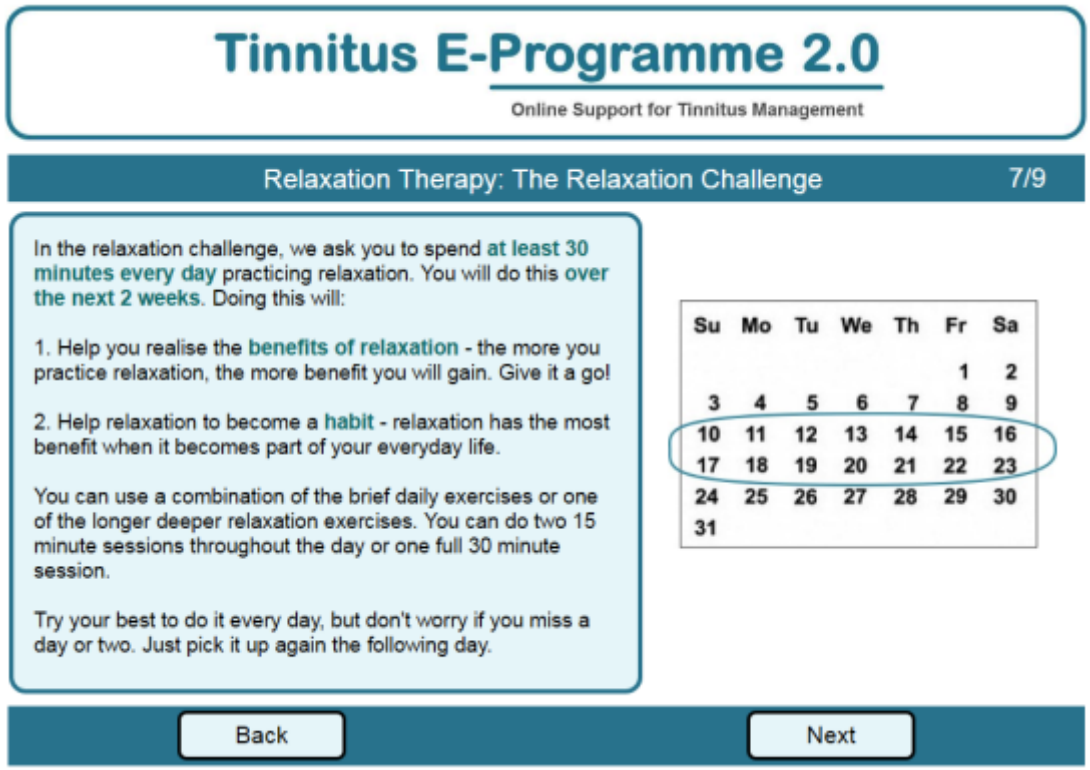

Figure 9.14 Screenshot of relaxation challenge (goal setting) page

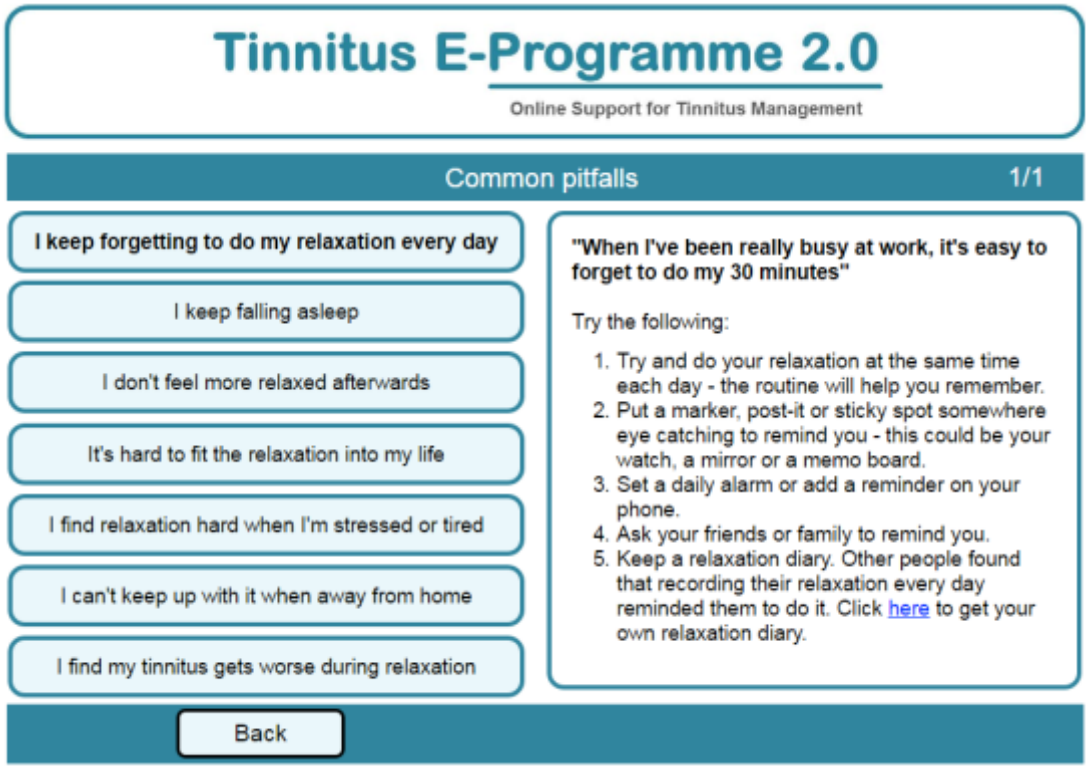

Figure 9.15 Screenshot of common problems when trying to meet daily relaxation goals and advice on how to overcome these problems

9.8. APPENDIX 8: THINK ALOUD TOPIC GUIDE

Prompts used throughout the think aloud interview:

- What are you thinking about now?
- How are you deciding where to go?
- What do you think of the information in this section?
- What are your thoughts about this page?
- Why did you choose to click on that?
- Can you tell me more about that?
- How helpful do you think this technique will be?

Questions asked during semi-structured interview:

- How easy to use was the programme?
- What did you like about the Tinnitus E-Programme? Why?
- What did you dislike about the Tinnitus E-Programme? Why?
- When do you think this programme would be helpful?
- When do you think that using this programme would not be helpful?
- How do you think the programme could be improved for future users?

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