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A Tinnitus Inventory Focusing on Body Function, Activities, and Participation Using the International Classification of Functioning, Disability and Health

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function, activities, and participation.

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Background and Objectives: This study describes the development of an International Classification for Functioning, Disability and Health (ICF)-based inventory for tinnitus (ICF-TINI) that measures the impact of tinnitus on the function, activities, and participation of an individual. Subjects and Methods: This cross-sectional study utilized the ICF-TINI, which included 15

items from the two ICF components of body function and activities. We included 137 respon-

dents with chronic tinnitus. Confirmatory factor analysis validated the two-structure framework (body function, activities and participation). The model fit was assessed by comparing fit values

of chi-square (df), root mean square error of approximation, comparative fit index, incremental

fit index, and Tucker-Lewis index, with the suggested fit criteria values. Cronbach's alpha was

used to assess internal consistency reliability. Results: The fit indices confirmed the presence

of two structures in ICF-TINI, while the factor loading values suggested each item's goodness

of fit. The ICF-internal TINI exhibited high consistency reliability (0.93). Conclusions: The ICF-

TINI is a reliable and valid tool for assessing the impact of tinnitus on an individual's body

Introduction

According to population studies from various countries, the prevalence of chronic tinnitus ranges between 7.6% and 20.1% for people under the age of 50 [1]. Tinnitus treatment remains challenging as the underlying causes are often idiopathic. Psychoacoustic or questionnaire-based evaluation can be used. While psychoacoustic measurements quantify tinnitus, they do not reflect the impact of tinnitus on a person's life. Individuals with loud tinnitus, for example, who adapt to the sensation of sound, may not experience significant interference with daily living activities and social well-being. Questionnaire-based evaluations are symptom-specific; they highlight the areas of life where tinnitus has an impact and aid in treat-

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ment planning. For example, if a person's sleep is disrupted by loud tinnitus, sound therapy could be an effective treatment option. Tinnitus maskers may also be considered if an individual requires tinnitus relief in a specific situation, such as reading in a quiet room. Treatment and counseling are based on an understanding of the specific effects of tinnitus on the individual.

Tinnitus Handicap Questionnaire (THO) [2], Tinnitus Reaction Questionnaire (TRQ) [3], Tinnitus Severity Scale [4], Tinnitus Handicap or Support Scale [5], and the Tinnitus Handicap Inventory (THI) [6] are some of the popular selfrating questionnaires used to obtain tinnitus severity ratings. Despite having three or more factors or categories, these questionnaires are limited by unidimensionality in the sense that "impairment leads to disability, disability leads to handicap." However, there is a push to adopt a more multidimensional paradigm based on the World Health Organization's (WHO's) International Classification of Functioning, Disability and Health (ICF) (2001). Aside from being multidimensional, using a universal standard to assess tinnitus improves the consistency of measuring the impact of tinnitus and the outcome of tinnitus treatment across different clinics that provide such services [7].

WHO developed the ICF framework in 2001 as part of the process of revising the International Classification of Impairments, Disabilities, and Handicaps (ICIDH) [8]. This new classification was conceived as a multi-dimensional model in which the impact of health condition on functioning is investigated. The functioning perspective is important to the health care seeker because these are indicators of treatment outcomes [9]. The ICF classification is divided into two sections: functioning and disability, and contextual factors. These two sections are further subdivided into four components: body function and structure, activities and participation, environmental factors, and personal factors (not classified). Each of these components is further classified into chapters (1st level) and categories (2nd to 4th level), with increasing specificity of description. It gives the user the ability to select the level of specificity required to describe the health condition under investigation [9].

It is acknowledged that the ICF, as an exhaustive classification, cannot be used directly as a clinical tool. Furthermore, not all ICF categories are required to describe a specific health condition. As a result, experts recommend developing core sets comprised of the most relevant ICF categories for specific health conditions. ICF core sets have been developed by groups of experts from around the world in 34 areas [10] including hearing loss [11-13] by groups of experts from different parts of the world. There are also generic and rehabilitative core sets that can be used as templates, with the emphasis on body function, activities, and participation [13].

Tinnitus questionnaires, due to their lack of distinctiveness, are frequently not sensitive to treatment-related changes [14]. The Tinnitus Functional Index (TFI) [15,16] is a 25-item questionnaire designed to be a robust tool that responds to treatment-related changes. This tool, however, contains some overlapping items related to emotional function. For example, anxious/worried, bothered/upset, and depressed are three distinct items, while concentrate and focus attention are two distinct items. However, such fine distinctions are difficult to perceive for a layperson, and thus are likely to affect overall scores. Furthermore, the tool's scoring is time-consuming.

ICF was used to conceptualize tinnitus and its related problems, hypothesizing that 100% of people with permanent tinnitus have impaired body function [17]. Furthermore, for those with clinically significant tinnitus, the associated problems have an impact on their activities and participation. Some researchers mapped the existing tools to ICF and examined the extent of fit to the ICF framework. The TFI and Tinnitus Questionnaire (TQ) items were mapped to ICF and it was found that both tools predominantly had items pertaining to mental functions under body functions [18]. Previously, THI items were also mapped to ICF, and was found that 20 of 25 THI items could be mapped to body function, while the remaining 5 could be mapped to activities and participation [19]. In one study, open-ended responses were mapped to ICF [20] and found responses were primarily related to body function.

As a result, there is a need for a standardized, universal framework to report the impact of tinnitus such that relevant items are included without skewing towards any one domain. Therefore, the purpose of this study was to develop an ICF-based inventory that can measure the impact of tinnitus on an individual, with a specific focus on the components of body function, activities, and participation, in accordance with the rehabilitative core set provided by the ICF Research Branch in 2013. "Body functions" are the physiological functions of body systems, including psychological functions, "activity" is an individual's execution of a task or action, and "participation" is involvement in a life situation [21].

Subjects and Methods

This study was approved by the relevant institutional ethics committee (IEC-NI/12/OCT/30/55). Informed consent was obtained from all participants prior to their participation in the study.

Development of ICF-Tinnitus Inventory (ICF-TINI)

To ensure thoroughness, efforts were made to replicate as many elements of the ICF core set development process [10]. One audiologist with ICF application and tinnitus rehabilitation experience reviewed the items in each chapter of ICF to eliminate those that were deemed irrelevant to the condition of tinnitus. Mental functions, sensory functions, and pain were chosen from the eight chapters of body function, and learning and applying knowledge, general tasks and demands, and community, social, and civic life were chosen from the nine chapters of activities and participation.

Two audiologists and two otolaryngologists reviewed the selected chapters to identify categories that could potentially describe the impact of tinnitus. This exercise yielded 13 items from body function and 10 items from activities and participation. All body function items were from the third level, five activities and participation items were from the second level, and five other items were from the third level classification

Table 1. Chapters and categories reviewed and selected for ICF-TINI by experts

Chapter	Domain	2nd level	3rd level
Body functions			
I. Mental functions	Global mental	b126 Temperament and	1. b1263 Psychic stability*
	functions	personality function	2. b1266 Confidence*
		b134 Sleep function	3. b1341 Onset of sleep*
			4. b1342 Maintenance of sleep*
			5. b1343 Quality of sleep
	Specific mental functions	b140 Attention function	6. b1400 Sustaining attention*
		b152 Emotional function	7. b1522 Regulation of emotion*
		b156 Perceptual functions	8. b1560 Auditory perception
		b160 Thought function	9. b1603 Control of thought
		b 164 Higher level cognitive	10. b1641 Organisation and
		functions	planning
			11. b1646 Problem solving
		b167 Mental function of	12. b16700 Reception of spoken
		language	language
II. Sensory functions	Hearing and vestibular	b230 Hearing function	13. b2301 Sound discrimination
and pain	functions		
Activities and participation			
I. Learning and	Applying knowledge	1. d160 Focusing attention	
applying knowledge			
		2. d163 Thinking (meditating)*	
		3. d166 Reading*	
	Purposeful sensory	4. d115 Listening to music*	
	experiences	5. d116 Listening to someone talk*	·
II. General tasks and dem	ands	d230 Carrying out daily routine	6. d2302 Completing the daily
		d240 Handling stress and other	routine*
		psychological demands	7. d2401 Handling stress*
III. Communication	Conversation and use	d350 conversation	8. d3503/4 Conversing with one
	of communication device	S	person or more*
		d360 Using communication	9. d3600 Using
		devices and techniques	telecommunication devices*
IV. Community, social and	d civic life	d920 Recreation and leisure	10. d9205 Socializing*

^{*}selected items for ICF-TINI. ICF, International Classification of Functioning, Disability and Health; ICF-TINI, ICF-Tinnitus Inventory

of categories (Table 1). These items were written as neutral statements, with definitions provided for some of them.

The same two audiologists and otolaryngologists content validated the 23 neutral statements based on ICF items. With regard to the condition of tinnitus, they rated each item as appropriate, appropriate with modifications, or inappropriate. The items that received 75% agreement from the four judges were included in the inventory. Items rated "appropriate with modifications" by three out of four judges were changed in accordance with the suggestions. Judges were consulted for final approval of the modified items, and the ICF-TINI was created with 15 items as a result (Table 1).

These items were rated using the ICF classification's universal qualifiers. The first qualifier was used to denote the range of functioning in both body function and activities and

participation. In the rating, 0 is "no problem," 1 is "mild problem," 2 is "moderate problem," 3 is "severe problem," and 4 is "complete problem." In accordance with the ICF qualifiers, a "not applicable" option, corresponding to the 0.9 qualifier in ICF, was also provided.

As a result, the lowest possible score is 0 and the highest possible score is 60. A score of 60 was assigned to a 100% problem, and the intervals for each qualifier were calculated using this as a reference. Supplementary Material 1 (in the online-only Data Supplement) contains the final inventory, as well as the rating scale and ICF codes for each item.

Because Tamil is the local language, it was felt necessary to translate the inventory into Tamil. The ICF-TINI was independently translated into Tamil by two native speakers, and a third person rated the translation's appropriateness. A linguist then back-translated the combined version. Ten randomly selected undergraduates and graduates rated the tool based on the context's understandability. Items deemed understandable by 75% of raters were included in the tool, while items deemed not understandable were reworded. The modified tool was then tested for face validity on 10 people. They provided feedback on understandability. The Tamil version of the ICF-TINI was finalized based on their feedback (Supplementary Material 2 in the online-only Data Supplement).

Participants

Individuals over the age of 18 years with unilateral or bilateral chronic tinnitus for at least 3 months, with or without hearing impairment, were eligible for the study. Tinnitus may be a transient condition in people who have acute middle ear infections, neurological disorders, vestibular symptoms, or psychological disorders. All subjects were individuals who had their hearing tested at the Audiology clinic of a tertiary care private hospital in Chennai city.

During their wait time after the case history was taken and before the audiological testing began, all participants completed the inventory with paper and pen. Inventory was given to some participants while they waited for their audiological reports.

Statistical analysis

Cronbach's alpha was used to assess the tool's internal consistency reliability. SPSS Amos 20.0 software (IBM Corp., Armonk, NY, USA) was used to perform confirmatory factor analyses (CFA). Because items were drawn from the two components of ICF, CFA was used to determine whether the data obtained from ICF-TINI belonged to a two factor structure (body function and activities and participation). To assess model fit, the root mean square error (RMSEA), chisquare statistics, comparative fit index (CFI), incremental fit index (IFI), and Tucker-Lewis index (TLI) were used.

Results

The ICF-TINI was administered to 137 people (89 males and 48 females). The participants' average age was 40 years (range: 18 to 70 years). Approximately 80% of the participants were employed adults, with the remaining 20% being geriatric participants who were either unemployed or working part-time. All participants had tinnitus for at least three months and had it either constantly or for the majority of the day. Tinnitus was most commonly described as buzzing (58%) followed by whistling (29%), with a small proportion (13%) describing their tinnitus as ringing, machine noise, or wind noise like. None of the participants had central or objec-

Table 2. Item wise reliability coefficient

ICF-TINI items	Item-total correlation
b1400	0.746
b1263	0.673
b1266	0.710
b1522	0.669
b1341	0.583
b1342	0.637
d3503	0.765
d115	0.692
d116	0.598
d3600	0.650
d2401	0.667
d2302	0.756
d9205	0.732
d166	0.525
d163	0.620

ICF, International Classification of Functioning, Disability and Health; ICF-TINI, ICF-Tinnitus Inventory

tive tinnitus, which was confirmed by tinnitus masking ability.

Internal consistency reliability

The ICF-TINI alpha coefficient was 0.93, indicating that the items have relatively high internal consistency. The item-wise correlation coefficient (Table 2) indicates a moderate to strong correlation. Cronbach's alpha was 0.87 for body function (6 items) and 0.90 for activities and participation (9 items).

Confirmatory factor analysis

Fig. 1 depicts the factor loading values obtained from the confirmatory factor analysis. The B and D in circles indicate the components of body function (B) and activities and participation (D), and they are linked to the items belonging to these components from the ICF-TINI, and are indicated in the boxes (b1400–b1342, d3503–d163). The arrows pointing from the circle to the boxes indicate the extent the component loads the item (factor loading). The double-headed arrows between B and D indicate the correlation between the two components. The e1–e15 indicate the measurement errors.

Since the factor loading values were all greater than 0.5, no ICF-TINI item was eliminated. Table 3 shows the fit indices, fit values, and suggested criteria. The obtained fit values for RMSEA, CFI, chi-square (df), IFI, and TLI meet the suggested criteria. As a result, the ICF-two-factor TINI's structure was confirmed.

Discussion

The ICF-TINI was developed using the same process as the

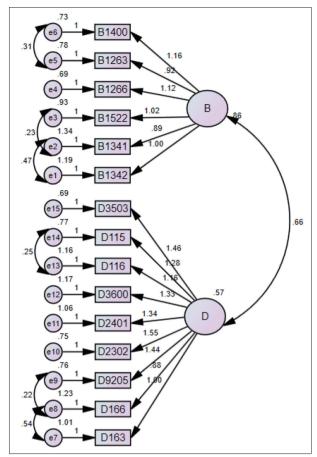


Fig. 1. Factor loading values for the two components of body function (B), activities and participation (D).

Table 3. Fit indices, fit values of ICF-TINI compared to suggested criteria

Fit indices	Model fit values	Suggested values
χ^2 /df	0.0005	≤5.00 (Hair, et al. [27])
RMSEA	0.070 < 0.08 (Hair, et al. [28	
CFI	0.952	>0.90 (Hu and Bentler [29])
IFI	0.953	Approaches 1
TLI	0.940	≥0.90 (Hair, et al. [27])

ICF, International Classification of Functioning, Disability and Health; ICF-TINI, ICF-Tinnitus Inventory; df, degree of freedom; RMSEA, root mean square error of approximation; CFI, comparative fit index; IFI, incremental fit index; TLI, Tucker-Lewis index

core set protocol [11] which included a systematic literature review, expert opinion, and data collection using a convenient sample in a cross-sectional design. While the standard protocol is to use a Delphi technique for the expert survey, a smaller group of judges was used in this study to assess the tool's content.

The ICF-TINI contains 15 items, 6 of which are components of body function and 9 of which are activities and participation. In total, four items were from the second level categories and 11 from the third level categories. According to

WHO in 2001, in real-world ICF applications, 3 to 18 codes are sufficient to describe a condition with two-level precision [22].

ICF was used to study the impact of tinnitus by mapping 25 items from THI and 5 additional items from activities and participation that were not previously covered in THI were added [19]. This 30-item tool contains more body function items, and several of these items are related to the same domain. For example, 9 items are associated with the code b152, b1522 (emotional function), and 6 items are associated with the code b1609 (function). The ICF-TINI and this tool (THI+ICF) share 10 common codes (4 in body function and 6 in activities and participation), but the ICF-TINI items are neutral, as defined in the ICF framework. Neutral items are likely to promote unbiased responses based on an individual's experience.

Item b240 from the ICF framework, which describes tinnitus, was not included because the ICF-TINI was designed for people who already had tinnitus. Similarly, experts excluded d230, which pertains to hearing function, as these items were deemed inappropriate to the specific condition of tinnitus, but relevant only when hearing loss co-exists. As a result, while the ICF-TINI inventory was designed for people with tinnitus, both with and without co-existing hearing loss, the items in the tool only assess the impact of tinnitus.

The inventory scoring is adapted from the universal qualifiers, ensuring consistency in reporting outcomes. Furthermore, the fact that ICF items are culture-free adds to this inventory's strength, as these items can be used anywhere in the world. For example, an item such as d163 Thinking, which is described in ICF-TINI as meditating/praying, may be retained as thinking if it is not appropriate for a specific region, as the ICF framework allows for such flexibility.

The internal consistency reliability of ICF-TINI was high comparable to THI [6] and TCQ [23]. Some tools such as TFI [16] and TRQ [3] have higher reliability. However, extremely high values (≥0.95) are undesirable because they indicate that the tool's items may be redundant [24]. This is also evident from the earlier mapping exercise that showed that several items of the THI belonged to the same domain in ICF framework [19]. However, each item of the ICF-TINI contributes to some unique information without redundancy.

Previously, the strengths and weaknesses of various tinnitus self-assessment questionnaires were evaluated [25]. When compared to the ICF framework, the THQ [2] despite having three factors; physical/social, interference with hearing, and patient's view of tinnitus, focuses on the component of "body function." The TRQ [3] primarily assesses psychological stress, which falls under body function and, more specifically, mental function in the ICF framework. The items in the emotional

and catastrophic subscales of the THI [6] pertain to the component of body functions, whereas the functional subscale has some items that assess activity limitation and participation restriction, but it also includes items that pertain to body function. Such a focus on a single concept can result in a higher score. The distinctness of THI subscales has previously been questioned [26].

The ICF-TINI confirmatory factor analysis indicates that the scale items are well-fitting, and the fit indices confirm the presence of two structures (body function and activities and participation) in this tool. There are no overlapping items in the tool, and each item evaluates a distinct aspect. The scoring is straightforward and adheres to the ICF qualifiers, meeting the need for a consistent reporting standard.

Therefore, the ICF-TINI is a reliable and valid tool for assessing the impact of tinnitus on an individual's body function, activities, and participation.

Supplementary Materials

The online-only Data Supplement is available with this article at https://doi.org/10.7874/jao.2022.00241.

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Conflicts of Interest

The authors have no financial conflicts of interest.

Author Contributions

Conceptualization: Vidya Ramkumar. Data curation: Vidya Ramkumar. Formal analysis: Vidya Ramkumar, Anitha Chandrasekaran. Investigation: Anitha Chandrasekaran. Methodology: Vidya Ramkumar. Project administration: Vidya Ramkumar, Anitha Chandrasekaran. Supervision: Vidya Ramkumar. Validation: Vidya Ramkumar. Visualization: Vidya Ramkumar, Anitha Chandrasekaran. Writing—original draft: Vidya Ramkumar, Anitha Chandrasekaran. Writing—review & editing: Vidya Ramkumar. Approval of final manuscript: Vidya Ramkumar, Anitha Chandrasekaran.

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Supplementary Material 1

ICF-TINNITUS INVENTORY (ICF-TINI)

Instruction: Please respond to these items with reference to your concern of tinnitus. Please put a $\sqrt{}$ against each statement as per the rating given below. Please mention as NA (Not applicable) if any of these items are not applicable to you.

0	if	No Problem
1	if	Mild Problem
2	if	Moderate Problem
3	if	Severe Problem
4	if	Complete Problem

Serial no.	ICF code	Items	0	1	2	3	4
1.	b1400	Sustaining attention in an activity					
2.	b1263	Psychic stability (ability to be calm and composed vs. feeling worried, irritated)					
3.	b1266	Confidence (assurance vs. feeling insecure)					
4.	b1522	Emotional stability (ability to regulate emotions vs. feeling angry, anxious)					
5.	b1341	Onset of sleep					
6.	b1342	Maintenance of sleep					
7.	d3503	Interacting with someone					
8.	d115	Listening to music or radio					
9.	d116	Listening to someone talk					
10.	d3600	Talking over the telephone using affected ear					
11.	d2401	Handling stressful situations					
12.	d2302	Satisfactorily completing job at workplace or home					
13.	d9205	Enjoying social activities such as going out for dinner or movie					
14.	d166	Reading					
15.	d163	Meditating or Praying					

Overall score:

0-2	No Problem	(0-4%)
3-14	Mild Problem	(5-24%)
15-29	Moderate Problem	(25-49%)
30-57	Severe Problem	(50-95%)
58-60	Complete Problem	(96-100%)

Supplementary Material 2

சர்வதேச செயல்பாடு, இயலாமை மற்றும் உடல் நல வகைப்பாடு சார்ந்த காதிரைச்சல் மேம்பாட்டு பட்டியல்

- 0 பிரச்சனை இல்லை,
- 1 குறைந்தளவு பிரச்சனை
- 2 மிதமான பிரச்சனை
- 3 கடும் பிரச்சனை
- 4 முழுமையான பிரச்சனை

S.No.	ICF CODE	ITEMS	0	1	2	3	4
1.	b1400	ஒரு வேலையில் கவனத்தை முழுமையாக ஈடுபடுத்துதலில்					
2.	b1263	சாந்தம் மற்றும் அமைதியுடன் இருப்பதில்					
3.	b1266	பாதுகாப்புடன் உணர்வதில்					
4.	b1522	மன உணர்வுகளுக்கு ஏற்ப மாறி கொள்ளுவதில்					
5.	b1341	உறங்குவதில்					
6.	b1342	உறக்கத்தை தடை இல்லாமல் தொடருவதில்					
7.	d3503	மற்றவருடன் உரையாடுவதில்					
8.	d115	இசை மற்றும் வானொலி கேட்பதில்					
9.	d116	ஒருவர் பேசுவதை கவனிப்பதில்					
10.	d3600	இரைச்சல் இருக்க காதைக் கொண்டு தொலைபேசியில் பேசுவதில்					
11.	d2401	மன அழுத்தமான சூழ்நிலையை கையாளுவதில்					
12.	d2302	வீட்டில் அல்லது வேலை செய்யும் இடத்தில் வேலையை மனநிறைவுடன் முடிப்பதில்					
13.	d9205	மற்றவர்களுடன் சேர்ந்து உண்ண செல்லும்பொழுது அல்லது படத்திற்கு செல்லும் பொழுது மகிழ்ச்சி அடைவதில்					
14.	d166	படிப்பதில்					
15.	d163	தியானம் அல்லது ஜெபிப்பதில்					
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ஓட்டுமொத்த மதிப்பெண்:

- 0-2 பிரச்சனை இல்லை (0-4%)
- 3-14 லேசான பிரச்சனை (5-24%)
- 15-29 மிதமான சிக்கல் (25-49%)
- 30-57 கடுமையான சிக்கல் (50-95%)
- 58-60 முழுமையான சிக்கல் (96-100%)