Development of an evidence-based measure of concentration for use in clinical trials of sound-based interventions for tinnitus in adults

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ABSTRACT

Tinnitus is a common auditory percept that is typically described as a ringing, hissing, or buzzing sound in the absence of a corresponding external acoustic stimulus. It becomes Tinnitus Disorder when associated with emotional distress, cognitive dysfunction, and/or autonomic arousal, leading to behavioural changes and functional disability. Various treatment approaches to tinnitus are in use and under development, however trials design and outcomes assessment has historically been very varied. Such a lack of standardisation in outcome assessment and reporting across clinical trials results in heterogeneity of outcome selection and reporting, impeding cross-trial comparability and evidence synthesis, impacting reliable evaluation of treatment efficacy. Standardisation in tinnitus trials is therefore desirable. A Core Outcome Set (COS) is a consensus-derived the minimum set of outcomes or domains that should be measured and reported in all clinical trials of interventions for a specific condition which ensure results of trials can be easily compared, contrasted, and combined when needed. The Core Outcome Measures in Tinnitus (COMiT) initiative recommended a COS with of five outcome domains when designing a clinical trial to assess the efficacy of sound-based interventions. These core outcomes are 'ability to ignore', 'concentration', 'quality of sleep', 'sense of control', and 'tinnitus intrusiveness'. This PhD focused on 'concentration' as the construct of interest because the definition had the highest consensus from the COMiT'ID project. The agreed upon definition of concentration comprised of three subdomains: sustained attention, control attention and effortfulness.

The first study presents a literature search that was conducted to identify existing measures of concentration that might be used in clinical trials of sound-based interventions of tinnitus. From this, 13 instruments for concentration were identified for further evaluation.

The second study aimed to understand from tinnitus experts who have experience in clinical trials what aspects of feasibility influence decisions when selecting a measurement instrument for a clinical trial. This study was carried out at the 12th Tinnitus Research Initiatives (TRI) conference in Taipei. I found that cost and duration of the measure were

crucial factors influencing selection. Of the 13 instruments identified in the literature search, only two were self-report and free of cost measures. These were the PROMIS Applied Cognition-Abilities Subset and the Dundee Stress State Questionnaire (DSSQ).

The third study involves a workshop to assess the content validity of the two instruments. The workshop was conducted in person with cognitive researchers and tinnitus patients. Based on the COSMIN guidelines, neither measure was assessed as overall relevant, comprehensive, and comprehensible enough to fulfil the purpose of measuring concentration for adults with tinnitus in clinical trials concentration difficulty in tinnitus trials. Therefore, a new evidence-based measure needed to be developed. The fourth study presents a qualitative online survey conducted to better understand when and how tinnitus impacts concentration, to inform the development of items for a new questionnaire. Eleven situations were identified overall through qualitative analysis, which varied by subdomains.

The fifth study involved development of the Tinnitus Concentration Questionnaire (TiCQ). A novel individualised approach was used based to ensure that the instrument would be relevant, meaningful, and applicable across a diverse adult population with tinnitus. A pilot questionnaire went through six iterations involving a readability analysis to ensure the questionnaire was of an appropriate reading level, and cognitive interviews with members of the public who had tinnitus to determine whether it was appropriate for the wider tinnitus population. Modifications were applied to finalise development of the questionnaire.

Future work should validate the instrument and investigate its psychometric properties before recommending the TiCQ for use in clinical trials, to ensure its reliability, validity, and responsiveness to measuring treatment-related change.

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PUBLICATIONS

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Pearson SE, Caimino C, **Shabbir M** and Baguley DM (2021). The impact of chemotherapy-induced inner ear damage on quality of life in cancer survivors: a qualitative study. *Journal of Cancer Survivorship*, 1-12.

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DECLARATION

I declare 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.

24/10/2025

Maryam Shabbir Date

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LIST OF ABBREVIATIONS AND DEFINITIONS

ACR	American College of Rheumatology
AMA	American Medical Association
ANT	Amsterdam Neuropsychological Tasks
ARI	Automated Readability Index
BRC	Nottingham Biomedical Research Centre
BRIEF-A	Behaviour Rating Inventory of Executive Function Adult Version
BTA	British Tinnitus Association
CANTAB	Cambridge Neuropsychological Test Automated Battery
CBT	Cognitive Behavioural Therapy
CFQ	Cognitive Failures Questionnaire
COMET	Core Outcome Measures in Effectiveness Trials
COMiT	Core Outcome Measures in Tinnitus
COMiT'ID	Core Outcome Measures in Tinnitus International Delphi
COS	Core Outcome Set
COSMIN	Consensus-based Standards for the selection of health Measurement Instruments
CPT	Continuous Performance Test
CPT-IP	Continuous Performance Test-Identical Pairs Version
CROSS	Consensus-Based Checklist for Reporting of Survey Studies
DSSQ	Dundee Stress State Questionnaire
DVT	Digit Vigilance Test
EDI	Equity Diversity and Inclusion
EMA	European Medicines Agency
EULAR	European League Against Rheumatism
FDA	US Food and Drug Administration
FKGL	Flesch-Kincaid Grade Level
FRE	Flesch Reading Ease Formula
GRIPP2	Guidance for Reporting Involvement of Patients and Public v2
HOME	Harmonizing Outcome Measures for Eczema
ICC	Intraclass Correlation Coefficients
IMMPACT	Initiative on Methods, Measurement, and Pain Assessment in Clinical Trials
ISPOR	International Society for Pharmacoeconomics and Outcomes Research
IVA CPT	Integrated Visual and Auditory Continuous Performance Test
MOT	Motor Screening Task
MYMOP	Measure Yourself Medical Outcomes Profile
NIHR	National Institute for Health and Care Research
OMERACT	Outcome Measures in Rheumatology
OMI	Outcome Measurement Instrument

Outcome	Refers to “what” is being measured. Also referred to as a construct or domain.
PC-COS	Post-COVID Core Outcome Set
PoPPIE	People and Patient Participation, Involvement and Engagement
PPI	Patient and Public Involvement
PROM	Patient Reported Outcome Measure
PROMIS	Patient-Reported Outcomes Measurement Information System
PVT	Psychomotor Vigilance Task
REC	Research Ethics Committee
RTI	Reaction Time
rTMS	Repetitive Transcranial Magnetic Stimulation
RVP	Rapid Visual Information Processing
tACS	Transcranial Alternating Current Stimulation
tDCS	Transcranial Direct Current Stimulation
TEA	Test of Everyday Attention
THI	Tinnitus Handicap Inventory
TiCQ	Tinnitus Concentration Questionnaire
TINNET	TINnitus NETwork
TQ	Tinnitus Questionnaire
TRI	Tinnitus Research Initiative
TRQ	Tinnitus Reaction Questionnaire
VNS	Vagus Nerve Stimulation
VTS	Vienna Test System
WG	Working Group
WHO	World Health Organisation

1 Introduction And Review of the Literature

1.1 Tinnitus

Tinnitus is a common auditory percept that is typically described as a ringing, hissing, or buzzing sound in the ears or in the head in the absence of a corresponding external acoustic stimulus which becomes Tinnitus Disorder “when associated with emotional distress, cognitive dysfunction, and/or autonomic arousal, leading to behavioural changes and functional disability.” (De Ridder et al., 2021). The prevalence of tinnitus worldwide varies from 11.9-30.3% of the population when tinnitus is defined as ‘tinnitus lasting for more than 5 minutes at a time’ (McCormak et al., 2016). However, due to variances in the definition of tinnitus in prevalence studies, the prevalence rate has substantial variation.

Tinnitus can be subdivided into two categories; objective and subjective tinnitus (Lockwood, Salvi and Burkard, 2002; De Ridder et al., 2014; Haider, Paço and Hall, 2018). Objective tinnitus is when the percept is audible by others. It is far less common than subjective tinnitus, accounting for less than 1% of all cases (Haider, Paço and Hall, 2018). Objective tinnitus may have a vascular or muscular cause (Lockwood, Salvi and Burkard, 2002; Sismanis, 2003; Folmer, Martin and Shi 2004) originating in the ear, head, or neck. Pulsatile tinnitus is caused by vibrations from turbulent blood flow that reach the cochlear (Lockwood, Salvi and Burkard, 2002). If the pulsating is synchronous with the heartbeat, then the origin may be vascular. If the pulsating is asynchronous, it may be due to myoclonus of middle-ear or palatal muscles, therefore having a muscular cause (Lockwood, Salvi and Burkard, 2002; Baguley, McFerran and Hall, 2013). More commonly observed, subjective tinnitus, is when the percept is perceived only by the individual affected. It has been associated with various co-existing otological conditions (for example, Meniere’s disease and noise-induced hearing loss) and non-otological conditions (for example, neck trauma and sleep disorders) (Henry, Dennis and Schechter, 2005; Baguley, McFerran and Hall, 2013; Haider, Paço and Hall, 2018). However, in many cases, it has also been considered idiopathic. Subjective tinnitus is known to be a heterogenous condition whose perceptual characteristics and impacts can vary greatly from person to person (Hall et al., 2018; Cederroth et al., 2019).

Aetiology of tinnitus is complex and can be examined at many levels. Even though different mechanisms seem to be responsible for different aspects of the condition (De Ridder et al., 2014), the exact pathophysiological mechanisms leading to subjective tinnitus remain unknown. Therefore, rather than being examined on pathophysiological variability, tinnitus heterogeneity is examined in terms of phenotypical variability.

1.1.1 Patient-reported tinnitus complaints

Due to the personal and individualised nature of tinnitus experience, the range of tinnitus complaints is very broad (Hall et al., 2016). Some people experiencing tinnitus do not find it bothersome and therefore do not seek any medical help. However, for others, quality of life and everyday functioning can be impaired (Nondahl et al., 2007; Hall et al., 2018). These complaints or problems describe various aspects of tinnitus referred to as "domains".

A review conducted by Hall et al. (2018) identified 42 "discrete unidimensional patient-reported domains" classified into supra-level domains such as physical health, psychological health, health-related quality of life, and negative attributes of tinnitus sound. These category headings were based on the conceptual framework of quality of life measured by the World Health Organisation (WHO, 1994). Examples of these domains include sleep difficulties, loss of appetite, cognitive difficulties, frustration, suicidal thoughts, and negative impact on individual activities. The findings from this review demonstrate how broadly tinnitus impacts an individual. It is rather difficult to quantify the impact or severity of tinnitus. A shorter but similar list of problem domains was also found in a subsequent qualitative study conducted by Watts et al. (2018).

1.1.2 Treatment and management of tinnitus

The substantial heterogeneity of the tinnitus experience has impeded not only treatment, but basic science research in the field. Currently there is no known treatment that completely eliminates tinnitus, and interventions rely on managing the symptoms of tinnitus (Baguley, McFerran and Hall, 2013; Hall et al., 2018).

There are currently two main categories of tinnitus management used clinically; sound-based and psychology-based approaches (Tunkel et al., 2014; Fuller et al., 2017). Sound-

based approaches include electronic devices such as hearing aids that aim to increase audibility related to comorbid hearing loss that exacerbates the tinnitus, or electronic devices such as sound generators and mobile phone applications that produce therapeutic sounds to mask or distract from tinnitus (Hoare et al., 2011; Baguley, McFerren and Hall, 2013; Hoare et al, 2014). Psychology-based approaches can include counselling to help manage how tinnitus impacts their emotions and behaviour and to empower people through mindfulness practices or Cognitive Behavioural Therapy (CBT) (Thompson et al., 2017).

While there are no medications approved for tinnitus, off-label prescriptions of a wide variety of therapeutic drugs have been used to try relieving the condition (Elgoyhen and Langguth, 2010). Licensed medication is also commonly prescribed to alleviate common comorbidities associated with tinnitus such as anxiety, depression, and insomnia. Therefore, pharmacology or drug-based approaches are an established medical practice and may be considered as a third management option. Additionally, non-prescription food supplements such as Gingko biloba and zinc supplements are also used to treat tinnitus symptoms (Cima et al., 2020). However, a recent Cochrane review on Gingko biloba found no evidence of its effectiveness in treating the symptoms but potential harmful effects when used alongside other drugs (Sereda et al., 2022). Additionally, a review by Kim et al. (2021) found that zinc supplements were ineffective in tinnitus patients with normal zinc concentrations and only effective when there was a zinc deficiency.

In research settings, other treatment approaches such as electrical stimulation are being developed and tested. These treatments aim to improve tinnitus or its symptoms using electrical stimulation of the brain or other parts of the nervous system (Hoare et al., 2024). Examples include repetitive transcranial magnetic stimulation (rTMS), transcranial direct current stimulation (tDCS), transcranial alternating current stimulation (tACS) and vagus nerve stimulation (VNS) (Cederroth, 2019). However, currently, national standard intervention options offered to people with tinnitus seeking professional advice fundamentally rely upon psychological and sound-based approaches (Cima et al., 2019; Lewis et al., 2020). Each type of intervention discussed has a different therapeutic rationale, therefore for each type of intervention (sound-, psychology-, and drug-based), a different

set of outcome domains would likely be required to evaluate intervention efficacy (Hall et al., 2018).

1.2 What is a Core Outcome Set and why is one needed for tinnitus?

A Core Outcome Set (COS) is a consensus-derived the minimum set of outcomes or domains that should be measured and reported in all clinical trials of interventions for a specific condition (Clarke, 2007; Williamson et al., 2012; Schmitt et al., 2015). It could be suitable not only for clinical trials but also for national clinical audits and research in general. Once a COS has been developed, it is important to agree how these domains are defined and measured (Williamson et al., 2012).

Since tinnitus is a heterogenous condition, the perception and reaction towards one's tinnitus is also entirely subjective (McCombe et al., 2001). Although objective markers (e.g., electrophysiological or neuroimaging) for the presence or impact of tinnitus are under investigation (Norena et al., 1999; Zimmerman et al., 2018), currently there are no established objective measures (Langguth et al., 2007) or observable clinical signs of tinnitus. Thus, diagnostic assessment and evaluation of treatment-related outcomes rely on the person's appraisal of their severity and self-reports of their tinnitus-related complaints (Hall et al. 2018).

Before investigating the "how", that is, what is the most appropriate measurement instrument to be recommended as a gold standard, it is important to discuss "what" needs to be measured (Williamson et al., 2012). Given the wide range of patient-reported domains of tinnitus problems (Hall et al., 2018), different treatment approaches (sound-based, psychology-, and drug-based) focus on alleviating different tinnitus-related complaints. This makes it challenging to assess which domains are most relevant for assessment in a clinical trial (Baguley, McFerran, and Hall, 2013; Hall et al., 2018).

A COS for clinical trials of tinnitus could best be achieved through a predefined, multidisciplinary (including not only primary care professionals, but also patients), international, and methodologically rigorous and transparent approach (de Vet et al., 2011; Hall et al., 2015; Londero and Hall, 2017). The Core Outcome Measures in Effectiveness

Trials (COMET) initiative, based in the UK, brings together researchers from all over the world, that are interested in the development and application of COSs that are standardised and agreed upon (Williamson et al., 2012; Prinsen et al., 2014).

Applying a COS to clinical trials does not imply that the trial is limited to only using those outcomes; it suggests the minimum reporting standard that should always be used. Therefore, if required, other outcomes might be added to the research. The aim of reporting a COS is to ensure results of trials can be easily compared, contrasted, and combined when needed.

1.2.1 Examples of Core Outcome Set (COS) groups for other health conditions

While the COMiT initiative represents a crucial step forward for tinnitus, the application of Core Outcome Sets in other health conditions is also a growing field.

1.2.1.1 Outcome Measures in Rheumatology (OMERACT)

OMERACT is an independent initiative of international health professionals interested in outcome measures in Rheumatology, initiated in 1992 (Tugwell et al., 2007). It has been one of the most well-known outcome measure groups as they have produced their own handbook to provide guidelines for other outcome measure groups on how to follow the process for developing and measuring COS (Boers et al., 2014, Beaton et al., 2019). OMERACT's recommendations have been widely adopted in rheumatology trials and have influenced regulatory guidance, including European League Against Rheumatism (EULAR) and the American College of Rheumatology (ACR) recommendations.

1.2.1.2 Harmonizing Outcome Measures for Eczema (HOME)

HOME was founded in 2008 to bring together the Eczema research community to standardise outcome measures by recommending a COS to be included in all eczema clinical trials. They have also published a methodological framework to use when developing and implementing a COS (Schmitt et al., 2015). HOME was also endorsement by the Cochrane Skin Group and use in systematic reviews, as well as integration into EU-funded trials and NIHR-funded research which now list the COS and instruments recommended for use.

1.2.1.3 Initiative on Methods, Measurement, and Pain Assessment in Clinical Trials (IMMPACT)

IMMPACT aimed to develop consensus reviews and recommendations for improving the design, implementation, and interpretation of clinical trials of treatments for pain (Turk et al., 2003; Dworkin et al., 2005). Their focus has been on acute and chronic pain in both adults and children. IMMPACT recommendations and systematic reviews have been widely cited, and their influence is seen in the design of clinical trials, other types of clinical research and regulatory guidance from the US Food and Drug Administration (FDA) and European Medicines Agency (EMA).

1.2.1.4 Post-COVID Core Outcome Set (PC-COS)

PC-COS project was set up in 2021 by a group of international health professionals, researchers, and people with lived experience of Post-COVID Condition, in collaboration with WHO, to develop a COS that should be consistently measured in both research and clinical care for people living with Post-COVID Condition (also known as Long COVID). Two separate core outcome sets were developed; one for adults (Munblit et al., 2022; Gorst et al., 2023) and one for children and young people (Seylanova et al., 2024), to address the distinct impacts of the condition across age groups. Despite its recent origin, PC-COS has been referenced in WHO guidelines and is being used in multi-country longitudinal studies on Long COVID, suggesting strong early uptake, particularly in international and interdisciplinary research.

1.3 Outcome measures in tinnitus clinical trials: introducing the COMiT initiative

According to Clarke and Williamson (2016), the inconsistent use of outcome measures is one of the biggest barriers to comparing and consolidating the findings of existing literature in any field. Clinical trials conducted in adults with tinnitus have assessed a variety of domains using at least 24 different patient-reported instruments. These instruments span various subjective symptoms, as well as co-occurring complaints and treatment-related outcomes (Hall et al., 2016). This finding highlights the lack of consensus about how to evaluate how well a tinnitus treatment works to inform evidence-based clinical decisions on how best to treat patients with tinnitus.

Establishing a set of standards for domains in clinical trials of tinnitus would enhance tinnitus research by informing sample-size calculations, enabling meta-analyses, and facilitating the identification of tinnitus subtypes, ultimately leading to improved treatments. The aim is to ensure results of trials can be easily compared, contrasted, and combined when needed. Such a goal is important not only for tinnitus, but for evaluating treatment-related benefits in any health condition (Clarke, 2007; Prinsen et al., 2014; Schmitt et al., 2015; Williamson et al., 2012).

Based on this need, Hall et al. (2018) applied the consensus-based decision-making method advocated by COMET (Williamson et al., 2017) to evaluate which domains are critically important to measure in all clinical studies when evaluating the efficacy of different interventions for alleviating tinnitus under a European funded consortium, TINnitus NETwork (TINNET) (Kleinjung and Schlee, 2017). This consortium consisted of five working groups (WG) covering clinical, database, neuroimaging, genetics, and measurement outcomes (Haider, Paço and Hall, 2018). The Core Outcome Measure in Tinnitus initiative was part of WG5 which aimed to establish an international standard for outcome measurements in clinical trials of tinnitus inspired by the work of the COMET initiative (**Figure 1.1**). The roadmap reflects a two-stage process; Stage 1- identifying and agreeing on a COS and Stage 2- identifying and agreeing on how to measure those outcome domains.

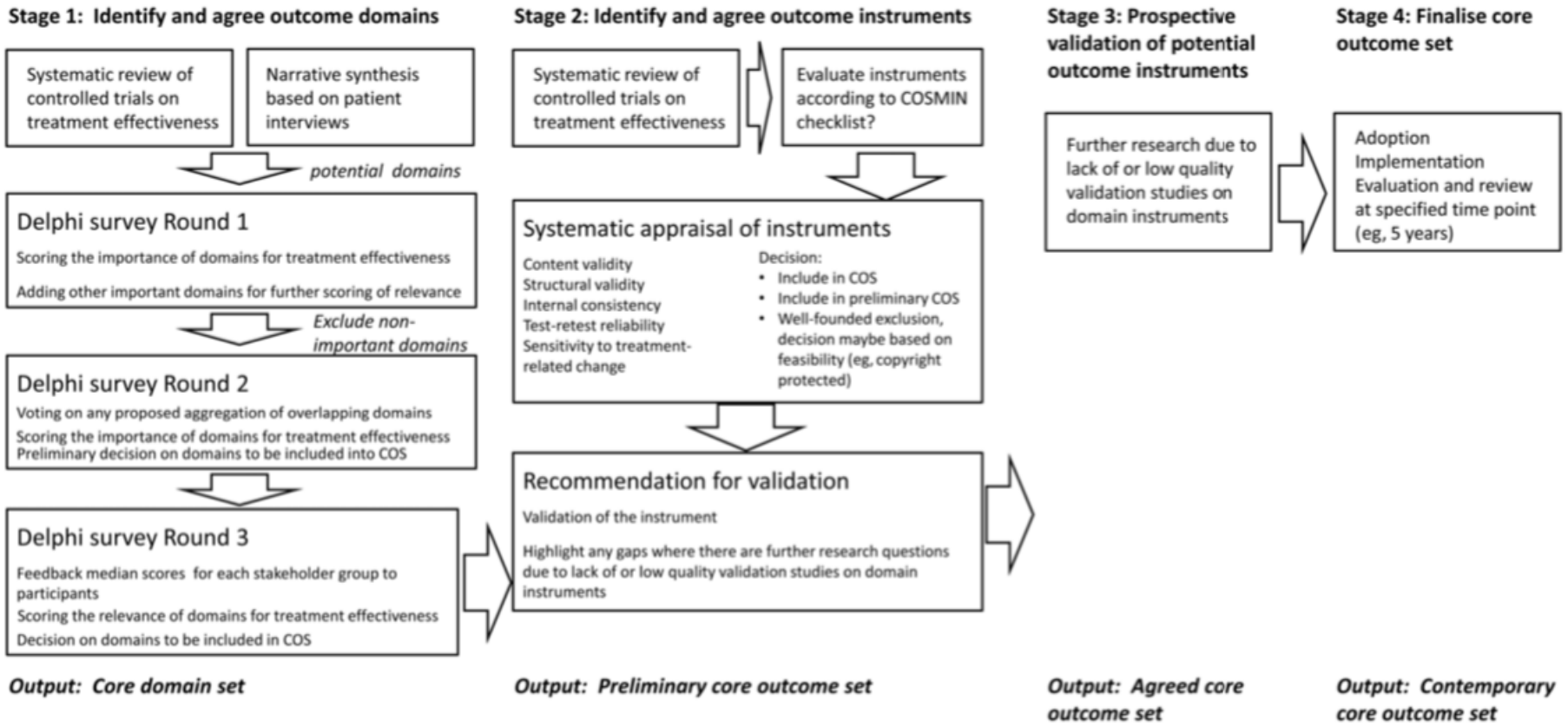

Figure 1.1 The proposed stepwise road map by the COMiT initiative for developing a COS for tinnitus (taken from Hall et al., 2015)

The Core Outcomes Measures in Tinnitus International Delphi (COMiT'ID) study used an online three-round Delphi method with separate surveys for the three intervention types (sound-based, psychology-based, and drug-based), followed by a face-to-face consensus meeting with engaged health-care users, health-care practitioners, clinical researchers, commercial representatives, and funders from across the world. This process led to three separate recommendations; a COS for each class of intervention (Hall et al., 2018; Hall et al., 2019). This provided a very important starting point for the standardisation of tinnitus research.

For sound-based interventions, the core outcome set included 'concentration', 'intrusiveness', 'ability to ignore', 'quality of sleep', and 'sense of control'. For psychology-based interventions, the core outcome set included 'intrusiveness', 'mood', 'acceptance of tinnitus', 'negative thoughts and beliefs', and 'sense of control'. For drug-based interventions only 'tinnitus intrusiveness' and 'tinnitus loudness' were included in the COS. As such, the domain Tinnitus intrusiveness was included in the COS for all three interventions. See **Figure 1.2** for the recommended COS for each intervention type.

Once the core outcome set (COS), i.e., *what* to measure is agreed, it is important to next agree *how* these domains should be measured (Williamson et al., 2012). A detailed definition of each outcome is a prerequisite for selecting appropriate measurement instruments (Prinsen et al., 2016). This definition should be clear and fully elaborated so that suitable measurement instruments can then be identified (Hibbert et al., 2020).

While COS have been established for tinnitus interventions trials there is no consensus on how they should be measured. Many multi-item questionnaires have been developed asking questions relevant to various tinnitus domains. However, the domains differ across existing questionnaires (Kuk et al., 1990; Newman et al., 1996; Meikle et al., 2012).

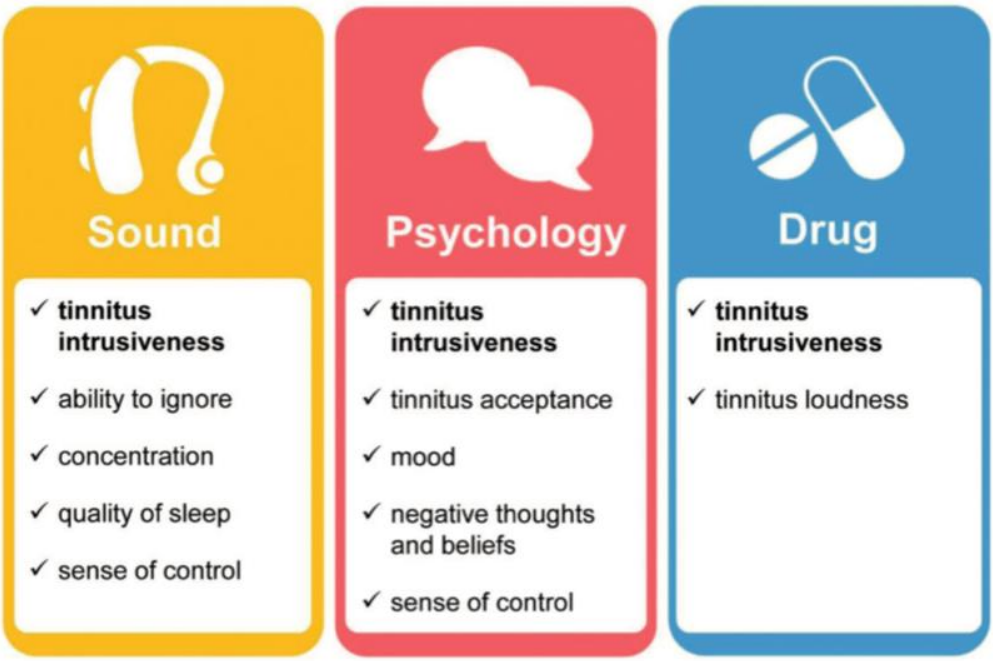

Figure 1.2 Graphic illustration of recommendations made by the COMiT'ID study for core outcome domain sets for each type of intervention available for chronic subjective tinnitus in adults taken from Hall et al., 2018

A systematic review by Hall et al. (2016) of the outcome domains and instruments used in clinical trials of tinnitus treatments identified 35 different outcome domains and 78 different primary outcome instruments in clinical trials for tinnitus. At that time, at least 29 different multi-item questionnaires existed that were being used to measure various domains of tinnitus-related complaints (Haider et al., 2016). However, which questionnaire(s) should be recommended for measuring treatment effects in clinical trials was unclear.

Langguth et al. (2007) recommended that there is a need for a single standardised questionnaire that has been validated in multiple languages and socioeconomic groups to measure treatment-related outcomes in all clinical trials for tinnitus. They recommended that either the Tinnitus Handicap Inventory (THI) (Newman et al., 1996), Tinnitus Handicap Questionnaire (THQ) (Kuk et al., 1990), Tinnitus Questionnaire (TQ) (Hallam et al., 1988) or the Tinnitus Reaction Questionnaire (TRQ) (Wilson et al., 1991) should be used as an

outcome assessment for therapeutic trials. The problem with the recommendation was that it was not based on a review of the psychometric properties of these instruments.

A review by Kamalski et al. (2010) assessed the psychometric properties of these recommended instruments and found that the statistical evidence was insufficient that they could sensitively measure treatment-related change. The recommendation from this review was that the validity, reliability, and responsiveness of each of these instruments should be further studied before drawing any final conclusions regarding the utility of these questionnaires in future clinical studies.

1.4 Theories of Concentration

Concentration refers to the ability to direct attention towards a specific task or stimuli. Multiple theoretical frameworks have been developed to conceptualise the mechanisms underpinning concentration. This section provides an overview of some of the key psychological theories of concentration, serving as a theoretical groundwork for understanding how attention is sustained, divided, and restored. These include control attention, sustained attention, attentional switching, the dual-task paradigm, resource theory, cognitive load theory, attention restoration theory, and flow theory.

1.4.1 Selective Attention

Selective attention refers to the ability to choose and focus on a specific task or stimulus while ignoring other stimuli or sources of information therefore being able to control your attention. It is often described as a filtering mechanism, such as being able to listen to one person in a crowded room while ignoring other conversations. Early models of selective attention, such as Broadbent's Filter Theory (1958), proposed that people can only process a limited amount of information at any given time, like a filter or a bottleneck, allowing selective processing based on physical characteristics of stimuli. Subsequent models, such as Treisman's Attenuation Theory (1960) and Deutsch and Deutsch's Late Selection Model (1963), refined these concepts by suggesting that unattended stimuli might still receive some level of semantic processing. Despite differences, these theories establish the critical role of selective attention to target relevant information and ignore distractions.

1.4.2 Sustained Attention

Sustained attention describes the ability to maintain focus on a task or stimulus for a prolonged period while resisting distractions and wandering thoughts. This form of attention is essential for tasks involving continuous monitoring, such as surveillance or reading a book for an extended period, without getting distracted. Research shows that sustained attention is resource-demanding, and performance often declines as time taken on a task increases. This phenomenon is known as vigilance decrement (Warm and Jerison, 1984). The decrement is often attributed to cognitive resource depletion or increased susceptibility to distraction over time (Parasuraman, Warm and Dember, 1987). Thus, sustained attention represents the endurance aspect of concentration.

1.4.3 Attentional Switching

Attentional switching refers to the ability to shift attention from one task or stimulus to another. This ability to switch attention is an essential aspect of cognitive flexibility, allowing disengagement from one activity and engagement with another, for example, stopping a video game to eat a meal. However, this switching typically incurs a temporary reduction in efficiency known as switch costs (Monsell, 2003). These costs reflect the cognitive demand of reorienting attention and reorganising mental resources in line with changing task requirements.

1.4.4 Dual-Task Paradigm

The dual-task paradigm examines cognitive performance under conditions requiring paying attention to two tasks simultaneously, for example, driving while following directions from a sat-nav. Findings from studies using a dual-task paradigm have consistently shown that multitasking typically reduces task performance for either one of the tasks or both overall, demonstrating the inherent limitations of attentional resources. The degree of interference between tasks often depends on their similarity and the cognitive demands placed on shared processing resources, highlighting the finite nature of attentional capacity (Della Sala et al., 1995).

1.4.5 Resource Theory

Resource theory conceptualises attention as a limited pool of cognitive resources that can be flexibly allocated among tasks (Kahneman, 1973). Within this framework, how cognitively demanding a task is determines the amount of attentional resources required to perform the task. Thus, suggesting that as tasks become more automated through practice, they demand fewer attentional resources while novel or complex tasks require significant cognitive resources.

1.4.6 Cognitive Load Theory

Cognitive Load Theory explores how cognitive overload can impact the ability to focus. If the cognitive load exceeds the capacity of the available cognitive resources, the ability to process information is impacted, leading to errors or slower performance. Sweller (1988) distinguishes three types of cognitive load: intrinsic, extraneous, and germane. Intrinsic load refers to the inherent difficulty of the task itself (for example, solving a calculus equation). This type of load is fixed as the nature of the task can not be changed. Extraneous load refers to the additional mental effort required due to ineffective instructional design (for example, unclear or disorganised instructions). This type of load can be reduced by improving how information is presented. Lastly, germane load pertains to productive cognitive effort that enhances understanding (for example, creating a mind map to summarise and connect key points from a lecture). Effective learning occurs when instructional strategies manage intrinsic load, minimise extraneous load, and maximise germane load, thus optimising cognitive resource allocation.

1.4.7 Attention Restoration Theory

Attention Restoration Theory proposes engagement with natural environments can restore attentional resources and reduce cognitive fatigue (Kaplan and Kaplan, 1989). According to this theory, interacting with nature counteracts the fatigue by engaging the mind in natural settings which promotes restorative experiences through 'soft fascination', a state of effortless attention elicited by engaging yet undemanding stimuli (for example, watching the clouds). A review of empirical studies found enhanced attentional performance following exposure to natural environments based on specific measures, highlighting the

restorative potential of environmental contexts in maintaining attentional capacity (Ohly et al., 2016).

1.4.8 Flow Theory

Flow theory describes the state of deep focus and enjoyment experienced when taking part in a challenging and engaging activity (Csikszentmihalyi, 1990). This state contrasts with cognitive overload, emphasising the optimal alignment of cognitive capacity and task requirements. Flow represents an ideal state of attentional functioning, wherein individuals experience optimal concentration without perceived effort (Payne et al., 2011).

Together, these theoretical frameworks provide a comprehensive understanding of the cognitive processes underpinning concentration, forming a robust foundation for exploring attention-related phenomena within clinical contexts.

1.5 Concentration and Tinnitus

Concentration difficulties are one of the most frequently reported complaints among people with tinnitus (Colagrosso et al., 2019; Mohamad, Hoare, and Hall, 2016). Hall et al. (2018) providing a synthesis of tinnitus-related complaints reported by patients and their significant others identified 42 discrete unidimensional patient-reported domains across 84 records. The review found good convergence between complaints collected using open- and closed-format questions. Patient-reported complaints such as ‘concentration difficulties’, ‘ability to ignore tinnitus’, and ‘cognitive difficulties’ were classified into a high-level, supra-domain called ‘Functional difficulties due to tinnitus’.

Another systematic review conducted by Mohamad, Hoare, and Hall (2016) found that tinnitus is associated with deficits in executive attention, while the evidence for impairments in other cognitive domains is mixed. This variability may be due to differences in sample characteristics, levels of tinnitus distress, or the presence of hearing loss. Nonetheless, the prevailing consensus seems to be that tinnitus, especially when it is chronic and distressing, imposes a significant burden on attention and thus concentration (Clarke et al., 2020).

Tinnitus can act as a persistent distractor, competing for attentional resources, making it challenging to maintain focus on tasks that require sustained concentration (Andersson, 2002; Hallam et al., 2004). The involuntary nature of the tinnitus percept means that attention is frequently redirected towards the tinnitus sound, especially in quiet environments or during cognitively demanding tasks. This disruption can interfere with all aspects of cognition, leading to significant impairments in daily functioning.

Research suggests that the presence or absence of hearing loss may influence both the tinnitus percept and its cognitive impact. Individuals with tinnitus and co-occurring hearing loss often experience different patterns of attentional interference to those with normal hearing. While hearing loss can exacerbate the perceptual salience of tinnitus, leading to greater cognitive load and distraction, some studies indicate that even some people with normal audiograms report concentration difficulties, highlighting the role of central auditory processing and attentional mechanisms beyond peripheral hearing (Sedley et al., 2016). The difference may lie in the brain's compensatory efforts to manage sensory deprivation, which can further deplete cognitive resources (Eggermont and Roberts, 2012).

Cognitive models of tinnitus often draw upon theories of attention to explain the impact of tinnitus on concentration. For example, the Attentional Resource Theory (Kahneman, 1973) suggests that cognitive performance is limited by a finite pool of attentional resources. In the case of tinnitus, its presence acts as an internal noise signal thereby depleting available attentional resources and limiting cognitive capacity for other tasks (Andersson and McKenna, 2006). Cognitive Load Theory (Sweller, 1988) would also suggest the continuous internal auditory stimulus of tinnitus consumes attentional resources, increasing cognitive load and subsequently impairing the performance of concurrent tasks (Khan and Husain, 2020). These theoretical frameworks underline the importance of attentional control in managing the perceived intrusiveness of tinnitus and its impact on cognitive performance.

Concentration was selected as the domain of interest as it was the only domain from the COS that received a 100% agreement when operationalising the constructs to ensure suitable measurement instruments can be identified or developed (Hibbert et al., 2020).

This work will help identify a framework for how to measure the other domains or constructs of interest from the agreed Core Outcome Set.

1.6 Aim and objectives of the PhD

The aim of this PhD was to develop a questionnaire to assess the core outcome of concentration in clinical trials of interventions for of tinnitus in adults.

The specific objectives of this project are as follows:

1. To create a list of existing measurement instruments that have been used to assess concentration to assess if any of them can be recommended for measuring concentration in tinnitus.
2. To carry out an exploratory survey at the 12th Tinnitus Research Initiatives (TRI) conference with these tinnitus experts to understand what aspects of feasibility influence researchers' decisions when selecting a measurement instrument for a clinical trial.
3. To conduct a workshop with cognitive researchers and members of the public with tinnitus to assess the content validity of the PROMIS Cognitive Abilities Subset and the Dundee Stress State Questionnaire.
4. To conduct an online survey to gather qualitative data on which situations concentration is impacted by tinnitus.
5. To develop a pilot questionnaire to assess concentration in adults with tinnitus to be used in clinical trials of sound-based interventions.

2 A Literature Search to Identify Measures Assessing 'Concentration' Within Research Literature

[A version of this chapter has been published as **Shabbir M**, Akeroyd MA and Hall DA. (2021) A comprehensive literature search to identify existing measures assessing "concentration" as a core outcome domain for sound-based interventions for chronic subjective tinnitus in adults. In: Progress in Brain Research. 'Tinnitus - An Interdisciplinary Approach Towards Individualized Treatment: From Heterogeneity to Personalized Medicine' vol. 262. Langguth B, de Ridder D, Kleinjung T, Vanneste S, Schlee W (Eds). Elsevier. pp.209-224. doi: 10.1016/bs.pbr.2021.01.027]

2.1 Introduction

Definitions of concentration vary greatly, both across literature and to the individual. Consistent themes within definitions, however, highlight that it is the deliberate and active decision to attend to a task or information set, whilst ignoring conflicting or distracting stimuli (Moran, 2012; Moray, 2017). It requires sustained and significant mental effort, within which the individual must appraise the importance of stimuli, and selectively attend to this, whilst filtering out unrequired components (Chun et al., 2011; Bridewell and Bello., 2016). To do so an individual will heavily rely on their working memory and executive functioning, which underpins their ability to hold and manipulate information, inhibit unwanted stimuli, and flexibly shift between and collate information (Engle, 2018).

Both concentration and its other associated cognitive domains can be heavily impacted and impaired by negative psychological and emotional wellbeing (Yang et al., 2017). Individuals experiencing depression and anxiety report and demonstrate impairment to cognitive functioning, particularly in the areas of sustaining attention and cognitive flexibility (Ionescu, 2012). The extensiveness of this effect is highlighted through the inclusion of impairment to concentration and cognitive functioning in the diagnosis of depression, anxiety, and other related conditions such as Post-Traumatic Stress Disorder (Taboada Gjorup et al., 2023; Hallion, Steinman, and Kusmierski, 2018; APA, 2013) and highlights the intricate and essential link between wellbeing and concentration.

Anecdotal reports of concentration difficulties by individuals with tinnitus could be seen across early literature (Tyler and Baker, 1983). However, research, utilising specifically

designed questionnaires (Clarke et al., 2020) indicate that, rather than tinnitus affecting concentration, the difficulties attending to and responding to information are a result of the impairment to listening and communication that tinnitus causes (Mohamad, Hoare, and Hall, 2016). Furthermore, tinnitus is found to detrimentally affect an individual's psychological and emotional wellbeing (Trevis, McLachlan and Wilson, 2018), leading to higher rates of depression and anxiety than in the general population (Bhatt, Bhattacharyya and Lin, 2017). Negative wellbeing, and associated psychological conditions, are associated with reduced working memory and executive functioning (Hallion, Steinman, and Kusmierski, 2018). It may therefore be reasonable to conclude that individuals with tinnitus may be likely to experience impairment to concentration because of poorer wellbeing and co-morbid conditions, rather than the tinnitus itself (Mohamad, Hoare, and Hall, 2016).

In the COMiT'ID study the definition hinged on the understanding that concentration is the ability to keep your attention focused. However, this differed from the understanding of stakeholders (Hibbert et al., 2020). A follow-up study was required and conducted to clarify and revise the definition utilising data collected via a web-based discussion forum involving a subset of the original COMiT'ID participants (Hibbert et al., 2020). The definition of concentration was described by participants as "the ability to keep your attention focused on whatever you wish", which were broken down into three subdomains: sustained attention, control attention and effortfulness (**Table 2.1**). This revised definition gives a construct that is sufficiently well operationalised to start to look for instruments that might measure concentration and its subdomains.

2.1.1 Aims and Objectives

The aim of this review was to identify existing measures of concentration that could potentially be used in clinical trial of sound-based interventions of tinnitus. The objective was to collate a list of existing measurement instruments that have been used to assess concentration.

Table 2.1 The concept of concentration in the context of a tinnitus-related complaint (Hibbert et al., 2020)

Original definition	Revised definition	Subdomains
Ability to keep your attention focused	The ability to keep your attention focused on whatever you wish	1. The importance of being able to control your concentration (control attention) 2. The ability to focus on whatever you wish or need to focus on at any given time and the ability to control the switching of attention (sustained attention) 3. The additional mental effort required because of the presence of tinnitus and the subsequent fatigue caused by that effort (effortfulness)

2.2 Methods

A literature search was conducted according to guidance available from the Consensus-based Standards for the selection of health Measurement Instruments (COSMIN) group (Prinsen et al., 2016). When looking for available outcome measurement instruments, COSMIN recommends a five-step approach (**Figure 2.1**).

Step 1: Investigate whether existing instruments measuring concentration have already been collated and reviewed.

To investigate whether existing instruments measuring concentration had already been collated and reviewed, a search was conducted to ascertain whether there were any existing systematic reviews of outcome measurement instruments for concentration (i.e., reviews of available instruments and their quality for measuring concentration in adults with chronic subjective tinnitus). Searches were conducted in the COSMIN Database for Systematic Reviews (Terwee et al., 2018a). No relevant reviews were found.

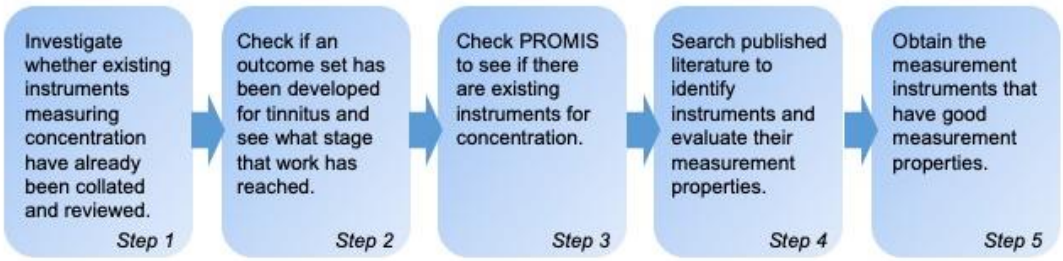

Figure 2.1 Process of identifying instruments that measure concentration

Step 2: Check whether an outcome set has been developed for tinnitus and if so what stage that work has reached.

The COMET database was searched to confirm whether an outcome set had been developed for tinnitus and what stage that work had reached. A set of five domains for sound-based interventions had already identified (Hall et al., 2018; 2019) with agreed definitions for each domain (Hibbert et al., 2020). However, no instruments had yet been reviewed and recommended for this set.

Step 3: Check PROMIS to confirm whether there are existing instruments for concentration.

COSMIN recommends checking PROMIS (Patient-Reported Outcomes Measurement Information System) (HealthMeasures, 2020) to check whether there are existing instruments for the domain of interest. PROMIS is a USA-based resource comprising efficient, reliable, and valid patient-reported outcome measurement instruments spanning physical, mental, and social health. No concentration-specific instruments were identified, however a potentially relevant instrument assessing cognitive function in adults was found called the PROMIS Item Bank v2.0 – Cognitive Function Abilities Subset (Lai et al., 2014).

Step 4: Search published literature to identify instruments and evaluate their measurement properties.

In the absence of a systematic review on the instruments measuring the construct of interest in the target population, the recommended fourth step is to perform a search for existing instruments in one or two databases (especially PubMed and or EMBASE) using the COSMIN search filter (Terwee et al., 2009), and evaluating the measurement properties of the instruments identified by the search. The search defined by COSMIN primarily identifies studies on measurement properties of target instruments and a standardised search syntax is also available on the COSMIN website. However, as it was not an objective of this study to evaluate the measurement properties of any instruments identified, the search syntax was modified. Additionally, based on the number of records identified, a comprehensive systematic review was not feasible, and a literature search was conducted instead to provide a broad snapshot of existing measures being reported in the literature.

2.2.1 Review eligibility criteria

Outcome measurement refers to measures conducted in studies post intervention (Granberg et al., 2014). However, for the purpose of this review, all reported assessments of concentration were considered, whether conducted at baseline only, or post-intervention. Only studies involving adults were included. Studies of children or animals were excluded. Only peer-reviewed journal publications were included. Grey literature such as books, conference proceedings, dissertations, theses, or manuals were excluded. Articles in all languages were included and were not restricted to English language at this stage. This was done in case a relevant instrument for concentration with an English language translation was available, reducing language bias (Boutron et al., 2019).

2.2.2 Information sources

To ensure a comprehensive and interdisciplinary sample of records, a search was performed in four databases instead of one or two, as recommended by COSMIN: PubMed, EMBASE, CINAHL, and PsycINFO. CINAHL provides access to research literature for nursing, occupational therapy, physical therapy and other allied health professions, therefore could include additional literature that may not be in PubMed and EMBASE, especially qualitative

studies (Wright et al., 2015). PsycINFO provides access to research literature on psychosocial aspects of health. As the domain concentration falls under cognitive psychology, the topic of review is related to the focus of PsycINFO (Bramer et al., 2017).

2.2.3 Search strategy

The search syntax was derived from two sources; COSMIN (Terwee et al., 2009) and the Patient Reported Outcomes Measurement (PROM) Group at the University of Oxford (PROM Group, 2010). Both search strategies included construct or domain of interest, population of interest, and types of measurement instruments of interest.

To capture as many existing measurement instruments as possible, various synonyms of concentration were included in the search syntax. The search terms were purposefully broad. For example, terms included cognitive failures, attention, vigilance, and working memory (**Table 2.2**). Terms were reviewed independently by two researchers from the COMiT initiative, drawing on patient and professional perspectives on concentration that had been reported during previous studies (Hall et al., 2019, 2018; Hibbert et al., 2020). The terms used were adapted accordingly to meet the conditions of each of the search engines used. The search strategy used for PubMed can be seen in **Table 2.2**. Further manual filters were applied in each of the four databases. See **Appendix 8.1, 8.2** and **8.3** for search strategies for all other databases used, including further filters applied per database.

2.2.4 Selection procedure

The use of relatively broad search terms resulted in a large sample of records. A total of 6,240 records were identified in total from the four databases (**Figure 2.2**). The records were processed through the reference system, EndNote, to identify duplicates. Duplicates were removed in addition to one thesis record which did not meet the eligibility criteria, leaving a total of 3,599 records.

Table 2.2. An example of the search strategy used

PubMed	
1	concentration[tw] OR "cognitive?failure"[tw] OR "cognitive?failures"[tw] OR "sustained?attention"[tw] OR "pay?attention"[tw] OR "working?memory"[tw] OR attentive[tw] OR attentiveness[tw] OR vigilant[tw] OR vigilance[tw] OR "focused?attention"[tw] OR "focusing?attention"[tw]
2	"patient?report*"[tw] OR "self?report*"[tw] OR "patient?rated"[tw] OR "self?rated"[tw] OR "patient?rating"[tw] OR "patient?ratings"[tw] OR "self?rating"[tw] OR "self?ratings"[tw] OR "proxy?report*"[tw] OR "carer?report*"[tw] OR "proxy?rated"[tw] OR "carer?rated"[tw] OR "proxy?rating"[tw] OR "proxy?ratings"[tw] OR "carer?rating"[tw] OR "carer?ratings"[tw] OR "performance?test"[tw] OR "performance?tests"[tw]
3	index[tw] OR indices[tw] OR instrument[tw] OR instruments[tw] OR measure[tw] OR measures[tw] OR questionnaire[tw] OR questionnaires[tw] OR profile[tw] OR profiles[tw] OR scale[tw] OR scales[tw] OR score[tw] OR scores[tw] OR status[tw] OR survey[tw] OR surveys[tw] OR tool[tw] OR tools[tw] OR test[tw] OR tests[tw] OR assessed[tw] OR assessment[tw] OR assessments[tw]
4	1 AND 2 AND 3
5	Filters activated: Humans, Adult: 19+ years

Based on the number of records identified, an alternative approach of random sampling was taken to make it more manageable, used a methodology by a previous study in the field of audiology (Granberg et al., 2014) (**Figure 2.2**). A total of 1,000 abstracts were selected randomly to assess eligibility. Half of them were randomly selected from Endnote using a random number generator (Pool I), and the other half were most recent publications from PubMed (2013-2018) (Pool II) creating two pools of 500 records each.

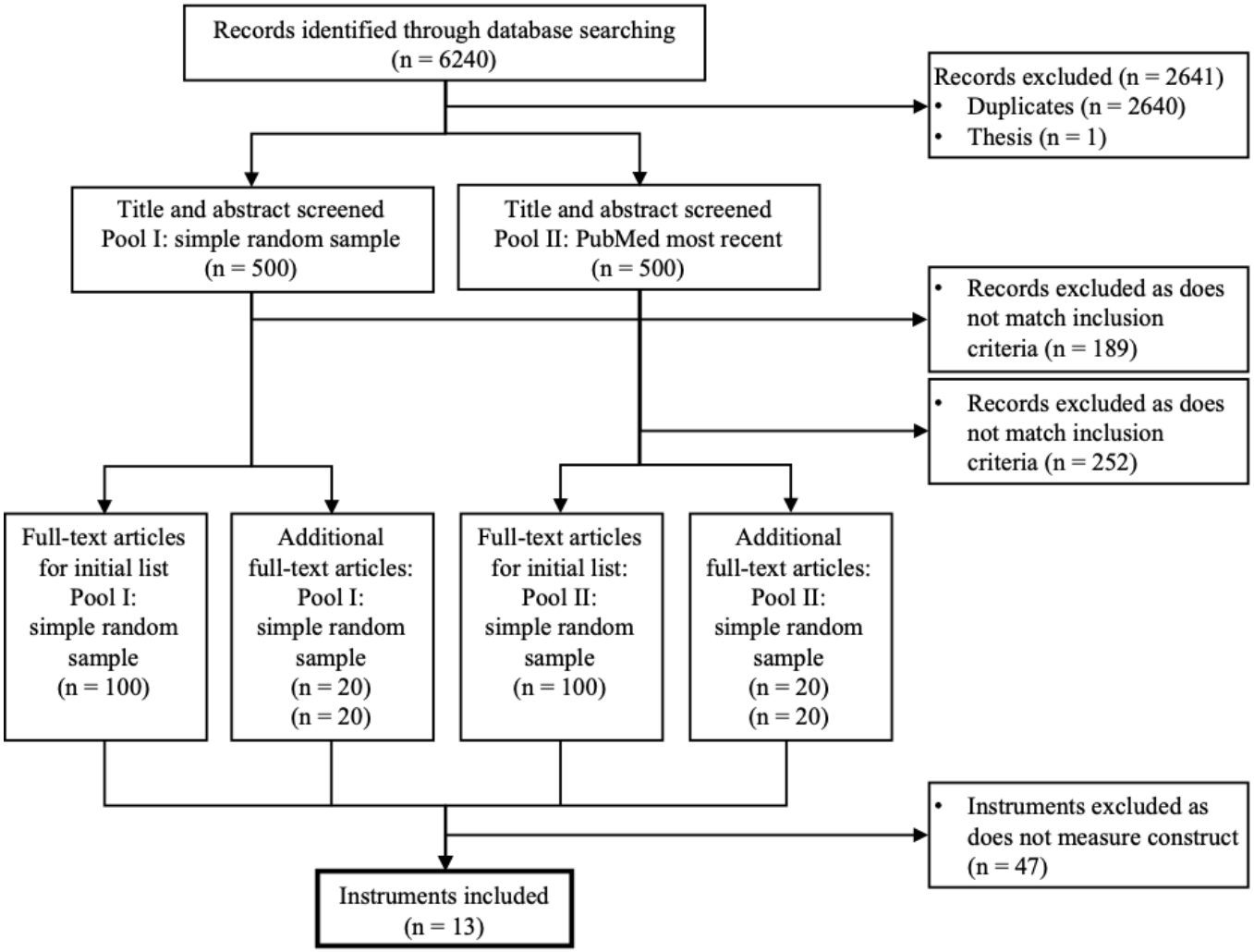

Figure 2.2 A flowchart displaying the screening process and articles included in the literature search.

2.2.5 Title and abstract screening

The initial intention had been for the assessment of eligibility of studies (title and abstract screening), and extraction of data from the eligible full texts to be done by at least two researchers independently, as recommended by Cochrane (Boutron et al., 2019). However, the volume of records identified meant that it was not feasible to screen all records in the time available. Therefore, the following methodology was undertaken. For a subset of 500 records (Pool I), two researchers independently screened the title and abstract to determine eligibility. Eligibility screening considered whether the journal article administered and scored a test or questionnaire measuring concentration and whether the test population comprised adults (18 years old).

To ensure consistency of approach, a guideline document was prepared for both the researchers to follow. Rating options were as follows: "0" = exclude (does not fit all of the inclusion criteria), "1" = include (fits all of the inclusion criteria), "2" = unsure (not clear if it fits the inclusion criteria), and "3" = incomplete reference (title and/or abstract were not pulled through to EndNote and cannot be found online). Records where at least one researcher had coded "1" (include), were passed to the full-text screening stage for data extraction. For any records that at least one researcher had coded "2" (unsure), a discussion between the two researchers confirmed the final rating code.

One screener included 311 records and the other included 299 records. Inter-rater agreement was calculated using Cohen's kappa, with a score >0.6 indicating substantial agreement (Landis and Koch, 1977; McHugh, 2012). For the 500 records in Pool I, inter-rater agreement was 0.92, indicating almost perfect agreement. This was considered appropriate for the Pool II records to be screened by one researcher only (MS). All records for which the abstracts were coded "1" (include) or "2" (unsure) were passed for full-text review.

2.2.6 Full-text screening

Full-text screening was first conducted on a subset of a 100 records from each pool (200 records in total). The first subset of records was chosen by randomly selecting 100 full texts from the 311 records in Pool I and 100 full texts from the 248 records in Pool II.

Once an initial list of concentration measurement instruments had been collated, a pre-defined data saturation criterion was applied to select instruments which were sufficiently well defined to be accessible and used by other investigators for research. Saturation was operationally defined as no new measurement instrument being identified after completing data extraction on each successive set of 20 additional records.

Full-text screening was then continued by further randomly selecting 20 full texts from each pool, 20 out of the remaining 211 in Pool I and 20 out of the remaining 148 in Pool II (and so on) to determine whether any additional concentration measures were identified that were not on the initial list.

Data saturation was reached after two rounds of additional full-text screening per pool (80 records in total), signifying no new concentration measurement instrument had been identified. Thus, full-text screening was stopped after screening a total of 280 out of 559 which were then passed for data extraction.

2.2.7 Data extraction and categorising the instruments.

From each study, information was extracted on age (minimum age, maximum age, mean age, SD age), population, authors' description of the construct being measured, and the corresponding outcome measurement instrument. The measurement instruments were then sorted into three categories: a) *Specified instruments* were those that had a specific name for example, the Attentional Function Index, b) *Not specified instruments* were those that referred to a type of measure without specifying the actual instrument for example, "a Reaction Time task was used", and c) *Authors' own instruments* were those created by the author and did not have any specific details for example, "participants were asked to do a swap task". Only the specified instruments were considered further. The 'not specified' and 'authors' own' instruments were not considered further. As the aim of this study was to only identify existing measures of concentration, frequency of how often the measures were found in the literature search was not required.

2.2.8 Evaluation of face validity

One of the most important psychometric properties is face validity. Face validity is whether the instrument appears to measure what it claims to measure at face value. Our concept of concentration encompassed three subdomains: sustained attention, control attention and effortfulness (**Table 2.1**). Two reviewers (MS and DAH) independently screened the 60 instruments for face validity by comparing this concept with the authors' description of the construct being measured by the instrument of interest. Only those measurement instruments that matched at least one of the three main subdomains of concentration were included in the final list of measures.

Step 5: Obtain the measurement instruments that have good measurement properties.

The last step according to COSMIN is to obtain the measurement instruments that have been selected. This was achieved through the journal articles published by the authors, websites, manuals, or electronic databases that were freely available. As it was not an objective of this study to evaluate the measurement properties of any instruments identified, all measures that were included based on face validity were obtained.

2.3 Results

After title and abstract screening, there were 559 records (311 records from Pool I and 248 records from Pool II). Based on the full-text data extraction conducted on the selected subset of 200 records, a) 317 specified instruments, b) 95 not specified instruments, and c) 13 authors' own instruments were identified. From the first successive set of 40 records, several additional instruments were identified. These were a) 54 specified instruments, b) nine not specified instruments, and c) two author's own instruments. However, from the successive 40 records, no new instruments were identified. Thus, we considered data saturation to be reached. The original list of 371 specified instruments was reduced to 60 distinct instruments because some of the performance-based tasks had multiple variations and types, created by different authors or developers. These were consolidated into one instrument descriptor for simplification. For example, for the Continuous Performance Test (CPT) there were multiple variations including the Continuous Performance Test-Identical Pairs Version (CPT-IP) (Yasuda et al., 2014), Integrated Visual and Auditory Continuous

Performance Test (IVA CPT) (Berginström et al., 2015), Conners' Continuous Performance Test II (Bueno et al., 2015) and III (Adams et al., 2017).

From this list of 60 specified instruments, 47 measurement instruments were excluded as having poor face validity. This was because the developer's definition of concentration did not match the definition by COMiT'ID and were measuring broader or different aspects of concentration that were not of interest in this review. Examples of such tests were the Behaviour Rating Inventory of Executive Function Adult Version (BRIEF-A) which measures executive function, the Cognitive Failures Questionnaire (CFQ) which measures absent-mindedness, and the N-back test which measures working memory. A complete list of all excluded measures can be found in **Appendix 8.4.** The final list of 13 instruments measuring concentration included two self-report questionnaires and 11 performance-based tasks (**Table 2.3**). Some instruments were subtests within much larger cognitive test batteries, such as the Cambridge Neuropsychological Test Automated Battery (CANTAB) and the Test of Everyday Attention (TEA). Thus, only these subtests were selected (**Table 2.3**).

Table 2.3 Instruments measuring concentration

Name of instrument	Details of instrument (subtests/sources)
Self-report	
Dundee Stress State Questionnaire (DSSQ)	Matthews et al. (1999)
Applied Cognition-Abilities Subset	PROMIS
Performance-based	
Amsterdam Neuropsychological Tasks	Focused Attention 2 letters
(ANT)	Focused Attention 4 letters
	Focused Attention Objects 1 key
	Focused Attention Objects 2 keys
	Sustained Attention Auditory
	Sustained Attention Dots
	Sustained Attention Objects 1 key
	Sustained Attention Objects 2 keys
Ann Arbor Publishers	Digit Vigilance Test (DVT)
Cambridge Neuropsychological Test	Motor Screening Task (MOT)
Automated Battery (CANTAB)	Rapid Visual Information Processing (RVP)
	Reaction Time (RTI)
Cogstate Battery	Identification
FePsy	Binary Choice Reaction Time
	Rhythm Task
	Vigilance Test
Halstead-Reitan Neuropsychological Test	(Seashore) Rhythm Test
Battery	Speech Sounds Perception Test
Hogrefe Ltd.	d2 Test of Attention
Test of Everyday Attention (TEA)	Elevator Counting
	Map Search
	Telephone Search
Continuous Performance Task (CPT)	Various sources
Psychomotor Vigilance Task (PVT)	Various sources
Vienna Test System (VTS)	Perception and Attention Functions Battery

	Reaction Test (Choice Reaction Test only)
	Sustained Attention
	Vigilance

2.4 Discussion

2.4.1 Summary of Findings

From 13 candidate instruments which assess the concept of concentration defined by our previous consensus work (Hibbert et al., 2020), two instruments were self-reported questionnaires which could be completed by the participant alone, and 11 were performance-based tasks or cognitive-behavioural tasks requiring administration by the investigator.

In terms of selecting which of the 13 instruments to recommend as an outcome measure in clinical trials of tinnitus, further work is needed to consider the practical and psychometric (measurement) properties of each instrument (i.e., Step 5). In addition to mode of completion, further considerations include the ability to define the test in such a way that it can be administered by others exactly as the original authors intended, and the availability of evidence for how the test performs in the target group of people with tinnitus.

With respect to the first point, two of the performance-based tasks, the Psychomotor Vigilance Task (PVT) and the Continuous Performance Test (CPT), do not appear to have a singular version. Instead, multiple test developers have created variations of the test. This lack of consistency means that it may be difficult to evaluate psychometric properties for the PVT and CPT because there is no definitive test specification.

With respect to the second point, from those records on which we conducted data extraction, only the CPT had been administered to a group of participants with tinnitus (Kallogjeri et al., 2017). This record reported an intervention study assessing the benefits of a cognitive training programme to improve attention, memory, and concentration. Only 40

people with tinnitus were tested, and so although the target group is relevant, the sample size is too small to reliably determine the general psychometric properties of the test (Prinsen et al., 2018). All other instruments were administered to different target populations such as; people with bipolar disorder (Sepede et al., 2012), attention deficit hyperactivity disorder (Virta et al., 2015) and schizophrenia (Dolan et al., 2004).

2.4.2 Limitations

The search strategy was intentionally broad to capture as many potentially relevant instruments measuring concentration as possible, including those not previously used in tinnitus research. Four databases were searched to ensure a comprehensive and interdisciplinary search of concentration measures, exceeding the COSMIN recommendation to search one or two databases (Prinsen et al., 2016; 2018). The search terms used were purposefully broad and the population of interest was not restricted to tinnitus. This was a strength of this review, but did lead to the return of many records, which presented challenges for screening due to limited resources and time available.

As per COSMIN methodology, the first step requires investigating whether existing instruments measuring concentration have already been collated and reviewed. The COSMIN Database for Systematic Reviews (Terwee et al., 2018a), was searched in accordance with the COSMIN recommendation and no relevant reviews were found. In addition, PubMed, EMBASE, CINAHL, and PsycINFO were searched, and again no relevant systematic reviews were found.

Cochrane Review guidance advises a minimum of two independent researchers for the selection and extraction of records to avoid selection bias (Boutron et al., 2019). In this review, due to constraints on resources, only one researcher (MS) was able to screen 500 of the records randomly selected. Nevertheless, bias was minimised by having two independent reviewers (MS and AH) screen the first 500 records selected randomly, and one researcher proceeded once a high inter-rater agreement score was confirmed.

There is only a finite pool of instruments that have been developed to measure concentration, and so inevitably many of those instruments are likely to be used repeatedly

across studies. While *a priori* data saturation criteria enabled collation of an exhaustive list of concentration measures, without conducting screening and data extraction on all 3,599 potentially eligible records, there does remains a possibility that some measurement instruments were missed.

2.5 Conclusion

For the 13 candidate instruments identified in this chapter, the next step was to assess feasibility of administration to confirm that the measures could reasonably be administered in a tinnitus clinical trial as some of the performance-based tests require purchasing a license, and/or having access to technical facilities such as equipment and software.

3 Practical Considerations When Selecting a Measure of Concentration for Use in Tinnitus Clinical Trials

3.1 Introduction

Feasibility of an instrument encompasses practical considerations that go beyond the traditional psychometric qualities of measurement tools such as the ease of application within constraints like time and cost (Schmitt et al., 2015). For example, if the license for an outcome measurement instrument costs thousands of pounds and takes an hour to complete, it will be less likely recommended than another tool which is free of cost and takes 10 minutes to complete.

3.1.1. Aims and objectives

The aim of this study was to understand from a committee of international tinnitus researchers and clinicians what aspects of feasibility influence researchers' decisions when selecting a measurement instrument for a clinical trial. The objective was to carry out an exploratory survey at the 12th Tinnitus Research Initiatives (TRI) conference with these tinnitus experts.

3.2 Methods

The 12th Tinnitus Research Initiatives (TRI) conference took place in Taipei, Taiwan from May 17-19, 2019. This event was used an opportunity to gather feedback from tinnitus experts who were coming from all over the world for the biggest annual tinnitus conference.

As the survey was only conducted to understand what aspects of feasibility are important when selecting measurement instruments for clinical trials as pre and post intervention measures, and the participants were clinical research professionals, a Research Ethics Committee (REC) review was not required for this study (NHS HRA, 2020).

This study is reported according to the Consensus-Based Checklist for Reporting of Survey Studies (CROSS) (Sharma et al., 2021).

3.2.1 Stakeholders – Tinnitus Experts

Participants for this study were recruited using a purposive sampling approach. Based on the list of invited speakers uploaded on the TRI conference website, a list of international clinical researchers and health-care practitioners that had experience with clinical trials in tinnitus was collated. This allowed for targeted input from individuals likely to have real-world experience making decisions about outcome measure selection as well as being the likely users of such outcome measures (Campbell et al., 2020).

These experts were contacted via email prior to the conference to schedule meetings in-between conference talks. The conference took place over 3 days (May 17-19, 2019), during which MS met with the experts to conduct the survey. While disseminating the study at the conference, additional tinnitus experts were identified and were also invited to take part in the survey. They were required to be a minimum of 18 years old and be proficient in English so they could read, comprehend, and complete the survey.

3.2.2 Survey design

The survey was created based on the COSMIN and COMET initiative feasibility guidelines (Prinsen et al., 2016). See **Table 3.1** for the full list from COSMIN and COMET initiative guidelines. Eight aspects of feasibility were selected from the original list of seventeen (**Table 3.1**) and these were:

- Cost of an outcome measurement instrument
- Completion time
- Ease of administration
- Clinician's comprehensibility
- Required equipment
- Type of administration
- Ease of score calculation
- Type of outcome measurement instrument

Table 3.1 Overview of all feasibility aspects (taken from Prinsen et al., 2016)

Feasibility aspects
Patient's comprehensibility
Interpretability
Ease of administration
Length of the outcome measurement instrument
Completion time
Patient's mental ability level
Ease of standardisation
Clinician's comprehensibility
Type of outcome measurement instrument
Cost of an outcome measurement instrument
Required equipment
Type of administration
Availability in different settings
Copyright
Patient's physical ability level
Regulatory agency's requirement for approval
Ease of score calculation

Questions were drafted for each of the eight selected aspects of feasibility. Questions on cost and time were open-ended, and participants were asked to provide their own upper limit estimates of what they considered would be feasible. For all other questions, three response options were provided; 'yes', 'no', or 'depends'. The option 'depends' was included for instances where participants' felt that their response was conditional and required more context. Space was provided after each response if the participant wanted to explain their response or share anything they felt was important regarding the questions asked. An additional question on the acceptability of using subscales was also included (Q9, **Table 3.2**) as the list of measurement instruments from the literature search identified relevant subscales (**Table 2.3**). See **Appendix 8.5** for the full survey.

Table 3.2. Questions based on the chosen feasibility aspects that were used for the final survey

Q#	
1	What is the maximum amount you would be willing to pay to obtain a license for a measurement instrument to use before and after the intervention? (answer in your own currency)
2	What should be the maximum duration for one measurement instrument to use before and after the intervention? (answer in minutes)
3	If a measurement instrument requires the administrator to be trained or be a specialist, would you use it?
4	For interpreting the scores, what would the measurement instrument need to have for you to use it? Here are some specific examples: a. clinical norms b. grading system c. continuous scale (such as one where a higher score means 'worse')
5	If a measurement instrument requires equipment, would you use it? Here are some specific examples: a. pen and paper b. online (access to the internet) c. standalone computer or tablet device d. loudspeakers e. headphones f. software to be installed (which is not needed for routine clinical practice)
6	If a measurement instrument needs to be administered in a particular way, would you use it? Here are some specific examples: a. self-administered by the patient (i.e. unsupervised) b. administered by yourself (i.e. supervised by a tinnitus expert) c. delegated to a team member (i.e. supervised but not a tinnitus expert)
7	Does the method of scoring the instrument matter to you? Here are some specific examples: a. automatic score calculation b. manual score calculation
8	Do you have a preference for the type of outcome? Here are some specific examples: a. questionnaires (self-report measures) b. performance-based measures
9	If yes for questionnaires, if the relevant domain or construct is just a subscale of a bigger questionnaire, would you use it?

The survey was developed based on factors that were hypothesised to impact instrument acceptability and criteria for selection, to differentiate instruments that were both self-report and performance based that had been shortlisted from the literature search already covered. The survey considered practical factors that might impact ease of use and feasibility. The survey was iteratively developed with regular feedback from PhD supervisors, MAA and DAH. A final version was agreed by all researchers involved.

3.2.3 Survey administration

The feasibility survey was completed in-person, using pen and paper. It explored the preferences of the tinnitus researchers and clinicians over the selected range of criteria for feasibility that would impact their instrument selection for pre and post comparison of concentration in clinical trials.

It took them approximately 15 mins to complete the survey and an additional 15 mins was used to gather informal discussion-based feedback to contextualise responses and ensure that nothing was missed.

3.2.4 Analysis

Data were analysed using descriptive statistics, and text responses were used to enrich insights and provide additional context to the frequency analysis and ensure that the richness of the data was captured.

3.3 Results

3.3.1 Participant characteristics

The sample consisted of 16 tinnitus experts (n=13 clinical researchers and n=3 non-clinical researchers) that have experience with tinnitus and clinical trials (**Table 3.3**). The sample was international with participants from the USA (n=3), UK (n=2), Netherlands (n=2), Belgium (n=2), Germany (n=2), and Singapore (n=1), France (n=1), Switzerland (n=1), Australia (n=1), and New Zealand (n=1).

Table 3.3 Characteristics of the participants

P #	Gender	Stakeholder	Profession	Country
P1	M	Clinical researcher	Psychiatrist & Professor	Germany
P2	M	Clinical researcher	Neurosurgeon & Professor	New Zealand
P3	F	Clinical researcher	ENT & Assistant Professor	Netherlands
P4	F	Researcher	Associate Professor	Netherlands
P5	M	Clinical researcher	Clinical Psychologist & Assistant Professor	France
P6	F	Clinical researcher	ENT and Professor	Belgium
P7	F	Clinical researcher	Physiotherapist & Assistant Professor	Belgium
P8	M	Clinical researcher	ENT & Professor	Switzerland
P9	M	Clinical researcher	Audiologist & Professor	Australia
P10	F	Clinical researcher	ENT & Professor	Germany
P11	M	Researcher	Professor	USA
P12	M	Clinical researcher	Audiologist & Professor	USA
P13	M	Clinical researcher	Audiologist & Professor	Singapore
P14	F	Clinical researcher	Audiologist & Assistant Professor	USA
P15	M	Clinical researcher	Audiologist & Professor	UK
P16	F	Researcher	Assistant Professor	UK

3.3.2 Main findings

A summary of the results from the survey can be found in **Table 3.4**.

Table 3.4 Results from the feasibility survey for questions 3-9

Q#		Yes	No	Depends
3	If a measurement instrument requires the administrator to be trained or be a specialist, would you use it?	6	3	7
4	For interpreting the scores, what would the measurement instrument need to have for you to use it? Here are some specific examples:			
	a. clinical norms	13	2	1
	b. grading system	13	2	1
	c. continuous scale (such as one where a higher score means 'worse')	12	2	2
5	If a measurement instrument requires equipment, would you use it? Here are some specific examples:			
	a. pen and paper	14	2	0
	b. online (access to the internet)	14	0	2
	c. standalone computer or tablet device	11	1	4
	d. loudspeakers	6	5	5
	e. headphones	7	5	4
	f. software to be installed (which is not needed for routine clinical practice)	10	4	2
6	If a measurement instrument needs to be administered in a particular way, would you use it? Here are some specific examples:			
	a. self-administered by the patient (i.e. unsupervised)	13	1	2
	b. administered by yourself (i.e. supervised by a tinnitus expert)	10	3	3
	c. delegated to a team member (i.e. supervised but not a tinnitus expert)	10	3	3
7	Does the method of scoring the instrument matter to you? Here are some specific examples:			
	a. automatic score calculation	12	2	2
	b. manual score calculation	9	4	3
8	Do you have a preference for the type of outcome? Here are some specific examples:			
	a. questionnaires (self-report measures)	11	3	2
	b. performance-based measures	12	0	4
9	If yes for questionnaires, if the relevant domain or construct is just a subscale of a bigger questionnaire, would you use it?	9	1	3

3.3.2.1 Cost of an outcome measurement instrument

When asked what would be the maximum amount they would be willing to pay for a measurement instrument, eight out of 16 respondents said the recommended instrument would need to be free of cost while the remainder said that it would depend on (1) funding, and (2) whether the domain being measured was a primary or secondary outcome measure. Five participants said that having funding available would be the most important factor when considering cost of an instrument. If they were aware of which instrument(s) they were going to use and the costs associated with them prior to applying for grants, then the costs for any secondary measures could be included in the grant application.

> *"If grant funded- whatever it takes, write the cost into the grant." P13*

> *"If it was funded, no maximum amount". P3*

Two participants mentioned that resources and cost allocation towards secondary outcome measures tends to take a backseat compared to the primary outcome measure. This was especially pertinent when there was limited funding and therefore would influence how much they would be willing to pay for a measure.

> *"For secondary measures we may not want to take the hassle to get licences and pay unless it is essential". P12*

However, it is important to note that some respondents that assigned a maximum value to what they were willing to pay for an instrument also mentioned that it would depend on the funding they had available for the research project.

3.3.2.2 Completion time

When asked what the maximum amount of time would be deemed feasible towards completion of a single instrument, the majority of respondents (11 out of 16) reported that up to 15 minutes would be the maximum acceptable. Two further participants reported that up to 30 minutes would be feasible, with the remainder of the sample (3 out of 16) endorsing responses of up to 60 minutes or longer.

Additionally, four participants discussed that an important consideration would be whether the measure was a primary or secondary outcome measure, as this would be a crucial in determining how much time they considered feasible to spend per measurement instrument. The consensus was that participants considered it more feasible to spend longer administering a primary outcome measure, but much less time on a secondary outcome measure.

> *"Primary outcome: 15min, secondary outcome: 5min." P3*

> *"We use primary measures even if it's long but for secondary measures we are interested in how long it takes to administer". P12*

3.3.2.3 Ease of administration

When asked if an instrument required the administrator to be trained or to be conducted by a specialist would they use it, six participants responded 'yes', three responded 'no' and seven responded 'depends'. Participants who selected 'depends' were then asked to provide additional context of what the feasibility would depend on, and a few factors arose. Firstly, respondents stated it would depend on the resources required as part of the training for the administrator i.e., time and costs. Secondly, it would depend on how easy or difficult the instrument was to administer as that would indicate how much training was required. Lastly, as mentioned for the previous two questions on cost and time, it would depend on if the measurement instrument was a primary or secondary measure.

> *"No for a specialist, but yes if this training is limited in time and requirements for the administrator. The training must be internally replicable, so more staff can be trained." P3*

> *"I would prefer the instrument to be self-administered, for many trials the follow up is not face to face." P16*

> *"It would depend on how important the domain was for the study." P7*

3.3.2.4 Comprehensibility

Participants were asked about score interpretability, and what would the measurement instrument need to have for them to use it in a clinical trial. In terms of clinical norms almost all respondents agreed that that clinical norms would be required (13 responded 'yes', two responded 'no' and one responded 'depends'). Some participants provided additional context stating it would depend on the nature and purpose of the instrument, and again, whether it was a primary or secondary outcome measure.

"Definitely yes if it were a biomarker/physiological test." P15

"Clinical norms would be more used when choosing a primary outcome measure." P12

When asked if a grading system was essential, most respondents said 'yes' (13 responded 'yes', 2 responded 'no' and 1 responded 'depends'.

"Not necessary a grade, a continuous scale is a second-best option." P3

When asked if a continuous scale was important, most participants said 'yes' (12 responded 'yes', two responded 'no' and two responded 'depends').

"Depends on what are you measuring." P10

3.3.2.5 Required equipment

When the participants were asked whether the instrument required the following equipment would they use it:

a) Pen and paper: 14 out of the 16 respondents said 'yes' and only 2 respondents said 'no'. It was mentioned that sometimes this mode of administration is much easier for the elderly.

b) Online: 14 out of the 16 respondents said ‘yes’ and only two respondents said ‘depends’. The same comment was made by PX that it would be easier for some audiences, such as the elderly, who may not be familiar or comfortable with using the internet. Another consideration that was raised in the discussions was the importance of how the layout and interface when using measures online could influence/ bias choices.

> *“Format of online administration influences our choice (e.g., navigating through each question in a new page).” P12*

c) Standalone computer or tablet device: 11 out of the 16 respondents said ‘yes’, one said ‘no’ and four said ‘depends’. Participants discussed that it would depend on whether the tablets were provided by the test providers and as mentioned above, it might not be user-friendly for the elderly, and they may prefer using pen and paper.

d) Loudspeakers: Six participants responded ‘yes’, five responded ‘no’ and five responded ‘depends’. Those who said ‘depends’ mentioned various factors such as how necessary it was for the study, and whether it would require a certain environment to administer. Environment seemed to be the main concern as it could lead to additional costs as sometimes appointments are conducted in smaller rooms where using equipment may not be possible or in waiting rooms, especially if they are secondary measures.

e) Headphones: Seven participants responded ‘yes’, five responded ‘no’ and four responded ‘depends’. The additional comments were the same as for loudspeakers.

f) Software (which is not needed for routine clinical practice): Ten out of the 16 participants responded ‘yes’, while four responded ‘no’, and two responded ‘depends’. The availability and cost of software were discussed by two participants.

3.3.2.6 Type of administration

Participants were asked about different modes of administration and whether they would use such measurement tools in clinical trials:

a) Self-administered by patient: 13 out of 16 respondents said 'yes', one said 'no' and two said 'depends'. Discussions were around if participants are "capable" of doing it on their own or would require assistance.

> *"If it is self-explanatory, something like TQ-yes, cognition-no." P10*

b) Administered by expert: Ten out of 16 respondents said 'yes', three said 'no', and three said 'depends'. The main concern for administering by experts was time and financial constraints. One participant also raised that not all follow ups are done face-to-face or in person and therefore self-administered would be more feasible.

c) Administered by a study team member: Ten out of 16 respondents said 'yes', three said 'no', and three said 'depends'. The additional comments were the same as for administered by experts.

3.3.2.7 Ease of score calculation

Participants were asked whether the method of calculating the scores on the instrument mattered to them.

a) Automatic score calculation: Most respondents said 'yes' (12 out of 16), while two said 'no', and two said 'depends'. Additional comments indicated automatic score calculation was considered helpful but not necessary.

> "*I would not base my decision to use the instrument on that feature but useful if the score needs to be calculated quickly." P16*

b) Manual score calculation: Just over half of the respondents said 'yes' (nine out of 16), while four said 'no', and three said 'depends'. Most participants stated the

method of calculating scores did not matter much to them, but automatic score calculation was considered more “fool proof”.

“I could work with both, automatic would be better in certain situations, like if there is reverse scoring.” P16

3.3.2.8 Type of outcome measurement instrument

Participants were asked whether they had a preference for the following type of measures.

a) Questionnaires: 11 participants responded ‘yes’, three responded ‘no’, and two responded ‘depends’. It was mentioned that if the patients were able to understand the questionnaire, then that would be a preference. Additionally, if a reliable objective measure did not currently exist for the domain in question, questionnaires may be the most feasible option.

b) Performance-based measures: 12 participants responded ‘yes’ and four responded ‘depends’. Preference for this type of outcome measure was more nuanced as while it is an objective measure, it can be harder to implement due to various constraints such as time, cost, and in-person appointments. Participants mentioned a trade-off between time and the importance of using a performance-based measure in the study.

“When the topic is really relevant to the study question because it takes more time.” P6

3.3.2.9 Acceptability of using subscales

The 13 participants who said ‘yes’ or ‘depends’ for using questionnaires were then asked if the relevant domain or construct was only a subscale of a larger questionnaire, would they use it. Nine out of the 13 responded ‘yes’, one responded ‘no’, and three responded ‘depends’. Participants mentioned that it would depend on (1) if it was necessary or nothing else was available, and (2) the measurement properties of the subscale.

"If reliable- depends on validation e.g. TFI has problems with subscale scores." P16

Based on the qualitative feedback gathered from the participants, 14 out of 16 highlighted that the main aspect of feasibility when selecting an outcome measurement instrument is cost and therefore that aspect was prioritised over the others.

3.4 Discussion

3.4.1 Summary of findings

Before evaluating the quality of the measurement instruments identified from the literature search in Chapter 2, it was crucial to first understand what influences the decision of the researcher when choosing how practical and feasible an instrument is. The responses for the first two questions; cost and duration, seemed the most interesting and crucial. Since half of the respondents required the instruments to be free, the instrument recommended would most likely have to be free of cost. Even though 25% of the respondents (n= 4) mentioned that the maximum amount they would be willing to pay would depend on the funding/grant, it would be important to make sure the recommended measurement instrument would be accessible to all researchers, irrespective of funding.

In terms of the maximum time, they would be willing to spend on a single measurement instrument, most respondents stated 5-15 minutes. However, it is important to note here that only three respondents made the distinction between primary and secondary outcome measures, stating that they would be willing to spend more time on a primary outcome measure than on secondary measures. Two of the three who differentiated between primary and secondary outcome measures stated that they would spend 5 minutes maximum on a secondary measure. A higher weightage should be given to these three responses as the minimum set of core outcome domains recommended by the COMiT'ID study are secondary outcome measures.

3.4.2 Limitations

Due to the opportunity-based methodology of recruiting the sample, there were a few limitations to this project. First and foremost, it was not possible to do qualitative interviewing of the participants, which impacted the richness of data available. It would have been helpful to gather more comprehensive data about the relative importance of the aspects of feasibility discussed in this survey. Many respondents informally gave the feedback that cost was the primary consideration, which informed later work, but it would have been preferable to explicitly ask for this information from all participants.

Secondly, not all stakeholders were able to be included. The sample included clinical and non-clinical researchers that have experience with tinnitus and clinical trials, but did not include the perspective of patients, funders, and public health officials.

Lastly, conferences, specifically international ones, are often associated with significant cost, time, and geographical barriers to attendance. As a result of this, there was an over representation of economically developed countries in the sample with the likelihood of respondents from institutions with greater financial and infrastructural support for international conference participation (Harris et al., 2017). This has implications for equity, diversity, and inclusion (EDI) of the sample as it likely excluded voices of specific or differing needs for stakeholders from low and middle-income countries. As clinical research increasingly emphasises the importance of inclusive research design (NIHR, 2020), future studies should seek to reduce such barriers by incorporating remote or hybrid recruitment strategies to allow broader participation across global health contexts. However, while it was limited in its diversity and representativeness, a sample size of 16 participants is considered sufficient for qualitative insights and exploratory surveys as a high level of saturation is typically reached with 12 interviews (Guest, Namey and Chen, 2020).

While the TRI conference was a unique opportunity to gather the potential richness of the data gatherable by speaking to experts in the field from across the world who have a plethora of experience conducting clinical trials, future research should address the limitations of in-person conference-based recruitment by utilising digital survey platforms and online workshops to reach a broader and more diverse sample of stakeholders. This

would allow inclusion of participants from underrepresented regions and professional backgrounds, as well as those with costs and time constraints associated with international travel, thus improving the diversity and inclusivity of perspectives. Expanding the sample to include healthcare commissioners, patient representatives, and funders would also strengthen future evaluations of feasibility considerations for outcome measure selection in tinnitus clinical trials.

3.5 Conclusion

The main finding from this study was that eight out of the 16 respondents said that the key criteria for acceptability was that the instrument needs to be free of cost. This was 50% of the group and overwhelmed the relevance of any other factor. The additional textual feedback explained that this was based on the volume of participants in trials. Limits of grant and institutional funding availability, the opportunity cost of allocating resources on measures as opposed to other expensive resources. Self-administration was deemed very important based on allocation of time and resources, participant burden and staff burden.

Of the instruments identified in Chapter 2, only two out of the 13 instruments were likely to be acceptable to the researcher and clinicians in this study as there were only two that were self-report free of cost measures. These were the PROMIS Applied Cognition-Abilities Subset and the Dundee Stress State Questionnaire (DSSQ). The next stage was then to conduct a content validity and feasibility analysis on those instruments with key stakeholders.

4 Stakeholder Involvement to Assess Content Validity of Concentration Instruments for Tinnitus Clinical Trials

4.1 Introduction

4.1.1 Stakeholders – Patient and Public Involvement

For this chapter, stakeholder involvement is described as Patient and Public Involvement (PPI) which refers to the process of involving patients or members of the public as collaborative partners during the research process. In the past, research on outcome measures has been primarily driven by researchers and clinical experts, who typically determine what should be measured and how when it comes to Patient Reported Outcome Measures (PROMs), with limited involvement from patients and the public. However, there has been a growing emphasis on PPI in health research, particularly in developing core outcome sets in recent years (Dodd et al., 2023). The Core Outcome Measures in Effectiveness Trials (COMET), a clinical initiative funded by the MRC and the NIHR in the UK, and the European Commission, has a working group dedicated to People and Patient Participation, Involvement and Engagement (PoPPIE). The aim of PoPPIE is to facilitate the involvement of people with the lived experience of the condition of interest (Young and Bagley, 2016)

The OMERACT initiative is an example of the impact of PPI in core outcome set development, where including patients in the research process identified previously overlooked factors (Kirwan et al., 2007). The development of a Core Outcome Set for fibromyalgia is another example where through PPI, important and novel insights led to the revision of diagnostic criteria (Wolfe et al., 2013).

4.1.2 Concepts and theory development

Using the COSMIN guidelines, content validity of the self-report instruments was assessed in this study. Content validity refers to the degree to which the content of an instrument is an adequate reflection of the construct to be measured and refers to the relevance, comprehensiveness, and comprehensibility of the concentration instrument for the construct, target population, and context of use of interest (Terwee et al., 2018b).

Thirteen candidate instruments for *concentration* were identified from the literature search (Chapter 2). A feasibility survey was conducted with tinnitus experts at the TRI 2019 conference in Taipei, Taiwan. It was identified by the panel of tinnitus experts that the instruments needed to be free of charge for recommendation for clinical trials as concentration may be a secondary measure. Therefore, if the instrument recommended is free of charge and self-administrable, it would be more widely measured (Chapter 3). From the 13 instruments, only two were free self-report instruments; Dundee Stress State Questionnaire (DSSQ), Cognitive Function Abilities Subset (PROMIS Item Bank v2.0).

4.1.3 Aims and objectives

The aim of this stakeholder involvement was to assess content validity of existing questionnaire measures of concentration. The objective was to conduct a workshop with cognitive researchers as well as people with tinnitus, to measure content validity by applying the consensus-based COSMIN method (Terwee et al., 2018b) to two questionnaire measures of concentration.

4.2 Methods

This workshop constituted PPI and is reported according to the GRIPP2 (Guidance for Reporting Involvement of Patients and Public v2) checklist (Staniszewska et al., 2017)

4.2.1 Survey design

To assess content validity, the COSMIN guidelines (Terwee et al., 2018b) recommend two independent reviewers and to ensure the perspective of patients is included. Therefore, an in-person workshop was conducted involving academic experts who work in the field of cognition, and members of the public who experience tinnitus. The benefit of an in-person workshop is that the interaction between participants allows for variation between participants to be directly addressed. Additionally, due to the nature of the content of workshop, it would require facilitation and a small research team and therefore would be difficult and not feasible to conduct efficiently online.

The COSMIN criteria and rating system for evaluating the content validity of measurement instruments was used for the two self-report measurement instruments identified from the literature search, PROMIS Item Bank v2.0 – Cognitive Function and Dundee Stress State Questionnaire (DSSQ). Content validity was assessed according to three categories (**Table 4.1**) Group consensus criteria was set at 80% agreement.

Table 4.1 Content validity criterion from the COSMIN guidelines

Aspects of content validity	Criterion
Relevance	1. Are the included items relevant for the construct of interest?
	2. Are the included items relevant for the target population of interest?
	3. Are the included items relevant for the context of use of interest?
	4. Are the response options appropriate?
	5. Is the recall period appropriate?
Comprehensiveness	6. Are all key concepts included?
Comprehensibility	7. Are the items appropriately worded?
	8. Do the response options match the question?

4.2.2 Stakeholders – Cognitive Experts and Patient and Public Involvement

Tinnitus patients were recruited through the BRC and COMiT databases. Experts in cognition were identified using Google Scholar using key words such as “cognitive psychology”, “cognition” and “concentration”. Experts were contacted and invited directly by MS via email. Thirteen experts in cognition and ten tinnitus patients were invited to attend an in-person workshop which was held on 8th October 2019. However, as participants were invited from across the country, due to travel and availability constraints, only three experts and three members of the public with tinnitus were available to participate in the workshop.

4.2.3 Self-report measurement instruments assessed in the workshop

4.2.3.1 Cognitive Function Abilities Subset (PROMIS Item Bank v2.0)

The Cognitive Function Abilities Subset from the Patient Reported Outcome Measurement Information System (PROMIS) Item Bank v2.0 is one of the two questionnaires that was reviewed during the workshop for content validity (**Appendix 8.7**). It is a self-report questionnaire and can be administered electronically, using Computerised Adaptive Testing or manually, using pen-and-paper. The electronic version using Computerised Adaptive Testing is a pay-for-service, however, the pen-and-paper version is available free of cost.

The Cognitive Function Abilities Subset measures a participant's perception of their cognitive function in areas such as concentration, memory, and mental acuity with a recall period of 7 days. The full-item version of the questionnaire consists of 31 items/statements. There are three short versions, a 4-tem version, a 6-item version, and an 8-item version. However, for this project the full-item version was used. The response options are on a 5-point Likert scale: 1 for “not at all”, 2 for “a little bit”, 3 for “somewhat”, 4 for “quite a bit” and 5 for “very much”. The total raw score range is 31-155. The raw score is then converted to a standardised score using the conversion tables provided by PROMIS to enable interpretation of the scores. All questions must be answered to produce a valid score using the scoring tables. The score can then be used to indicate how a participant’s performance relates to the average and standard deviation of a population.

This aim of this project is to look at outcome measures for concentration only but even though this questionnaire has no defined subscale just for concentration, the PROMIS authors indicate that a tailored short form can be created by selecting items from the PROMIS bank of items therefore it was deemed relevant to be included in the content validity assessment. However, the scoring for any tailored versions would require using the PROMIS Scoring Service, which is a pay-for-service.

For ease of reference, the Cognitive Function Abilities Subset will be referred to as the ‘PROMIS questionnaire’ from this point on in the thesis.

4.2.3.2 Dundee Stress State Questionnaire (DSSQ)

The Dundee Stress State Questionnaire is the second questionnaire that was reviewed during the workshop for content validity (**Appendix 8.8**). The DSSQ is a self-report task-stress measure that differentiates three underlying aspects of the stress response: a) distress, b) task engagement, and c) worry. It is concerned with the participant's thoughts and feelings. The concentration subscale assesses the perceived efficiency of attention while at baseline and after performing a task.

It is administered using pen-and-paper. Part 1 of the questionnaire is administered at baseline and asks participants to consider how they feel *at the moment*. Part 2 is administered after completing a task and asks participants to consider how they felt *while performing the task*. The task to be performed is typically conducted in a controlled setting with the investigator present.

The questionnaire consists of four sections: 1) mood state, 2) motivation, 3) thinking style and 4) thinking content. Concentration is assessed as a subscale of Section 3, 'thinking style'. The concentration subscale has seven items/statements (#19-22 and #24-26). These statements ask about thoughts regarding one's efficiency of attention. The response options are on a 5-point Likert scale; 0 for "not at all", 1 for "a little bit", 2 for "somewhat", 3 for "very much" and 4 for "extremely".

To calculate the total score for concentration, the scores for seven items are summed, and then subtracted from the value 28. The raw score range is 0-28. High scores indicate good concentration. However, there is no guidance on how to interpret the raw score or the difference between the raw scores on the two versions of the questionnaire, with respect to the population.

4.2.4 Workshop design

Prior to the in-person workshop, participants were emailed a brief background and purpose of the meeting:

"During the meeting, we will be discussing the best way to measure concentration in adults with chronic subjective tinnitus in clinical research. We will be considering two instruments during the meeting. Our discussions will focus on whether the questions are asking about things directly relevant to concentration, as well as anything you particularly like or dislike about the questions. It's not essential, but you might like to think about these topics in advance."

In the same email, they were sent the following material (**Appendix 8.6**)

- Cognitive Function Abilities Subset (PROMIS Item Bank v2.0) (summary sheet and questionnaire)
- Dundee Stress State Questionnaire (DSSQ) (summary sheet and questionnaire)
- Summary sheet on our working definition of concentration

A summary sheet for each questionnaire was put together to send to the participants in advance of the workshop so they could familiarise themselves with the content of the session and ask questions in advance if they had any. Along with the summary sheets of the questionnaires, a summary sheet of our working definition of *concentration* as well as the questionnaires was also provided (**Appendix 8.6**).

MS led this study by organising and designing the workshop. This included:

- Identifying and inviting participants to the workshop. This included scheduling and organising the workshop including booking a venue, ordering catering and refreshments, booking some of the participants' travel, managing all participant communications pre and post the workshop and ensuring the participants completed all the forms needed to compensate them for their time and travel costs.
- Designing and preparing all the activities and materials used for the workshop: pre-workshop summary sheets that were sent to all participants in advance of the workshop, the worksheets for all the of activities for the day, a PowerPoint slide to

guide the session with visual tools, a comprehensive facilitator guide with the agenda and clear step-by step instructions for each session.

- Identifying and engaging an independent facilitator to moderate the session
- Supporting the facilitator on the day and providing any advice or clarifications as needed.
- Providing an introductory presentation to the project and the research conducted by COMiT leading to this stage.
- Conducting all the data analysis by collecting and scoring all the worksheets after each session to assess whether consensus was reached at each stage for both instruments being evaluated.

While MS was present to support the facilitator and introduce the project to the participants, MS did not conduct the workshop on the day to avoid researcher bias and therefore a facilitator (PK) was appointed to moderate. Administrative and technical support (JF) was present to help set up the room and equipment, as well as provide MS with logistical assistance. Additionally, to ensure the members of the public with tinnitus had physical assistance present on the day due to their complex medical needs, a 'healthcare user buddy' (HS) was also present.

The workshop was divided into Session 1: housekeeping/ ground rules, Session 2: purpose of the meeting and context to the project, Session 3: evaluating first two criteria of relevance for PROMIS, Session 4: evaluating all the relevance criteria for DSSQ, Session 5: evaluating the comprehensibility criteria for DSSQ, Session 6: evaluating the last three criteria of relevance for PROMIS, and Session 7: evaluating comprehensibility criteria for PROMIS.

The sessions for relevance for PROMIS were split into two sessions, Session 3 and Session 6, because the PROMIS questionnaire comprised of 31 items, and it was deemed excessively arduous for participants to assess them all if they were not relevant to the first two criteria: definition of interest, and the population of interest. Therefore, only the items that were

common across all the participants from Session 2 were then used for Session 6 and Session 7 to complete the evaluation of relevance and comprehensibility.

When asked about the first criteria of relevance for both PROMIS and the DSSQ, i.e. is it relevant to our definition of concentration, participants were provided with the three subdomains of concentration to choose from for each item:

1) Sustained attention: sustain focus on whatever you wish
2) Control attention: ability to control your attention
3) Effortfulness: cognitive effort and mental fatigue required when concentrating

These were explained clearly in Session 2 but also displayed on the slides through out for them to refer to when needed. Due to time constraints, the criteria for comprehensiveness, i.e. are all key concepts included was combined in the same relevance criteria 1 task (**Appendix 8.9** and **8.10**). During each of the sessions, MS collected the worksheets completed by the participants to conduct the scoring based on the COSMIN guidelines to assess if consensus was reached at each stage.

4.2.4.1.1 Session 1: Housekeeping/ ground rules

The facilitator, started Session 1 presenting housekeeping / ground rules, introducing the research team, and setting the scene for how the workshop was run and what to expect from the meeting.

4.2.4.1.2 Session 2: Purpose of the meeting and context to the project

MS presented the background of the project and played a short video from the COMiT'ID study to provide a summary of the work done to date and context of what concentration is and the 3 subdomains of concentration: sustain, control and effort as mentioned above. Participants were then briefed as to the purpose of meeting, and an agenda for the afternoon was provided.

For sessions 3-7, the facilitator introduced one of the two instruments and a subset of the criteria for relevance and/or comprehensibility and asked that participants discuss and then rate each item in the selected instrument against each of the selected criteria with a binary

Yes (i.e., this item meets this criteria) or No (the item does not meet this criteria). For each participant, a percentage was then calculated for each criterion (i.e. for each criterion, what percentage of items on that measure were deemed to have met the criteria) and scores above 85% were interpreted as the measure meeting these criteria overall (Terwee et al., 2017).

If consensus was not reached on an item, the facilitator was instructed to ask the group to share their dissenting opinions on that item. The group was also given the opportunity to have a further discussion with the aim of reaching consensus, i.e. agreement of at least 80% of the participants. This was repeated for each statement where consensus was not reached initially.

4.2.4.1.3 Session 3: Evaluating first two criteria of relevance for PROMIS

For this session, the facilitator guided the group through a discussion and then rating of each statement on the PROMIS questionnaire on the first two criteria of relevance:

1) Relevant to our definition of concentration, i.e. the ability to keep your attention focused on whatever you wish.
2) Relevant to the population of interest, i.e. adults with chronic subjective tinnitus

4.2.4.1.4 Session 4: Evaluating all the relevance criteria for DSSQ

For this session, the facilitator guided the group through evaluating relevance for the DSSQ on the five criteria for relevance:

1) Relevant to our definition of concentration
2) Relevant to the population of interest
3) Relevant for the context of use of interest, i.e. pre and post intervention in clinical trials.
4) Response options are appropriate
5) Recall period is appropriate

4.2.4.1.5 Session 5: Evaluating the comprehensibility criteria for DSSQ

For this session, the facilitator guided the group through evaluating comprehensibility for the DSSQ on the two criteria for comprehensibility:

1) Items appropriately worded
2) Response options match the question

4.2.4.1.6 Session 6: Evaluating the last three criteria of relevance for PROMIS

For this session, the facilitator brought the group back to evaluating relevance for PROMIS questionnaire instrument on the last three criteria for relevance. This was done for the common PROMIS items:

1) Relevant for the context of use of interest
2) Response options are appropriate
3) Recall period is appropriate

4.2.4.1.7 Session 7: Evaluating comprehensibility criteria for PROMIS

For the last session, the facilitator guided the group through evaluating comprehensibility for the common items on the PROMIS questionnaire on the two criteria for comprehensibility:

1) Items appropriately worded
2) Response options match the question

4.3 Results

A total of six participants took part in the workshop: three cognitive experts and three members of the public with tinnitus. Group consensus was only reached for four out of the eight criteria for both the PROMIS and DSSQ questionnaires (**Table 4.2**).

Table 4.2 COSMIN criteria and rating system for evaluating the content validity of PROMIS and DSSQ

Criteria	PROMIS consensus	DSSQ consensus
Relevance		
1. Are the included items relevant for the construct of interest?	100% N	50% Y 50% N
2. Are the included items relevant for the target population of interest?	50% Y 50% N	67% Y 33% N
3. Are the included items relevant for the context of use of interest?	100% Y	100% Y
4. Are the response options appropriate?	67% Y 33% N	67% Y 33% N
5. Is the recall period appropriate?	100% Y	100% Y
Comprehensiveness		
6. Are all key concepts included?	100% Y	100% Y
Comprehensibility		
7. Are the PROM items appropriately worded?	50% Y 50% N	50% Y 50% N
8. Do the response options match the question?	50% Y 50% N	100% Y

4.3.1 PROMIS

4.3.1.1 Relevance

For the first criterion, whether the statements were relevant to our construct, consensus was reached at 100%. All six participants rate it as 'N', that is, the PROMIS questionnaire was not relevant to concentration. For the second criterion, whether the statements were relevant to our population, consensus was not reached as 50% rated it 'Y' and 50% rated it 'N'. Of the six participants, three participants felt PROMIS was relevant for people with tinnitus, while the other three participants felt it was not.

From the 31 items, eight common items were selected to use. These items were items 3, 9, 10, 16, 22, 27, 28 and 29 (**Table 4.3**).

Table 4.3 Eight common items selected from PROMIS.

Item #	Statements
3	I have been able to pay attention and keep track of what I am doing without extra effort
9	I have been able to keep track of what I am doing, even if I am interrupted
10	I have been able to concentrate
16	I have been able to remember things as easily as usual without extra effort
22	My ability to follow driving directions has been as good as usual
27	My ability to concentrate has been good
28	I have been able to focus my attention
29	I have been able to mentally focus

For the third criterion, whether the statements were relevant to the context of use, consensus reached at 100% rating it as 'Y'. All six participants felt that that the common PROMIS items were relevant to be used in clinical trials as a measure pre and post intervention. For the fourth criterion, whether the response options were relevant, consensus was not reached as 67% rated it 'Y' and 33% rated it 'N'. Of the six participants, four participants felt that the response options on the common PROMIS items were relevant, while two participants felt they were not. For the last criterion of relevance, whether the recall period is appropriate, 100% 'Y' consensus was reached. All six participants felt that the 7-day recall period for the common PROMIS items were relevant.

4.3.1.2 Comprehensiveness

The criterion for comprehensiveness was whether all the key concepts were included. The eight common items on the PROMIS questionnaire were considered comprehensive as they met the 85% consensus agreement for the criterion. However, there was a lack of agreement on which items reflected which of the subdomains of concentration, i.e. sustain, control or effort.

4.3.1.3 Comprehensibility

For the first criterion, whether the statements are appropriately worded, consensus was not reached as 50% rated 'Y' and 50% rated 'N'. Of the six participants, three participants felt that the common items on the PROMIS questionnaire were appropriately worded, while the

other three participants felt they were not. For the second criterion, whether the response options matched the statements, again consensus was not reached as 50% rated 'Y' and 50% rated 'N'. Of the six participants, three participants felt that the response options did match the statements on the common items on the PROMIS questionnaire, while the other three participants felt they did not.

4.3.2 DSSQ

4.3.2.1 Relevance

For the first criterion, whether the statements are relevant to our construct, consensus was not reached as 50% rated 'Y' and 50% rated 'N'. Of the six participants, three participants felt that the DSSQ is relevant to concentration, while the other three participants felt it was not. For the second criterion, whether the statements are relevant to our population, consensus was not reached as 67% rated 'Y' and 33% rated 'N'. Of the six participants, four participants felt DSSQ was relevant for people with tinnitus, while two participants felt it was not. For the third criterion, whether the statements are relevant to the context of use, consensus reached at 100%, 'Y'. All six participants felt that that the DSSQ was relevant to be used in clinical trials as a measure pre and post intervention. For the fourth criterion, whether the response options are relevant, consensus was not reached as 67% rated 'Y' and 33% rated 'N'. Of the six participants, four participants felt that the response options on the DSSQ were relevant, while two participants felt they were not.

For the DSSQ, there were two recall periods, one at baseline 'at the moment' and one retrospectively post-task, 'while performing the task'. Therefore, the last criterion of relevance, whether the recall period is appropriate, was asked for both recall periods. For both 'at the moment' and 'while performing the task', 100% 'Y' consensus was reached. All six participants felt that both recall periods for the DSSQ were relevant.

4.3.2.2 Comprehensiveness

The criterion for comprehensiveness was whether all the key concepts were included. All seven items on the DSSQ were considered comprehensive as they met the 85% consensus agreement for the criterion. However, just like for PROMIS, there was a lack of agreement

on which items reflected which of the subdomains of concentration, i.e. sustain, control or effort.

4.3.2.3 Comprehensibility

For the first criterion, whether the statements are appropriately worded, consensus was not reached as 50% rated 'Y' and 50% rated 'N'. Of the six participants, three participants felt that the statements on the DSSQ was appropriately worded, while the other three participants felt they were not. For the second criterion, whether the response options matched the statements, consensus was reached at 100% 'Y'. All six participants felt that the response options did match the statements on the DSSQ.

4.4 Discussion

4.4.1 Summary of findings

The COSMIN methodology for assessing content validity of PROMs (Terwee et al., 2018b) states that for a measure to be relevant, at least criteria 1 and 2 need to have a consensus of 'Y' and at least two out of criteria 3-5 on relevance need to have a consensus of 'Y'. The first two criteria (relevant for construct and population) are the most important and therefore need a consensus rating of 'Y'. However, a maximum of one criterion rated 'N' is allowed. For comprehensiveness and comprehensibility, all the criteria need to have a consensus rating of 'Y'. Based on this guidance, PROMIS and DSSQ were judged not relevant to the construct of interest, the instruments do not measure concentration, and were not relevant to the population of interest, adults with tinnitus. While they did deem PROMIS and DSSQ relevant for the context of use, to be used in clinical trials as pre and post intervention measures, and with a relevant recall period, they did not think the response options were relevant. Both PROMIS and DSSQ were considered comprehensive even though consensus could not be reached on which items reflected which subdomains. And finally, both measures were not considered to be comprehensible as for PROMIS both criteria were not met and for DSSQ only one criterion out of two was met.

A key strength of the current study is that it followed COSMIN methodology, which, some years later is unchanged, and the same approach and care would be expected to be taken in this stage of COS development.

4.4.2 Limitations

There were a few limitations in this study. While it is crucial to involve patients in research, it is not always beneficial. Decisions need to be tailored based on the purpose and content of the research study. In this case, the patients found it difficult to comprehend the measurement property jargon, even when it was simplified and in hindsight due to the nature of the content, it may have been more useful to restrict the reviewing of content validity to researchers and clinicians. Additionally, people with tinnitus have various comorbidities/ health conditions and in the workshop study, we found that they struggled to keep up. One participant had previously had a stroke and that made it difficult for them to physically complete the scoring sheets, even with a Healthcare User Buddy that was assigned to help them, they struggled to keep up with the content of what was being discussed.

Another limitation was time. While the workshop managed to cover all the criteria of content validity, in hindsight it could have been more beneficial to have a full day session rather than a half-day session. This could have led to more flexibility with the time allocated to the discussion and rating of each criterion. Unfortunately, due to logistics and availability based on people travelling in from different parts of the country, only a half-day session on the selected day was possible.

While the initial scope was to have more participants attending the workshop (thirteen experts in cognition and ten tinnitus patients were invited), only six participants were able to attend (three experts and three members of the public with tinnitus) due to travel and availability constraints (maternity leave, familial responsibilities, and various other commitments). However, the smaller sample made the workshop more manageable and ensured that there was an equal voice of patients and cognition experts; everyone had a chance to voice their opinions during group discussions. Further workshops were considered, but as the world was entering into a pandemic stage and since both instruments

were not considered fit for purpose based on the results from the current workshop, another workshop did not seem practical or necessary.

4.5 Conclusion

Having established that no existing measurement tool provides a useful and valid measure of concentration for the purpose of assessing concentration for adults with tinnitus in clinical trials, a new questionnaire needs to be developed for this purpose. The next step will use an online survey to ask the population what various difficulties they face relating to concentration due to their tinnitus to help inform and develop items on the questionnaire.

5 The Impact of Tinnitus on Concentration: A Qualitative Study

5.1 Introduction

Evidence collected in the feasibility study (Chapter 3) and in the content validity workshop (Chapter 4) confirmed that the two shortlisted measures of concentration, PROMIS and DSSQ, were not appropriate for measuring concentration for adults with subjective tinnitus in clinical trials. Thus, the development of a self-report questionnaire for measuring concentration in adults with tinnitus for this purpose was indicated.

Development of a questionnaire measure as opposed to a performance-based tool is also preferred because, although concentration is a very common patient-reported complaint (Fackrell et al., 2016), when aspects of cognitive functioning are measured through performance-based objective measures the evidence is mixed in support of the impact of tinnitus (Mohamad, Hoare, and Hall, 2016). A meta-analysis conducted by Clarke et al., (2020) found that subjective tinnitus is associated with modest impairments in certain cognitive domains, particularly attention, memory, and executive function. However, the strength of these associations varied across studies, suggesting a complex relationship between tinnitus perception and cognitive performance.

Furthermore, there are various challenges associated with performance-based measures. First and foremost, there is a positive correlation between tinnitus severity and hearing loss (Mazurek et al., 2010). Therefore, confounding factors such as hearing loss may make it difficult for patients to complete performance-based measures. Additionally, licenses for most cognitive batteries are costly and require the need of a clinician, researcher, or trained administrator to be administered as they can usually not be self-administered. This would require resources and time. Some performance-based tasks also require equipment which is an additional cost. When discussing aspects of feasibility with tinnitus experts, concerns around prices of licenses, equipment and resources overall were raised, especially when the domain being measured is a secondary measure, resource allocation is usually prioritised for primary measures. Therefore, it is important that the measure be quick, free of cost, and self-administrable for it to be widely used.

5.1.1 Aim and objectives

The aim of this study was to identify and understand how people with tinnitus experience problems with concentration. The objective of this study was to gather qualitative data on which situations their concentration is impacted and how to help develop items on the new questionnaire. This was achieved through an online survey.

5.2 Methods

5.2.1 Sampling

Stratified sampling was used to ensure that the participant sample was reflective of the full spectrum of tinnitus severity, to enhance the representativeness and generalisability of the findings. Stratified sampling is a probabilistic sampling method in which the population is divided into distinct subgroups, or strata, based on a specific characteristic, and participants are then sampled from each stratum in predetermined proportions (Robertson and Sibley, 2018). This approach is particularly advantageous when working with heterogeneous populations as it allows for meaningful comparisons across subgroups and ensures that smaller or underrepresented segments are adequately captured in the data.

In this study, tinnitus severity served as the stratification variable, and the following proportion of participants were recruited for each of the five severity categories, based on Handscomb et al. (2020):

- Not a problem: 10%
- A small problem: 25%
- A moderate problem: 30%
- A big problem: 25%
- A very big problem: 10%

This ensured that the sample included a balanced representation across the range of, which was critical for examining the relationship between concentration and differing levels of tinnitus impact.

Adults with tinnitus were invited to participate in this study through various channels and organisations. The first was through Tinnitus UK, previously known as the British Tinnitus Association (BTA), by inviting the subscribers of their "Quiet" magazine as well as their wider community through their monthly newsletter, FOCUS as well as through their website (**Appendix 8.11**). Potential participants were also invited from the Nottingham Biomedical Research Centre (BRC) database and the international participant database from the COMIT'ID study to reach a broad range of people with tinnitus.

5.2.2 Eligibility criteria

Inclusion criteria for this study were:

- Adults (18 years and older)
- Chronic subjective tinnitus (symptoms persisting for 3 months or longer)
- Fluent in written and spoken English
- Have access to the internet.

5.2.3 Survey design

The study protocol was designed and submitted to FMHS REC for ethical approval, which was granted on 23 June 2020 (FMHS 34-0620).

The survey was designed by MS and reviewed by PhD supervisors, DAH and MAA. Using a list of multi-item tinnitus questionnaires collated by Haider et al., (2016), a list of concentration items was extracted and out together to assess if any existing items of concentration would be useful to include or adapt. It was decided that none of the existing concentration items were exploratory and since the aim of this survey was to understand when and how concentration is impacted, the questions needed to be open text and qualitative rather than quantitative. It was also important to understand the impact with regards to the three subdomains of concentration, i.e. sustained attention, control attention and mental effort. Therefore, the questions needed to be split by each domain. Based on the this, it was decided to use open ended questions asking participant, to list their top three situations where they feel each subdomain is most impacted and then to describe how it is impacted in those situations (**Table 5.1**).

Table 5.1 Questions from the Tinnitus Problems Survey

Questions	Response options
As someone with tinnitus, please describe what concentration means to you.	[open text]
Does your tinnitus impact your ability to sustain focus on whatever you intend to focus upon?	• Yes • No
Please state (when) and describe (how) situations where tinnitus impacts your ability to sustain focus on whatever you intend to focus upon (maximum 3 situations).	[open text]
Does your tinnitus impact your ability to control your attention?	• Yes • No
Please state (when) and describe (how) situations where tinnitus impacts your ability to control your attention (maximum 3 situations).	[open text]
Because of your tinnitus, do you require additional mental effort while concentrating?	• Yes • No
Please state (when) and describe (how) situations where additional mental effort is required because of the presence of tinnitus.	[open text]

Once the survey and participant information sheet were prepared by MS, a final review was conducted by the Hearing Sciences PPI group to ensure that the final version would be comprehensible and appropriate for the tinnitus population (**Appendix 8.12**). The PPI group only made edits to the Participant Information Sheet. These edits included tweaking the language such as “IP address” to “email address”, “people with tinnitus” instead of “tinnitus population” to ensure the language was accessible and any jargon was avoided. The final survey was then programmed by MS using JISC, an online platform recommended by the University of Nottingham, School of Medicine. The duration of the final survey was approximately 10 minutes.

5.2.4 Data collection

The survey was in field from 05 August 2020 to 07 September 2020 until sampling proportions were reached for each of the tinnitus severity groups.

5.2.5 Data analysis

The data were exported from JISC, and a separate spreadsheet was made for each of the concentration domains, i.e., sustain, control, and effort. A content analysis (Wilkinson, 2000) was conducted using NVivo to identify situations where tinnitus explicitly affected the three different aspects of concentration. This type of analysis involves a more structured approach to analysing textual data, focusing on the explicit content of the information, and categorising it in higher level groups, i.e. in this study the three sub domains of interest (Wilkinson, 2000, Kleinheksel et al., 2020).

While this study was designed and conducted by MS, good practice in analysis of qualitative data recommends two independent coders to reduce researcher bias and increase trustworthiness (Patrick et al., 2011a, Skjott Linneberg and Korsgaard, 2019). Therefore, a second independent coder (MMG) was only appointed for this stage of the study.

An inductive coding approach was adopted by both coders to identify situational codes from the qualitative data. The two coders independently reviewed the participants' responses, each generating a preliminary coding manual comprising of identified situations for each of the three subdomains (**Table 5.2** and **Table 5.3**). Following this independent coding phase, MS and MMG met to discuss their codes. Any discrepancies between codes were reviewed and resolved through discussion and consensus, resulting in a final, agreed-upon coding manual (**Table 5.4**).

MS then continued the last step of the data analysis on her own. This step aimed to quantify the qualitative data by calculating the frequency of each coded situation, thereby identifying which contexts were most frequently reported as impacting control attention, sustained attention, and effortfulness. MS did this by using the final agreed-upon coding manual to go through the responses to get familiar with the language used by the participants. However, in the data the same situation was described in multiple ways using different words, for

example “talking”, “conversation” and “speaking”, therefore MS identified similar words used in the responses for each code first and then a text search analysis was run to calculate the frequency of each situation and quantify the qualitative data. (**Table 5.5**).

Table 5.2 Codes identified by first coder MS

Sustain	Control	Effort
Conversation	Conversation	Conversation
Driving	Driving	Driving
Household tasks	Meditating	Listening to music
Listening to music	Noisy environment	Noisy situations
Noisy environment	Quiet environment	Quiet situations
Quiet environment	Radio	Reading
Reading	Reading	Sleeping
Relaxation	Sleeping	Television
Sleeping	Television	Working
Television	Working	
Working		

Table 5.3 Codes identified by second coder MMG

Sustain	Control	Effort
Distracted by tinnitus	Distracted by tinnitus	Affects memory
Tinnitus volume	Exhaustion	Affects MH
Being quiet	Not being able to hear clearly	Reduction, avoidance in tasks
Computer use	Tinnitus volume	Tinnitus dominance
Daily tasks	Conversation, listening	Tinnitus volume
Listening, in conversation	Driving	Tiredness
Reading	Headaches	Cooking
Relaxing	In crowds	Driving
Sleeping	Reading	In conversation, listening
Socialising	Relaxing	Reading
Thinking	Sleeping	Sleeping
Watching TV	Thinking	Thinking
Working, studying	TV	TV
	Working, studying	

Table 5.4 Final coding manual base on the agreed codes by both coders

Sustain	Control	Effort
Conversation	Conversation	Conversation
Driving	Driving	Driving
Household tasks	Listening to music/radio	Household tasks
Listening to music/radio	Noisy environment	Listening to music/radio
Noisy environment	Quiet environment	Noisy situations
Quiet environment	Reading	Quiet situations
Reading	Relaxing	Reading
Relaxing	Sleeping	Sleeping
Sleeping	Television	Television
Television	Working/studying/computer	Working/studying/computer
Working/studying/computer		

Table 5.5 Text search for the situations identified for each subdomain

Situations	Text search
Conversation	speak(ing), talk(ing), conversation(s), discussion, chat, saying, said
Driving	drive, driving, SATNAV
Household tasks	Household, kitchen, cooking, stove, daily
Music/radio	listening, music, radio, speaker
Noisy environment	noisy, shout, not quiet, loud(er), restaurant, pub
Quiet environment	quiet
Reading	read(ing)
Relaxing	relax(ing), relaxation, mind(ful)(ness), meditate, meditation, meditating, rest(ing), yoga
Sleeping	sleep(ing), asleep, bedtime, night
Television	watching, television, TV, telly, films, movies
Working/studying/computer	work(ing), worked, study(ing), computer, PC, meeting, conference, office, homework, learning, revision

5.3 Results

5.3.1 Sample characteristics

Responses were received from 236 people with tinnitus (**Table 5.6**). Of the 236 respondents, 120 were female and 116 were male. Participants' ages ranged from 18 to 88 years (*M* = 57.81, *SD* = 13.83). In terms of tinnitus severity, the breakdown was 'Not a problem' (*n* = 10), 'A small problem' (*n* = 89), 'A moderate problem' (*n* = 71), 'A big problem' (*n* = 44), and 'A very big problem' (*n* = 22).

Table 5.6 Characteristics of the sample achieved

	Tinnitus severity				
	Not a problem	A small problem	A moderate problem	A big problem	A very big problem
N (%)	10 (4%)	89 (38%)	71 (30%)	44 (19%)	22 (9%)
Age*					
M	53.4	54.1	60.6	61.4	59.0
SD	12.3	15.3	11.7	12.4	14.3
Sex					
Female	7	52	33	18	10
Male	3	37	38	26	12

**N = 234 for age due to two participants' not providing their age*

5.3.2 Main findings

Using content analysis, codes were identified for each concentration domain. The codes were the situations in which the participants felt their concentration was most impacted by tinnitus. Eleven situations were identified for sustain, 10 situations were identified for control, and 10 situations were identified for effortfulness.

Based on the text search analysis conducted on the responses, frequency of each situation was calculated for each of the subdomains (**Table 5.7**). For sustain (sustain focus on whatever you wish), the top five situations identified were reading (n=89),

working/studying/computer (n=89), conversation (n=72), television (n=46), and quiet environment (n=46). For control (ability to control your attention), the top five situations identified were conversation (n=45), reading (n=41), working/studying/computer (n=41), television (n=34), and quiet environment (n=20). For effort (cognitive effort and mental fatigue required when concentrating), the top fiv5 situations identified were reading (n=52), working/studying/computer (n=51), conversation (n=47), music/radio (n=46), and television (n=25).

Table 5.7 Frequency of all situations from responses for each subdomain based on the text analysis search

Situations	Sustain	Control	Effort
Conversation	72	45	47
Driving	4	5	9
Household tasks	5	N/A	2
Music/radio	31	16	46
Noisy environment	10	8	12
Quiet environment	46	20	18
Reading	89	41	52
Relaxing	23	10	N/A
Sleeping	30	16	16
Television	46	34	25
Working/studying/computer	89	41	51

5.3.2.1 Sustain

For this subdomain participants described difficulty sustaining their focus in the various situations. Some examples from participants have been highlighted:

- *"When doing household duties, e.g. washing up, I am bothered by the continual sound of my tinnitus unless I sing or have background music on."*
- *" It's easy to forget which sentence you on were when reading with tinnitus affecting my concentration."*
- *"During work when everything else is quiet it's sometimes a challenge to remain focused on my tasks."*

5.3.2.2 Control

For this subdomain participants described difficulty controlling their attention in the various situations. Some examples from participants have been highlighted:

- *"Tinnitus can dominate my mindfulness and make it difficult for a short time to control my attention."*
- *"During meetings it can be hard to keep focused on details as your head fills up with distracting noise."*
- *"Sometimes when watching tv, I become aware of the ringing noise and tend to lose the plot."*

5.3.2.3 Effort

For this subdomain participants described requiring more cognitive effort and mental fatigue when concentrating in the various situations. Some examples from participants have been highlighted:

- *"When reading, the silence amplifies 'T' and requires more effort to remain focused on what I'm reading."*
- *"When my tinnitus was bad, it meant that I couldn't transcribe for too long at a time - it became too stressful and tiring."*
- *"I sometimes have to apply extra mental effort to concentrate on driving and try to ignore the tinnitus."*

5.4 Discussion

5.4.1 Summary of findings

The exploratory survey aimed to identify how tinnitus impacts concentration, more specifically in what situations for each of the subdomains; sustain, control, and effort. For each of the subdomains, using content analysis, a list of situations was collated based on data extraction by two intendent coders, MS and MMG. For sustain 11 situations were identified which were: conversation, driving, household tasks, music/radio, noisy environment, quiet environment, reading, relaxing, sleeping, television and

working/studying/computer. For control 10 situations were identified which were: conversation, driving, music/radio, noisy environment, quiet environment, reading, relaxing, sleeping, television and working/studying/computer. And lastly for effort, 10 situations were identified which were conversation, driving, household tasks, music/radio, noisy environment, quiet environment, reading, sleeping, television and working/studying/computer.

Although the study was an online survey, the design and analysis were qualitative in nature, using open-ended questions to explore lived experiences of tinnitus and concentration difficulties. This sample is considerably larger than the typical sample sizes used in qualitative interview-based studies, where data saturation is often achieved within 12-30 participants (Guest et al., 2006; Braun and Clarke, 2022). However, given the use of stratified sampling to capture variability across tinnitus severity, and the aim of developing items for a new questionnaire, a larger and more diverse sample was both appropriate and advantageous. Braun and Clarke (2022) note that qualitative surveys, particularly when aiming to explore breadth across diverse experiences, can justify larger samples, especially when responses are shorter and designed to inform broader thematic development.

5.4.2 Limitations

The Nottingham Biomedical Research Centre (BRC) database and the international participant database from the COMIT'ID study were used to disseminate the survey as there is a responsibility to those who sign up to research databases. However, people who sign up to such databases are those that are motivated to take part in research and clinical trials and therefore are unlikely to be representative of the wider tinnitus population who do not traditionally engage with research. The Tinnitus UK database was also used which does not only include those who are interested in research, nevertheless efforts to use a variety of channels to represent the wider tinnitus population should be made.

Additionally, in the survey when asking participants for their demographic information, information on their location was not asked. As the survey was distributed via the COMiT'ID database, which has participants from all over the world, gathering geographic characteristics of the participants would have been useful would have be helpful to expand

and generalise the findings beyond people with tinnitus in the UK. Furthermore, the only tinnitus characteristic which was asked about was tinnitus severity, however asking if they experienced any hearing loss would also have been useful to quantitatively compare whether the issues reported were more prevalent and perhaps conflated by those who had comorbid hearing loss.

Lastly, content analysis requires researchers to interpret and categorise textual information based on predefined criteria, which can introduce bias and variability in the analysis process (Guthrie et al., 2004).

5.5 Conclusion

Situations identified included conversation, driving, household tasks, music/radio, reading, relaxing, sleeping, television, working/studying, and thinking. Participant descriptions of how their concentration is impacted in these situations will be used alongside concentration items from existing measures to draft a pilot questionnaire which will then go through cognitive interviews before a final pilot questionnaire is developed.

6 Creation of an Evidence-Based Measure to Assess "Concentration" for Sound-Based Interventions for Adults with Chronic Subjective Tinnitus

6.1 Introduction

The primary goal when developing items for a new questionnaire is to effectively capture all relevant aspects of the intended concept. It is recommended that the initial pool of items is broad and comprehensive (Clark and Watson, 2019). This inclusivity ensures that the items initially selected are as comprehensive as possible and all aspects of what is being aimed to measure have been covered. As the developers work through iterations of the questionnaire, the items are further refined, and any unrelated or weaker items can be removed. Insufficient items for each subdomain can impact the comprehensiveness and validity of the final questionnaire (Terwee et al., 2018b).

Chapters 2-4 of this thesis identified a list of existing concentration measures. However, the final shortlisted instruments were not valid for our concept of concentration. Chapter 5 reports two sources of items: 1) the tinnitus problems survey which helped identify how and when tinnitus impacts concentration with regards to each subdomain, and 2) a list of all the concentration items from existing tinnitus questionnaires.

6.1.1 Aims and objectives

The aim of this study was to create a new questionnaire measure of concentration. The objective was to use situations derived from the survey data in Chapter 5 to create items for the pilot questionnaire.

6.2 Methods

The questionnaire was developed using the situations identified from the tinnitus problems survey in Chapter 5. An excel sheet was also formulated to gather concentration specific questions from existing tinnitus questionnaires to inform items for this novel questionnaire.

An individualised and patient-centred approach was adopted in the design of this questionnaire to ensure that the instrument would be relevant, meaningful, and applicable across a diverse adult population with tinnitus. This approach was particularly important given the heterogeneity in lifestyles and the variety of situations in which concentration difficulties may occur. For example, a fixed set of items assessing concentration while working, reading, or driving may not be appropriate or answerable for people who are retired, do not drive, or do not engage in reading regularly. Additionally, there could be some situations which are not a problem for some people with tinnitus, while those situations could be a big problem for someone else. Without the ability to choose, such individuals may be forced to respond to items that lack relevance, compromising the accuracy and validity of the data. A flexible approach is therefore warranted that allows patients to select situations where they feel their concentration is impacted the most.

This approach has been used previously in an individualised outcome measure called the Measure Yourself Medical Outcomes Profile (MYMOP) (Paterson, 1996) where patients are asked to list the two most important symptoms that they are most impacted by. The MYMOP demonstrated that enabling respondents to select personally relevant domains increases the instrument's responsiveness and face validity, as it centres the patient's lived experience rather than imposing a universal set of items.

6.2.1 Item generation and survey design

Items were developed by MS and then reviewed and refined in consensus with the supervisory panel, DAH, DJH, and MAA. The questionnaire went through multiple iterations with the supervisory panel to ensure it covered the criteria for questionnaire development (Patrick et al., 2011a; Patrick et al., 2011b). The first version of the questionnaire used a standardised approach using the five most common situations from content analysis of the online survey (Chapter 5) before agreement that a patient-centred approach would be most

appropriate for the population of interest. The second version then adopted a patient-centred approach where the instructions and response options were modified to reflect the change. Noisy and quiet situations were then removed from the list of situations and added as separate questions in this version as they were prominent in the qualitative study. In the third version, these two questions were removed as it was agreed that other situations in the list overlapped. For example, reading is usually considered a quiet situation activity. Therefore, noisy and quiet situations were overarching situations, and it would be more useful to understand in which specific/individual situations patients felt their concentration was most impacted by their tinnitus. The fourth iteration only had slight changes to the instruction text to ensure it was simpler and clearer for patients to understand. The fifth iteration followed a readability analysis to ensure the questionnaire was of the recommended reading level. The final iteration was reached after cognitive interviews were conducted with members of the public who experience tinnitus. See **Table 6.1** for a summary of the iterations of the TiCQ.

Table 6.1 Summary TiCQ pilot questionnaire versions and amendments

Questionnaire version	No. of items	Amendments	Rationale
v1.1	15 items	• Standardised approach used vs patient-centred approach • Modified instructions • Modified response options • Modified final score	Used the most common situations for each of the three domains (top 5 situations per domain)
v1.2	11 items	• Patient-centred approach was used • Modified instructions • Modified response options • Removed noisy and quiet environments from drop-down list of situations • Added two separate questions on noisy and quiet environments • Modified final score	Used patient-centred approach as range of tinnitus experience and impact varies person-to-person Noisy and quiet situations separated as they were more overarching situations
v1.3	9 items	• Modified instructions • Removed the two separate questions on noisy and quiet environments • Final score modified	Noisy and quiet situations removed as they were overlapping with individual situations. Asking specific situations was considered more useful.
v1.4	9 items	• Modified instructions	Made the instruction text simpler and clearer to understand
v1.5 (post readability analysis)	9 items	• Minor changes to wording throughout questionnaire	Based on the readability assessment, some 3 syllable words were changed to 2 syllable words to lower overall grade level
v1.6 (post cognitive interviews)	9 items	• Minor changes to questionnaire lay out • Minor changes to wording in the instructions	After the cognitive interviews, edits were made based on recommendations from health-care users

6.2.2 Readability analysis

Readability analysis was conducted to test the reading level of the item text. The recommended reading level for healthcare questionnaires is typically between the 5th to 6th grade (10-12 years old) according to the American Medical Association (AMA) (Margol-Gromada et al., 2020). Readability level was assessed using an online readability calculator https://readabilityformulas.com/contact-us/, which assesses readability based on seven commonly used readability formulas:

- Linsear Write Formula
- SMOG Index
- Coleman-Liau Index
- Flesch-Kincaid Grade Level (FKGL)
- Flesch Reading Ease Formula (FRE)
- Automated Readability Index (ARI)
- FORCAST Readability Formula

6.2.3 Cognitive interviews

Cognitive interviewing entails administrating the pilot questionnaire to a few participants from the target population, using PPI and asking them to verbalise their mental process while they go through the questionnaire and provide their responses (Willis, 2005). The aim was to gather feedback on the pilot questionnaire and address comprehension of the survey regarding question phrasing, format, and response scales.

Participants were recruited through the NIHR Nottingham Biomedical Research Centre participant database (**Appendix 8.13**). Interested participants were asked to contact MS to make sure they were eligible. To take part, participants had to (1) be 18 years or older, (2) experience tinnitus for 3 months or longer, (3) be fluent in written and spoken English, and (4) have access to the internet.

For this study, a single round of cognitive interviews was conducted using a semi-structured interview guide (**Appendix 8.14**) with six individuals with tinnitus. Although eight participants were initially recruited, one withdrew due to a scheduling conflict and one

cancelled last minute due to personal reasons. Interviews were conducted in May 2022 online via Zoom and lasted approximately 60 minutes. All participants were compensated £25 for their time.

6.3 Results

6.3.1 Readability analysis

Results from the analysis ranged from Grade Level 8-10 (children aged 12-15 years old and reading level standard/ average too difficult to read). Based on this, edits were made to words with more than 3 syllables, such as “additional” to “extra” and the updated version of the questionnaire was ready for cognitive interviews.

6.3.2 Cognitive interviews

The questionnaire was edited in line with the recommendations made by the participants. Most of the changes were layout and formatting recommendations to ensure a smooth user experience when completing the questionnaire online such as changing to a matrix/grid format and making sure the survey platform restricts respondents to only selecting three situations. Additionally, a change to the instruction text was recommended- “we will be asking about all three parts in turn below” to “we will be asking about each of these areas”. See **Appendix 8.15** for final questionnaire.

6.4 Discussion

6.4.1 Summary of findings

This chapter describes the approach taken to develop the pilot questionnaire. Importantly, a list of situations was identified from people with tinnitus to understand in depth when and how tinnitus impacts their concentration with respect to the three subdomains of interest. This led to the adoption of a patient-centred and individualised approach to develop the Tinnitus Concentration Questionnaire (TiCQ), as people with tinnitus have a wide range of situations in which their concentration is impacted; this varies on an individual basis as one person may not drive and therefore there is no impact on their concentration as compared to someone who drives and feels like their tinnitus has a significant impact on their concentration when driving. In the pilot questionnaire, patients can select their top three situations where they feel tinnitus has the most impact on their concentration based on the activities, they take part in in their day-to-day lives. There was also PPI involvement during the cognitive interviewing stage to ensure patients' perspective was considered when developing the questionnaire as they are the target audience for the use of this measure.

6.4.2 Limitations

Although the sample size for the current study was small, sample size requirements for cognitive interviewing can be flexible and depend on several contextual factors. The current study had six participants and while Willis (2005) suggests that seven to ten interviews may be adequate, the actual number required is influenced by the complexity of the instrument, the diversity of the target population, and the extent of revisions anticipated. In cases where the questionnaire is relatively focused and the target group is well-defined; a smaller number of interviews can still provide meaningful insight. Despite the modest sample size, the participants reflected a range of tinnitus severity. Additionally, the aim of cognitive interviews was to make sure the questionnaire is comprehensible, by using PPI and not generalisability. Cognitive interviews of a similar sample size have also been conducted in a recent study developing a questionnaire assessing the impact of tinnitus in children (Smith et al., 2024). Lastly, there was no selection bias and all adults through the various channels were invited to take part.

6.5 Conclusion

The Tinnitus Concentration Questionnaire (TiCQ) was developed using a patient-centred approach. The TiCQ went through multiple iterations to ensure it covered the criteria for questionnaire development using the ISPOR guidelines and was suitable for the population of interest. A readability assessment and cognitive interviews were also conducted to ensure relevance, comprehensiveness and comprehensibility. Future work assessing the psychometric properties of the TiCQ needs to be carried out before it can be used in clinical trials.

7 General Discussion

The aim of this PhD was to develop a questionnaire to measure the impact of tinnitus on concentration, for use in clinical trials of sound-based interventions for adults with tinnitus, the Tinnitus Concentration Questionnaire (TiCQ). Development was accomplished following best practice guidelines for PROM development. A feasibility survey was carried out with tinnitus experts to understand which variables were most important when recommending a PROM. Content validity of two candidate no-cost questionnaires was assessed by cognitive experts and members of the public with tinnitus in an in-person workshop. After concluding the two candidate questionnaires were not optimal for assessing concentration in adults with tinnitus, development of a new questionnaire was indicated. First, an online survey was conducted to gain an in-depth understanding of how concentration is impacted in adults with tinnitus. This survey indicated which situations and how in those situations' concentration is most impacted by tinnitus. Candidate items were developed based on the situations and the TiCQ was designed using a patient-centred approach. The pilot version of the TiCQ went through six iterations in total. After three iterations, a readability assessment was conducted on v1.4. The refinements based on the analysis led to v1.5 which was then used for cognitive interviews. Based on the feedback, a final version was created (v1.6).

As detailed in Chapter 1, Selective Attention Theory describes the capacity to prioritise task-relevant stimuli while filtering out distractions; classic filter and late-selection models illustrate how unattended inputs may be attenuated or blocked entirely. Sustained Attention Theory refers to the endurance of focus over prolonged periods, with performance decrements (vigilance decrements) reflecting resource depletion or growing susceptibility to distraction. Cognitive load theory further posits that working memory has finite capacity, such that intrinsic and extraneous demands can exceed available resources, impairing concurrent task performance.

Concentration as defined by the COMiT'ID study (Hibbert et al., 2020) comprised of three subdomains, control attention which is the ability to control your attention on whatever you wish, sustained attention which is the ability to sustain focus on whatever you wish, and

effortfulness which refers to the cognitive effort and mental fatigue required when concentrating which map directly onto these theoretical constructs. The TiCQ uses the three subdomains of interest as its framework, and for each of these subdomains there is a corresponding item in the TiCQ that asks participants to select three situations in which these aspects of concentration are impacted. They are asked to rate from 0-10 how difficult they find it to sustain their focus, control their attention, and the extra mental effort required for each of the situations they have selected.

The control attention item assesses a respondent's perceived ability to ignore or filter out the tinnitus percept, reflecting participants' qualitative reports of tinnitus as a constant distractor in the situations they believe is most impacted. The sustained attention item measure how difficult respondents find it to maintain concentration over time during whichever situations they have selected, despite recurring tinnitus intrusions, mirroring the endurance aspect of attention outlined by vigilance research. The effortfulness item quantifies the extra mental effort or strain required to concentrate in the presence of tinnitus, embodying Sweller's notion of cognitive load when intrinsic demands (tinnitus severity) and extraneous demands (environmental or task factors) combine to burden working memory.

An individualised, patient-centred approach underpinned the development of the TiCQ to ensure its relevance, meaningfulness, and applicability across the heterogeneous tinnitus population. Recognising that concentration difficulties occur in variable contexts which differ from person to person such as work, reading, or driving, a fixed set of items would risk asking respondents about situations that are inapplicable or irrelevant to their daily lives. This would not only undermine a respondent's experience but also impact the validity of the results by forcing participants to score on items that do not reflect their personal experience. By contrast, the TiCQ's flexible format allows individuals to select and rate only those situations in which they perceive their tinnitus to impair concentration the most. This novel approach preserves content validity, enhances sensitivity to change, and reflects the lived realities of people with tinnitus, thereby optimising the instrument's utility in clinical trials, research and regular clinical practice.

7.1 Strengths and limitations

7.1.1 Strengths

A key strength of this PhD was the involvement of various key stakeholders throughout the research project. Tinnitus researchers (clinicians and non-clinicians), cognitive researchers, and members of the public with tinnitus were involved in the research process providing valuable insights at each stage to ensure that the TiCQ is a relevant and comprehensive tool that is applicable to assess concentration in adults with tinnitus. PPI has become an integral part of conducting healthcare research and should be at the core of the development of any new measurement instrument.

A further strength of this thesis is that the COSMIN methodology was followed, the recognised gold standard for the development and evaluation of patient-reported outcome measures which remains unchanged since its inception, meaning the same approach to developing this questionnaire would be taken today, i.e., the work is still as methodologically valid today as it was when first conducted. Moreover, by also drawing on best-practice guidance from other bodies like ISPOR (Patrick et al., 2011a; Patrick et al., 2011b) and established COS groups such as OMERACT (Boers et al., 2014), this PhD aligns its processes with international benchmarks, thereby enhancing the TiCQ's credibility, comparability and potential for uptake in both research and clinical settings.

As seen in the literature, tinnitus reported complaints can be subjective and of a wide range depending on each individual and their day-to-day activities. Therefore, using a patient-centred approach in the development of the TiCQ enables people with tinnitus to select the areas of their life where they feel tinnitus has the most impact on concentration, providing a more sensitive and tailored evaluation to assess the efficacy of sound- and electrical-stimulation-based interventions.

When conducting the tinnitus problems survey (Chapter 5), qualitative insights were gathered from over 200 people with tinnitus across the range of tinnitus severity using stratified sampling. A sample of this size is less common for qualitative study but ensured robust and rich data collection to gain an in-depth and detailed understanding to

understand when and how concentration is impacted by tinnitus across the range of tinnitus severity.

7.1.2 Limitations

Involving members of the public, especially patients, while very important, has its own limitations. Measurement property jargon, even when simplified, can be difficult for non-researchers to understand. People with tinnitus have various comorbidities and additional health conditions and in the workshop study, we found that they struggled to keep up. One participant had previously had a stroke and that made it difficult for them to physically complete the scoring sheets, even with a Healthcare Buddy that was assigned to help them, they struggled to keep up with the content of what was being discussed.

Another potential limitation was sample size, specifically for the workshop on content validity in Chapter 4 and perhaps to a lesser degree, the cognitive interviewing in Chapter 6. In the case of the workshop the sample were very much in agreement that the questionnaires under discussion were not fit for purpose. However, had the sample been greater, there may have been more debate or new perspectives. In the case of the cognitive interviews, six rather than the minimum recommended seven participants took part. Again, a larger sample could have added more diversity with potentially alternative views. Despite a broad invitation list, owing to scheduling conflicts, personal reasons and last-minute cancellations the intended sample size was not achieved but was as close to the amount recommended in the literature as possible. Moreover, although sample characteristics such as age, sex and tinnitus severity were routinely collected, future studies should collect additional characteristics such as geographical region, hearing-loss status, socioeconomic indicators and comorbidities to enable broader analyses and strengthen external validity. Finally, reliance on the BRC and COMiT'ID databases for recruitment, while efficient and good practice, may have introduced volunteer bias by over-representing highly motivated individuals; wider outreach through community settings and routine clinical pathways is therefore recommended to enhance representativeness.

Due to limited resources, when conducting the literature search to identify existing measures of concentration (Chapter 2), only one researcher was able to continue full-text

screening the records identified. However, to ensure quality control and avoidance of bias, two researchers screened a subset of records in the title and abstract screening stage to assess eligibility, and an inter-rater agreement sore was calculated. Additionally, due to the large number of records identified, a data saturation approach had to be used due time constraints.

7.2 Future directions

7.2.1 Extensive validation study

While the present study focused on developing a novel questionnaire, time and resource constraints prevented psychometric testing. A powered online validation study testing various psychometric properties of the questionnaire to ensure robustness is critical. This will provide a comprehensive assessment of the measurement properties of the TiCQ before it can be recommended for use in clinical trials.

The validation study should assess the following measurement properties, in line with the COSMIN guidelines when recommending a health-related PROM (Terwee et al., 2007; Mokkink et al., 2010):

1. Test-retest reliability: The stability of the measure over time should be evaluated by administering the questionnaire to the same sample on two occasions, separated by a recommended 1-2 week interval. A minimum sample size of 50 participants would be required to ensure appropriate power to detect reliability estimates (Terwee et al., 2007). Intraclass correlation coefficients (ICCs) would be calculated, with values above 0.70 indicating acceptable stability.

2. Internal consistency: Internal consistency should be assessed using Cronbach's alpha to determine the extent to which individual items measure the same underlying construct. An alpha value between 0.70 and 0.95 is generally considered acceptable, reflecting both item homogeneity and lack of redundancy.

3. Construct validity: Construct validity should be evaluated through two approaches:
    a. Convergent validity: This approach tests the degree to which two measures that are designed to assess the same construct produce similar results, in this case by correlating the TiCQ against an existing validated tool that assesses the same or closely related construct. This could be done using the concentration subscale of the Tinnitus Functional Index (TFI). A strong positive correlation would provide evidence that the TiCQ is measuring the construct of interest.
    b. Divergent validity: This approach tests the degree to which two measures that are designed to assess different construct produce different results, in this case by assessing the correlation between the TiCQ and a questionnaire designed to measure an unrelated construct. This could be done by using, for example, an anxiety or depression questionnaire measure. A weak correlation would support the specificity of the instrument.

4. Floor and ceiling effects: The distribution of patient scores should be examined to ensure that the TiCQ is sensitive enough to detect both deterioration and improvement over time. Instruments with floor or ceiling effects exceeding 15% are generally considered to have limited measurement range (Terwee et al., 2007).

Completion of psychometric testing would be essential before recommending the TiCQ for use in clinical trials, to ensure its reliability, validity, and responsiveness to measuring treatment-related change.

7.2.2 Questionnaire use and uptake

After the TiCQ is validated and ready to be recommended and widely used, successful implementation of the Tinnitus Concentration Questionnaire (TiCQ) in clinical research will depend upon overcoming barriers to questionnaire use, including instrument length, administrative burden and variability in patient health literacy (Philpot et al., 2018). To address these concerns, the TiCQ was developed, guided by the feasibility study reported in Chapter 3, to be free of charge, quick to complete, self-administered and equipment-free.

These characteristics should mitigate respondent fatigue, minimise resource requirements for both administrators and clinicians, and accommodate individuals with lower literacy levels. In recognition of diverse research settings, the TiCQ will be available in both digital and pen-and-paper formats; however, the latter will require further layout optimisation to ensure clarity, legibility and accessibility for all user groups.

To further enhance uptake, the TiCQ should be translated and adapted to be used for comparisons across populations divided by language in accordance with established good-practice guidelines for translation and cultural adaptation of patient-reported measures (Hall et al., 2018). This will involve preparation (assembling a multidisciplinary team, confirming permissions and intended use), forward translation into the target language by at least two bilingual translations, back-translation into the source language by at least one bilingual translator, expert committee review to reconcile discrepancies and refine wording, field testing using cognitive interviews with the target-language respondents to assess clarity and cultural relevance, and final review using pilot data, proofreading, formatting checks as well publishing a report on the final translation. This will help facilitate reliable use of the TiCQ in multinational trials and among linguistically diverse populations.

Additionally, a comprehensive user manual should be produced to accompany the TiCQ, detailing instructions for administration, scoring, interpretation of scores and examples of application in both clinical and research contexts (Mokkink et al., 2010). By providing clear, standardised instructions, the manual will aim to reduce training burden, promote consistent use and embed the TiCQ within routine practice.

7.2.3 Core Outcome Set (COS) uptake

In recent years, awareness and consideration of Core Outcome Sets (COS) have increased among researchers and systematic review authors; however, uptake remains inconsistent across healthcare research. As mentioned in Chapter 1, the use of COS is crucial to improve standardisation of outcomes and evidence synthesis of efficacy of interventions across health care research.

To facilitate uptake of COS, there needs to be an increased awareness of the existence of the COS for any health condition. The Cochrane Handbook now explicitly recommends that systematic reviews identify and align selected outcomes with existing COS from the COMET database, where available, thereby promoting awareness and standardisation to enhance the quality of evidence synthesis (Saldanha et al., 2024).

Furthermore, major research funders including the National Institute for Health and Care Research (NIHR) have begun to explicitly require applicants to justify the selection of outcomes in grant applications through reference to established COS. For example, NIHR commissioning briefs now commonly stipulate the inclusion of relevant COS unless clear justification is provided otherwise. Additionally, Shea et al. (2024) emphasise the importance of stakeholder engagement and partnership-building strategies as complementary approaches to further embed COS usage within research practice, underscoring the necessity of both top-down and collaborative mechanisms to ensure wide adoption.

Within tinnitus research, the uptake and standardisation of Core Outcome Sets (COS) are particularly significant due to the heterogeneous nature of the condition and variability in outcome measurement. The Tinnitus Research Initiative (TRI), an international non-profit foundation dedicated to the development of effective treatments for tinnitus, has previously demonstrated leadership in the standardisation of tinnitus measurement. Notably, the TRI consensus meeting in Regensburg in 2006 produced recommendations for standardising tinnitus patient assessments and treatment outcomes, resulting in the widely adopted TRI consensus guidelines (Langguth et al., 2007).

Building on this, TRI has recently prioritised an international effort to define and standardise measures for all tinnitus core outcomes, including pledging to lead initiatives to determine a consensus on which outcomes should be primary and secondary measures as a standard (Vanneste, 2025). This underscores the tinnitus research community's commitment to COS implementation, supporting more consistent reporting, improved data comparability, and ultimately advancing effective tinnitus management strategies.

Electrical stimulation interventions were not included in the COS development during the COMiT'ID study due to limited evidence available at the time whereas extensive efforts in clinical research for tinnitus have been made internationally for sound, psychology and drug-based interventions. However, in subsequent years there has been an increase in the types of electrical stimulation interventions and in the number of studies evaluating their efficacy as treatment options for tinnitus. Due to the growth of electrical stimulation clinical trials, a COS has now been developed for this type of intervention to ensure a minimum reporting standard is being used across these studies, facilitating comparability of research findings. The COS for electrical stimulation was developed using an online Delphi study and the established set includes five outcomes: 'tinnitus intrusiveness', 'ability to ignore', 'concentration', 'helplessness', and 'treatment satisfaction' (Labree et al., 2025).

The introduction of this COS addresses the previously unmet need for standardised outcome reporting in electrical stimulation trials, further enhancing comparability and evidence synthesis across tinnitus intervention studies. Additionally, given that 'concentration' is a core domain for both sound-based and electrical stimulation interventions, the TiCQ will be an important measure in future trials using either intervention. Equally, trials in this space offer the opportunity for nested studies to examine the psychometric properties of the TiCQ.

7.3 Conclusion

This PhD brings new understanding specifically of how tinnitus impacts concentration in adults with tinnitus and is the first tinnitus questionnaire that accesses concentration specifically. The various studies conducted have contributed to the development of the TiCQ with regards to sustaining attention, control attention, and the additional mental effort required when concentrating. A validation study on TiCQ is crucial as it not only offers a potential tool when assessing the impact of tinnitus on concentration to sensitively assess the efficacy of sound, but also electrical stimulation-based interventions. It may also be used in routine clinical practice and research studies that seek to further understand how concentration is impacted in adults with tinnitus and how this can be mitigated.

8 APPENDICES

8.1 Appendix 1: Search syntax used for PyscINFO (Ovid)

PyscINFO (Ovid)		
1	(concentration or cognitive failure? or sustained attention or pay attention or working memory or attentive or attentiveness or vigilant or vigilance or focused attention or focusing attention).ti,ab.	86933
2	(patient report* or self report* or patient rated or self rated or patient rating? or self rating? or proxy report* or carer report* or proxy rated or carer rated or proxy rating? or carer rating? or performance test?).ti,ab.	133867
3	(index or indices or instrument? or measure? or questionnaire? or profile? or scale? or score? or status or survey? or tool? or test? or assessed or assessment?).ti,ab.	1927648
4	1 and 2 and 3	3059
5	limit 4 to (human and adulthood <18+ years> and "300 adulthood <age 18 yrs and older>" and "0100 journal" and human)	2081

8.2 Appendix 2: Search syntax used for EMBASE (Ovid)

EMBASE (Ovid)		
1	*mental concentration/	81
2	(cognitive failure? or sustained attention or pay attention or working memory or attentive or attentiveness or vigilant or vigilance or focused attention or focusing attention).ti,ab,kw.	80297
3	1 or 2	80363
4	(patient report* or self report* or patient rated or self rated or patient rating? or self rating? or proxy report* or carer report* or proxy rated or carer rated or proxy rating? or carer rating? or performance test?).ti,ab.	245826
5	(index or indices or instrument? or measure? or questionnaire? or profile? or scale? or score? or status or survey? or tool? or test? or assessed or assessment?).ti,ab.	9442970
6	3 and 4 and 5	2990
7	limit 6 to (human and (article or article in press) and (adult <18 to 64 years> or aged <65+ years>))	1551

8.3 Appendix 3: Search syntax used for CINAHL (EBSCO)

CINAHL (EBSCO)			
1	TI (concentration OR “cognitive failure?” OR “sustained attention” OR “pay attention” OR “working memory” OR attentive OR attentiveness OR vigilant OR vigilance OR “focused attention” OR “focusing attention”) OR AB (concentration OR “cognitive failure?” OR “sustained attention” OR “pay attention” OR “working memory” OR attentive OR attentiveness OR vigilant OR vigilance OR “focused attention” OR “focusing attention”)	Limiters - Research Article; Human; Age Groups: All Adult	30777
2	TI (“patient report*” OR “self report*” OR “patient rated” OR “self rated” OR “patient rating?” OR “self rating?” OR “proxy report*” OR “carer report*” OR “proxy rated” OR “carer rated” OR “proxy rating?” OR “carer rating?” OR “performance test?”) OR AB (“patient report*” OR “self report*” OR “patient rated” OR “self rated” OR “patient rating?” OR “self rating?” OR “proxy report*” OR “carer report*” OR “proxy rated” OR “carer rated” OR “proxy rating?” OR “carer rating?” OR “performance test?”)	Limiters - Research Article; Human; Age Groups: All Adult	38729
3	TI (index OR indices OR instrument? OR measure? OR questionnaire? OR profile? OR scale? OR score? OR status OR survey? OR tool? OR test? OR assessed OR assessment?) OR AB (index OR indices OR instrument? OR measure? OR questionnaire? OR profile? OR scale? OR score? OR status OR survey? OR tool? OR test? OR assessed OR assessment?)	Limiters - Research Article; Human; Age Groups: All Adult	377494
4	1 AND 2 AND 3		784

8.4 Appendix 4: List of all the excluded measures.

Name of instrument	Construct as defined by author
Addenbrooke's Cognitive Examination Revised (ACE-R)	Orientation, attention, memory, verbal fluency, language, visuospatial ability
Adult Self-Report (ASR)	Aggression and oppositionality, anxiety, attention problems and hyperactivity, depression and mood, personality traits, psychotic and atypical behaviour, risk taking and impulsive behaviour, somatic complaints, substance use
Attention-Related Cognitive Errors Scale (ARCES)	Absent-mindedness
Attention-Related Driving Errors Scale (ARDES-US)	Attention-related errors while driving
Attentional Function Index (AFI)	Effectiveness in common activities requiring attention and working memory
Attentional Network Test (ANT)	Alerting, orienting and executive attention
Automated Neuropsychological Assessment Metrics (ANAM)	Processing speed/efficiency, retention/memory, working memory
Automated Working Memory Assessment (AWMA)	Working memory
Barkley Deficits in Executive Functioning Scale - Short Form (BDEFS)	Time management, organization and problem solving, self-restraint, self-motivation, and self-regulation of emotions
Barratt Impulsivity Scale 11th revision (BIS–11)	Personality/behavioural construct of impulsiveness
Behaviour Rating Inventory of Executive Function Adult Version (BRIEF-A)	Executive function
Bourdon-Wiersma Test/Dot Cancellation Test	Combined visual perception and vigilance
Brief Assessment of Cognition in Schizophrenia (BACS)	Cognitive impairment in patients with schizophrenia
Brief test of adult cognition by telephone (BTACT)	Verbal memory (immediate and delayed), working memory span, verbal fluency, attention-switching/reaction time, reasoning, speed of processing
Cognitive Failures Questionnaire (CFQ)	Absent-mindedness
Computerized Neurocognitive Battery (CNB)	Attention problems and hyperactivity, cognitive and executive function, motor/sensorimotor function, short

	term memory, verbal learning, working memory
Consonant Trigram Test (CTT) / Brown-Peterson technique	Working memory
Controlled Oral Word Association Test (COWAT)	Verbal fluency
Corsi Blocks Test	Short term memory task
Delis-Kaplan Executive Function System battery (D-KEFS)	Higher-level thinking and cognitive flexibility
Digit Ordering Test (DOT)	Verbal working memory
Digit Span	Short term verbal working memory
Digit Symbol Substitution Test (DSST)	Processing speed, working memory, visuospatial processing and attention
Dysexecutive Questionnaire (DEX)	Emotional, motivational, behavioural and cognitive
Esame Neuropsicologico Breve (ENB, Short Neuropsychological Examination)	*(Excluded as it is an Italian battery and not available in English language)*
Frontal Assessment Battery (FAB)	Conceptualization, mental flexibility, programming, sensitivity to interference, inhibitory control, environmental autonomy
Judgment of Line Orientation Test	Visuospatial skills
LOGOS	*(Excluded as it is a Norwegian computerized test for reading processes)*
MicroCog Assessment of Cognitive Functioning	Attention/mental control, memory, reasoning / calculation, spatial processing, reaction time
Mindful Attention Awareness Scale (MAAS)	Dispositional mindfulness, namely, open or receptive awareness of and attention to what is taking place in the present
N-back test	Working memory
Operation Span Task (OSPAN)	Working memory capacity
Paced Auditory Serial Addition Task (PASAT)	Auditory information processing speed and flexibility, as well as calculation ability
Questionnaire of Cognitive Failures in Everyday Life (KFA)	Absent-mindedness
Rao's Brief Repeatable Battery (BRB)	Sensitive measure of cognitive impairment in multiple sclerosis (MS) (cognitive impairment not defined)
Repeatable Battery for the Assessment of Neuropsychological Status (RBANS)	Immediate memory, visuospatial/constructional, language, attention, delayed memory

Short Imaginal Processes Inventory (SIPI)	Daydreaming style and content, mental style, and general inner experience
Stroop	Cognitive interference
Sustained Attention to Response Task (SART)	Working memory, sustained attention, and impulse/inhibitory control
Symbol-Digit Modalities Test (SDMT)	Information processing speed and efficiency
Syndrom-Kurztest-Short Cognitive Performance Test (SKT)	Memory and attention
Thought Characteristics Questionnaire (TCQ)	Distraction, social control, worry, punishment and reappraisal
Tower of London Task / Tower of Hanoi Task	Executive function, specifically planning
Trail Making Test (TMT)	Processing speed, sequencing, mental flexibility, visual motor skills
Wechsler	Processing speed, working memory, visuospatial processing and attention
Wender Utah Rating Scale (WURS)	Retrospective diagnosis of childhood attention deficit hyperactivity disorder (ADHD) used to evaluate adults for ADHD
Wisconsin Card Sorting Test (WCST)	Executive function, cognitive reasoning, perseveration and abstract thinking

8.5 Appendix 5: Feasibility survey at TRI Conference

Feasibility aspects of measurement instruments

Imagine that you are setting up a clinical trial to investigate the effect of a sound-based intervention for tinnitus. In your opinion:

1. What is the maximum amount you would be willing to pay to obtain a license for a measurement instrument to use before and after the intervention? (answer in your own currency)

   _____

2. What should be the maximum duration for one measurement instrument to use before and after the intervention? (answer in minutes)

   _____

3. If a measurement instrument requires the administrator to be trained or be a specialist, would you use it?
   i. yes
   ii. no
   iii. depends

   _____
   _____

4. For interpreting the scores, what would the measurement instrument need to have for you to use it? Here are some specific examples:
   a. clinical norms
      i. yes
      ii. no
      iii. depends

      _____
      _____

   b. grading system
      i. yes
      ii. no
      iii. depends

      _____
      _____

   c. continuous scale (such as one where a higher score means 'worse')
      i. yes
      ii. no
      iii. depends

      _____
      _____

5. If a measurement instrument requires equipment, would you use it? Here are some specific examples:
    a. pen and paper
        i. yes
        ii. no
        iii. depends

        _____
        _____

    b. online (access to the internet)
        i. yes
        ii. no
        iii. depends

        _____
        _____

    c. standalone computer or tablet device
        i. yes
        ii. no
        iii. depends

        _____
        _____

    d. loudspeakers
        i. yes
        ii. no
        iii. depends

        _____
        _____

    e. headphones
        i. yes
        ii. no
        iii. depends

        _____
        _____

    f. software to be installed (which is **not** needed for routine clinical practice)
        i. yes
        ii. no
        iii. depends

        _____
        _____

6. If a measurement instrument needs to be administered in a particular way, would you use it? Here are some specific examples:
    a. self-administered by the patient (i.e. unsupervised)
        i. yes
        ii. no
        iii. depends

        _____
        _____

    b. administered by yourself (i.e. supervised by a tinnitus expert)
        i. yes
        ii. no
        iii. depends

        _____
        _____

    c. delegated to a team member (i.e. supervised but not a tinnitus expert)
        i. yes
        ii. no
        iii. depends

        _____
        _____

7. Does the method of scoring the instrument matter to you? Here are some specific examples:
    a. automatic score calculation
        i. yes
        ii. no
        iii. depends

        _____
        _____

    b. manual score calculation
        i. yes
        ii. no
        iii. depends

        _____
        _____

8. Do you have a preference for the type of outcome? Here are some specific examples:
    a. questionnaires (self-report measures)
        i. yes
        ii. no
        iii. depends

        _____
        _____

    b. performance-based measures
        i. yes
        ii. no
        iii. depends

        _____
        _____

9. If yes for questionnaires, if the relevant domain or construct is just a subscale of a bigger questionnaire, would you use it?
        i. yes
        ii. no
        iii. depends

        _____
        _____

8.6 Appendix 6: Materials sent to participants before the content validity workshop.

CONCENTRATION SUMMARY SHEET

CONCENTRATION

Our working definition of concentration is:
"The ability to keep your attention focused on whatever you wish".

This refers to the ability to **control your attention** and **sustain focus** on whatever it is you intend to focus upon, with successful tinnitus interventions enhancing the ability to concentrate by making it easier and **less effortful.**

Illustrative examples given by our tinnitus experts to explain these aspects of concentration include:

"So concentration is the ability to exercise attentional control, to stay focused on something of our own choice. This ability is impeded when you have tinnitus".

"I would consider a sound-based treatment successful if it restored, even partially, my ability to immerse myself in a task and for this to feel less of an effort than it is now. Ideally, the treatment should reduce the occurrence of cognitive tiredness that makes sustained concentration difficult."

SUMMARY OF PROMIS QUESTIONNAIRE SHEET

Name of instrument: Cognitive Function Abilities Subset (PROMIS Item Bank v2.0)
Source: Patient Reported Outcome Measurement Information System (PROMIS)
Type of instrument: questionnaire
Cost of instrument: free of charge

Overall purpose of questionnaire:
The PROMIS Cognitive Function Abilities subset measures a participant's perception of cognitive function in areas such as concentration, memory, and mental acuity “in the last 7 days”.

This questionnaire has no defined subscale for concentration, but the PROMIS authors indicate that a tailored short form can be created by selecting items from the PROMIS bank of items.

How it is administered:

- The PROMIS Cognitive Function Abilities subset can be administered electronically, using Computerized Adaptive Testing (this is a pay-for-service).
- It could also be given using pen-and-paper (free of charge).

Structure of questionnaire:

- The full-item version of the questionnaire consists of 31 items/statements.
- Response options are on a 5-point Likert scale; 1 for “not at all”, 2 for “a little bit”, 3 for “somewhat”, 4 for “quite a bit” and 5 for “very much”

Scoring:
To find the total raw score with all questions answered, sum the values of the response to each question. The raw score range is 31-155. The raw score is then converted to a standardised score using the conversion tables provided by PROMIS to enable interpretation of the scores. All questions must be answered in order to produce a valid score using the scoring tables.

Scoring for a tailored version would require using the PROMIS Scoring Service (this is a pay-for-service).

Interpretation of scores:
The score can be used to indicate how your performance relates to the average and standard deviation of the population.

Recall period:
7 days

SUMMARY OF DSSQ SHEET

Name of instrument: Dundee Stress State Questionnaire (DSSQ)
Source: Matthew et al., 1999; 2002
Type of instrument: questionnaire
Cost of instrument: free of charge (need permission from author)

Overall purpose of questionnaire:
The Dundee Stress State Questionnaire (DSSQ) is a self-report task-stress measure that differentiates three underlying aspects of the stress response; i) distress, ii) task engagement, and iii) worry. It is concerned with the participant's thoughts and feelings.

The concentration subscale assesses the perceived efficiency of attention while at baseline and performing a task.

How it is administered:

- It is administered using pen-and-paper.
- One version of the questionnaire is administered at baseline and asks you to consider how you feel *at the moment*. A second version is administered after completing a task and asks you to consider how you felt *while performing the task*. The task to be performed is typically conducted in a controlled setting with the investigator.

Structure of questionnaire:

- The questionnaire consists of four sections: 1) mood state, 2) motivation, 3) thinking style and 4) thinking content. Concentration is assessed as a subscale of section 3.
- The concentration subscale has 7 items/statements (#19-22 and #24-26).
- These are all statements about your thoughts about your efficiency of attention.
- Response options are on a 5-point Likert scale; 0 for "not at all", 1 for "a little bit", 2 for "somewhat", 3 for "very much" and 4 for "extremely".

Scoring:
To find the total score for concentration, sum the 7 items and subtract total from the value 28. The raw score range is 0-28. We could not find any information about how to handle missing data.

Interpretation of scores:
High scores indicate good concentration. However, there is no guidance on how to interpret the raw score or the difference between the raw scores on the two versions of the questionnaire, with respect to the population.

Recall period:

- First version (baseline): N/A since it is asking about *at the moment*
- Second version (task-related version): Immediately after the task

8.7 Appendix 7: PROMIS questionnaire

Cognitive Function Abilities Subset

Please respond to each question or statement by marking one box per row.

	In the past 7 days…	**Not at all**	**A little bit**	**Somewhat**	**Quite a bit**	**Very much**
PC20r	I have been able to bring to mind words that I wanted to use while talking to someone.....	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
PC27r	I have been able to remember to do things, like take medicine or buy something I needed.....	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
PC29_2r	I have been able to pay attention and keep track of what I am doing without extra effort.....	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
PC4r	I have been able to think clearly.....	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
PC43_2r	My mind has been as sharp as usual	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
PC44_2r	My memory has been as good as usual....	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
PC45_2r	My thinking has been as fast as usual	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
PC46_2r	I have been able to shift back and forth between two activities that require thinking.....	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
PC47_2r	I have been able to keep track of what I am doing, even if I am interrupted.....	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
PC6r	I have been able to concentrate	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

In the past 7 days...

		Not at all	A little bit	Somewhat	Quite a bit	Very much
PC-CaPS1r	I have been able to form thoughts clearly	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
PC-CaPS10r	I have been able to remember telephone numbers	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
PC-CaPS11r	I have been able to get my point across when talking with someone	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
PC-CaPS12r	I have been able to remember the name of a familiar object	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
PC-CaPS13r	I have been able to think as clearly as usual without extra effort	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
PC-CaPS14r	I have been able to remember things as easily as usual without extra effort	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
PC-CaPS16r	My ability to remember important dates has been as good as usual	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
PC-CaPS17r	My ability to remember names has been as good as usual	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
PC-CaPS19r	My ability to keep track of lists has been as good as usual	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
PC-CaPS2r	My thinking has been clear	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
PC-CaPS20r	My ability to count money has been as good as usual	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

	In the past 7 days...	Not at all	A little bit	Somewhat	Quite a bit	Very much
PC-CaPS21r	My ability to follow driving directions has been as good as usual	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
PC-CaPS22r	I have been able to handle many tasks at once without losing track of what I was doing.....	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
PC-CaPS23r	My ability to remember things that I need to do has been as good as usual.....	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
PC-CaPS24r	I have been able to multi-task as easily as usual without extra effort	☐ 1	☐ 2	☐ 3	☐ 3	☐ 5
PC-CaPS3r	I have been able to think clearly without extra effort.....	☐ 1	☐ 2	☐ 3	☐ 3	☐ 5
PC-CaPS4r	My ability to concentrate has been good..	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
PC-CaPS5r	I have been able to focus my attention.....	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
PC-CaPS6r	I have been able to mentally focus	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
PC-CaPS8r	I have been able to remember the name of a familiar person.....	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
PC-CaPS9r	I have been able to learn new things easily, like telephone numbers or instructions.....	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

8.8 Appendix 8: DSSQ

3. THINKING STYLE

In this section, we are concerned with your thoughts about yourself: how your mind is working, how confident you feel, and how well you expect to perform on the task. Below are some statements which may describe your style of thought **RIGHT NOW**. Read each one carefully and indicate how true each statement is of your thoughts **AT THE MOMENT**. To answer, circle one of the following answers:

Extremely = 4 Very much = 3 Somewhat = 2 A little bit = 1 Not at all = 0

1.	I'm trying to figure myself out.	0 1 2 3 4
2.	I'm very aware of myself.	0 1 2 3 4
3.	I'm reflecting about myself.	0 1 2 3 4
4.	I'm daydreaming about myself.	0 1 2 3 4
5.	I'm thinking deeply about myself.	0 1 2 3 4
6.	I'm attending to my inner feelings.	0 1 2 3 4
7.	I'm examining my motives.	0 1 2 3 4
8.	I feel that I'm off somewhere watching myself.	0 1 2 3 4
9.	I feel confident about my abilities.	0 1 2 3 4
10.	I am worried about whether I am regarded as a success or failure.	0 1 2 3 4
11.	I feel self-conscious.	0 1 2 3 4
12.	I feel as smart as others.	0 1 2 3 4
13.	I am worried about what other people think of me.	0 1 2 3 4
14.	I feel confident that I understand things.	0 1 2 3 4
15.	I feel inferior to others at this moment.	0 1 2 3 4
16.	I feel concerned about the impression I am making.	0 1 2 3 4
17.	I feel that I have less scholastic ability right now than others.	0 1 2 3 4
18.	I am worried about looking foolish.	0 1 2 3 4
19.	My attention is directed towards things other than the task.	0 1 2 3 4
20.	I am finding physical sensations such as muscular tension distracting.	0 1 2 3 4
21.	I expect my performance will be impaired by thoughts irrelevant to the task.	0 1 2 3 4
22.	I have too much to think about to be able to concentrate on the task.	0 1 2 3 4
23.	My thinking is generally clear and sharp.	0 1 2 3 4
24.	I will find it hard to maintain my concentration for more than a short time.	0 1 2 3 4
25.	My mind is wandering a great deal.	0 1 2 3 4
26.	My thoughts are confused and difficult to control.	0 1 2 3 4
27.	I expect to perform proficiently on this task.	0 1 2 3 4
28.	Generally, I feel in control of things.	0 1 2 3 4
29.	I can handle any difficulties I encounter	0 1 2 3 4
30.	I consider myself skillful at the task	0 1 2 3 4

3. THINKING STYLE

In this section, we are concerned with your thoughts about yourself: how your mind is working, how confident you feel, and how well you believed you performed on the task. Below are some statements which may describe your style of thought during task performance. Read each one carefully and indicate how true each statement was of your thoughts **WHILE PERFORMING THE TASK**. To answer circle one of the following answers: Extremely = 4 Very much = 3 Somewhat = 2 A little bit = 1 Not at all = 0

1.	I tried to figure myself out.	0 1 2 3 4
2.	I was very aware of myself.	0 1 2 3 4
3.	I reflected about myself.	0 1 2 3 4
4.	I daydreamed about myself.	0 1 2 3 4
5.	I thought deeply about myself.	0 1 2 3 4
6.	I attended to my inner feelings.	0 1 2 3 4
7.	I examined my motives.	0 1 2 3 4
8.	I felt that I was off somewhere watching myself.	0 1 2 3 4
9.	I felt confident about my abilities.	0 1 2 3 4
10.	I was worried about whether I am regarded as a success or failure.	0 1 2 3 4
11.	I felt self-conscious.	0 1 2 3 4
12.	I felt as smart as others.	0 1 2 3 4
13.	I was worried about what other people think of me.	0 1 2 3 4
14.	I felt confident that I understood things.	0 1 2 3 4
15.	I felt inferior to others.	0 1 2 3 4
16.	I felt concerned about the impression I was making.	0 1 2 3 4
17.	I felt that I had less scholastic ability than others.	0 1 2 3 4
18.	I was worried about looking foolish.	0 1 2 3 4
19.	My attention was directed towards things other than the task.	0 1 2 3 4
20.	I found physical sensations such as muscular tension distracting.	0 1 2 3 4
21.	My performance was impaired by thoughts irrelevant to the task.	0 1 2 3 4
22.	I had too much to think about to be able to concentrate on the task.	0 1 2 3 4
23.	My thinking was generally clear and sharp.	0 1 2 3 4
24.	I found it hard to maintain my concentration for more than a short time.	0 1 2 3 4
25.	My mind wandered a great deal.	0 1 2 3 4
26.	My thoughts were confused and difficult to control	0 1 2 3 4
27.	I performed proficiently on this task.	0 1 2 3 4
28.	Generally, I felt in control of things.	0 1 2 3 4
29.	I was able to handle any difficulties I encountered	0 1 2 3 4
30.	I consider myself skillful at the task	0 1 2 3 4

8.9 Appendix 9: DSSQ scoring sheet for the content validity workshop:

Are the 7 DSSQ statements relevant to our definition of concentration?		
Item	**Example**	Does the item specifically assess one of the following? i) sustaining focus on whatever you wish, ii) being able to control your attention, iii) the cognitive effort and mental fatigue required when concentrating? iv) 'not applicable' means none of the above *Please circle your rating*
19	My attention is directed towards things other than the task.	Sustain / Control / Effort / Not applicable
20	I am finding physical sensations such as muscular tension distracting.	Sustain / Control / Effort / Not applicable
21	I expect my performance will be impaired by thoughts irrelevant to the task.	Sustain / Control / Effort / Not applicable
22	I have too much to think about to be able to concentrate on the task.	Sustain / Control / Effort / Not applicable
24	I will find it hard to maintain my concentration for more than a short time.	Sustain / Control / Effort / Not applicable
25	My mind is wandering a great deal.	Sustain / Control / Effort / Not applicable
26	My thoughts are confused and difficult to control.	Sustain / Control / Effort / Not applicable
Decision criteria		Y = 6 or more statements of the 7 items are rated as 'sustain', or 'control' or 'effort' N = 1 or more statements are rated as 'not applicable'

	Y / N

Are the 7 DSSQ statements relevant to our target population of interest?		
Item	**Example**	Is the statement relevant to the majority of adults with chronic subjective tinnitus? *Please circle your rating*
19	My attention is directed towards things other than the task.	Y / N
20	I am finding physical sensations such as muscular tension distracting.	Y / N
21	I expect my performance will be impaired by thoughts irrelevant to the task.	Y / N
22	I have too much to think about to be able to concentrate on the task.	Y / N
24	I will find it hard to maintain my concentration for more than a short time.	Y / N
25	My mind is wandering a great deal.	Y / N
26	My thoughts are confused and difficult to control.	Y / N
Decision criteria		Y = 6 or more statements of the 7 items are rated as Y N = 1 or more statements are rated as N
		Y / N

[Scoring sheets for the study team are in blue]

Table 1

Are the 7 DSSQ statements relevant to our definition of concentration? (see page 1 of DSSQ)						
	Participant 01	Participant 02	Participant 03	Participant 04	Participant 05	Participant 06
Rating (Y/N)						
Consensus?						
Note: Consensus is reached IF 5/6 participants have rated Y OR 5/6 participants have rated N						

Table 2

Are all the key concepts of concentration covered by the 7 items from DSSQ? (see page 1 of DSSQ) *Please transfer individual participant responses to this table by circling their answers below*							**Comprehensive** **= IF at least one out the seven items is a 'S' AND 'C' AND 'E'** (mark* items where there is lack of agreement about the content)
Item	# 01	# 02	# 03	# 04	# 05	# 06	
19	S / C / E/ NA	S / C / E/ NA	S / C / E/ NA	S / C / E/ NA	S / C / E/ NA	S / C / E/ NA	
20	S / C / E/ NA	S / C / E/ NA	S / C / E/ NA	S / C / E/ NA	S / C / E/ NA	S / C / E/ NA	
21	S / C / E/ NA	S / C / E/ NA	S / C / E/ NA	S / C / E/ NA	S / C / E/ NA	S / C / E/ NA	

22	S / C / E/ NA	S / C / E/ NA	S / C / E/ NA	S / C / E/ NA	S / C / E/ NA	S / C / E/ NA	
24	S / C / E/ NA	S / C / E/ NA	S / C / E/ NA	S / C / E/ NA	S / C / E/ NA	S / C / E/ NA	
25	S / C / E/ NA	S / C / E/ NA	S / C / E/ NA	S / C / E/ NA	S / C / E/ NA	S / C / E/ NA	
26	S / C / E/ NA	S / C / E/ NA	S / C / E/ NA	S / C / E/ NA	S / C / E/ NA	S / C / E/ NA	

Table 3

Are the 7 DSSQ statements relevant to our target population of interest? (see page 1 of DSSQ)						
	Participant 01	Participant 02	Participant 03	Participant 04	Participant 05	Participant 06
Rating (Y/N)						
Consensus?						
Note: Consensus is reached IF 5/6 participants have rated Y OR 5/6 participants have rated N						

Are the 7 DSSQ statements relevant for using in a clinical research setting?		
Item	**Example**	Is the statement relevant for using in a clinical research setting? Think about being in a clinical trial to evaluate the benefit of a sound-based intervention for tinnitus, such as a hearing aid. This questionnaire would just one of a set of many questionnaires, and the results would only be secondary to answering the main question about whether or not the intervention is effective. *Please circle your rating*

19	My attention is directed towards things other than the task.	Y / N
20	I am finding physical sensations such as muscular tension distracting.	Y / N
21	I expect my performance will be impaired by thoughts irrelevant to the task.	Y / N
22	I have too much to think about to be able to concentrate on the task.	Y / N
24	I will find it hard to maintain my concentration for more than a short time.	Y / N
25	My mind is wandering a great deal.	Y / N
26	My thoughts are confused and difficult to control.	Y / N
Decision criteria		Y = 6 or more statements of the 7 items are rated as Y N = 1 or more statements are rated as N
		Y / N

Are the response options appropriate for the DSSQ statements?								
Question for consideration	**Example**	**Not at all**	**A little bit**	**Somewhat**	**Very much**	**Extremely**	**Decision criteria**	**Y/N**
Are the response options appropriate?	The type of response options should be appropriate to the concept of concentration and the range of options should cover the whole range of possible experiences.						At least 4 of the 5 response options are appropriate for assessing concentration in adults with chronic subjective tinnitus in clinical research	Y/N

Is the recall period appropriate for the DSSQ statements?			
Question for consideration	**Example**	**Decision criteria**	**Y/N**
Is the recall period appropriate?	DSSQ has two recall periods: *at the moment* and *while performing the task*. The recall period should be appropriate for measuring concentration such that a difference in scores at T1 and T2 would be likely due to the sound-based intervention, not some other reason which could be subject to short-term fluctuations.	The recall period minimises the influence of short-term fluctuations in concentration i) *at the moment* ii) *while performing the task*	Y/N Y/N

Table 4

Consensus on the remaining three criteria for relevance: the DSSQ items (see page 4 of DSSQ)						
	Participant 01	Participant 02	Participant 03	Participant 04	Participant 05	Participant 06
Clinical setting rating (Y/N)						
Consensus?						
Response option rating (Y/N)						
Consensus?						
Recall period *at the moment* rating (Y/N)						
Consensus?						
Recall period *while performing the task* rating (Y/N)						
Consensus?						
Note: Consensus is reached IF 5/6 participants have rated Y OR 5/6 participants have rated N						

Interpretation:
The 7 DSSQ items are rated as relevant to concentration only if two out of the three criteria reach consensus

Comprehensibility of the DSSQ statements										
Question for consideration	**Evaluation criteria**	**19**	**20**	**21**	**22**	**24**	**25**	**26**	**Decision criteria**	**Y/N**
Are the statements and response options appropriately worded for our target population of interest?	1. Reading level should be appropriate for a twelve-year-old child								At least 6 out of 7 of the statements meet *all* of these 6 criteria	
	2. The statement and response option should be unambiguous in their meaning.									
	3. The statement and response option should be a single statement (i.e. not asking about two or more things).									
	4. The statement and response option should be free from jargon or technical language.									
	5. The statement and response option should be neutral in their tone so that they do not lead you towards a particular response.									
	6. The statement and response option should be a reasonably concise and avoid unnecessary words.									
	Total (how many criteria are scored Y?)									
Question for consideration	**Example**	**19**	**20**	**21**	**22**	**24**	**25**	**26**	**Decision criteria**	**Y/N**
Do the response options match the statement?	The type of response options should match how true you might think each statement is and should be linguistically linked to the content of the statement.								At least 6 out of the 7 statements have matching	

									response options	

#	Items	Not at all	A little bit	Somewhat	Very much	Extremely
19	My attention is directed towards things other than the task.					
20	I am finding physical sensations such as muscular tension distracting.					
21	I expect my performance will be impaired by thoughts irrelevant to the task.					
22	I have too much to think about to be able to concentrate on the task.					
24	I will find it hard to maintain my concentration for more than a short time.					
25	My mind is wandering a great deal.					
26	My thoughts are confused and difficult to control.					

Table 5

Consensus on the two criteria for comprehensibility: the 7 DSSQ items (see page 6 of DSSQ)						
	Participant 01	Participant 02	Participant 03	Participant 04	Participant 05	Participant 06
Appropriately worded rating (Y/N)						
Consensus?						
Response option match statements rating (Y/N)						
Consensus?						

Note: Consensus is reached IF 5/6 participants have rated Y OR 5/6 participants have rated N

Interpretation:
The 7 DSSQ items are rated as comprehensible only if both criteria reach consensus

8.10 Appendix 10: PROMIS scoring sheet for the content validity workshop:

Are the 31 PROMIS statements relevant to our definition of concentration?		
Item	**Example**	Does the item specifically assess one of the following: i) sustaining focus on whatever you wish, ii) being able to control your attention, iii) the cognitive effort and mental fatigue required when concentrating? iv) 'not applicable' means none of the above *Please circle your rating*
01	I have been able to bring to mind words that I wanted to use while talking to someone	Sustain / Control / Effort / Not applicable
02	I have been able to remember to do things, like take medicine or buy something I needed	Sustain / Control / Effort / Not applicable
03	I have been able to pay attention and keep track of what I am doing without extra effort	Sustain / Control / Effort / Not applicable
04	I have been able to think clearly	Sustain / Control / Effort / Not applicable
05	My mind has been as sharp as usual	Sustain / Control / Effort / Not applicable
06	My memory has been as good as usual	Sustain / Control / Effort / Not applicable
07	My thinking has been as fast as usual	Sustain / Control / Effort / Not applicable
08	I have been able to shift back and forth between two activities that require thinking	Sustain / Control / Effort / Not applicable
09	I have been able to keep track of what I am doing, even if I am interrupted	Sustain / Control / Effort / Not applicable

10	I have been able to concentrate	Sustain / Control / Effort / Not applicable
11	I have been able to form thoughts clearly	Sustain / Control / Effort / Not applicable
12	I have been able to remember telephone numbers	Sustain / Control / Effort / Not applicable
13	I have been able to get my point across when talking with someone	Sustain / Control / Effort / Not applicable
14	I have been able to remember the name of a familiar object	Sustain / Control / Effort / Not applicable
15	I have been able to think as clearly as usual without extra effort	Sustain / Control / Effort / Not applicable
16	I have been able to remember things as easily as usual without extra effort	Sustain / Control / Effort / Not applicable
17	My ability to remember important dates has been as good as usual	Sustain / Control / Effort / Not applicable
18	My ability to remember names has been as good as usual	Sustain / Control / Effort / Not applicable
19	My ability to keep track of lists has been as good as usual	Sustain / Control / Effort / Not applicable
20	My thinking has been clear	Sustain / Control / Effort / Not applicable
21	My ability to count money has been as good as usual	Sustain / Control / Effort / Not applicable
22	My ability to follow driving directions has been as good as usual	Sustain / Control / Effort / Not applicable
23	I have been able to handle many tasks at once without losing track of what I was doing	Sustain / Control / Effort / Not applicable
24	My ability to remember things that I need to do has been as good as usual	Sustain / Control / Effort / Not applicable

25	I have been able to multi-task as easily as usual without extra effort	Sustain / Control / Effort / Not applicable
26	I have been able to think clearly without extra effort	Sustain / Control / Effort / Not applicable
27	My ability to concentrate has been good	Sustain / Control / Effort / Not applicable
28	I have been able to focus my attention	Sustain / Control / Effort / Not applicable
29	I have been able to mentally focus	Sustain / Control / Effort / Not applicable
30	I have been able to remember the name of a familiar person	Sustain / Control / Effort / Not applicable
31	I have been able to learn new things easily, like telephone numbers or instructions	Sustain / Control / Effort / Not applicable
Decision criteria		Y = 26 or more statements of the 31 items are rated as 'sustain', or 'control' or 'effort' N = 5 or more statements are rated as 'not applicable'
		Y / N

Are the 31 PROMIS statements relevant to our target population of interest?		
Item	**Example**	Is the statement relevant to the majority of adults with chronic subjective tinnitus? *Please circle your rating*
01	I have been able to bring to mind words that I wanted to use while talking to someone	Y / N
02	I have been able to remember to do things, like take medicine or buy something I needed	Y / N
03	I have been able to pay attention and keep track of what I am doing without extra effort	Y / N
04	I have been able to think clearly	Y / N
05	My mind has been as sharp as usual	Y / N
06	My memory has been as good as usual	Y / N
07	My thinking has been as fast as usual	Y / N
08	I have been able to shift back and forth between two activities that require thinking	Y / N
09	I have been able to keep track of what I am doing, even if I am interrupted	Y / N
10	I have been able to concentrate	Y / N
11	I have been able to form thoughts clearly	Y / N
12	I have been able to remember telephone numbers	Y / N
13	I have been able to get my point across when talking with someone	Y / N
14	I have been able to remember the name of a familiar object	Y / N
15	I have been able to think as clearly as usual without extra effort	Y / N
16	I have been able to remember things as easily as usual without extra effort	Y / N
17	My ability to remember important dates has been as good as usual	Y / N
18	My ability to remember names has been as good as usual	Y / N
19	My ability to keep track of lists has been as good as usual	Y / N
20	My thinking has been clear	Y / N
21	My ability to count money has been as good as usual	Y / N

22	My ability to follow driving directions has been as good as usual	Y / N
23	I have been able to handle many tasks at once without losing track of what I was doing	Y / N
24	My ability to remember things that I need to do has been as good as usual	Y / N
25	I have been able to multi-task as easily as usual without extra effort	Y / N
26	I have been able to think clearly without extra effort	Y / N
27	My ability to concentrate has been good	Y / N
28	I have been able to focus my attention	Y / N
29	I have been able to mentally focus	Y / N
30	I have been able to remember the name of a familiar person	Y / N
31	I have been able to learn new things easily, like telephone numbers or instructions	Y / N
Decision criteria		Y = 26 or more statements of the 31 items are rated as Y N = 5 or more statements are rated as N
		Y / N

[Scoring sheets for the study team are in blue]

Table 1

Are the 31 PROMIS statements relevant to our definition of concentration? (see pages 1-2 of PROMIS)						
	Participant 01	Participant 02	Participant 03	Participant 04	Participant 05	Participant 06
Rating (Y/N)						
Consensus**?**						
Note: Consensus is reached IF 5/6 participants have rated Y OR 5/6 participants have rated N						

Table 2

Could any of the PROMIS statements be used to create a subscale? (see pages 1-2 of PROMIS) (i.e. are they commonly rated as being relevant to concentration across the workshop?) *Please transfer individual participant responses to this table by circling their answers below*							**Common = IF 5/6 people have rated the statement as 'S' OR 'C' OR 'E'**	**Comprehensive = IF at least one common item is in 'S' AND 'C' AND 'E'** (mark* items where there is lack of agreement about the content)
Item	# 01	# 02	# 03	# 04	# 05	# 06		
01	S / C / E/ NA	S / C / E/ NA	S / C / E/ NA	S / C / E/ NA	S / C / E/ NA	S / C / E/ NA		
02	S / C / E/ NA	S / C / E/ NA	S / C / E/ NA	S / C / E/ NA	S / C / E/ NA	S / C / E/ NA		
03	S / C / E/ NA	S / C / E/ NA	S / C / E/ NA	S / C / E/ NA	S / C / E/ NA	S / C / E/ NA		
04	S / C / E/ NA	S / C / E/ NA	S / C / E/ NA	S / C / E/ NA	S / C / E/ NA	S / C / E/ NA		
05	S / C / E/ NA	S / C / E/ NA	S / C / E/ NA	S / C / E/ NA	S / C / E/ NA	S / C / E/ NA		
06	S / C / E/ NA	S / C / E/ NA	S / C / E/ NA	S / C / E/ NA	S / C / E/ NA	S / C / E/ NA		
07	S / C / E/ NA	S / C / E/ NA	S / C / E/ NA	S / C / E/ NA	S / C / E/ NA	S / C / E/ NA		
08	S / C / E/ NA	S / C / E/ NA	S / C / E/ NA	S / C / E/ NA	S / C / E/ NA	S / C / E/ NA		
09	S / C / E/ NA	S / C / E/ NA	S / C / E/ NA	S / C / E/ NA	S / C / E/ NA	S / C / E/ NA		
10	S / C / E/ NA	S / C / E/ NA	S / C / E/ NA	S / C / E/ NA	S / C / E/ NA	S / C / E/ NA		
11	S / C / E/ NA	S / C / E/ NA	S / C / E/ NA	S / C / E/ NA	S / C / E/ NA	S / C / E/ NA		
12	S / C / E/ NA	S / C / E/ NA	S / C / E/ NA	S / C / E/ NA	S / C / E/ NA	S / C / E/ NA		
13	S / C / E/ NA	S / C / E/ NA	S / C / E/ NA	S / C / E/ NA	S / C / E/ NA	S / C / E/ NA		
14	S / C / E/ NA	S / C / E/ NA	S / C / E/ NA	S / C / E/ NA	S / C / E/ NA	S / C / E/ NA		
15	S / C / E/ NA	S / C / E/ NA	S / C / E/ NA	S / C / E/ NA	S / C / E/ NA	S / C / E/ NA		
16	S / C / E/ NA	S / C / E/ NA	S / C / E/ NA	S / C / E/ NA	S / C / E/ NA	S / C / E/ NA		
17	S / C / E/ NA	S / C / E/ NA	S / C / E/ NA	S / C / E/ NA	S / C / E/ NA	S / C / E/ NA		
18	S / C / E/ NA	S / C / E/ NA	S / C / E/ NA	S / C / E/ NA	S / C / E/ NA	S / C / E/ NA		
19	S / C / E/ NA	S / C / E/ NA	S / C / E/ NA	S / C / E/ NA	S / C / E/ NA	S / C / E/ NA		

20	S / C / E/ NA	S / C / E/ NA	S / C / E/ NA	S / C / E/ NA	S / C / E/ NA	S / C / E/ NA		
21	S / C / E/ NA	S / C / E/ NA	S / C / E/ NA	S / C / E/ NA	S / C / E/ NA	S / C / E/ NA		
22	S / C / E/ NA	S / C / E/ NA	S / C / E/ NA	S / C / E/ NA	S / C / E/ NA	S / C / E/ NA		
23	S / C / E/ NA	S / C / E/ NA	S / C / E/ NA	S / C / E/ NA	S / C / E/ NA	S / C / E/ NA		
24	S / C / E/ NA	S / C / E/ NA	S / C / E/ NA	S / C / E/ NA	S / C / E/ NA	S / C / E/ NA		
25	S / C / E/ NA	S / C / E/ NA	S / C / E/ NA	S / C / E/ NA	S / C / E/ NA	S / C / E/ NA		

Table 2

Could any of the PROMIS statements be used to create a subscale? (see pages 1-2 of PROMIS) (i.e. are they commonly rated as being relevant to concentration across the workshop?) *Please transfer individual participant responses to this table by circling their answers below*							**Common = IF 5/6 people have rated the statement as 'S' OR 'C' OR 'E'**	**Comprehensive = IF at least one common item is in 'S' AND 'C' AND 'E'** (mark* items where there is lack of agreement about the content)
Item	# 01	# 02	# 03	# 04	# 05	# 06		
26	S / C / E/ NA	S / C / E/ NA	S / C / E/ NA	S / C / E/ NA	S / C / E/ NA	S / C / E/ NA		
27	S / C / E/ NA	S / C / E/ NA	S / C / E/ NA	S / C / E/ NA	S / C / E/ NA	S / C / E/ NA		
28	S / C / E/ NA	S / C / E/ NA	S / C / E/ NA	S / C / E/ NA	S / C / E/ NA	S / C / E/ NA		
29	S / C / E/ NA	S / C / E/ NA	S / C / E/ NA	S / C / E/ NA	S / C / E/ NA	S / C / E/ NA		
30	S / C / E/ NA	S / C / E/ NA	S / C / E/ NA	S / C / E/ NA	S / C / E/ NA	S / C / E/ NA		
31	S / C / E/ NA	S / C / E/ NA	S / C / E/ NA	S / C / E/ NA	S / C / E/ NA	S / C / E/ NA		

Table 3

Are the 31 PROMIS statements relevant to our target population of interest? (see page 3 of PROMIS)						
	Participant 01	Participant 02	Participant 03	Participant 04	Participant 05	Participant 06
Rating (Y/N)						
Consensus?						
Note: Consensus is reached IF 5/6 participants have rated Y OR 5/6 participants have rated N						

The task on page 7 of PROMIS consider only the subset of common PROMIS items

Are the common PROMIS statements relevant for using in a clinical research setting?		
Item	**This activity is only to be conducted for those statements that were identified as common and so could be used to create a subscale.** **All the items are included below, and so the study team should delete those not relevant and print out scoring sheets after editing**	Is the statement relevant for using in a clinical research setting? Think about being in a clinical trial to evaluate the benefit of a sound-based intervention for tinnitus, such as a hearing aid. This questionnaire would just one of a set of many questionnaires, and the results would only be secondary to answering the main question about whether or not the intervention is effective. *Please circle your rating*
01	I have been able to bring to mind words that I wanted to use while talking to someone	Y / N
02	I have been able to remember to do things, like take medicine or buy something I needed	Y / N
03	I have been able to pay attention and keep track of what I am doing without extra effort	Y / N
04	I have been able to think clearly	Y / N
05	My mind has been as sharp as usual	Y / N
06	My memory has been as good as usual	Y / N
07	My thinking has been as fast as usual	Y / N
08	I have been able to shift back and forth between two activities that require thinking	Y / N
09	I have been able to keep track of what I am doing, even if I am interrupted	Y / N
10	I have been able to concentrate	Y / N
11	I have been able to form thoughts clearly	Y / N
12	I have been able to remember telephone numbers	Y / N
13	I have been able to get my point across when talking with someone	Y / N
14	I have been able to remember the name of a familiar object	Y / N
15	I have been able to think as clearly as usual without extra effort	Y / N

16	I have been able to remember things as easily as usual without extra effort	Y / N
17	My ability to remember important dates has been as good as usual	Y / N
18	My ability to remember names has been as good as usual	Y / N
19	My ability to keep track of lists has been as good as usual	Y / N
20	My thinking has been clear	Y / N
21	My ability to count money has been as good as usual	Y / N
22	My ability to follow driving directions has been as good as usual	Y / N
23	I have been able to handle many tasks at once without losing track of what I was doing	Y / N
24	My ability to remember things that I need to do has been as good as usual	Y / N
25	I have been able to multi-task as easily as usual without extra effort	Y / N
26	I have been able to think clearly without extra effort	Y / N
27	My ability to concentrate has been good	Y / N
28	I have been able to focus my attention	Y / N
29	I have been able to mentally focus	Y / N
30	I have been able to remember the name of a familiar person	Y / N
31	I have been able to learn new things easily, like telephone numbers or instructions	Y / N
Decision criteria		Y = 85% or more common statements are rated as Y N = 15% or more common statements are rated as N
		Y / N

Are the response options appropriate for the common PROMIS statements?								
Question for consideration	**Example**	**Not at all**	**A little bit**	**Somewhat**	**Quite a bit**	**Very much**	**Decision criteria**	**Y/N**
Are the response options appropriate?	The type of response options should be appropriate to the concept of concentration and the range of options should cover the whole range of possible experiences.						At least 4 of the 5 response options are appropriate for assessing concentration in adults with chronic subjective tinnitus in clinical research	Y/N

Is the recall period appropriate for the common PROMIS statements?			
Question for consideration	**Example**	**Decision criteria**	**Y/N**
Is the recall period appropriate?	PROMIS has a recall period of 7 days. The recall period should be appropriate for measuring concentration such that a difference in scores at T1 and T2 would be likely due to the sound-based intervention, not some other reason which could be subject to short-term fluctuations.	The recall period minimises the influence of short-term fluctuations in concentration.	Y/N

Table 4

Consensus on the remaining three criteria for relevance: the common PROMIS items (see pages 7-8 of PROMIS)						
	Participant 01	Participant 02	Participant 03	Participant 04	Participant 05	Participant 06
Clinical setting rating (Y/N)						
Consensus?						
Response option rating (Y/N)						
Consensus?						
Recall period rating (Y/N)						
Consensus?						
Note: Consensus is reached IF 5/6 participants have rated Y OR 5/6 participants have rated N						

Interpretation:
The common PROMIS items are rated as relevant to concentration only if two out of the three criteria reach consensus

This activity is only to be conducted for those statements that were identified as common and so could be used to create a subscale. The study team should edit the columns in the table below (tbc) so that there is one column for each included item, and print out scoring sheets after editing

Comprehensibility of the common PROMIS statements														
Question for consideration	**Evaluation criteria**	**tbc**	**tbc**	**tbc**	**tbc**	**tbc**	**tbc**	**tbc**	**tbc**	**tbc**	**tbc**	**tbc**	**Decision criteria**	**Y/N**
Are the statements and response options appropriately worded for our target population of interest?	1. Reading level should be appropriate for a twelve-year-old child												At least 85% of the common statements meet *all* of these 6 criteria	
	2. The statement and response option should be unambiguous in their meaning.													
	3. The statement and response option should be a single statement (i.e. not asking about two or more things).													
	4. The statement and response option should be free from jargon or technical language.													
	5. The statement and response option should be neutral in their tone so that they do not lead you towards a particular response.													
	6. The statement and response option should be a reasonably concise and avoid unnecessary words.													

	Total (how many criteria are scored Y?)													
Question for consideration	**Example**	**tbc**	**tbc**	**tbc**	**tbc**	**tbc**	**tbc**	**tbc**	**tbc**	**tbc**	**tbc**	**tbc**	**Decision criteria**	**Y/N**
Do the response options match the statement?	The type of response options should match how true you might think each statement is and should be linguistically linked to the content of the statement.												At least 85% of the common statements have matching response options.	

#	Items **The study team should delete those not relevant and only leave items included above (see page 10 of PROMIS) and print out scoring sheets after editing**	Not at all	A little bit	Somewhat	Quite a bit	Very much
01	I have been able to bring to mind words that I wanted to use while talking to someone					
02	I have been able to remember to do things, like take medicine or buy something I needed					
03	I have been able to pay attention and keep track of what I am doing without extra effort					
04	I have been able to think clearly					
05	My mind has been as sharp as usual					
06	My memory has been as good as usual					
07	My thinking has been as fast as usual					
08	I have been able to shift back and forth between two activities that require thinking					
09	I have been able to keep track of what I am doing, even if I am interrupted					
10	I have been able to concentrate					
11	I have been able to form thoughts clearly					
12	I have been able to remember telephone numbers					
13	I have been able to get my point across when talking with someone					
14	I have been able to remember the name of a familiar object					
15	I have been able to think as clearly as usual without extra effort					
16	I have been able to remember things as easily as usual without extra effort					
17	My ability to remember important dates has been as good as usual					
18	My ability to remember names has been as good as usual					
19	My ability to keep track of lists has been as good as usual					
20	My thinking has been clear					
21	My ability to count money has been as good as usual					

22	My ability to follow driving directions has been as good as usual					
23	I have been able to handle many tasks at once without losing track of what I was doing					
24	My ability to remember things that I need to do has been as good as usual					
25	I have been able to multi-task as easily as usual without extra effort					
26	I have been able to think clearly without extra effort					
27	My ability to concentrate has been good					
28	I have been able to focus my attention					
29	I have been able to mentally focus					
30	I have been able to remember the name of a familiar person					
31	I have been able to learn new things easily, like telephone numbers or instructions					

Table 5

Consensus on the two criteria for comprehensibility: the common PROMIS items (see page 10 of PROMIS)						
	Participant 01	Participant 02	Participant 03	Participant 04	Participant 05	Participant 06
Appropriately worded rating (Y/N)						
Consensus?						
Response option match statements rating (Y/N)						
Consensus?						
Note: Consensus is reached IF 5/6 participants have rated Y OR 5/6 participants have rated N						

Interpretation:
The common PROMIS items are rated as comprehensible only if both criteria reach consensus

8.11 Appendix 11: Advertisement used on the Tinnitus UK (previously BTA) website

Understanding how tinnitus impacts concentration

My name is Maryam Shabbir, and I am a PhD student at the University of Nottingham. I am currently conducting an online survey as part of my PhD project.

The survey should take approximately 10 minutes. The survey entails providing some basic demographic information followed by questions regarding the impact tinnitus has on your ability to concentrate. No personal identifiable information will be asked to ensure anonymity, and your participation is entirely voluntary. Through this survey, we hope to examine how tinnitus impacts your concentration which will help us develop a new questionnaire and we would like your insight to design it!

We have received a lot of responses for bothersome tinnitus, and we would like an equal representation of the tinnitus population and thus we are now looking for input from adults with not/less bothersome tinnitus.

You are eligible if:

- you are 18 years or older
- you have persistent tinnitus (symptoms persisting for 3 months or longer)
- not/less bothersome tinnitus (not a problem or a small problem)

If you fit the eligibility criteria and are interested in participating, I'd love to hear from you. Please use the survey link provided below:
https://nottingham.onlinesurveys.ac.uk/tinnitus-concentration-problems-2

You can download the information sheet attached before you decide to participate as this will provide you with more details about the study. The information sheet is also part of the link if you would prefer to read it there. Your explicit consent will be required at the start of the survey before you begin. In case you have any questions or concerns, please feel free to contact us (details have been provided below).

Thank you for your time!

Researcher: Maryam Shabbir (maryam.shabbir@nottingham.ac.uk)
Supervisors: Prof. Michael Akeroyd (michael.akeroyd@nottingham.ac.uk) and Prof. Deborah Hall

<information sheet pdf>

8.12 Appendix 12: Tinnitus Problems Survey

I have read and understood the information and consent form, I confirm that I am 18 years old or older and by clicking the NEXT button to begin the online survey, I indicate my willingness to voluntarily take part in this study.

1. Please state your age (in years).

2. What is your sex?
   - Female
   - Male
   - Intersex
   - Prefer not to say

3. How much of a problem is your tinnitus?
   - Not a problem
   - A small problem
   - A moderate problem
   - A big problem
   - A very big problem

4. As someone with tinnitus, please describe what concentration means to you.

5. Does your tinnitus impact your ability to sustain focus on whatever you intend to focus upon?
   - Yes
   - No

   5a. Please state (when) and describe (how) situations where tinnitus impacts your ability to sustain focus on whatever you intend to focus upon (maximum 3 situations).

6. Does your tinnitus impact your ability to control your attention?
   - Yes
   - No

   6a. Please state (when) and describe (how) situations where tinnitus impacts your ability to control your attention (maximum 3 situations).

7. Because of your tinnitus, do you require additional mental effort while concentrating?
   - Yes
   - No

   7a. Please state (when) and describe (how) situations where additional mental effort is required because of the presence of tinnitus.

8.13 Appendix 13: Advertisement used to recruit for Cognitive Interviews

ADVERT:

Do you experience tinnitus and would like to help us with a new questionnaire? Researchers at the University of Nottingham Hearing Sciences are developing a new questionnaire to assess the ability to concentrate for people with tinnitus. We are looking for people with tinnitus to review and provide feedback on our pilot questionnaire and help us make sure it is suitable for the intended purpose.

Interviews will be held online via Zoom (subtitles are available). The interview will last approximately 45-60 mins, and you will be compensated £25 for your valuable time. Should you prefer to interview in person, reasonable travel expenses will be reimbursed. If you are interested or have any questions, please do not hesitate to contact the PhD student researcher, Maryam Shabbir (Maryam.Shabbir@nottingham.ac.uk).

8.14 Appendix 14: Cognitive Interviews Guide

Tinnitus Concentration Questionnaire (TiCQ)

One-to-one Zoom discussion

(30-60 minutes)

https://nottingham.onlinesurveys.ac.uk/tcq-ppi-cog-interviews-copy

[Take permission to record]

Introduction/ briefing:

Thank you for agreeing to take part in my research. We have created a questionnaire to measure concentration in adults with tinnitus. This will be used to measure concentration before and after a sound-based treatment, such as hearing aids, cochlear implants, sound generators etc, to help us understand if the sound-based treatment has improved concentration in adults with tinnitus.

Therefore, we would like adults who experience tinnitus to help us make the questionnaire better. Do not worry as there are no right or wrong answers. You are the expert, and we want to know what you think.

Before we continue, I just want to remind you that this discussion is being recorded with your permission so that I can focus on our discussion and do not have to worry about frantically taking notes. These recordings will only be listened to by me to type up my notes and no one else. This is part of my PhD project so ethical approval has been obtained, and all data will follow GDPR guidelines. Should you want any further information on this, I can email you the university data policies. Also, it is okay not to answer, and you can stop at any time as your participation in completely voluntary.

Additionally, to help us understand feedback across a range of tinnitus severity, could you please tell me how much of a problem is your tinnitus?

- Not a problem
- A small problem
- A moderate problem

- A big problem
- A very big problem

Questionnaire:

- Explain the questionnaire to the participant.
- Make participant complete the questionnaire.

General Feedback:

- What did you like about the questionnaire?
- What did you dislike about the questionnaire?
- Was it easy or difficult to complete? Why?
- Is there anything that was confusing or didn't make sense?
- Do you think there are any aspects of concentration that were missed in this questionnaire?

Prompted feedback:

1. **Instructions:**

- Did the instructions make sense to you?
- Do you have any suggestions to make it better?

2. **Question phrasing and understanding:**

- Were the questions clear?
- Which questions were unclear?
- How can they be rephrased in a clearer way?
- Are there any words that are too technical/ difficult to understand? We want to make sure this is understandable to adults of all ages and backgrounds.

3. **Response scale:**

- What do you think of the response scale?
- Do they make sense in relation to what is being asked?
- Was it easy or difficult to use?
- What does a 4 mean to you on the scale?

- What does a 6 mean to you on the scale?
- Would you prefer a middle point descriptor like 0 and 10?
- If so, what would you label it?

4. Length:

- What do you think about the length of the questionnaire/ number of questions?
- Too long? Too short?

5. Situations:

- We want to make sure the list of situations is applicable to everyone and that at least 3 are applicable to anyone. Do you think the list of situations cover most day-to-day activities that people engage in?
- Are there any other situations that you would include in the list?

Specific questions:

- In the instructions "we will be asking about all 3 parts in turn below."
    - What did you understand from this statement?
    - Is it easy or difficult to understand?
    - If not, how would you rephrase it?
- Which ones are most important to you?
    - What did you understand from this statement?
    - Is it easy or difficult to understand?
    - If not, how would you rephrase it?
- What do you think about the response scale for extra mental effort?
    - What did you understand from these options?
    - Does no extra effort to extreme extra effort make sense?
    - Is there any way we could phrase it, so it is easier to understand?
- What did you think of the definition of concentration?
    - Are the terms to technical?

Is there anything else you want to tell me about how you found the questionnaire? Any general thoughts or things I may have missed that you think would be useful?

8.15 Appendix 15: Final Tinnitus Concentration Questionnaire (TiCQ) v1.6

Tinnitus Concentration Questionnaire (TiCQ)

Instructions:

The following questions will ask how much your concentration is affected due to your tinnitus.

Please read the information below carefully before answering the questionnaire.

You can think of concentration as 'the ability to keep your attention focused on whatever you want'.

The above definition of concentration has 3 parts:

1) sustaining focus

2) controlling your attention

3) the extra mental effort needed to focus

We will be asking about each of these areas.

For each question, select ONLY THREE situations that closest describe those that are most important to you.

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PART 1: SUSTAINING FOCUS

The following questions will ask about how tinnitus affected your ability to **SUSTAIN YOUR FOCUS** on whatever you wanted over the past week.

This part of the survey uses a table of questions, view as separate questions instead?

1. Because of your tinnitus, how difficult was it for you to **SUSTAIN YOUR FOCUS** while... (Please only select the **THREE** most important situations to you)

	0 not difficult	1	2	3	4	5	6	7	8	9	10 very difficult
Having a conversation	○	○	○	○	○	○	○	○	○	○	○
Driving	○	○	○	○	○	○	○	○	○	○	○
Doing household tasks	○	○	○	○	○	○	○	○	○	○	○
Listening to music or the radio	○	○	○	○	○	○	○	○	○	○	○
Reading	○	○	○	○	○	○	○	○	○	○	○
Relaxing	○	○	○	○	○	○	○	○	○	○	○
Sleeping	○	○	○	○	○	○	○	○	○	○	○
Watching television	○	○	○	○	○	○	○	○	○	○	○
Working	○	○	○	○	○	○	○	○	○	○	○
Studying	○	○	○	○	○	○	○	○	○	○	○
Using a computer	○	○	○	○	○	○	○	○	○	○	○

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PART 2: CONTROLLING YOUR ATTENTION

The following questions will ask about how tinnitus affected your ability to **CONTROL YOUR ATTENTION** on whatever you wanted over the past week.

This part of the survey uses a table of questions, view as separate questions instead?

2. Because of your tinnitus, how difficult was it for you to **CONTROL YOUR ATTENTION** while... (Please only select the **THREE** most important situations to you)

	0 not difficult	1	2	3	4	5	6	7	8	9	10 very difficult
Having a conversation	○	○	○	○	○	○	○	○	○	○	○
Driving	○	○	○	○	○	○	○	○	○	○	○
Doing household tasks	○	○	○	○	○	○	○	○	○	○	○
Listening to music or the radio	○	○	○	○	○	○	○	○	○	○	○
Reading	○	○	○	○	○	○	○	○	○	○	○
Relaxing	○	○	○	○	○	○	○	○	○	○	○
Sleeping	○	○	○	○	○	○	○	○	○	○	○
Watching television	○	○	○	○	○	○	○	○	○	○	○
Working	○	○	○	○	○	○	○	○	○	○	○
Studying	○	○	○	○	○	○	○	○	○	○	○
Using a computer	○	○	○	○	○	○	○	○	○	○	○

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PART 3: EXTRA MENTAL EFFORT

The following questions will ask about how tinnitus affected the **EXTRA MENTAL EFFORT** needed to focus on whatever you wanted over the past week.

This part of the survey uses a table of questions, view as separate questions instead?

3. Because of your tinnitus, how much **EXTRA MENTAL EFFORT** was needed to focus while... (Please only select the **THREE** most important situations to you)

	0 no extra mental effort	1	2	3	4	5	6	7	8	9	10 extreme extra mental effort
Having a conversation	○	○	○	○	○	○	○	○	○	○	○
Driving	○	○	○	○	○	○	○	○	○	○	○
Doing household tasks	○	○	○	○	○	○	○	○	○	○	○
Listening to music or the radio	○	○	○	○	○	○	○	○	○	○	○
Reading	○	○	○	○	○	○	○	○	○	○	○
Relaxing	○	○	○	○	○	○	○	○	○	○	○
Sleeping	○	○	○	○	○	○	○	○	○	○	○
Watching television	○	○	○	○	○	○	○	○	○	○	○
Working	○	○	○	○	○	○	○	○	○	○	○
Studying	○	○	○	○	○	○	○	○	○	○	○
Using a computer	○	○	○	○	○	○	○	○	○	○	○

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