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Research Paper

Performance of the Tinnitus Functional Index as a diagnostic instrument in a UK clinical population

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ABSTRACT

Objectives: The Tinnitus Functional Index (TFI) has been optimised as a diagnostic tool for quantifying the functional impact of tinnitus in US veteran and civilian groups. However, the TFI has not been fully evaluated for use in other English-speaking clinical populations despite its increasingly popular uptake. Here, a prospective multi-site longitudinal validation study was conducted to evaluate psychometric properties relevant to the UK clinical population. Guided by quality criteria for the measurement properties of health-related questionnaires, we specifically evaluated three diagnostic properties relating to the degree to which the TFI (i) covers the eight dimensions proposed to be important for diagnosis, (ii) reliably distinguishes individual differences in severity of tinnitus, and (iii) reliably measures the functional impact of tinnitus. We also examine whether clinically meaningful interpretations of the scores can be produced for the UK population.

Methods: Twelve National Health Service audiology clinics across the UK recruited 255 tinnitus patients to complete questionnaires at four time-intervals, from initial clinical assessment and then over a nine-month period. Patients completed the TFI, the Tinnitus Handicap Inventory (THI), tinnitus case history questions, a Global rating of Perceived Problem with tinnitus and a Clinical Global Impression of perceived change in tinnitus. Baseline TFI data were used to examine the factor structure, construct validity and interpretability of the TFI. Follow-up TFI data were used to examine reliability.

Results: Confirmatory factor analysis suggested that of the eight subscales (factors) initially established for the TFI, the 'Auditory' subscale did not contribute to the overall construct 'functional impact of tinnitus', and a modified seven-factor model (TFI-22) better fit the variance in the patient scores. Both the global 25-item TFI and the global TFI-22 scores showed exceptionally high internal consistency ($\alpha \geq 0.95$), high construct validity with the THI ($r = 0.80$) and high test-retest reliability (ICC = 0.87). Test-retest agreement however was only deemed to be borderline acceptable (89%). Receiver Operator Characteristic analysis indicated the 25-item TFI and TFI-22 has excellent ability to distinguish between different levels of impact (Area under the curve > 0.7).

Conclusion: The TFI was confirmed to cover multiple symptom domains, measuring a multi-domain construct of tinnitus, and satisfies a range of psychometric requirements for a good clinical measure, including having excellent reliability, stability over time and sensitivity to individual differences in tinnitus severity. However, a modified seven-factor structure without the Auditory subscale (TFI-22) is recommended for calculating a global composite score for UK patients. Using patients' experience and Receiver Operator Characteristic analysis, a grading system was presented which identifies the distinct

Abbreviations and acronyms used throughout: AUC, Area Under the receiver operator characteristic Curve; AUD, Auditory subscale; CFA, Confirmatory Factor Analysis; CFI, Comparative Fit Index; COG, Cognition subscale; EFA, Exploratory Factor Analysis; EMO, Emotional subscale; EPC, Expected Parameter Change; ICC, IntraClass Correlations; INTR, Intrusiveness subscale; LoA, Limits of Agreement; MI, Modification Index; NHS, National Health Service; QOL, Quality of life subscale; REL, Relaxation subscale; RMSEA, Root Mean Square Error of Approximation; ROC, Receiver Operator Characteristic; S-B χ^2 , Satorra-Bentler scaled Chi-square; SEM, Standard Error of Measurement; SLP, Sleep subscale; SOC, Sense of control subscale; SRMR, Standardised Root Mean Square Residual; T0, Baseline; T1, 3 month follow up; T2, 6 month follow up; T3, 9 month follow up; TFI, Tinnitus Functional Index; THI, Tinnitus Handicap Inventory; THQ, Tinnitus Handicap Questionnaire; THS, Tinnitus and Hearing Survey; TLI, Tucker-Lewis Index; TQ, Tinnitus Questionnaire; TRQ, Tinnitus Reaction Questionnaire; VA, Veteran's Affairs

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grades of tinnitus impact in the UK clinical population that is broadly comparable to the US-based system.

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1. Introduction

The experience of tinnitus involves much more than the 'phantom' sensation of sound since the condition can also impact on daily functioning and cause emotional distress (Henry et al., 2016; Mohamad et al., 2016; Pierzycki et al., 2016; Szczepek et al., 2014). Thus, for those who do find tinnitus bothersome, it can be described as a multi-dimensional condition. As such, it is best captured using a multi-domain patient-reported questionnaire whereby multiple items ask about particular aspects/domains of the condition which are deemed to be important (Hall et al., 2016; Henry et al., 2016). Many tinnitus questionnaires, such as the Tinnitus Questionnaire (TQ; Hallam, 2008, 1996; Hiller and Goebel, 1992), Tinnitus Handicap Inventory (THI; Newman et al., 1996), Tinnitus Reaction Questionnaire (TRQ; Wilson et al., 1991), and Tinnitus Handicap Questionnaire (THQ; Kuk et al., 1990), have known measurement properties that are consistent with their use in clinical diagnosis i.e. good discriminative power (Kamalski et al., 2010; Kirshner and Guyatt, 1985). However, in a systematic review of the psychometric properties of tinnitus questionnaires, Kamalski et al. (2010) did not identify or report any evidence on whether authors had provided clinically meaningful interpretations of the scores. More recently, Fackrell et al. (2014) reviewed the validity, reliability, responsiveness, and interpretability of tinnitus questionnaires using an internationally recognised set of criterion (Terwee et al., 2007) and reported that the evidence for the discriminative capabilities of these tinnitus questionnaires varied widely. The evidence was limited and hard to determine for content validity of the TQ, TRQ, and THI, for structural validity of the TQ, and TRQ, and for the clinical interpretation of the scores of the TQ, TRQ, and THQ (Fackrell et al., 2014). The authors concluded that, although the THQ has provided normative data, the ability to provide clinical interpretations of the scores has only been determined for the THI, with a defined established UK-based grading system. It was noted, however, that this grading system was solely based on expert opinion and the statistical properties of the scores. As such, these grades do not necessarily reflect the actual patient experience.

Importantly, the evaluation by Fackrell et al. (2014) included the Tinnitus Functional Index (TFI; (Meikle et al., 2012)). First published in 2012, the TFI differs from previous tinnitus questionnaires in a number of important and positive ways; namely its careful development, comprehensive coverage of many important tinnitus complaints, interpretability of scores and responsiveness to treatment-related change (Fackrell et al., 2014). Not surprisingly, the tinnitus community at large appears eager to embrace its use. In the period 2012–2015, the TFI has established itself as the second most commonly used tinnitus questionnaire in UK National Health Service (NHS) tinnitus services; the THI is most commonly used (Hoare et al., 2015). However, it is important for our communities to appreciate that the statistical properties of the TFI are not immutable. Whilst it might be valid, reliable, and interpretable in one target population, it may behave in quite a different way in a different population (e.g. Streiner et al., 2014). As the TFI gains in international popularity in the clinic, it is important that its discriminative properties be evaluated thoroughly for each new setting and population.

It is well documented that the TFI was developed using data collected in the US, some in specialist tinnitus clinics but principally in Veteran's Affairs (VA) hospitals (58% of patients) (Meikle et al., 2012). In VA hospitals, those patients tend to be male, with an active military background, potentially experiencing a range of service-related co-morbidities, and their tinnitus is considered as a service-related condition which may entitle them to compensation. This rather unique provenance of the TFI warrants caution in terms of how well those psychometric properties transfer to different target populations.

Since the development of the TFI (Meikle et al., 2012), several evaluations of the questionnaire have been conducted in English speaking and non-English speaking countries. These evaluations increase our understanding and optimising the use of this questionnaire for research and clinical practice alike. To date, the American-English version of the TFI has been evaluated in US Veterans (Henry et al., 2016), a general clinical population in New Zealand (Chandra et al., 2014) and a research population drawn from the general public in the UK (Fackrell et al., 2016). The psychometric exploration reported by Henry et al. (2016) has the same potential limitation (not generalizable) as was noted in the original development study (Meikle et al., 2012). Fackrell et al. (2016) raised some doubts of the stability of the 8-factor structure of the TFI when used in a UK-based research population, namely that the auditory subscale appeared not to contribute to the measure of global functional impact of tinnitus. There have been four independent evaluations in different target populations, where the TFI has been translated into Dutch (Rabau et al., 2014), Swedish (Hoff and Kähäri, 2016; Müller et al., 2016), and Polish (Wrzosek et al., 2016). In general, evaluations of these translated versions showed the TFI to have good discriminative properties. However, there was also some uncertainty over its proposed factor structure. In all of those studies, Exploratory Factor Analysis (EFA) was conducted which identified different patterns in the data, typically with only five or six factors initially identified, although all reported forced eight-factor models as being satisfactory (Rabau et al., 2014; Hoff and Kähäri, 2016; Müller et al., 2016; Chandra et al., 2014). Only the Polish study included Confirmatory Factor Analysis (CFA) to test the proposed eight-factor structure, finding it to be unsatisfactory (Wrzosek et al., 2016). Instead, their EFA indicated that a five-factor solution best explained the Polish population data. Interpretability was not assessed in any of those studies.

Meikle et al. (2012) have proposed interim grading systems for the TFI, but the question of whether this interpretability of the global scores, an essential requirement for the suitability of a questionnaire in clinical practice or research, is transferable to other populations is yet to be addressed in any subsequent psychometric evaluation.

In the present study, we examined the psychometric properties of the TFI for a large clinical sample of UK NHS patients treated for tinnitus. In designing this study we were guided by quality criteria for the measurement properties of health-related questionnaires as outlined by Mokkink et al. (2012) and Terwee et al. (2007). Unlike our previous work (Fackrell et al., 2016), this study was specifically designed to evaluate the TFI as a reliable and valid measure of tinnitus severity for use in a tinnitus clinical population, and to determine its responsiveness and interpretability. This study is

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