AJA

Research Article

Development and Validation of the Tinnitus Primary Function Questionnaire

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Purpose: To create a questionnaire focused on the primary activities impaired by tinnitus and therefore more sensitive to treatments.
Method: Questions were developed on (a) emotions, (b) hearing, (c) sleep, and (d) concentration. A 20-item questionnaire was administered to 158 patients. First, confirmatory factor analysis was used to select 3 questions per domain. Second, factor analysis was used to evaluate the appropriateness of the 12-item questionnaire.
Results: The analysis indicated that the selected questions successfully represented 4 independent domains. Scores were correlated with the Tinnitus Handicap Questionnaire ($r = .77$, $p < .01$) and loudness ($r = .40$, $p < .01$). The Sleep subscale correlated with the Pittsburgh Sleep Index ($r = .68$, $p < .01$); the Emotion subscale correlated with the Beck Inventory ($r = .66$, $p < .01$) and the Trait Anxiety questionnaire ($r = .67$, $p < .01$). The average scores went from 51% to 38% following treatment.
Conclusion: The Tinnitus Primary Function Questionnaire is valid, reliable, and sensitive and can be used to determine AQ1 in clinical trials.

Key Words: assessment, tinnitus, efficacy

In Dauman and Tyler (1992), the authors proposed a psychological model of tinnitus in which the overall impact of tinnitus is influenced by the characteristics of the tinnitus (pitch, loudness, and quality) and the psychological makeup of the individual. It was suggested that treatments that are aimed at reducing reactions to tinnitus should use questionnaires, whereas treatments aimed at reducing the magnitude of the tinnitus should focus on tinnitus measures (loudness and masking; Tyler, 1992).

Several questionnaires have now been developed to document the handicapping nature of tinnitus and to measure change in clinical trials (Meikle, Stewart, Griest, & Henry, 2008; Newman & Sandridge, 2004; Tyler, 1993, 2000). Some widely used questionnaires are the Tinnitus Handicap Inventory (THI), developed by Newman, Jacobson, and Spitzer (1996); the Tinnitus Reaction Questionnaire by Wilson, Henry, Bowen, and Haralambous (1991); the Tinnitus AQ2 Functional Index (TFI) by Meikle et al. (2011); and the Tinnitus Questionnaire (Hiller & Goebel, 2004).

Our own involvement with tinnitus questionnaires began by simply asking the patients to list the problems that they attributed to their tinnitus (Tyler & Baker, 1983). We later used these patient responses to develop the Tinnitus Handicap Questionnaire (THQ; Kuk, Tyler, Russell, & Jordan, 1990). One goal in developing the THQ was to create a tool that could determine the extent of handicap experienced by tinnitus patients coming into the clinic. We reported the cumulative probability of tinnitus handicap so that clinicians could compare the handicap experienced by their patient with that of typical clinical patients who have participated in the survey. We recommended that this approach be used to plan tinnitus treatment (Stouffer & Tyler, 1990; Tyler & Babin, 1986; Tyler & Bentler, 1987; Tyler & Stouffer, 1989). A second goal in developing the THQ was to provide a tool that could be used to document changes in performance over time (i.e., as might occur in a clinical trial). The THQ has been used widely, both in clinical trials AQ3 (e.g., Coelho, Witt, Hansen, Gantz, & Tyler, 2013; De Ridder, Vanneste, Engineer, & Kilgard, 2013; Dobie, 1999; Pan, Tyler, Ji, Coelho, Gehringer, & Gogel, 2009; Searchfield, Kaur, & Martin, 2010; Tyler, Noble, Coelho, & Ji, 2012). It has also been translated into many languages, and a downloadable, automated scoring version of the THQ is available online.[1] FN1 The test–retest reliability of the THQ was evaluated independently by Newman, Wharton, and Jacobson (1995). They stated that "the Tinnitus Handicap Questionnaire is broad in scope" (Newman et al., 1995, p. 718), and "the

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[1]See http://www.uihealthcare.com/depts/med/otolaryngology/clinics/tinnitus/questionnaires/index.html.

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total questionnaire, as well as factors 1 and 2, can be used as an index of change in self-perceived tinnitus handicap following medical (e.g., drug trials), surgical (e.g., vascular decompression), or rehabilitative (e.g., tinnitus masking devices, counseling) treatment" (Newman et al., 1995, p. 722).

AQ4 The World Health Organization (2002) proposed an International Classfication of Functioning, Disability and Health. An Impairment represents a problem in body function (including psychological functions). The Impairment can have an effect on the Activities of life. Participating in activities is influenced by Environmental Factors. In hearing loss, the impairment would be difficulty hearing, and the activities affected would be communication and acoustic awareness of the environment. Secondary activities might include socialization, work, cognition, and general quality of life.

Since the development of the THQ, the domains in which tinnitus affects people are now more clearly understood. A common impact is on emotional well-being, including depression and anxiety (e.g., Andersson, Baguley, McKenna, & McFerran, 2005; Erlandsson & Hallberg, 2000). Many sufferers have difficulties with sleep (e.g., Folmer & Griest, 2000; McKenna & Daniel, 2006; Tyler & Baker, 1983) and with concentration (Erlandsson, 2000; Kochkin, Tyler, & Born, 2011). For some, tinnitus interferes with understanding speech and other everyday sounds. These primary disabilities can have several secondary effects on social, work, and leisure activities (Tyler, Noble, Coelho, Haskell, & Bardia, 2009). We have applied the World Health Organization model to the psychological and body functions impaired
F1 by tinnitus (see Figure 1), which we believe are thoughts and emotions, hearing, sleep, and concentration. Secondary activities might include socialization, work, and general quality of life.

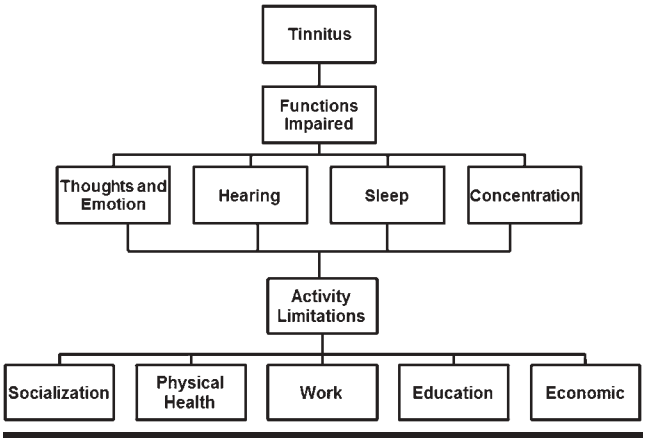
Some further discussion of the affect of tinnitus on hearing is warranted. If tinnitus were like an acoustic signal (a modulated tone or noise band), then it should be expected that tinnitus could mask some aspects of speech. In addition, many tinnitus patients report that they often confuse the tinnitus with another external sound (e.g., telephone) and that they have to hear over their tinnitus. Tyler and Baker (1983) noted that >50% of the patients they surveyed reported that their tinnitus interfered with hearing (including music). Stouffer and Tyler (1990) found that 20% of tinnitus patients indicated that tinnitus interfered with hearing. It might also be noteworthy that receiving hearing aids often results in a perceived benefit for the tinnitus (Kochkin & Tyler, 2008). Most people with tinnitus also have a hearing loss, and many will have difficulty discerning hearing problems associated with hearing loss from tinnitus. Nonetheless, we believe it is important to acknowledge that at least in some patients, tinnitus can interfere with hearing, which has been supported in other research (e.g., Ward & Baumann, 2009).

We have developed a new questionnaire designed to specifically evaluate how tinnitus affects the primary ways tinnitus impacts a person's life. Focusing on these four areas provides several advantages:

- It is likely to provide a more sensitive tool to measure changes in clinical trials because it does not include secondary issues related to general quality of life;
- It is more efficient;
- It allows for subscale scores in each of the four categories;
- It highlights areas that are likely to benefit from counseling and sound therapy.

In the present article, we report the design and validation of a new questionnaire based on these principles.

Figure 1. Application of the World Health Organization model of how tinnitus can affect primary functions and how these can influence
AQ5 and limit secondary activities (adapted from Tyler et al., 2009).



Method

Materials

Questionnaire

Our preliminary version of the Tinnitus Primary Function Questionnaire was developed in 2003 (we referred AQ6 to this earlier version as the Tinnitus Activities Questionnaire). On the basis of our previous experience, questionnaires (e.g., Kuk et al., 1990; Stouffer & Tyler, 1990; Tyler & Baker, 1983), clinical experience, talking with patients, and consulting with other professionals in the field, we developed 20 items (see Appendix A) that have been published (e.g., Tyler et al., 2006), translated into several lan- AQ7 guages, and used worldwide.

Subjects

The 20-item questionnaire was administered to subjects who participated in ongoing tinnitus research studies at our clinic from May 2005 to January 2009. There were a total of 158 subjects who participated (50 female and 108 male). Biographical and tinnitus history information was obtained from the Tinnitus Intake Questionnaire (Stouffer & Tyler, 1990). This measure included basic demographic information such as age, duration of tinnitus in years, and cause of the subject's tinnitus. All subjects were asked to rate the loudness of their tinnitus using a scale ranging from

0 (*very faint*) to 100 (*extremely loud*). Subjects were asked to report the duration of their tinnitus.

Validity Measures

Four additional questionnaires, described below, were administered in the same session.

THQ (Kuk et al., 1990). This questionnaire consists of 27 items and measures a tinnitus patient's perceived handicap. Questions on this self-report measure include both physical (i.e., "tinnitus makes me feel tired") and psychological (i.e., "tinnitus causes stress") aspects of the effects of tinnitus. Subjects were asked to respond to each item using a 0–100 scale, where 0 indicated that they strongly disagreed with the statement and 100 indicated they agreed. The total score for the THQ was computed by summing responses from all 27 items and ranged from 0 to 100.

Beck Depression Inventory (Beck, Ward, Mendelson, Mock, & Erbaugh, 1961). This questionnaire is composed of 21 multiple-choice items and is widely used to assess the severity of depression. A modified version was implemented in this study, in which one item on lack of interest in sex was removed (requested by our Internal Review Board). Thus, the depression questionnaire used in this study consisted of 20 items. Subjects were instructed to indicate which statement out of several multiple choices best represented their feelings. Each item from the questionnaire was assigned a score ranging from 0 to 3 (one item had a 0–2 rating). These individual item scores were then added together to create a total score, ranging from 0 to 59. The higher the score on the questionnaire, the higher the level of depression reported by the subject.

Trait Anxiety Questionnaire (Spielberger & Gorsuch, 1983). This was administered to determine each subject's general state or feelings and consists of 20 items. Subjects were asked to assign a number from 1 to 4 indicating how they generally feel about themselves. Responses from all 20 items were summed to produce a total score, ranging from 20 to 80. A higher total score on the questionnaire represented a higher level of trait anxiety.

Pittsburgh Sleep Quality Index. This questionnaire was administered to inquire about the subjects' sleep habits and was adopted from the Pittsburgh Sleep Quality Index (Buysse, Reynolds, Monk, Berman, & Kupfer, 1989), which contains 24 total items. Nineteen of the 24 items were included in this questionnaire, and five items were deleted from the Pittsburgh Sleep Quality Index where sleep habits are reported by a bed partner (although these were not scored in the original index). Consistent with the Pittsburgh Sleep Quality Index, the remaining 19 items were combined to create seven component scores, each with a range of 0–3. The seven component scores were added to create a total score, ranging from 0 to 21, where 0 indicates no difficulty and 21 indicates severe difficulties in all areas affected by sleep.

Sensitivity Measures

A subset of subjects (n = 100) were simultaneously administered the Tinnitus Primary Function Questionnaire and the THQ at two separate times to determine whether the questionnaire was sensitive to changes in tinnitus following a treatment protocol. An early version of the picture-based Tinnitus Activities Treatment was used (e.g., Tyler, Gehringer, et al., 2006). Subjects completed the two questionnaires "pre" and "post" treatment, or before and after receiving counseling and/or counseling and sound therapy, and scores were compared among the two questionnaires at these two times.

Results

Table 1 shows the demographic information for all 158 subjects. The subjects' ages ranged from 28 to 76 years, with the average age for the female subjects at 56.2 years and 53.9 years for the male subjects. When asked about the loudness of their tinnitus, the subjects reported that their tinnitus was 72.7% on a 100-point scale. The average duration for experiencing tinnitus was 11.4 years for all subjects, but slightly higher for men (12.4 years) than women (9.1 years). Additionally, likely causes of tinnitus were either unknown (39.2%) or other (18.4%); least likely to be causes were drugs or medicine (3.8%) and surgery (0.6%). Pearson correlation coefficients were computed to compare subjects' ages as well as loudness and duration of tinnitus with scores on the 20-time questionnaire. A small but significant correlation was found with the age of the subjects ($r = -.18$, $p < .05$) and the duration of tinnitus ($r = -.10$, $p > .05$). **T1** **AQ8**

To determine the influence of gender on the data, mean scores for men and women were compared. This difference was not statistically significant, $t(156) = 0.7$, $p > .05$. Therefore, questionnaire data from men and women was compiled for further analyses.

Scores Averaged Across Patients

The mean score was 56.5% (range = 50.6%–57%) (see Table 2). For women, the mean score was 58.3 (SE = 3.0, SD = 21.1); for men, the mean score was 55.6 (SE = 2.2, SD = 22.6). The Emotion and Hearing subscales produced the highest mean scores (63.0% and 58.6%, respectively), whereas the Sleep subscale produced the lowest mean score (48.8%). The mean score for the Concentration subscale was 55.5%. Mean scores are also shown for the four validity **T2**

Table 1. Basic demographic information for all subjects (N = 158).

	Male	Female	All
Variable	*M* (*SE*, *SD*)	*M* (*SE*, *SD*)	*M* (*SE*, *SD*)
Age	53.9 (0.9, 9.8)	56.2 (1.4, 9.9)	54.6 (0.8, 9.8)
Duration (years)	12.4 (1.3, 13.9)	9.1 (1.7, 11.5)	11.4 (1.1, 13.2)
Loudness rating	70.2 (2.0, 20.4)	78.5 (2.7, 18.2)	72.7 (1.6, 20.1)

Note. Cause of tinnitus: unknown, 39.2%; other, 18.4%; noise, 17.7%; hearing loss, 7%; accident, 7%; illness, 6.3%; drugs/medicine, 3.8%; surgery, 0.6%.

Table 2. Mean scores and number of subjects for the 20-item version of the Tinnitus Activities Questionnaire total score, the four predefined subscales, and the four test measures.

Test measure	*M* (*SE*, *SD*)	*n*
Questionnaire total	56.5 (1.8, 22.1)	158
Subscales		
Concentration	55.5 (2.3, 28.4)	158
Emotion	63.0 (2.0, 24.6)	158
Hearing	58.6 (2.1, 26.2)	158
Sleep	48.8 (2.7, 34.4)	158
Validity measures		
Sleep Index	8.9 (0.4, 4.2)	133
Depression Inventory	9.7 (0.7, 8.2)	154
Trait Anxiety	42.0 (1.0, 12.8)	154
THQ	54.3 (1.5, 19.4)	158

Note. THQ = Tinnitus Handicap Questionnaire.

measures including the THQ, the Beck Depression Inventory, the Trait Anxiety Questionnaire, and the Pittsburgh Sleep Quality Index.

Reliability

Cronbach's alpha and item-total correlation coefficients were used to determine the reliability of the 20-item questionnaire. A high Cronbach's alpha (i.e., above .7; Nunnally, 1978) would suggest better internal consistency reliability for a particular questionnaire. For the 20-item version, Cronbach's alpha was 0.92 for all 20 items. In addition, a Cronbach's alpha was computed for all four subscales. For Concentration, Cronbach's $\alpha = 0.88$; for Emotion, $\alpha = 0.84$; for Hearing, **T3** $\alpha = 0.81$; and for Sleep, $\alpha = 0.94$. Table 3 shows item-total correlations for the 20-item version. The item-total correlations ranged from .36 to .80. The median value was .66,

Table 3. Item-total correlation coefficients for the Tinnitus Activities Questionnaire (*N* = 158).

Item	Item-total correlation
1	.49
2	.41
3	.67
4	.66
5	.65
6	.56
7	.77
8	.73
9	.59
10	.66
11	.80
12	.36
13	.62
14	.43
15	.73
16	.76
17	.47
18	.76
19	.75
20	.77

indicating that the 20 individual items correlated moderately well with the total score from the questionnaire. Additionally, interitem correlations were also computed, and the coefficients are provided in Table 4. As expected, gen- **T4** erally questions from the same subscale are correlated with each other, whereas questions from different subscales are not.

Construct Validity

A Pearson correlation coefficient was calculated by comparing the total score from the 20-item questionnaire with the THQ. As shown in Table 5, a high correlation of .77 **T5** was found between the two test measures. Interestingly, the total scores were nearly identical (56.5% vs. 54.3%; see Table 2). In addition, Pearson correlation coefficients were also computed to compare results for the Beck Depression Inventory, the Trait Anxiety Questionnaire, and the Pittsburgh Sleep Quality Index with the subscale scores. Correlations between the questionnaire, including the total and subscale scores (shown in rows), and the four validity test measures (shown in columns) are indicated in the table using boldface type to distinguish important comparisons. In all four of the test measures, a higher number on the questionnaire or scale indicates a greater amount of disability. Therefore, all correlations between the test measures and the 20-item questionnaire would be expected to be in a positive direction.

The results revealed that the Emotion subscale correlated well with the Beck Depression Inventory and the Trait Anxiety Questionnaire ($r = .65$, $r = .65$, respectively). The Sleep subscale was also moderately correlated with the Pittsburgh Sleep Quality Index ($r = .66$, $p < .01$). These correlations between the subscales and total scores to other test measures were statistically significant at $p < .01$.

As a second approach to validity, one would expect a louder tinnitus to be more annoying (see the model proposed by Dauman & Tyler, 1992). Across subjects, a correlation is often found between loudness and annoyance (e.g., Halford & Anderson, 1991; Hazell et al., 1985; Kuk et al., 1990). However, we note that these correlations are weakened because different individuals have different definitions and anchor points for loudness. However, within an individual subject, a louder tinnitus is more annoying. We believe a more appropriate view of the relationship between loudness and annoyance is within subjects, following an individual patient over time. We have shown such data for two subjects in a drug trial, documenting consistency between loudness, masking, and tinnitus severity in two patients (Tyler, Babin, & Niebuhr, 1984).

In the present study, a moderate, significant correlation was observed between the subject's total score on the 20-item version and estimates of tinnitus loudness ($r = .41$, $p < .01$).

Sensitivity

Another important issue of questionnaire development is the ability to measure the effectiveness of a treatment, referred to as *sensitivity*. We compared questionnaire results

Table 4. Interitem correlation coefficients with the 20-item version (N = 158).

Item	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20
1	—																			
2	.19	—																		
3	.26	.53	—																	
4	.43	.04	.37	—																
5	.30	.00	.28	.34	—															
6	.22	.27	.37	.26	.32	—														
7	.43	.28	.63	.52	.37	.44	—													
8	.37	.14	.43	.76	.37	.31	.57	—												
9	.28	.28	.39	.39	.22	.44	.47	.46	—											
10	37	.08	.31	.70	.26	.30	.52	.77	.43	—										
11	.34	.29	.63	.53	.36	.36	.81	.64	.46	.60	—									
12	.52	.02	.15	.42	.11	.20	.25	.38	.26	.39	.27	—								
13	.19	–.02	.19	.26	.79	.28	.31	.31	.17	.26	.35	.07	—							
14	.12	.76	.47	.07	.09	.32	.25	.12	.29	.09	.27	–.05	.04	—						
15	.32	.16	.42	.52	.46	.42	.60	.51	.45	.45	.59	.28	.41	.16	—					
16	.27	.11	.35	.38	.70	.35	.48	.53	.32	.45	.54	.13	.80	.15	.53	—				
17	.11	.68	.49	.10	.08	.35	.24	.20	.31	.15	.28	.08	.01	.80	.28	.17	—			
18	.26	.08	.38	.43	.71	.31	.49	.47	.34	.41	.56	.16	.78	.08	.56	.80	.18	—		
19	.41	.13	.40	.50	.57	.31	.60	.51	.26	.45	.63	.23	.56	.14	.65	.59	.22	.62	—	
20	.27	.15	.39	.38	.71	.30	.52	.46	.32	.40	.58	.19	.77	.16	.52	.82	.16	.83	.65	—

from 100 subjects with tinnitus who participated in a research study in which treatment was provided in an effort to suppress or eliminate tinnitus. The Tinnitus Primary Function Questionnaire and the THQ were administered to the same subjects at two separate times, and the total score from the two questionnaires was computed for a comparison. The first administration of the questionnaires, defined as *pre*, was completed before treatment initiated. Comparatively, the second administration of the questionnaires, defined as *post*, was completed posttreatment after 12 months.

Figure 2 shows the pre- versus posttreatment data. For the 20-item version, mean scores of 55% (SE = 2.25) and 42% (SE = 2.55) were found for the pre- and posttreatment, respectively. For the THQ, mean scores of 54% (SE = 1.91) and 40% (SE = 2.20) were found for pre- and posttreatment. A paired t test was completed for both questionnaires to compare results pre- and posttreatment. Results for the Tinnitus Primary Function Questionnaire, $t(99) = 3.85$, $p < .001$, and THQ, $t(99) = 5.08$, $p < .001$, showed a significant improvement from pre- to posttreatment. Additionally, the amount of improvement resulting from both questionnaires between these conditions was similar

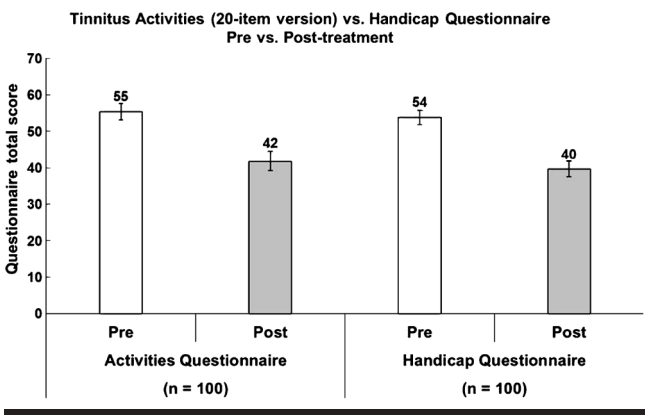
Table 5. Pearson correlation coefficients among scores on the 20-item version (total score and subscale scores) and the four validity test measures.

Variable	Sleep Index	Depression Inventory	Trait Anxiety	THQ
Total				
r	.52**	.63**	.58**	**.77****
n	133	154	154	**158**
p	<.01	<.01	<.01	**<.01**
Emotion				
r	.33**	**.65****	**.65****	**.68****
n	133	**154**	**154**	**158**
p	<.01	**<.01**	**<.01**	**<.01**
Hearing				
r	.12	.26**	.23**	.57**
n	133	154	154	158
p	.18	<.01	<.01	<.01
Sleep				
r	**.66****	.47**	.40**	.48**
n	**133**	154	154	158
p	**<.01**	<.01	<.01	<.01
Concentration				
r	.41**	.58**	.54**	**.69****
n	133	154	154	**158**
p	<.01	<.01	<.01	**<.01**

Note. Important correlations between the total and subscale scores on the questionnaire and the four validity test measures appear in boldface to better highlight these comparisons.

*$p < .05$. **$p < .01$.

Figure 2. Results from the 20-item questionnaire and the Tinnitus Handicap Questionnaire comparing total scores pre- to posttreatment (n = 100 subjects). The white bars show pretreatment scores, and the gray bars show posttreatment scores following 12 months.



AQ9 (13% and 14% for Tinnitus Handicaps and Handicap Questionnaires, respectively).

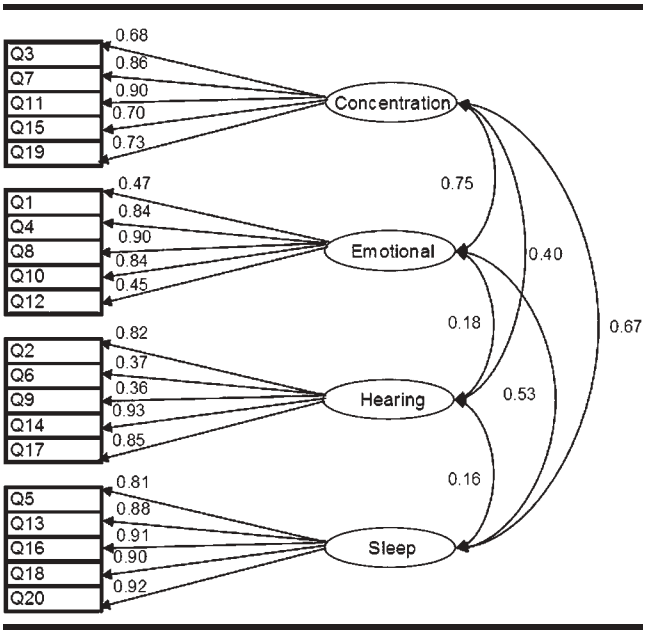
Confirmatory Factor Analysis for the 20-Item Version

We used a confirmatory factor analysis (Jöreskog, 1969) to explore the validity of our four chosen subscales. It is expected that there exists a relationship between observed variables and their underlying latent constructs. Initially, the subjects-to-variables ratio is often used to determine the appropriateness of factor analysis. For our evaluation, the ratio was 8:1 (158 subjects ÷ 20 items = 7.9), which exceeds the 5:1 recommended ratio from previous researchers (Osborne & Costello 2004).

For the confirmatory factor analysis, the PROC CALIS procedure (SAS 9.3) was used to determine the adequacy of model fit to the data with several statistical tests. The comparative fit index ranges from 0 to 1, with a value of 0.95 or greater indicating acceptable model fit (Hu & Bentler, 1999). Root-mean-square error of approximation ranges from 0 to 1, with a value of 0.06 or less indicating acceptable model fit (Hu & Bentler, 1999). A first-step confirmatory factor analysis was completed to analyze the 20 items and compare the factor loadings F3 with the defined four subscales. Figure 3 shows the loading of each item to the subscales, the correlation between the four subscales, and the confirmatory factor analysis model fit statistics. Results showed that all the item loadings were between 0.36 and 0.93. As with the 20-item questionnaire, the correlations between the Concentration and Emotion (r = .75) and Concentration and Sleep (r = .67) subscales were moderately high. The comparative fit index was equal to 0.88 (below criterion of 0.95), the standardized root-mean-square residual statistic was equal to 0.11 (above criterion of 0.05), and the root-mean-square error of approximation statistic was higher than the threshold (0.13 compared with 0.06), indicating that not all questions are quite appropriate or fit nicely for the four predefined subscales (see Figure 3).

In order to pick the best questions for the 12-item version, we chose the questions in each subscale with highest loadings (Questions 7, 11, and 15 for Concentration; Questions 4, 8, and 10 for Emotion; Questions 2, 14, and 17 for Hearing; Questions 16, 18, and 20 for Sleep). Question 15 ("My inability to think about something undisturbed is one of the worst effects of my tinnitus") and Question 19 ("I have trouble concentrating while I am reading in a quiet room because of tinnitus") have similar loadings, and we chose Question 15. This enabled us to select the appropriate 12 items (see Appendix B).

Figure 3. Results from the confirmatory factor analysis completed using the 20-item version. Correlations among the subscales and items to subscales are shown. The loading for each item is shown above the arrow on the left side, and the correlation coefficients among the four subscales are shown beside the lines between the subscales. Q = Question.



Tinnitus Limitations Questionnaire: 12-Item Version

Scores Averaged Across Patients

Table 6 displays the total and mean subscale scores T6 on the 12-item version. A mean total score of 51.7% was found for the 12 items, which is slightly below the mean score for all 20 items (56.5%). Mean subscale scores ranged from 46.1% to 57.4%, with the highest scores reported on the Concentration and Hearing subscales.

Reliability

Cronbach's alpha was also calculated for all 12 items and the four subscales for the short version. Results revealed a high Cronbach's α of 0.89 for the 12-item version of the questionnaire. For the Concentration subscale, Cronbach's α = 0.86; for the Emotion subscale, α = 0.90; for the Hearing subscale, α = 0.90; for the Sleep subscale, α = 0.93. From these results, the 12-item version of the questionnaire demonstrates good reliability.

Subscores and Factor Analysis

Construct validity. Pearson correlation coefficients shown in Table 7 were computed to compare results for T7

Table 6. Mean scores and number of subjects for the 12-item version; total score and the subscales.

Test measure	*M* (*SE*, *SD*)	*n*
Total	51.7 (1.9, 24.2)	158
Emotion	46.1 (2.6, 33.2)	158
Hearing	57.1 (2.6, 32.7)	158
Sleep	46.2 (2.8, 35.3)	158
Concentration	57.4 (2.4, 29.5)	158

Table 7. Pearson correlation coefficients among scores on the 12-item version and the four validity test measures.

Variable	Sleep Index	Depression Inventory	Trait Anxiety	THQ
Total				
r	.49**	.63**	.58**	**.77****
n	133	154	154	**158**
p	<.01	<.01	<.01	**<.01**
Emotion				
r	.35**	**.66****	**.67****	**.67****
n	133	**154**	**154**	**158**
p	<.01	**<.01**	**<.01**	**<.01**
Hearing				
r	.02	.14	.10	**.44****
n	133	154	154	**158**
p	>.05	.08	>.05	**<.01**
Sleep				
r	**.68****	.50**	.41**	.52**
n	**133**	154	154	158
p	**<.01**	<.01	<.01	<.01
Concentration				
r	.38**	.57**	.54**	**.66****
n	133	154	154	**158**
p	<.01	<.01	<.01	**<.01**

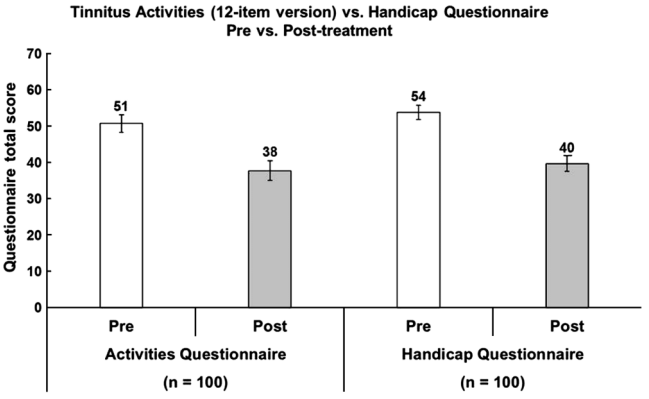
Note. Important correlations between the total and subscale scores on the questionnaire and the four test measures appear in boldface to better highlight these comparisons.

*$p < .05$. **$p < .01$.

AQ10 the Pittsburgh Sleep Quality Index, the Beck Depression Inventory, the Trait Anxiety questionnaire, and the THQ with the short version total score and subscale scores. Correlations between the questionnaire, including the total and subscale scores (shown in rows), and the four test measures (shown in columns) are indicated in the table using boldface to distinguish important comparisons. As with the longer version of the questionnaire, a higher number on the questionnaire or scale indicates a greater amount of disability, and all correlations between the test measures and the 12-item version are expected to be in a positive direction.

The total score from the 12-item version was significantly correlated with all four test measures. Among the four test measures, the highest correlation to the 12-item total score was found with the THQ ($r = .77$, $p < .01$),
AQ11 and the lowest correlation was found with the Sleep questionnaire ($r = .49$, $p < .01$). In addition, the subscale scores from the 12-item questionnaire were also compared with other test measures. The Sleep subscale was highly correlated with the Sleep questionnaire ($r = .68$, $p < .01$); the Emotion subscale correlated well with the Beck Depression Inventory and the Trait Anxiety Questionnaire ($r = .66$ and $r = .67$, respectively). The Concentration subscale was also significantly correlated to the Beck Depression Inventory, the Trait Anxiety Questionnaire, and THQ ($r = .57$, .54, and .66; $p < .01$, respectively). Comparing the Hearing subscale with the other test measures, it correlated strongest with the THQ ($r = .44$, $p < .01$).

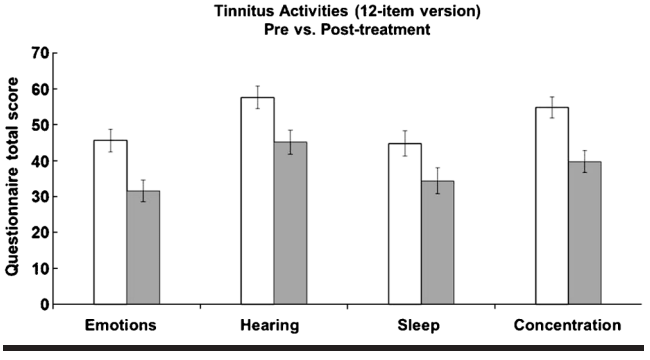
Figure 4. Results on the 12-item questionnaire and the Tinnitus Handicap Questionnaire obtained pre- and posttreatment ($n = 100$ subjects). The white bars show scores obtained pretreatment, and the gray bars show data obtained following treatment after 12 months.



Sensitivity. As shown in Figure 4, pre- versus post- **F4** treatment data were compared for 100 subjects using the 12-item version (shown on the left of Figure 4) and the THQ (shown on the right of Figure 4). Mean scores of 51% ($SE = 2.41$) and 38% ($SE = 2.62$) were found for the pre- and posttreatment, respectively, for the 12-item version. For the THQ, mean scores of 54% ($SE = 1.91$) and 40% ($SE = 2.20$) were found for pre- and posttreatment. A paired t test comparing questionnaire results revealed a significant improvement from pre- to posttreatment for both the 12-item questionnaire, $t(99) = 6.56$, $p < .001$), and THQ, $t(99) = 5.08$, $p < .001$. In addition, the amount of improvement observed between pre- and posttreatment was essentially the same at 14% and suggests that the 12-item version of the Tinnitus Primary Function Questionnaire was equally sensitive to changes in tinnitus function following treatment.

Figure 5 shows the pre–post scores for each of the **F5** subscales. Pre–post treatment mean scores dropped from

Figure 5. Results on the 12-item questionnaire showing the four subscale scores obtained pre- and posttreatment ($n = 100$ subjects). The white bars show scores obtained pretreatment, and the gray bars show data obtained following treatment after 12 months.

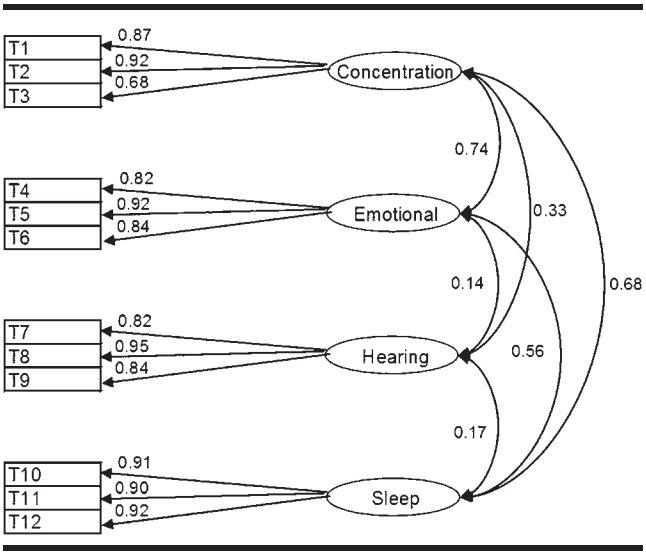


46 (*SE* = 3.1) to 32 (*SE* = 3.1) for Emotions, from 58 (*SE* = 3.2) to 45 (*SE* = 3.3) for Hearing, from 45 (*SE* = 3.5) to 34 (*SE* = 3.6) for Sleep, and from 55 (*SE* = 2.9) to 40 (*SE* = 3.1) for Concentration. A paired *t* test revealed a significant improvement from pre- to posttreatment for Emotions, $t(99) = 6.0$, $p < .001$; Hearing, $t(99) = 4.3$, $p < .001$; Sleep, $t(99) = 3.9$, $p < .001$; and Concentration, $t(99) = 6.3$, $p < .001$.

Confirmatory Factor Analysis for the 12-Item Version

A second-step confirmatory factor analysis was completed to analyze the 12-item questionnaire and compare the factor loadings with the defined four subscales. Figure 6 shows the loading of each item to the subscales, the correlation between the four subscales, and the confirmatory factor analysis model fit statistics. Results showed that all the item loadings were greater than 0.6. As with the 20-item questionnaire, the correlations between the subscales of Concentration and Emotion ($r = .74$) and of Concentration and Sleep ($r = .68$) were moderately high. Additionally, the confirmatory factor analysis model fit statistics were within acceptable ranges. Namely, the comparative fit index was equal to 0.98 (above the criterion of 0.95), and the standardized root-mean-square residual statistic was equal to 0.04 (below the criterion of 0.05). Only the root-mean-square error of approximation statistic was higher than the threshold (0.07 compared with 0.06), indicating that confirmatory factor analysis is reasonably appropriate, and the four subscales fit well for this data set.

Figure 6. Results from the confirmatory factor analysis completed using the 12-item version. Correlations among the subscales and items to subscales are shown. The loading for each item is shown above the arrow on the left side, and the correlation coefficients among the four subscales are shown beside the lines between the subscales.



Discussion

We believe there is a need for a new questionnaire that focused on the primary handicaps of tinnitus. It is important that the questionnaire be valid, reliable, and sensitive, and the results in this study indicated that the Tinnitus Primary Function Questionnaire met all these requirements. Available questionnaires on tinnitus severity and function primarily differ on the (a) scales used, (b) functions assessed, and (c) number of questions. A discussion of each of these areas follows.

Traditionally, questionnaire development involves validity, reliability, and sensitivity (e.g., Flamme, 2001). Validity indicates the test measures what it purports to measure. This is usually demonstrated by comparing it with a previously published similar test. For example, the TFI (Meikle et al., 2012) was validated with the THI, which was in turn validated with the THQ. Reliability indicates that consistent results will be obtained when it is readministered in the same or different situation when the handicap does not change.

Sensitivity indicates that the scales used are appropriate to measure a change if a change occurs. This is often established by independent researchers in subsequent clinical trials. The TFI attempted to improve sensitivity in its questionnaire by having "experts" rate (using a three-label category scale) two early versions of the TFI to eliminate questions thought to be unresponsive to treatment. (In the researchers' Prototype 1, this was accomplished with 11 subjects who improved, 45 subjects who were unchanged, and nine subjects who became worse following treatment.) Whether this approach is effective, and how the ability of the TFI compares with other established questionnaires to quantify clinical effectiveness, remains to be seen.

Mathematical Manipulations of Scales in Human Psychophysics

Stevens and Davis (1938) and Stevens (1946) were careful to distinguish among four different levels of measurement, including (a) "nominal" and (b) "ordinal" scales (later to be known as "category scales"), (c) "interval" and (d) "ratio," or numeric scales. Nominal scales would include labels such as *red*, *blue*, or *green*; *true* or *false*, with any implied relationships among the labels. Ordinal/category scales (such as extremely painful, very painful, slightly painful, not painful) do have an implied order. With these ordinal/category scales, they believed it was invalid to perform arithmetic operations such as mean and standard deviation because the intervals on the scales are not equal in magnitude. For instance, is a change from very extremely painful to very painful equal to a change from slightly painful to not painful? In the tinnitus domain, it is not clear that the difference between "yes" and "sometimes" is equal to the difference between "sometimes" and "no"; categories on the THIy (Newman et al., 1996). The Tinnitus Reaction Questionnaire uses "TRUE, PARTLY TRUE, NOT TRUE" (Wilson et al., 1991). Nunnally (1967) referred to the

"ordinal scale," where an order is defined, but "there is no indication of how far apart the objects are" (p. 12). He also suggested that rank ordering was the most primitive form of measurement and, further, did not believe that "categorization" should even be considered a form of measurement. In comparison, interval scales imply the "distance" between levels is known, and ratio scales imply the "absolute" value of the scale is known (e.g., inches). Although the advantages of an interval scale were advocated, Stevens and Davis (1938) did caution about the difficulty of producing a truly numeric scale. For example, with a 0–100 scale, is 60 twice as great as 30? Despite these concerns, the advantages of using a numeric scale are many in that all the statistical measures can be used to analyze the data. For this reason, many questionnaires including the TFI (Meikle et al., 2012) and the Tinnitus Primary Function Questionnaire reported here use an interval or numeric scale.

AQ13 Another important scale is their sensitivity. If an individual with tinnitus receives treatment for his or her tinnitus and finds that his or her sleeping behavior improves after treatment, it is important to be able to measure this effect. A coarse scale, such as a scale from 1 to 5 or from 1 to 7, might not be able to distinguish a small improvement in sleep versus a moderate improvement in sleep. (We provide an example of this comparing a three-label scale with **AQ14** a 0–100 interval scale; Tyler et al., 2007).

In some tasks, respondents are required to mark a 100-mm line using a visual analog scale. This would likely provide sufficient resolution, but if done manually requires additional measurement by the examiner to determine the exact response by the subject. Further, visual analog scales have been reported to be more difficult for subjects as compared with other types of scales, especially for the elderly (Meikle et al., 2008). Allowing subjects to choose numbers from 1 to 7 or from 0 to 10 is common but provides less resolution. Many questionnaires also use 0–100 scales that provide adequate resolution for comparing and contrasting results. In our experience, most subjects choose at five-digit intervals, for example, 15, 20, 25, 30, 35, resulting in a 21-level scale.

Primary Functions Affected by Tinnitus

Our research and clinical experience has led us to believe there are four primary effects of tinnitus on daily life, including (a) thought and emotions, (b) hearing, (c) sleep, and (d) concentration. Each person is affected differently by tinnitus. This led us to develop the Tinnitus Activities Treatment (Tyler et al., 2006; Tyler, Gogel, & Gehringer, 2007), an individualized therapy plan for which cognitive behavior modification strategies are used, including relaxation exercises, acceptance, and existential principals.

The observation that tinnitus can affect different primary functions in different patients creates an intriguing challenge for questionnaires. For example, if a patient has no sleep problems attributed to his or her tinnitus, the questions on sleep are "wasted," that is, not relevant. This could make the questionnaire insensitive to treatment effects. We have suggested and explored (Tyler, Noble, & Coelho, 2006) that one approach to this issue would be to eliminate questions that showed no significant handicap pretreatment from the posttreatment evaluation (this would be decided before the experiment began). Then, the treatment efficacy can be determined on the basis of only primary functions affected by tinnitus in the individual, which should make the questionnaire more sensitive.

There are a number of secondary areas that can be affected. For example, if someone has difficulty concentrating because of his or her tinnitus, then they might also have difficulty at work. If someone is anxious because of his or her tinnitus, then this might influence his or her social life. A tinnitus questionnaire should focus on all of these areas important to daily functioning. The score on a particular questionnaire, and its sensitivity to treatment effects, will be influenced by the primary and secondary areas represented and the number of questions assigned to each area.

We believe a potential problem with the TFI (Meikle et al., 2012) is that it includes questions related to secondary affects. For example, it asks whether tinnitus has interfered with "your enjoyment of life"; "your relationships with family, friends and other people"; and "how often did your tinnitus cause you to have difficulty performing your work or other tasks, such as home maintenance, school work, or caring for children or others?" (Meikle et al., 2012, p. 19). These secondary affects are just as likely to be influenced by a wide variety of daily life activities as they would be by a tinnitus treatment. Therefore, we believe the TFI will be more likely to be influenced by other activities and less sensitive to changes in tinnitus than a questionnaire focused on primary tinnitus handicaps.

Number of Questions

The fewer the number of questions contained in a questionnaire, the faster the questionnaire can be completed. For simple constructs, a single question can be used. For example, Stouffer and Tyler (1990) used the following: "Please write a single number between 0 and 100 to indicate how annoying you find your tinnitus, where 0 would indicate it is not annoying at all and 100 would indicate it is extremely annoying." However, most areas of human function, including the impact of tinnitus on daily life, require multiple questions for a complete assessment. The Tinnitus Primary Function Questionnaire contains 12 questions that are sensitive to treatment effects.

Importance of Comparisons to Past Studies

First, although we believe the Tinnitus Activities Questionnaire has important advantages over current questionnaires, the THQ has been used for decades to evaluate treatment-related changes in medications (e.g., Coelho et al., 2013; Dobie, Sullivan, Katon, Sakai, & Russo, 1992), devices (e.g., Searchfield et al., 2010), cochlear implants (e.g., Pan et al., 2009), and vagal nerve stimulation (e.g., De Ridder

et al., 2013). Thus, we recommend clinical trials continue to include the THQ so that future treatments can be compared with many of those done in the past.

Acknowledgments

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Appendix A

Iowa Tinnitus Primary Function Questionnaire (20-Item Version)

Please indicate your agreement with each statement on a scale from 0 (*completely disagree*) to 100 (*completely agree*).

	Concentration	
3	When there are lots of things happening at once, my tinnitus interferes with my ability to attend to the most important thing.	
7	I feel like my tinnitus makes it difficult for me to concentrate on some tasks.	
11	I have difficulty focusing my attention on some important tasks because of tinnitus.	
15	My inability to think about something undisturbed is one of the worst effects of my tinnitus.	
19	I have trouble concentrating while I am reading in a quiet room because of tinnitus.	
	Emotion	
1	My tinnitus is annoying.	
4	My emotional peace is one of the worst effects of my tinnitus.	
8	I am depressed because of my tinnitus.	
10	I am anxious because of my tinnitus.	
12	I just wish my tinnitus would go away. It is so frustrating.	
	Hearing	
2	My tinnitus masks some speech sounds.	
6	The effects of tinnitus on my hearing are worse than the effects of my hearing loss.	
9	My tinnitus, not my hearing loss, interferes with my appreciation of music and songs.	
14	In addition to my hearing loss, my tinnitus interferes with my understanding of speech.	
17	One of the worst things about my tinnitus is its effect on my speech understanding, over and above any effect of my hearing loss.	
	Sleep	
5	I have difficulty getting to sleep at night because of my tinnitus.	
13	The difficulty I have sleeping is one of the worst effects of my tinnitus.	
16	I am tired during the day because my tinnitus has disrupted my sleep.	
18	I lie awake at night because of my tinnitus.	
20	When I wake up in the night, my tinnitus makes it difficult to get back to sleep.	

Appendix B

Iowa Tinnitus Primary Function Questionnaire (12-Item Version)

Please indicate your agreement with each statement on a scale from 0 (*completely disagree*) to 100 (*completely agree*).

		Previous item #
	Concentration	
1	I feel like my tinnitus makes it difficult for me to concentrate on some tasks.	7
2	I have difficulty focusing my attention on some important tasks because of tinnitus.	11
3	My inability to think about something undisturbed is one of the worst effects of my tinnitus.	15
	Emotion	
4	My emotional peace is one of the worst effects of my tinnitus.	4
5	I am depressed because of my tinnitus.	8
6	I am anxious because of my tinnitus.	10
	Hearing	
7	My tinnitus masks some speech sounds.	2
8	In addition to my hearing loss, my tinnitus interferes with my understanding of speech.	14
9	One of the worst things about my tinnitus is its effect on my speech understanding, over and above any effect of my hearing loss.	17
	Sleep	
10	I am tired during the day because my tinnitus has disrupted my sleep.	16
11	I lie awake at night because of my tinnitus.	18
12	When I wake up in the night, my tinnitus makes it difficult to get back to sleep.	20

AUTHOR QUERIES

AUTHOR PLEASE ANSWER ALL QUERIES

AQ1: The phrase "...and sensitive and can be used to determine in clinical trials" seems incomplete. This measure can be used to determine what exactly? The presence of tinnitus?

AQ2: You've cited Meikle et al. (2011) as the source for the TFI in a number of instances throughout your article. The year has been changed to 2012 for agreement with the reference list. If this should be reversed, or there are Meikle et al. references for both 2011 and 2012, please let us know.

AQ3: The sentence beginning "The THQ has been used widely, both in clinical trials..." appears incomplete. Both in clinical trials and in what other instance? Please clarify your intended meaning here.

AQ4: The following references are cited in your article but have no corresponding reference in the list. Please provide the missing references for the following citations (listed in the order in which they appear in your article): World Health Organization (2002); Erlandsson and Hallberg (2000); McKenna and Daniel (2006); Erlandsson (2000); Joreskog (1969); Hu and Bentler (1999); Stevens and Davis (1938); Nunnally (1967).

AQ5: To what extent is Figure 1 adapted from Tyler et al. (2009)? Lippincott likely holds the copyright for this work and, depending on how much the new figure borrows from or draws on the earlier one, formal written permission from the publisher may be needed to reproduce the figure in print and electronically.

AQ6: Please provide a complete reference citation for the preliminary version of the Tinnitus Primary Function Questionnaire (2003).

AQ7: You have two citations that shorten to Tyler et al. (2006). Which applies in "...that have been published (e.g., Tyler et al., 2006), translated into several languages..."?

AQ8: Just checking whether you mean instead "...($r = .10$, $p < .05$)"? Specifically, checking that the direction of the less than/greater than symbol appears correctly here for a "significant correlation."

AQ9: Are you referring to the Tinnitus Primary Function and the THQ when you mention "...(13% and 14% Tinnitus Handicaps and Handicap Questionnaires, respectively)"? Please clarify.

AQ10: Correct that you're referring to the Pittsburgh Sleep Quality Index when you originally mentioned "sleep questionnaire" in "Pearson correlation coefficients shown in Table 7..."? Otherwise, please clarify what you mean by "sleep questionnaire."

AQ11: Please clarify "sleep questionnaire" in several places in the paragraph beginning "The total score from the 12-item version was significantly correlated with all four test measures. . . ." Do you mean the Sleep subscale?

AQ12: Please check my edit for "researchers'" in "(In the researchers' Prototype 1,. . .)"? Otherwise, it wasn't clear who "their" was.

AQ13: The sentence "Another important scale is their sensitivity" is unclear. Please clarify your meaning here.

AQ14: You have two citations that shorten to Tyler et al. (2007). Which applies in "(We provide an example of this comparing a three-label scale with a 0–100 interval scale;. . .)"?

AQ15: The following references appear in your list but are not cited in text. Please either cite them, or allow us to delete them from the reference list: Andersson and Vretblad (2000); Hallam et al. (1998); Langenbach et al. (2005); Rizzardo et al. (1998); Tyler, Coelho, et al. (2008); Tyler, Oleson, et al. (2007).

AQ16: Please provide complete page ranges for Osborne and Costello (2004) and Tyler et al. (2009) and the book title for Tyler and Babin (1986).

AQ17: I did not find via GoogleScholar the journal article title for Stouffer and Tyler (1990). Please ensure that the article title, volume, and page numbers are accurate, and spell out the journal name.

END OF ALL QUERIES