

Development and psychometric validation of a questionnaire assessing the impact of tinnitus on significant others

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Highlights

- The consequences of tinnitus on significant others questionnaire was developed to identify tinnitus impact on significant others.
- Psychometric validation indicated good questionnaire properties.
- Score can be meaningfully interpreted to show mild, significant or severe effects.
- The questionnaire is suitable to measure third-party disability for tinnitus.

Abstract

Introduction: Despite evidence showing that tinnitus can have a detrimental impact on significant others (SOs), no standardized self-reported measure is currently available that specifically assesses the presence of third-party disability for tinnitus. The aim of this study was to develop and assess the psychometric properties of a newly developed self-reported measure for SOs of tinnitus and assess how scores could be meaningfully interpreted.

Methods: The research consisted of two phases. During Phase I, the Consequences of Tinnitus on Significant Others Questionnaire (CTSOQ) was developed using the The COnsensus-based Standards for the selection of health Measurement INstruments (COSMIN) guidance. Phase II

included the assessment of psychometric properties of the CTSOQ including the construct validity, internal consistency, interpretability, and responsiveness. Pairs of 194 individuals with tinnitus and their SOs completed a series of online questionnaires. SOs completed the CTSOQ measure while individuals with tinnitus completed measures related to tinnitus distress, anxiety, depression, insomnia, and quality of life.

Results: A 25 item CTSOQ was developed using a formative model. The questionnaire validation process indicated good psychometric properties with an internal consistency of .93 and inter-item correlation of .60. Support was found for the construct and discriminative validity of the measure. Floor and ceiling effects were negligible. Scores can be meaningfully interpreted to indicate mild, significant, or severe effect of tinnitus on SOs. The questionnaire was also found to be responsive to treatment-related changes.

Conclusions: The CTSOQ was found to have sufficient measurement properties suggesting that it is a suitable measure of third-party disability for SOs of individuals with tinnitus. Further research should be initiated to measure face validity and what scores reflect clinically meaningful change.

Keywords: Significant others, Third-party disability, Tinnitus, Outcome measurement, Psychometric properties, Questionnaire validation

1. Introduction

Tinnitus experiences are variable both in their presentation and people's reactions to them. Tinnitus is classified into subjective and objective tinnitus (Bauer, 2018). Subjective tinnitus is the perception of unwanted sounds that are only audible to the individual and not associated with any external sound source. Such tinnitus is linked to changes within the peripheral and central auditory system. In contrast to subjective tinnitus, objective tinnitus is less common and can be heard by both the individual and examiners listening from close proximity. Conditions causing objective tinnitus include middle ear myoclonus, patulous Eustachian tube, and vascular abnormalities

(Knipper et al., 2020). Widely varying prevalence rates have been reported (i.e., 5.1 to 42.7%), partly due to varying methodologies used in collecting prevalence data (McCormick et al., 2016). Furthermore, tinnitus onset is associated with a wide range of ontological, personal, socioeconomic, and disease-related risk factors, although hearing loss is one of the greatest risk factors (Kim et al., 2015; Oosterloo et al., 2021). Due to this association with tinnitus and hearing loss, use of hearing aids and sound generators can be valuable in reducing the tinnitus percept (Yakuninua, Lee, Ryu, & Nam, 2019).

Of those with tinnitus, the majority are not bothered, however, for a proportion (estimated 2-10%), tinnitus interferes markedly with daily life (Oosterloo et al., 2020). For those bothered by tinnitus, there are various interventions that may be helpful including the use of sound therapies and psychological interventions that are delivered by tinnitus professionals or via self-help formats such as mobile and internet-interventions (Kutyba et al., 2021). Such interventions are recommended as people with bothersome tinnitus are found to be at higher risk of lower emotional wellbeing, depression, and anxiety, possibly because of people's frustration with their inability to escape or control their condition (Salazar et al., 2019; Trevis, McLachlan, Wilson, 2018). Tinnitus may also make it difficult to sleep, listen, and concentrate, which can affect day-to-day functioning (Basso et al., 2021; Mantello et al., 2020). To ensure that tinnitus is not altered by changes in the sound environment, many individuals living with tinnitus regulate their environments by trying to avoid silence and noisy situations, as well as ensuring a constant low level of background sound is present (Beukes et al., 2018a). Some may limit social activities and reduce participation in events, such as going out to restaurants or music concerts, in fear of causing a worsening of their tinnitus (Manchaiah et al., 2018a) or due to increased sound sensitivity (Raj-Koziak et al., 2021).

Activity limitations and participation restrictions may not only have a direct impact on the individual with tinnitus, but also the significant others (SOs), such as partners, close family members, or other individuals who have a close relationship to the individual with tinnitus. Recognition that health conditions may also affect SOs has led to the concept of third-party

disability in the World Health Organization International Classification of Functioning, Disability and Health (ICF) framework (ICF, 2001). Third-party disability refers to the difficulties faced by SOs due to a patient's health condition. Acknowledgement of third-party disability has been identified for various hearing and balance disorders (e.g., Grawburg et al., 2014; Manchaiah et al., 2013, 2018b; Nandurkar & Shende, 2020; Pyykkö et al., 2015; Threats, 2020; Scarinci et al., 2009a, 2009b), and other conditions associated with tinnitus, such as chronic pain (e.g., Meints & Edwards., 2018). Nevertheless, only a limited number of studies have explored the impact of tinnitus on SOs, which may be related to there being no validated self-reported measure currently available to assess and quantify the impact of tinnitus on SOs. Such measures of third-party disability do exist for hearing loss, such as the Significant Other Scale for Hearing Disability (SOS-HEAR; Scarinci et al., 2009).

Due to the need for a self-reported measure to access the third-party disability for SOs of individuals with tinnitus, we outline development and validation of such a measure. Specifically, we describe: (i) the development of the Consequences of Tinnitus on Significant Others Questionnaire (CTSOQ); and (ii) the measurement (psychometric) properties thereof, including its construct validity, internal consistency reliability, floor and ceiling effects, interpretability, and responsiveness.

2. Materials and Methods

This research was approved by the Institutional Review Board at Lamar University, Beaumont, Texas, US (IRB-FY17-209 and IRB-FY20-200). The COnsensus-based Standards for the selection of health Measurement INstruments (COSMIN) checklist (Mokkink et al., 2010a, 2012) was used as a guide for reporting the study results.

2.1 Phase I: Questionnaire Development

When developing a SOs questionnaire, we followed the recommendations from COSMIN (Mokkink et al., 2010a; 2012). Initially, the construct to be measured was identified, which was the impact of third-party disability of individuals with tinnitus on their SOs. The origin of this construct was based on available studies indicating that tinnitus can negatively affect SOs (e.g., El Refaie et al., 2004; Pugh et al., 2004; Sullivan et al., 1994; Mancini et al., 2018, 2019) and acknowledgement of third-party disability (ICF, 2001). The target population were any SOs that had a close relationship with the individual with bothersome tinnitus (e.g., spouse, partner, parent, child, sibling, other family members, carer, house mate, or a close friend). The intended usage was in both research and clinical contexts, particularly where individuals with tinnitus were identified to have more severe difficulties. A formative model was used to gather the items to form the construct of the questionnaire and propose suggested themes to explore, which were grouped together to form separate subscales of the construct. This approach contrasts with a reflective model, whereby all items are a manifestation of the same underlying construct (Mokkink et al., 2019). The subscales were generated from research investigating the impact of tinnitus on SOs in previous studies, such as tinnitus affecting the SO, the relationship, and the SOs ability to provide support for individual with tinnitus. This involved conducting preliminary research considering similar questionnaires for SOs for other health and communication problems (e.g., the SOS-HEAR). These suggestions were refined continuously by the research team using an iterative process. The structure was considered to ensure the questionnaire was comprehensive but not too long. Consideration for the instructions and response options, including the scoring algorithm, were debated amongst the research team and refined accordingly. Once a questionnaire draft was agreed upon, three individuals with tinnitus and their SOs piloted the questionnaire. Their responses led to further refinements intended to ensure the instrument's suitability and usability. Both paper and online versions were tested to ensure its functionality being presented in any administrative mode before confirming the final 25-item

questionnaire structure, henceforth referred to as the Consequences of Tinnitus on Significant Others Questionnaire (CTSOQ).

2.2 Phase II: Assessing Measurement Properties of the CTSOQ

2.2.1 Participants

To validate the CTSOQ, pairs of individuals with bothersome tinnitus seeking an intervention for their condition and their self-selected SOs were recruited. The study participants were part of a larger clinical trial who had sought help to manage their tinnitus in the form of an 8-week Internet-based cognitive behavioral therapy (ICBT) intervention for tinnitus (Beukes et al., 2021b, 2021c, 2021d). The inclusion criteria for the study were adults aged ≥ 18 years with self-reported bothersome tinnitus. Participants were to have access to an internet-enabled computer and not be undergoing any concurrent tinnitus therapies. These individuals could optionally self-select SOs to whom they could pass the CTSOQ questionnaire link to. The SOs had the opportunity to consider their involvement in the study. Both individuals with tinnitus and their SOs had to provide informed consent before completing the questionnaires.

A minimum sample size of 100 participants, or seven times the number of items in the questionnaire (i.e., 25 items \times 7 = 175 participants), has been indicated as an adequate sample size for questionnaire validation studies (Terwee et al., 2007). In the current study, the aim was to recruit more than 175 individuals with tinnitus and their SOs to ensure an adequate sample size.

2.2.2 Data Collection

Online questionnaires were used throughout the study by all participants. All participants completed a pre-intervention demographic questionnaire which provided data on age, gender, and the relationship between those with tinnitus and their SOs, as well as whether they lived together. Both individuals with tinnitus and their SOs completed a series of standardized measures at baseline (i.e.,

pre-intervention) and immediately after completion of the 8-week ICBT intervention for tinnitus (i.e., post-intervention).

SOs completed the CTSOQ only, which assessed third-party disability for tinnitus. Individuals with tinnitus completed a range of standardized measures, including tinnitus severity using the Tinnitus Functional Index (TFI; Meikle et al., 2012), anxiety symptoms using the Generalized Anxiety Disorder – 7 (GAD7; Spitzer et al., 2006), depression symptoms using the Patient Health Questionnaire – 9 (PHQ-9; Kroenke et al., 2011), sleep disturbance using the Insomnia Severity Index (ISI; Bastien et al., 2001), and the health-related quality of life (HRQoL) using the EQ-5D-5L and EQ-5D-5L Visual Analogue Scale (VAS) (Rabin & de Charro, 2001).

2.3 Data Analysis

To ensure that the CTSOQ had adequate psychometric properties in accordance with published standards for assessing instruments underpinned by a formative model (i.e., COSMIN: Mokkink et al., 2010a; 2012) and criteria recommendations by Terwee et al. (2007), construct validity, internal consistency reliability, floor and ceiling effects, interpretability, and responsiveness were assessed as outlined in the sections below. The data were analysed using IBM SPSS Statistics for Windows Version 27.0. The analysis was conducted and reported in accordance with published recommendations (Terwee et al., 2007). Considering the ordinal nature of the data generated from a 5-point Likert scale used in CTSOQ, non-parametric statistics were deemed appropriate.

2.3.1 Construct Validity: The extent to which an instrument measures what it is hypothesised to measure. According to Terwee et al. (2007), construct validity can be assessed by testing specific, predefined hypotheses and is confirmed when at least 75% of *a priori* hypotheses are supported.

First, we assessed *convergent validity*, which refers to the extent to which an instrument is correlated with other instruments that measure similar constructs. Given the limited evidence assessing the impact of tinnitus on SOs (Hall et al., 2018), we conservatively predicted that CTSOQ

scores would have a moderate, positive correlation (.30 to .59) with the TFI completed by individuals with tinnitus, including all subscales. In addition, given that tinnitus severity has been shown to be associated with anxiety, depression, and general health-related quality of life (Salazar et al., 2019; Trevis et al., 2018), it was also predicted that the CTSOQ would have at least moderate, positive correlations with the GAD-7, PHQ-9, ISI, and EQ-5D-5L, and a moderate, negative correlation with EQ VAS. Spearman's rank order correlation coefficients (r_s) were used to assess these predictions.

Second, we assessed *known-groups (or discriminative) validity*, which refers to the ability of an instrument to distinguish between different subgroups (De Vet et al. 2011). It was predicted that SOs of individuals with a 'severe problem' (TFI scores of >50; Henry et al., 2016; Meikle et al. 2012) would obtain significantly higher CTSOQ scores compared to those with a 'mild' (TFI score of below 25) or 'significant problem' (TFI scores of 25 to 50). A Mann-Whitney U test was used to test this prediction.

2.3.2 Internal Consistency Reliability: The extent to which items that purport to measure the same general construct produce similar scores. Cronbach's alpha was used to assess this property, which should fall within the range of .70 to .95 for an instrument or its subscales (De Vet et al. 2011). Internal consistency was also assessed via the mean inter-item correlation, which should fall within the range of .30 to .70, and the mean corrected item total correlation, which should be $\geq .30$ (Ferketich, 1991; Heffernan et al., 2019).

2.3.2 Floor and Ceiling Effects: The proportion of respondents scoring the lowest (floor) or highest (ceiling) possible score on an instrument. Floor and ceiling effects are problematic as they suggest that an instrument is unable to differentiate between respondents at either extreme of the scale. Floor and ceiling effects were considered to be present if >15% of respondents achieved the lowest or highest possible score (Terwee et al., 2007).

2.3.3 Interpretability: The degree to which qualitative meaning can be attributed to the quantitative scores of a measure (Terwee et al. 2007). This property was assessed using Receiver Operating Characteristic (ROC) analyses, which assessed the ability of the CTSOQ to accurately distinguish between categories of tinnitus severity as measured by the TFI (Henry et al., 2016; Meikle et al., 2012). Specifically, the CTSOQ was assessed in terms of its ability to accurately differentiate between SOs of individuals with different tinnitus severity as listed below:

- A ‘mild problem’ (TFI score <25).
- A ‘significant problem’ (TFI score = 25-50).
- A ‘severe problem’ (TFI score >50).

ROC curves plotted sensitivity on the y-axis and 1 – specificity on the x-axis. The Area Under the ROC Curve (AUC) provided a global summary statistic representing the ability of the CTSOQ to accurately discriminate between SOs of individuals in different tinnitus severity categories. An AUC of .5 means that there is a 50% probability that the measure cannot differentiate between two adjacent categories of patients. An AUC value $\geq .7$ is considered desirable (Fackrell et al., 2018; Heffernan et al., 2019). ROC analyses were also used to identify CTSOQ cut-off scores for each category that had the optimal balance of sensitivity and specificity.

2.3.4 Responsiveness: This is also referred to as longitudinal validity and can be defined as the ability of an instrument to detect change over time (Mokkink et al., 2010b). According to Mokkink et al. (2010a), a construct approach to responsiveness can be tested by comparing change scores before and after intervention with other outcome measurement instruments. Although SOs did not undertake the ICBT intervention, the effect of the intervention for individuals with tinnitus was also hypothesised to affect CTSOQ scores in SOs. It was predicted that CTSOQ change scores (i.e., the difference between pre- and post-ICBT intervention) would have a moderate, negative correlation with the TFI change scores (i.e., the difference between pre- and post-intervention), including all

subscales. Spearman's rank order correlation coefficients (r_s) were used to assess these predictions in SOs who completed the CTSOQ both pre- and post-intervention.

3. Results

3.1 Phase I: Questionnaire Development

The final structured questionnaire consisted of 25 items which focus on four sub-scales: (a) observations about the individual with tinnitus (10 questions); (b) personal impact (4 questions); (c) relationship impact (5 questions); and (d) providing support (6 questions). The instructions provided to participants asked them to rate the extent to which they agreed or disagreed with each statement and to rate responses according to experiences over the last two weeks. Each item is scored on a 5-point Likert scale with labeled points (from 0 = *strongly disagree*, to 4 = *strongly agree*). The scores for each question are added together to provide range between 0 to 100, and an overall score reported. Higher scores indicate substantial effects of tinnitus on SOs and their relationship with the individual with tinnitus. The questionnaire could be administered in paper or online format.

3.2 Phase II: Psychometric Validation

Of the 309 participants registering for ICBT, 194 (63%) individuals with tinnitus and their SOs completed all the questionnaires at baseline (i.e., pre-intervention) and were included in this study. Individuals with tinnitus not passing-on the SO questionnaire explained that this was because they did not have an appropriate SO to involve. SOs were asked to complete the CTSOQ post-intervention, after the individual with tinnitus had completed the ICBT intervention. At this stage, 63 (32%) pairs completed all outcome measures. Table 1 indicates that while a higher proportion of individuals with tinnitus were female (60%), the gender ratio was approximately equal for the SOs. The ages between individuals with tinnitus and SOs were similar, with a mean age of 55-years, and the majority of SOs being partners (84%) and living with the person with tinnitus (87%).

Table 1. Demographic information of individuals with tinnitus and their significant others.

Demographic variable	Individuals with Tinnitus	Significant others
Gender (n)		
Male	77 (39.7%)	100 (51.5%)
Female	117 (60.3%)	94 (48.5%)
Age (years)		
Mean	55.93	55.03
SD	11.85	13.84
Range	21-81	18-84
Self-reported tinnitus (n)		
Yes	194 (100%)	34 (17.5%)
No	0 (0%)	160 (82.5%)
Relationship (n)		
Partners		163 (84.0%)
Child/Parent		3 (1.5%)
Parent/Child		13 (6.7%)
Relatives		9 (4.6%)
Friends		6 (3.1%)
Living together (n)		
Yes		168 (86.6%)
No		26 (13.4%)

3.3 Construct Validity

Overall, 86% convergent validity predictions were confirmed; CTSOQ scores moderately correlated with tinnitus severity (TFI), anxiety (GAD-7), depression (PHQ-9), sleep disturbance (ISI), and health-related quality of life (EQ-5D-5L and EQ VAS), as shown in Table 2. Similarly, the known-groups validity prediction was confirmed; SOs of individuals with a severe tinnitus problem (i.e., an overall TFI score >50) obtained significantly higher CTSOQ scores (*Median* = 47; *IQR* = 20.5; *n* =

110) compared to those with a mild or significant tinnitus problem (*Median* = 30; *IQR* = 21.5; *n* = 84) as shown in the Mann-Whitney U test [$U(194) = 2.18, z = -6.0, p < .001$] (Figure 1).

Table 2. Spearman’s rank order correlation coefficients to test convergent validity for the CTSOQ. Bold indicates moderate correlations (.3 to .59). Note: *TFI*= Tinnitus Functional Index; *GAD-7*= Generalised Anxiety Disorder-7 item; *PHQ-9*= Patient Health Questionnaire-9 item.

Instrument	<i>r_s</i>	<i>p</i>
Tinnitus Functional Index (TFI) Overall	.517	<.001
TFI Intrusive subscale	.211	.003
TFI Sense of Control subscale	.325	<.001
TFI Cognitive subscale	.449	<.001
TFI Sleep subscale	.418	<.001
TFI Auditory subscale	.280	<.001
TFI Relaxation subscale	.390	<.001
TFI Quality of Life subscale	.523	<.001
TFI Emotional subscale	.541	<.001
Generalized Anxiety Disorder Scale (GAD-7)	.496	<.001
Patient Health Questionnaire (PHQ-9)	.493	<.001
Insomnia Severity Index (ISI)	.401	<.001
Health-related quality of life (EQ-5D-5L)	.380	<.001
Health-related quality of life (EQ-5D-5L Visual Analogue Scale)	-.330	<.001

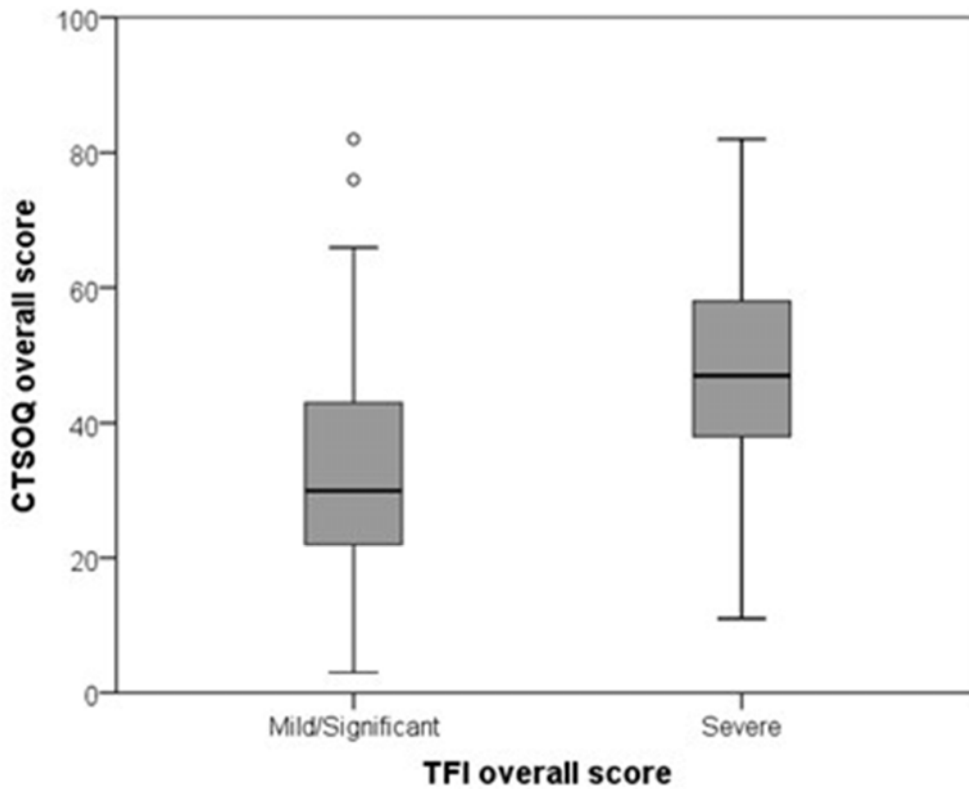


Figure 1. Boxplot showing overall scores for the Consequences of Tinnitus on Significant Others Questionnaire (CTSOQ)

3.4 Internal Consistency Reliability

All internal consistency statistics fell within the required range (Table 3).

Table 3. Internal consistency statistics for the Consequences of Tinnitus on Significant Others Questionnaire (CTSOQ).

Instrument	Cronbach's α^*	Mean inter-item correlation [†]	Mean corrected item total correlation [‡]
CTSOQ Overall	.93	.35	.58
CTSOQ Observations subscale	.90	.47	.64
CTSOQ Personal impact subscale	.79	.49	.60
CTSOQ Relationship subscale	.88	.61	.73
CTSOQ Support subscale	.77	.35	.51

*Value should fall between .70 and .95

†Value should fall between .30 and .70

‡Value should be >.30

3.5 Floor and Ceiling Effects

CTSOQ scores were normally distributed (Figure 2), with skewness of .02 (SE = .18) and kurtosis of -.50 (SE = .35). No respondents scored the lowest (0) or highest (100) possible score (Mean = 40.92; SD = 17.32; range = 3-82), suggesting that floor and ceiling effects were negligible.

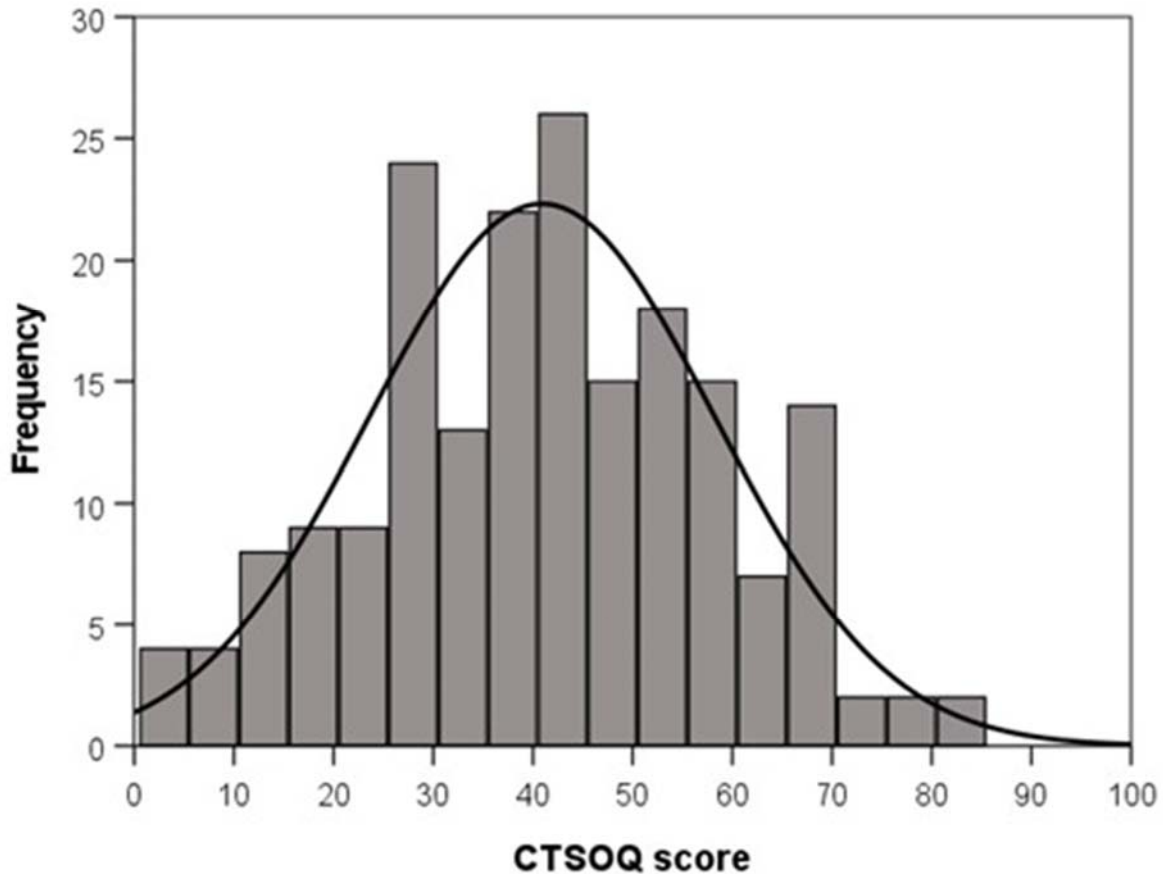


Figure 2. Distribution of the Consequences of Tinnitus on Significant Others Questionnaire (CTSQQ) overall scores across all respondents (N= 194).

3.6 Interpretability

The first ROC analysis (Figure 3) assessed the ability of the CTSQQ overall score to accurately identify 13 SOs whose partner with tinnitus reported ‘mild problems’ from 71 individuals in the ‘significant problems’ category. The AUC was 0.83 (95% CI = 0.74 to 0.923, $p < .001$). A CTSQQ cut-off score of 26.5 provided the best accuracy for the distinction between these two categories (sensitivity 76%, specificity 85%).

The second ROC analysis assessed the ability of the CTSOQ overall score to accurately identify 71 SOs whose partner with tinnitus was in the ‘significant problems’ category from 110 individuals in the ‘severe problems’ category. The AUC was 0.73 (95% CI = 0.66 to 0.81, $p < .001$). A CTSOQ cut-off score of 39.5 provided the best accuracy for the distinction between these two categories (sensitivity 71%, specificity 68%).

These analyses demonstrate the ability of the CTSOQ questionnaire to accurately discriminate between the level of difficulty in SOs, namely, mild difficulties for scores of 0-26, significant difficulties for scores of 27-39, and severe for scores of 40-100.

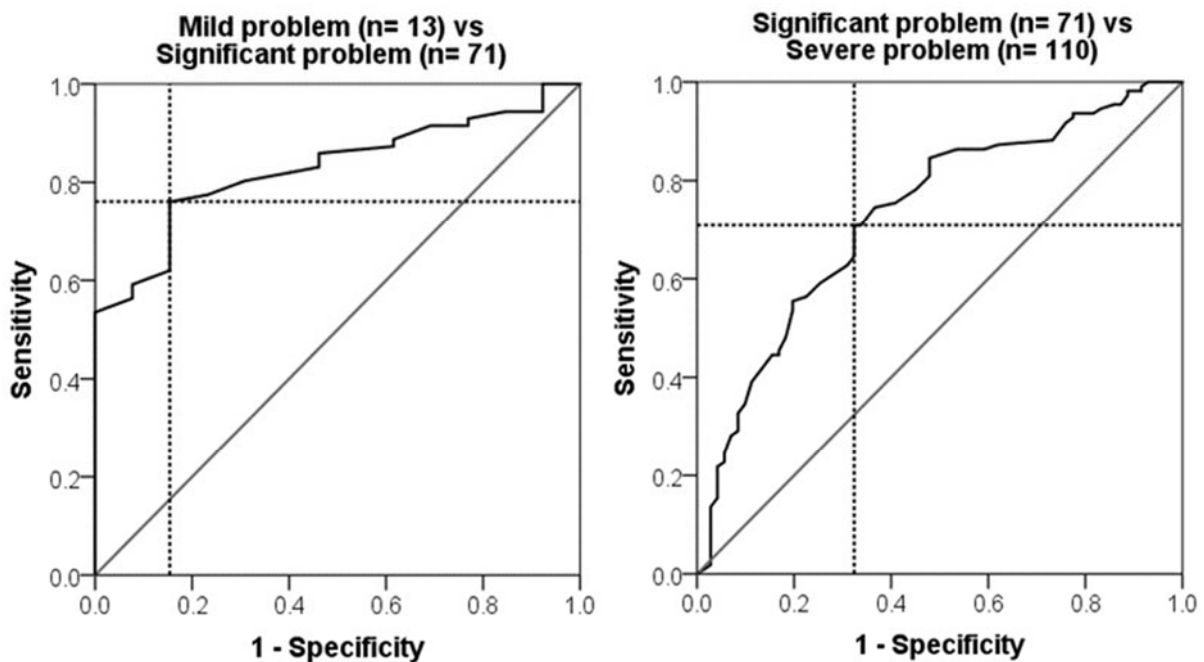


Figure 3. Receiver Operating Characteristic (ROC) curves for identifying optimal cut-off scores for the CTSOQ.

Sensitivity is plotted on the y-axis and 1 - specificity is plotted on the x-axis. The solid black line outlines the Area Under the ROC Curve (AUC). The solid grey line denotes 50% probability of accurately classifying tinnitus severity. The intersection of the broken black lines displays the cut-off score that provides an optimal balance of sensitivity and specificity.

3.7 Responsiveness

Overall, 67% predictions were confirmed, whereby CTSOQ change scores moderately correlated with TFI overall and subscale change scores (Table 4). This value may be affected by the lower sample size, as only 63 responses were obtained post-intervention.

Table 4. Spearman’s rank order correlation coefficients to test responsiveness for CTSOQ (i.e., the change between pre- and post-ICBT intervention). Bold indicates moderate correlations (.3 to .59). Note: TFI= Tinnitus Functional Index.

Instrument	r_s	p
TFI Overall	.40	.001
TFI Intrusive subscale	.24	.055
TFI Sense of Control subscale	.37	.003
TFI Cognitive subscale	.41	<.001
TFI Sleep subscale	.37	.003
TFI Auditory subscale	.35	.005
TFI Relaxation subscale	.38	.002
TFI Quality of Life subscale	.21	.097
TFI Emotional subscale	.16	.210

4. Discussion

Despite evidence showing that tinnitus can have a detrimental impact on SOs, no standardized questionnaires are currently available that assess the presence of third-party disability in tinnitus. Therefore, this research study reports the development of a new self-report questionnaire and an assessment of its measurement (psychometric) properties. During the development of the CTSOQ, the perspectives of SOs from previous studies were considered. This resulted in the generation of 25 items, each rated on a five-point Likert scale (from 0 = *strongly disagree*, to 4= *strongly agree*). The length of the CTSOQ corresponds with most tinnitus outcome measures, such as the ‘gold-standard’ TFI (Meikle et al., 2012), as well as analogous questionnaires assessing third-party disability in hearing loss, namely, the SOS-HEAR (Scarinci et al., 2009b). Moreover, having 25-

items ensures that the instrument comprehensively assesses the impact of tinnitus on SOs, which included separate subscales (i.e., observations, personal impact, relationship, and support). In addition, scoring of the CTSOQ is straight-forward as raw scores for each item are summed to produce an overall score out of 100, with higher score indicative of greater third-party tinnitus disability (or activity limitations).

The questionnaire validation process indicated similar psychometric properties to the SOS-HEAR, with an internal consistency of CTSOQ overall scores being .93, compared with the .94 for the SOS-HEAR, and an inter-item correlation of .60 that was within the desired range of (i.e., .30 to .70). Floor and ceiling effects were negligible, suggesting that the CTSOQ can discriminate between respondents at both extremes of the scale. Furthermore, construct validity was confirmed; as predicted, moderate positive correlations were found between the CTSOQ and measures of tinnitus severity, anxiety, depression, and health-related quality of life. With regards to interpretability, ROC analyses demonstrated that the CTSOQ questionnaire can accurately discriminate between SOs of individuals with different levels of tinnitus severity, namely, greater tinnitus severity results in higher CTSOQ scores, suggestive of greater third-party disability. The correlations on the subscales of the TFI were also particularly sensitive to the impact of tinnitus on SOs, including auditory, relaxation, emotional, and quality of life subscales. The SOs of persons with tinnitus that score highly on these TFI subscales may be at higher risk of third-party disability. Taken together, therefore, these results suggest that the CTSOQ is a suitable quantitative measure of third-party disability for SOs of individuals living with bothersome tinnitus.

4.1 Limitations and Future Directions

This is the first standardized questionnaire developed to assess third-party disability in SOs of individuals with tinnitus and used a structured approach to assess its measurement properties.

Nevertheless, while this study has provided some insights, these need to be considered within the

context of this study. The sample selected for this research were individuals with bothersome tinnitus who were actively seeking help in the form of an ICBT intervention for their tinnitus. As a result, this sample may not be representative of the general tinnitus population. However, we anticipate that SOs of individuals with more severe tinnitus are the ones who may have more burdened by their condition. As such, we consider this population appropriate for the purpose of this study. Even so, the CTSOQ could be further validated in SOs of individual's non-bothersome tinnitus to determine whether the questionnaire is suitable for this population also.

A further potential limitation was that, in the absence of other structured measures for assessing the third-party disability in SOs, we used several measures of individuals with tinnitus when assessing some of the psychometric properties (i.e., convergent validity, interpretability, responsiveness) of the CTSOQ. Although this approach seems reasonable, not all SOs may respond to their problems in the same way. For example, some SOs may have better coping mechanisms and positive attitudes toward an individual's tinnitus. As such, they may experience less third-party disability even when an individual living with tinnitus has high severity. To address this, future research could, for example, assess SOs levels of anxiety, depression, and/or quality of life, using these results for validation. This may also explain why only 67% predictions in relation to responsiveness were confirmed, whereby CTSOQ change scores moderately correlated with TFI scores, instead of the recommended 75%. Alternatively, this finding may have arisen as a consequence of insufficient power and may be addressed by increasing sample size, since only 63 respondents completed the CTSOQ post-intervention.

It should also be noted that, in the current study, we opted to use traditional psychometric analysis techniques to assess the properties of the CTSOQ. These techniques are an important part of questionnaire development outlined in the COSMIN checklist, which can be used to assess the methodological quality of studies investigating the measurement properties of an outcome measure

(Mokkink et al., 2010a; 2012). In accordance with this checklist, we did not opt to employ ‘modern’ psychometric analysis techniques, such as Rasch analysis or item response theory (IRT). According to Mokkink et al. (2019), Rasch analysis and IRT are suitable when assessing certain psychometric properties of questionnaires that are based on a reflective model, where all items are a manifestation of the same underlying construct and are expected to be highly correlated and interchangeable. By comparison, the CTSOQ was based on a formative model, with items categorised according to separate subscales that together formed the construct (i.e., the impact of tinnitus on SOs).

Nevertheless, in the future, modern psychometric analyses could be used to reduce the number of CTSOQ items to generate a brief yet valid measure, which could be utilised in contexts where there is a need to rapidly assess the impact of tinnitus on SOs. A similar approach has recently been undertaken in the hearing loss literature where limited time constraints in clinical appointments, for instance, do not permit extensive outcome measurement (Heffernan et al., 2019).

Development of the CTSOQ may encourage more robust studies investigating the effect of tinnitus on SOs. The number of published studies regarding the effects of tinnitus on SOs is scarce. One study indicated that family members have found that they had a greater understanding of tinnitus after the individuals with tinnitus undertook a tinnitus intervention (El Refaie et al., 2004). The same study also reported that SOs reported that tinnitus interventions helped the individual with tinnitus cope better with the tinnitus. Other studies have generally examined the role of the spouse in moderating tinnitus experiences (e.g., Pugh et al., 2004; Sullivan et al., 1994; Mancini et al., 2018, 2019). More recently a study using open-ended questions identified that the impact on SOs included increased responsibility of household duties and childcare, as well as a reduction in attending social events, music concerts, and functions (Beukes et al., 2021a). In some cases, this can lead to an emotional toll due to the increased stress and frustration experienced by the SOs, which in turn also may have a negative effect on the relationship between the SO and the individual with

tinnitus (Beukes et al., 2021a). These studies provide useful insights from which further research can be developed.

4.2 Clinical Implications

Due to the growing recognition of third-party disability of SOs of individuals with tinnitus, the results have direct implications for clinical practice and future research. Although further validation is required, particularly in relation to clinically meaningful change, use of this questionnaire can provide an indication of the presence of third-party disability and is made freely available by the authors for both research and clinical practice. This will ensure clinical practice considers the wider context of the individual with tinnitus. It is possible that third-party disability of the SO may be an additional burden on those with tinnitus, hence increasing their distress. Use of the CTSOQ is particularly recommended for SOs of individuals who are more bothered by their tinnitus. For these individuals, involving them in the rehabilitation process may be helpful (Beukes et al., 2021a; Mancini et al., 2018, 201). This should involve both support to SOs and increasing their understanding of tinnitus and how to help individuals with tinnitus (El Refaie et al., 2004). It will also be helpful to monitor both the SO and the individual with tinnitus to ensure that their tinnitus severity also improves, using validated outcome measures (e.g., Gos et al., 2020; Skarżyński et al., 2020).

Many strategies recommended for tinnitus could be practiced together, such as doing relaxation exercises. At present, no models for such interventions currently exists, and considerations to this provision should be made, ensuring interventions are available. Internet-based interventions can be one way to offering accessible and affordable management options for SOs as they have been found to be effective for individuals with tinnitus (Beukes et al., 2018c, 2018d). There are examples of Internet-based CBT for SOs in other health areas (e.g., Biliunaite et al., 2021; Cicila, Georgia, & Doss, 2014; Magnusson et al., 2019; Nilsson et al., 2018), although, to our knowledge, none exist in

the area of tinnitus. Nevertheless, this joint approach could benefit both the SO and those with tinnitus (Manchaiah & Taylor, 2018). Thus, more research should be done to identify effective joint care models as not such intervention presently exists.

4.3 Conclusions

The current study describes the development of a questionnaire for assessing the impact of tinnitus on SOs, as well as an examination of its measurement (psychometric) properties. Overall, the study shows that the newly developed CTSOQ has adequate construct validity, internal consistency, interpretability, and responsiveness. Therefore, we surmise that the CTSOQ is a valid measure that will aid in quantifying the third-party disability of SOs of individuals with tinnitus. This could not only inform more holistic, patient-centred approaches to tinnitus management and care, but could also lead to better support for SOs who are in need to reduce their third-party disability. By involving SOs in the rehabilitation process, some of the negative effects of tinnitus on both individuals with bothersome tinnitus and their SOs could be addressed. Use of the CTSOQ may be helpful for these purposes.

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