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Research paper

Psychometric properties of the Tinnitus Functional Index (TFI): Assessment in a UK research volunteer population

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ABSTRACT

Objectives: Questionnaires are essential for measuring tinnitus severity and intervention-related change but there is no standard instrument used routinely in research settings. Most tinnitus questionnaires are optimised for measuring severity but not change. However, the Tinnitus Functional Index (TFI) claims to be optimised for both. It has not however been fully validated for research purposes. Here we evaluate the relevant psychometric properties of the TFI, specifically the questionnaire factor structure, reproducibility, validity and responsiveness guided by quality criteria for the measurement properties of health-related questionnaires.

Methods: The study involved a retrospective analysis of data collected for 294 members of the general public who participated in a randomised controlled trial of a novel tinnitus device (ClinicalTrials.gov Identifier: NCT01541969). Participants completed up to eight commonly used assessment questionnaires including the TFI, Tinnitus Handicap Inventory (THI), Tinnitus Handicap Questionnaire (THQ), a Visual Analogue Scale of loudness (VAS-Loudness), Percentage Annoyance question, the Beck's Depression Inventory (BDI), Beck's Anxiety Inventory (BAI), and the World Health Organisation Quality of Life-Bref (WHOQOL-BREF). A series of analyses assessed the study objectives. Forty four participants completed the TFI at a second visit (within 7–21 days and before receiving any intervention) providing data for reproducibility assessments.

Results: The 8-factor structure was not fully confirmed for this general (non-clinical) population. Whilst it was acceptable standalone subscale, the 'auditory' factor showed poor loading with the higher order factor 'functional impact of tinnitus'. Reproducibility assessments for the overall TFI indicate high internal consistency ($\alpha = 0.80$) and extremely high reliability (ICC: 0.91), whilst agreement was borderline acceptable (93%). Construct validity was demonstrated by high correlations between scores on the TFI and THI ($r = 0.82$) and THQ ($r = 0.82$), moderate correlations with VAS-L ($r = 0.46$), PR-A ($r = 0.58$), BDI ($r = 0.57$), BAI ($r = 0.39$) and WHOQOL ($r = -0.48$). Floor effects were observed for more than 50% of the items. A smallest detectable change score of 22.4 is proposed for the TFI global score.

Conclusion: Even though the proposed 8-factor structure was not fully confirmed for this population, the TFI appears to cover multiple symptom domains, and to measure the construct of tinnitus with an excellent reliability in distinguishing between patients. While the TFI may discriminate those whose tinnitus is not a problem, floor effects in many items means it is less appropriate as a measure of change in this subgroup. Further investigation is needed to determine whether these effects are relevant in other populations.

1. Introduction

The experience of tinnitus can involve much more than the 'phantom' sensation of sound, it can also impact on daily functioning, causing insomnia, difficulties in listening and

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concentrating, impaired symptom-specific quality of life, and poor psychological well-being (Tyler and Baker, 1983; Robinson et al., 2003; Stevens et al., 2007; Langguth et al., 2011; Nondahl et al., 2011; Pierce et al., 2012). But quantifying the severity of this impact, or how this severity changes as a result of time or intervention, is difficult. Psychoacoustic estimates of tinnitus loudness may partially explain some of the variance attributed to the functional impact or perceived annoyance/intrusiveness of tinnitus (Dauman and Tyler, 1992; Andersson, 2003). But ratings of loudness, annoyance or awareness of tinnitus made using a Visual Analogue Scale (VAS), recommended by some as standalone measures of tinnitus severity, do not correlate strongly with either psychoacoustic or multi-item questionnaire measures of tinnitus (Adamchic et al., 2012). Given that tinnitus is a multi-dimensional symptom, researchers typically rely on multi-attribute self-report questionnaires to quantify tinnitus severity and to assess intervention-related change over time.

Numerous questionnaire measures of tinnitus have been developed to date (for reviews see Fackrell et al., 2014; Meikle et al., 2008; Newman and Sandridge, 2004), and recommended for clinical use (Department of Health, 2009; Langguth et al., 2007; Tunkel et al., 2014). For tinnitus research, the international standards proposed by Landgrebe et al. (2012) calls for the routine use of the Tinnitus Handicap Inventory (THI; Newman et al., 1996), and that researchers define a validated tinnitus questionnaire as at least one of the primary outcome measures. Questionnaires are widely used in tinnitus research to either characterise the participant population (e.g. to aid comparison across different studies; Boyen et al., 2013; Melcher et al., 2013), to measure the effects of experimental intervention (e.g. Hoare et al., 2014a; Song et al., 2013), or to explore correlations between self-reported tinnitus severity and biological observations (e.g. Song et al., 2013; Szczepek et al., 2014). The approaches taken to validate tinnitus questionnaires to date have sometimes limited their utility (Meikle et al., 2008; Fackrell et al., 2014). For example, although the interpretability of the Tinnitus Handicap Questionnaire (THQ; Kuk et al., 1990) has been examined this has not led to defined categories of severity (Newman et al., 1995). The THI was developed specifically as a diagnostic tool with defined categories of severity (Newman et al., 1996; McCombe et al., 2001), and has been criticised for lacking sensitivity to change (Meikle et al., 2007). The Tinnitus Functional Index (TFI; Meikle et al., 2012) was developed to provide (i) comprehensive coverage of the broad range of symptoms associated with tinnitus severity, (ii) reliable measurement of tinnitus severity that distinguishes between individuals from those whose tinnitus is 'not a problem' to those whose tinnitus is a 'very big problem', and (iii) responsive measurement of change in tinnitus severity. It may therefore have a number of applications in research studies. The questionnaire underwent a systematic process of development to distil an initial item pool of 175 items through two prototypes (prototype 1 had 43 items, prototype 2 had 30 items) to arrive at a final questionnaire containing 25 items each mapping onto one of eight functional subscales (see Meikle et al., 2012 for details). The subscales (factors) were defined through Exploratory Factor Analysis and named as (i) Intrusiveness (items 1–3), (ii) Sense of control (items 4–6), (iii) Cognition (items 7–9), (iv) Sleep (items 10–12), (v) Auditory (items 13–15, (vi) Relaxation (items 16–18), (vii) Quality of life (items 19–22), and (viii) Emotional distress (items 23–25). The development pathway included a process of exploratory factor analysis, assessment of content validity, test-retest reliability, internal consistency, and convergent and discriminant validity. Development of the TFI used data collected from clinics in the USA, primarily specialist tinnitus clinics (42% of participants) and Veterans' Affairs (VA) hospitals (58% of participants). Those recruited from the VA sites tended to be male and experienced a range of co-morbidities, such as Post-Traumatic Stress Disorder (PTSD). Validation of the TFI is understood therefore relative to this mixed clinical population. It cannot be assumed that the questionnaire will show the same properties when administered to a different population. In fact the final 25-item version of the TFI has never been directly subjected to formal psychometric evaluation. The only assessment of validity and reliability was based on analysis of a subset of data collected for the 30-item prototype 2 of the questionnaire, and confirmatory factor analysis was not conducted (Meikle et al., 2012).

Here we examine the properties of the TFI for a general sample of UK adults experiencing tinnitus who presented themselves to take part in a clinical trial guided by quality criteria for the measurement properties of health-related questionnaires (Terwee et al., 2007; see also Fackrell et al., 2014). Specifically, the psychometric validation reported here focuses on assessing (a) the reliability of the 8-factor TFI structure reported by Meikle et al. (2012), i.e. verifying item identification with each factor and the underlying construct using Confirmatory Factor Analysis, and (b) the ability of the TFI to reliably measure tinnitus severity, distinguishing between individual differences in tinnitus-related distress, and responsively measure change in tinnitus severity.

2. Materials and methods

2.1. Participants and procedure

This was a retrospective analysis of data collected during a two-centre clinical trial conducted at the National Institute for Health Research Nottingham Hearing Biomedical Research Unit (BRU) and the University College London Ear Institute (RESET2, ClinicalTrials.gov ID:NCT01541969; Hoare et al., 2013). For that trial, participants were recruited via adverts placed on the website of the Nottingham Hearing BRU or in local hearing clinics, or to publicity in the national media. Participants reflected a mix of those who had previously attended clinical appointments for their tinnitus, and those who had never sought medical help for their tinnitus. Although none of the participants were receiving any clinical interventions for their tinnitus at the time of assessment, all participants were strongly motivated to seek a specific treatment by volunteering for this clinical trial in which a novel sound therapy for tinnitus was prescribed for a period of 36 weeks of daily use. The intake assessment for eligibility onto the trial provided data for the psychometric validation analysis. Assessment included Percentage Annoyance question, a VAS of tinnitus loudness, the TFI, THI, THQ, the Beck Anxiety Inventory (BAI; Beck and Steer, 1990) and Beck's Depression Inventory (BDI-II; Beck et al., 1996), and the World Health Organisation Quality of Life (WHOQOL-BREF; The WHOQOL group, 1998). In the clinical trial, 391 were assessed for eligibility but 291 were excluded from the trial at either telephone screening or eligibility appointments because they did not meet the inclusion criteria (stated in ClinicalTrials.gov Identifier: NCT01541969, but not relevant for the present study), or withdrew. Hence, 100 participants were allocated to one of the study arms and received treatment. The data contributing to the present study comprised 294 individuals (212 male, 82 female), with an average age of 52.8 years (range: 18 to 82) and tinnitus duration of 9.0 years (range: 4 months to 50 years). We have TFI data at the initial assessment from 285 individuals (two were excluded due of missing data) and of those, 12% reported tinnitus as not a problem (range: 0–17), 27% reported tinnitus as a small problem (range: 18–31), 31% as a moderate problem (range: 32–53), 24% as a big problem and 5% as a very big problem (range: 73–100). This distribution was comparable to that reported by some of the clinical centres participating in the original development of the TFI Protocol 1 (Meikle et al.,