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Research Article

Reliability and Validity of the Persian Version of the 12-Item Tinnitus Primary Function Questionnaire

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Highlights

- The 12-item P-TPFQ has excellent content and face validity
- The P-TPFQ has high internal consistency and test-retest reliability
- Its total score is correlated with THI, BDI, and PSQI scores

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ABSTRACT

Background and Aim: Tinnitus creates socioeconomic challenges. Questionnaires are widely used to assess their impact on daily life. This study aimed to validate the Persian version of the 12-item Tinnitus Primary Function Questionnaire (P-TPFQ) to provide a culturally appropriate tool for evaluating tinnitus-related disability in Persian speakers.

Methods: This study with a cross-sectional design was conducted on 56 adults experiencing tinnitus. The TPFQ was translated according to the international quality of life assessment protocol. Content validity and face validity was evaluated using the Content Validity Ratio (CVR), Content Validity Index (CVI) and the Face Validity Index (FVI). Internal consistency was determined using Cronbach's alpha. Convergent validity was tested by assessing the correlation with the scores of the Tinnitus Handicap Inventory (THI), Beck Depression Inventory-II (BDI-II), and Pittsburgh Sleep Quality Index (PSQI). Test-retest reliability was assessed using the Intraclass Correlation Coefficients (ICC). Confirmatory Factor Analysis (CFA) examined the construct validity.

Results: Content and face validity were excellent (CVR=1.0, CVI=1.0, FVI=1.0). The CFA confirmed a four-factor structure with high loadings (0.85–0.97). Internal consistency was high (Cronbach's α=0.956 for the overall scale; 0.922–0.969 for the subscales). The total P-TPFQ score had a strong and significant correlation with the THI score (r=0.845), and a moderate and significant correlation with BDI-II (r=0.600) and PSQI (r=0.416) scores ($p<0.001$). Test–retest reliability was high (ICC=0.956).

Conclusion: The P-TPFQ with 12 items and four subscales has excellent reliability and validity. As a multidimensional tool, it can be used for assessing tinnitus-related behavioural aspects.

Keywords: Tinnitus; questionaries; tinnitus primary functional questionaries; validity; reliability

Introduction

Tinnitus, characterized by the perception of sound in the absence of external or internal auditory stimuli, represents a significant global health concern affecting millions and posing substantial challenges at both individual and societal levels. Subjective tinnitus, as the most prevalent form, is frequently correlated with hearing impairment, sleep disturbances, and psychological comorbidities, including depression and anxiety. Global prevalence rate for tinnitus ranges from 4.6% to 30%, with approximately 1% experiencing severe and debilitating symptoms. In the United States, tinnitus affects nearly 15% of the general population and 22% of adults over the age of 50 years. Approximately 90% of tinnitus cases are associated with some degree of hearing impairment [1]. In Iran, a study conducted in 2009 reported a tinnitus prevalence of 4.5%. Although more recent epidemiological data are not available in Iran, it is plausible that the number of individuals experiencing tinnitus may have increased [2]. The identification of tinnitus and the evaluation of its consequences primarily rely on patient self-report, as there is currently no objective method for directly detecting the presence of tinnitus [3]. However, subjective assessment methodologies, including behavioral tests and the use of questionnaires, are available for investigating tinnitus. These approaches enable researchers and clinicians to gather crucial information regarding the nature and impact of tinnitus on individuals [4]. A well-structured questionnaire facilitates a comprehensive evaluation of patient condition, enabling healthcare providers to make informed clinical decisions and monitor treatment progress. Comprehensive questionnaires with validated translations in multiple languages, such as the Tinnitus Handicap Questionnaire (THQ) [5], the Tinnitus Handicap Inventory (THI) [6], and the Tinnitus Functional Index (TFI) [7], are essential for the accurate assessment of tinnitus. Evidence suggests that shorter forms of questionnaires tend to exhibit higher rates of patient compliance, both in hospital and primary care settings [8]. THI is considered a standard outcome measure in clinical trials, facilitating comparisons across studies and ensuring consistency in evaluating treatment effectiveness. The use of THI as a standardized tool enhances the comparability and reliability of tinnitus severity assessments [9].

The Tinnitus Primary Function Questionnaire (TPFQ) is an alternative questionnaire designed to provide insights into the intensity and impact of tinnitus on essential daily activities. The TPFQ has a shorter length compared to the THI while maintaining the capacity to capture important aspects related to tinnitus and its interference with daily life. This brevity can be advantageous in clinical settings where there are time constraints or when a more focused assessment is intended. The TPFQ facilitates a more efficient evaluation of tinnitus-related activity limitations, making it a valuable tool for assessing the impact of tinnitus in individuals. Developed in 2014 by Tyler et al. [10] in two 20-item and 12-item versions, the TPFQ has been translated into multiple languages, including Korean [11], Chinese [12], Mandarin [13], Arabic [14], Brazilian [15], Hindi [16], and Persian (for the 20-item version) [17]. The TPFQ employs affirmative statements about daily activities, which patients should rate quantitatively based on the perceived impact of each statement on their quality of life. Its score provides valuable information regarding the patient's subjective response to tinnitus. The TPFQ is used for measuring clinical changes and identifying specific areas where patients may benefit from counseling to improve their tinnitus management [10].

Although instruments such as the THI have been validated in the Persian language and are available for assessing tinnitus severity, they tend to be lengthy and may not be practical in fast-paced clinical environments. The TPFQ with 12 items offers a brief yet multidimensional alternative that captures the functional impact of tinnitus across concentration, emotions, hearing, and sleep. The present study aimed to translate the 12-item TPFQ into the Persian language and subsequently evaluate its reliability and validity.

Methods

Study design and participants

This is a psychometric study with a cross-sectional design. The study population included patients diagnosed with chronic tinnitus, aged 18–70 years, referred to the tinnitus clinic at Amir Alam Hospital, Tehran, Iran. The sample size was determined using the subject-to-item ratio rule of thumb, with at least 5 per item, as recommended in the literature [18]. Sixty participants were initially included in the study, of whom four were excluded during the data analysis phase. The final

sample size was then 56, consisting of 32 males and 24 females. Detailed patient history regarding tinnitus was recorded, encompassing tinnitus duration, perceived laterality, and subjective ratings of pitch and loudness. Also, pure tone audiometry (AC 33, Interacoustic Co., Denmark) with TDH 39 headphones (Telephonics Co., USA) was performed for all participants. The Pure-Tone Average (PTA) was calculated as the average of the air conduction thresholds at 0.5, 1, 2, and 4 kHz. Inclusion criteria were age 18–70 years, no neurological disorders such as multiple sclerosis, Alzheimer's disease, or dementia, no significant dizziness or vertigo, no pulsatile tinnitus, tinnitus duration of at least six months [19], and being a native Persian speaker to ensure accurate comprehension of questionnaires and assessments. Exclusion criteria were unwillingness to continue participation and the occurrence of any issues during the study that could potentially compromise data collection or analysis.

Questionnaire

The 12-item TPFQ, developed in 2014 by Tyler et al. [10], has four domains: Concentration, emotions, hearing, and sleep. Each item is rated on a scale ranging from 0 (completely disagree) to 100 (completely agree). The total score is derived by averaging the summed scores across the four domains, yielding a total score of 0–100, with a higher score indicating higher tinnitus-related difficulties across all assessed domains [10].

Procedures

Initially, permission for translation of the TPFQ was obtained from its developer, Dr. Richard Tyler, via email correspondence. Subsequently, the TPFQ underwent a rigorous translation into Persian and cultural adaptation to ensure adaptation to the Iranian context. Following translation, the Persian TPFQ (P-TPFQ) was subjected to content and face validity assessments. In the subsequent phase, to evaluate convergent validity, participants were administered the Persian versions of the THI [20], Beck Depression Inventory-II (BDI-II) [21], and Pittsburgh Sleep Quality Index (PSQI) [22].

Translation

In the translation process, we followed the International Quality of Life Assessment (IQOLA) protocol [23]. The translation was performed independently by two expert translators, who translated the TPFQ from English to Persian. To assess the similarity and accuracy of the translated questionnaire, the Persian draft was then back-translated to English by two other translators. For further confirmation of content matching, the back-translated version was sent to the main author for review.

Content validity

To assess the content validity of the P-TPFQ, the Content Validity Ratio (CVR) based on the Lawshe method and the Content Validity Index (CVI) using the Waltz-Basel method were calculated. For the CVR calculation, the Persian version was presented to 10 audiologists. They were asked to review each item and rate it as "essential", "useful but not essential", or "not essential". The CVR was then calculated based on the Lawshe method, considering the number of experts who rated an item as "essential". The minimum acceptable CVR for 10 experts is 0.62 [23]. To assess the CVI, the same group of experts evaluated the relevancy, clarity, and simplicity of each item using a 5-point Likert scale. The CVI was then calculated by considering the number of experts who rated the relevance and clarity of an item as either 4 or 5. Based on the feedback and ratings provided by the experts, necessary corrections were made to the draft in the wording, clarity, or structure of certain items, ensuring that the questionnaire accurately captures the intended constructs and is understandable to the target population. The minimum acceptable value for CVI for 10 experts is 0.78 [24].

Face validity

To evaluate the face validity, 10 experts and 10 participants assessed its wording, layout, and simplicity using a Likert scale. The Face Validity Index (FVI) was calculated based on expert ratings for item simplicity (from 1=not simple to 5=highly simple), as follows: FVI=number of experts rating the item as relevant (i.e., 4 or 5)/total number of experts. Items scoring 4 or 5 were considered acceptable. An FVI score of 0.78 or higher is generally considered acceptable, indicating adequate face validity [25].

Reliability

To determine the internal consistency, Cronbach's alpha coefficient, corrected item-total correlation, and average inter-item correlation were used. Cronbach's alpha coefficient values greater than 0.7 indicate acceptable internal consistency [25]. To investigate

test-retest reliability, 21 participants randomly selected from the larger sample group, were asked to complete the questionnaire again two weeks after the initial administration. Then, the Intraclass Correlation Coefficient (ICC) value was calculated. An ICC value falling within the ranges of >0.5, 0.5–0.75, 0.75–0.90, and <0.90 represents weak, moderate, and strong reliability, respectively [25].

Construct validity

To evaluate the factor structure of the questionnaires, Confirmatory Factor Analysis (CFA) was conducted using the maximum likelihood method based on the variance-covariance matrix. The following indices were calculated: chi-square ($\chi 2$), relative chi-square ($\chi 2/df$), Comparative Fit Index (CFI), Normalized Fit Index (NFI), Incremental Fit Index (IFI), Root Mean Square Error of Estimation (RMSE), and Standardized Root Mean Square Residual (SRMSR). The CFA was performed on different factor models, including a single-factor model, a first-order four-factor model, and a second-order four-factor model.

Convergent validity

To determine the convergent validity of the P-TPFQ, the Persian versions of three additional questionnaires were administered, including THI, BDI, and PSQI.

The THI consists of 25 items and three subscales: functional subscale (11 items), emotional subscale (9 items), and catastrophic subscale (5 items). Each item has three potential responses: Yes (4 points), sometimes (2 points), No (0 points). The total score ranges from 0 to 100; scores 0–16 indicate no handicap, scores 18–36 indicate mild handicap, scores 38–56 indicate moderate handicap, scores 58–76 indicate severe handicap, and scores 78–100 indicate maximum handicap [20]. The BDI-II is a widely used questionnaire designed to assess the severity of depression. It has 21 items rated on a scale from 0 to 3. The total score ranges from 0 to 63, with higher scores indicating a greater level of depression [21]. The PSQI includes 24 questions or items that need to be rated (0 to 3 for 20 items, while 4 items are open-ended), 19 items are self-reported, and 5 items require secondary feedback from a companion [22].

Data analysis

For quantitative variables, the values were expressed as mean (standard deviation) or median (interquartile range). Qualitative variables were represented as frequency (percentage). The normality of the P-TPFQ score was assessed using the Shapiro-Wilk test or the Kolmogorov-Smirnov test. To examine the relationship between P-TPFQ-12, THI, BDI-II, and PSQI scores, Spearman's correlation test was used. The data analysis was performed in SPSS software.

Results

Characteristics of participants

The participants had a mean age of 46.09±14.64 years. Among them, 32 were male (57.1%) and 24 were female (42.9%). The PTA at 500–4000 Hz was 28.02±20.67 dB HL. Among participants, 29 individuals (51.8%) reported experiencing tinnitus in both ears, while 13 (23.2%) reported tinnitus in the right ear and 14 (25%) in the left ear. In terms of tinnitus type, 40 participants (71.4%) had tonal tinnitus, while 16 (28.6%) had noisy tinnitus, evenly distributed between males and females. Descriptive statistics for the total score of the P-TPFQ and its subscales are presented in Table 1. Among the subscales, concentration had the highest score, whereas sleep had the lowest score.

Table 1. Descriptive indices of tinnitus primary function questionnaire-12 total score and its subscale scores in participants with tinnitus (n=56)

TPFQ-12	Possible amounts	Observed amount	Mean(SD)	Median
Concentration	0-100	0-100	34.3(31.5)	23.3
Emotions	0-100	0-100	30.7(29.9)	20.0
Hearing	0-100	0-100	30.3(34.3)	15.0
Sleep	0-100	0-90	23.3(26)	10.0
Total score	0-100	0-92.5	29.6(26.4)	20.0

TPFQ-12; the 12-item tinnitus primary function questionnaire

Content and face validity

All P-TPFQ items showed CVR and CVI values of 1, indicating excellent content validity for the questionnaire items. The FVI was calculated as 1 based on feedback from both experts and participants. The questionnaire achieved an average total score of 5, reflecting its simplicity and confirming a satisfactory level of face validity.

Reliability

Cronbach's alpha coefficient for the entire scale was 0.956, which was at an excellent level; Cronbach's alpha coefficients for the subscales of concentration, emotions, hearing, and sleep were 0.949, 0.922, 0.969, and 0.936, respectively (Table 2). The average inter-item correlation for the entire questionnaire and the subscales of concentration, emotions, hearing, and sleep (Table 2) was at an adequate level. The results of the test-retest reliability using the ICC are shown in Table 3.

Construct validity

The fit indices indicated that the single-factor model does not fit the data well ($\chi2/df=6.11$, CFI=0.79, NFI=0.77, IFI=0.79, RMSEA=0.312, and SRMR=0.120). For the first-order four-factor model, the indices showed that the model had a good fit to the data ($\chi2/df=1.96$, CFI=0.95, NFI=0.93, IFI=0.95, RMSEA=0.132 [90% CI=0.11–0.15], and SRMR=0.066), since the relative chi-square value was less than 2, the CFI, NFI, and IFI indices were greater than 0.90, and the SRMR index was less than 0.08. Only the RMSEA index was not in the acceptable range. All standardized factor loadings were significant, ranging from 0.85 to 0.97. Almost the same results were obtained for the second-order four-factor model; therefore, the second-order four-factor model also had a good fit to the data (Figure 1).

Convergent validity

As shown in Table 4, a strong and statistically significant positive correlation was found between the total P-TPFQ score and the total THI score (r=0.845, p<0.001). Additionally, significant positive correlations were observed between the scores of all P-TPFQ subscales and all THI subscales (p<0.001). The total P-TPFQ score also had a significant positive correlation with the BDI-II score (r=0.600, p<0.001) and the PSQI score (r=0.416, p≤0.001). Also, weak to strong positive correlations were observed between the scores of P-TPFQ subscales and the total scores of the BDI-II and PSQI (Table 5).

Table 2. Internal consistency reliability of the tinnitus primary function questionnaire-12 questionnaire in participants with tinnitus (n=56)

TPFQ-12 questionnaire subscale	Number of items	Cronbach's alpha	Corrected item-total correlation	Mean inter-item correlation
Concentration	3	0.949	0.829–0.939	0.863
Emotions	3	0.922	0.796–0.879	0.799
Hearing	3	0.969	0.919–0.947	0.914
Sleep	3	0.936	0.821–0.908	0.834
Total score	12	0.956	0.632–0.889	0.638

TPFQ-12; the 12-item tinnitus primary function questionnaire

Table 3. Intraclass correlation coefficient values for tinnitus primary function questionnaire-12

TPFQ-12	Interclass correlation*	95% confidence interval
Concentration	0.949	0.921–0.969
Emotions	0.922	0.875–0.951
Hearing	0.969	0.952–0.981
Sleep	0.936	0.900–0.961
Total score	0.956	0.937–0.971

TPFQ-12; the 12-item tinnitus primary function questionnaire
* ICC values equal to >0.5, 0.5–0.75, 0.75–0.9, and <0.9 indicate poor, moderate, good, and excellent reliability, respectively

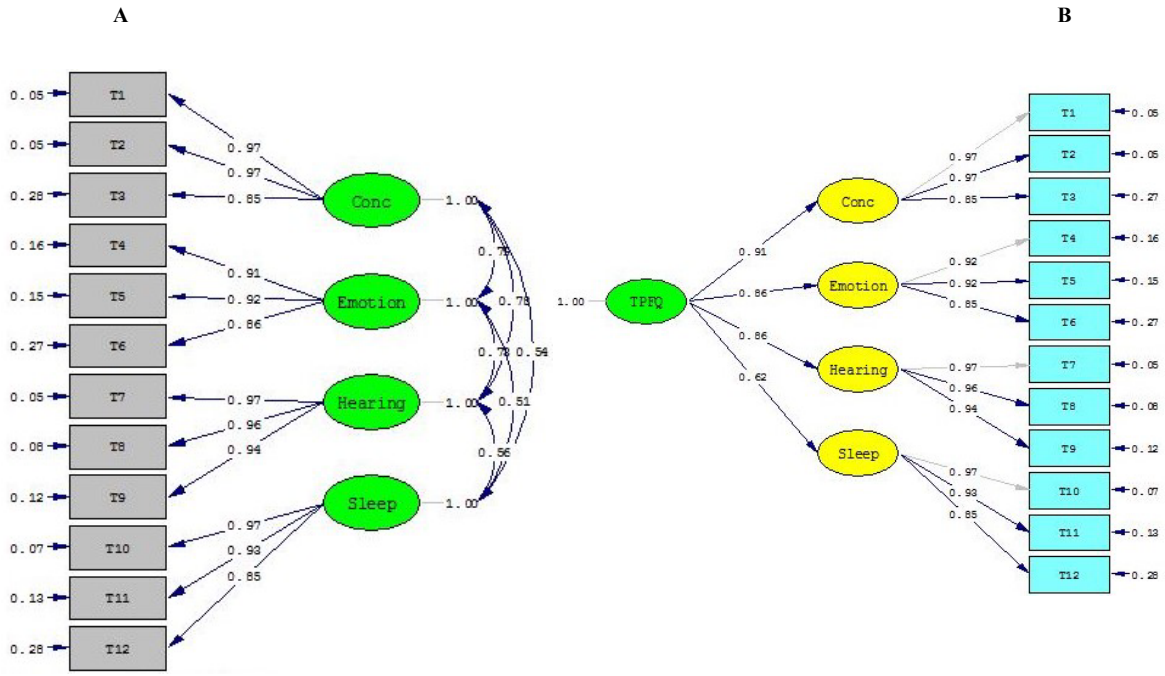

Figure 1. Confirmatory factor analysis of first-order (A) and second-order (B) four-factor model of the tinnitus primary function questionnaire-12. Conc; concentration, TPFQ; tinnitus primary function questionnaire

Table 4. Spearman's correlation coefficients between tinnitus primary function questionnaire-12 scores and tinnitus handicap inventory scores in participants with tinnitus (n=56)

TPFQ-12 questionnaire subscale	THI questionnaire-functional	THI questionnaire-emotional	THI questionnaire-catastrophizing	THI questionnaire-total score
Concentration	0.820	0.737	0.715	0.819
Emotions	0.832	0.830	0.775	0.867
Hearing	0.588	0.456	0.430	0.546
Sleep	0.654	0.544	0.522	0.623
Total score (TPFQ-12)	0.853	0.765	0.731	0.845

TPFQ-12; the 12-item tinnitus primary function questionnaire, THI; tinnitus handicap inventory
Correlation coefficient values of 0.1–0.3, 0.3–0.5, and <0.5 indicate weak, moderate, and strong correlation, respectively

Table 5. Spearman correlation coefficients between tinnitus primary function questionnaire-12 scores and Beck's depression inventory and Pittsburgh sleep quality index scores in participants with tinnitus (n=56)

TPFQ-12 questionnaire	PSQI total score		BDI-II total score	
	p	r	p	r*
Concentration	0.010	0.343	<0.001	0.602
Emotions	0.003	0.389	<0.001	0.660
Hearing	0.154	0.193	0.008	0.353
Sleep	<0.001	0.502	0.007	0.356
Total score	0.001	0.416	<0.001	0.600

PSQI; Pittsburgh sleep quality index, BDI-II; Beck depression inventory-II, TPFQ-12; the 12-item tinnitus primary function questionnaire
* Correlation coefficient values of 0.1–0.3, 0.3–0.5, and <0.5 indicate weak, moderate, and strong correlation, respectively

Relationship of age and gender with the tinnitus primary function questionnaire score

There was no significant relationship between the factors of age (r=0.014, p=0.916) and gender (r=0.8, p=0.649) and the total P-TPFQ score.

Discussion

The statistical analyses confirmed that the 12-item P-TPFQ had high content validity, with CVR and CVI values of 1. These results suggest that the translation successfully preserved the original version's integrity, as no content modifications were made. This alignment indicates that the P-TPFQ retains the content validity of the English version, making it applicable to Persian-speaking populations. The internal consistency was confirmed using Cronbach's alpha for the overall scale and all subscales. For the original English version, Tyler et al. [10] reported a Cronbach's alpha of 0.89, while in our study Cronbach's alpha for the overall scale was 0.95, indicating enhanced consistency possibly due to cultural resonance or refined item selection. However, these high alpha values should be interpreted cautiously; they reflect statistical reliability but not necessarily the qualitative experience of tinnitus severity, which may vary subjectively among respondents. Shaurya et al. reported a lower Cronbach's alpha (0.734) for the Indian version, suggesting cultural or methodological differences [16]. The TPFQ versions with Cronbach's alpha values close to the Persian version are the Mandarin version (α=0.925) [13], Arabic version (α=0.806–0.819) [14], Chinese version (α=0.92) [12], Brazilian Portuguese (α=0.94–0.95) [15], and Korean version (α=0.94–0.95) [11], all showing high internal consistency. This cross-cultural robustness underscores the P-TPFQ's reliability, though differences may reflect linguistic nuances or sample characteristics.

The convergent validity findings provided robust evidence for the 12-item P-TPFQ's clinical utility. Its strong significant correlation with the THI score (r=0.845) is according to theoretical expectations, as both instruments measure tinnitus-related disability, but through distinct conceptual frameworks; TPFQ focuses on functional domains (concentration, emotions, hearing, sleep) while THI emphasizes handicap perception. The high convergence confirms that the 12-item P-TPFQ captures core constructs of tinnitus handicap while offering multidimensional granularity. Its emotion subscale correlated strongly with BDI-II score (r=0.66), validating its sensitivity to affective comorbidities, while the sleep subscale showed the highest association with the PSQI score (r=0.68), demonstrating specificity to sleep disturbance, a common tinnitus comorbidity. These domain-specific patterns mirror findings in the original validation (r=0.77 with THQ) [10]. The observed moderate correlations of P-TPFQ with BDI-II (r=0.600) and PSQI (r=0.416) scores further reinforce the instrument's construct validity. These values are clinically meaningful, reflecting that tinnitus-related dysfunction shares variance with butis not reducible to depression or sleep pathology alone. This correlation is consistent with other TPFQ versions, such as Chinese (r=0.65 with BDI) and Mandarin (r=0.49 with PSQI) versions [13], underscoring the universal interplay between tinnitus and these domains. The test-retest reliability, measured by the ICC, was 0.956 for the overall scale and 0.922–0.969 for the subscales, indicating excellent temporal stability of the P-TPFQ, consistent with other versions with ICCs ranging from 0.82 to 0.95 [25].

In this study, participants were recruited from the tinnitus clinic of one tertiary hospital in Tehran. This may cause selection bias toward individuals with higher tinnitus severity or greater healthcare access, potentially limiting generalizability to community-dwelling populations or those with mild symptoms. Self-reported measures such as the BDI are potentially influenced by response bias, as some individuals may have withheld honest answers due to personal discomfort or social stigma. Also, the sample size was relatively small, warranting further studies to perform CFA on a larger sample size to further strengthen the evidence for the model's construct validity.

Conclusion

The Persian version of the 12-item Tinnitus Primary Function Questionnaire (P-TPFQ) is a reliable and valid instrument for assessing tinnitus-related behavioural impacts in Persian-speaking individuals. These findings have important implications for clinical practice especially monitoring of tinnitus treatment and future research in the field of tinnitus.

Ethical Considerations

Compliance with ethical guidelines

Ethical approval was obtained from the University of Medical Sciences with reference number IR.TUMS.FNM.REC.1402.033. All participants signed written informed consent forms.

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Authors' contributions

AR: Conceptualization, study design, acquisition of data, interpretation of the results, statistical analysis, drafting and revising the manuscript; VR: Conceptualization, study design, interpretation of the results, drafting and revising the manuscript; ET: Interpretation of the results and drafting the manuscript; RT: Study design, revising the manuscrip; MA: Acquisition of data, drafting the manuscript.

Conflict of interest

We have no conflicts of interest to disclose.

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