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Translation and Adaptation of Three English Tinnitus Patient-Reported Outcome Measures to Spanish

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Abstract

Objective: The objective of this study was to improve the range of standardized tinnitus Spanish Patient-Reported Outcome Measures (PROMS) available by translating and ensuring cross-cultural adaptation of three English PROMs to Spanish.

Design: The Tinnitus and Hearing Survey, Tinnitus Cognition Questionnaire, and Tinnitus Qualities Questionnaire were translated to Spanish using recently established good practice guidelines (Hall et al., 2018).

Study Sample: The translation process addressed 22 items included in six main steps specified in the guidelines. The translated PROMs were field tested on a sample of tinnitus patients who were recruited through convenience sampling using cognitive debriefing (n=5) and pilot testing (n=10) methods.

Results: The translation process employed the required steps and provided specific details about the process and procedures. In addition, practical issues encountered while translating and adapting the questionnaires that may influence future translations were revealed.

Conclusions: This is the first account of translating and adapting PROMs from one language to another using the good practice guidelines specific to hearing-related questionnaires. Following

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Conflict of Interest

None to declare.

the rigorous procedures should ensure that the translated PROMs have linguistic and cultural equivalence to the original versions, although psychometric evaluation would remain necessary to confirm the functional equivalence.

Keywords

Tinnitus; questionnaires; patient-reported outcome measures; translation; cross- cultural adaptation

Introduction

Evaluating the outcome of a health intervention should be an important component of both clinical care and health intervention research. Health-related outcomes may consist of various elements including findings during a clinical examination as well as patient-perceived effects post-intervention (Coster, 2013). The use of such Patient-Reported Outcome Measures (PROMs) can provide a valuable addition to clinical or experimental findings particularly in the field of audiology. PROMs focusing on hearing-related outcomes, such as the Hearing Handicap Inventory for Elderly (HHIE; Ventry & Weinstein, 1982), identified the functional impact pre-intervention and the patient's perceptions of improvement post-intervention. When used together with clinical assessments (e.g. a speech recognition assessment), PROMs would support comprehensive assessment of the presenting difficulties and related improvements. PROMs were of particular value when clinical examinations were not possible or relevant. For certain disorders such as tinnitus, the use of PROMs were recommended in clinical practice guidelines over routine psychoacoustic testing (Tunkel et al., 2014), as PROMS may be more helpful than these clinical measures for diagnostic purposes, guiding intervention and assessing outcomes. For example, tinnitus PROMs such as the Tinnitus Functional Index (TFI; Meikle et al., 2012) are useful in quantifying the impact of the tinnitus with regard to tinnitus intrusiveness, its effect on sleep, relaxation, hearing, emotions, and quality of life.

Audiologists may use numerous standardized health-related PROMs; however, most were developed in English-speaking countries such as the USA or Australia. Thus, PROMs may be available only in English, thereby complicating outcome assessment in non-English-speaking patient groups. Although some standardized PROMS were translated and adapted into various languages for non-English speaking populations, depending on the context, the translation process varied substantially. In some instances, only one person translated the PROM, while in others, a study team used a more rigorous approach incorporating forward-backward translation (Beaton et al., 2000; Thammaiah et al., 2016). Due to this variability, a good practice guideline for translating and adapting hearing-related questionnaires for different languages and cultures was proposed by a working group in association with the International Collegium of Rehabilitative Audiology (ICRA) and TINnitus Research NETwork (TINNET;(Hall et al., 2018). Applications of such guidelines would be important for future translations of hearing-related PROMS.

The need for standardized health-related PROMs to be translated into Spanish was identified when initiating work on adapting an Internet-based Cognitive Behavioral Therapy (ICBT) intervention for tinnitus, originally developed in Europe (Anderson et al., 2002; Weise et al.,

2016), for a U.S. population (Beukes et al., 2018a, 2018b). Due to the large Hispanic population in the U.S., the aim was to provide the ICBT program in both English and Spanish. The intervention was thus adapted both from a cultural and linguistic perspective and the intervention materials were translated into Spanish (Beukes et al., Submitted). To evaluate the efficacy of such an intervention for adults with tinnitus in the U.S. a clinical trial was registered (https://clinicaltrials.gov/ct2/show/NCT04004260). The use of PROMS should be critical to the assessment process, and the TFI was selected as the primary outcome measure related to tinnitus distress. Various additional secondary outcome measures assessing, for instance, anxiety, depression, and insomnia, added to the comprehensive and multi-dimensional outcome assessment battery of the ICBT intervention. These PROMs included the Tinnitus and Hearing Survey (THS; Henry et al., 2015), Tinnitus Cognition Questionnaire (TCQ; Wilson & Henry, 1998), and recently developed Tinnitus Qualities Questionnaire (TQQ), none of which were available in Spanish. The THS was previously translated into Brazilian Portuguese (Scheffer & Garcia Mondelli, 2019), however we could not identify published records of translations of TCQ and TQQ into other languages, including Spanish. The objective of this study was thus to improve the range of standardized Spanish PROMS available by translating and adapting three English PROMs to Spanish using good practice guidelines (Hall et al., 2018).

Method

Study Design and Translation Process

The study used a cross-sectional design. Ethical approval (IRB-FY19–332) was obtained from the Institutional Review Board at Lamar University, Beaumont, Texas, USA. The study design selected centered on translation of three PROMs in order to ensure best practice. The recently developed international guidelines, by Hall et al. (2018) were selected as the most current best practice guidelines to follow. These guidelines outline six stages of the translation process, namely: (1) preparation for translation; (2) undertaking forward translation; (3) include backward translation; (4) expert committee review of the translated materials; (5) field testing by letting individuals use the translated materials; and (6) reviewing and finalizing the translations. For the current project, each stage was broken down into additional guidelines in the form of 22 smaller steps. These components were identified as item 1a, 1b, and so forth. The guidelines specified a checklist for each item, rationale, identify the risks of omitting items, and specified who should perform the step. Careful consideration was given to these steps as outlined in the supplementary information. The methods and results for each step appear in the results section.

Questionnaires Selected for Translation

Three English questionnaires, the THS (Henry et al., 2015), TCQ (Wilson & Henry, 1998) and TQQ were translated into Spanish. The Tinnitus Qualities Questionnaire (TQQ) was recently developed to monitor tinnitus pitch and loudness on a weekly basis during the course of an intervention. Validation studies of this questionnaire are still underway.

Results

Each of the 6 steps from the international guidelines by Hall et al. (2018) were completed.

Step 1: Preparation for Translating a Questionnaire

Item 1a as the first step in the preparation process was to explore whether Spanish-translated versions of the THS and TCQ existed. Scientific databases and Internet searches did not identify any previously-translated versions. This step was not required for the TQQ as it was only recently developed specifically for use with the ICBT intervention. Item 1b, the second step, involved obtaining permissions. The original PROM developer of the THS, Dr. James Henry, was contacted to explore whether he knew of any Spanish translated versions. He confirmed no Spanish version existed, and provided permission for the THS to be translated. Item 1c involved recruiting a source-language developer. The source-language developer of the THS agreed to examine whether the backward translations (i.e., English versions) had the same meaning as the original version. As a general rule, the copyright for the translated version would remain with the original developer under a non-exclusive, non-sub licensable, and non-transferable license agreement. However, the original developers of TCQ are deceased and there were no copyright issues found for this measure. Hence, this measure was translated without the standard permission agreement.

Item 1d set out the key objectives. This step involved identifying which Spanish dialect to use during the translation process. As the key objective of this translation process was to translate and adapt this for the Spanish speaking population in the U.S., the Spanish dialect spoken in the U.S. was selected over other dialects (e.g., South American Spanish). A further key objective was to establish word choices. The decision was made to retain the word “tinnitus” instead of making a literal translation of this word to Spanish as “acúfeno” as “tinnitus” was more commonly used by the Spanish speaking population in the U.S.

According to Item 1e a template for recording the translation and adaption processes was created to keep track of the changes. The last preparation step, Item 1f was to develop definition and concepts for each questionnaire item. Important concepts and definitions for each questionnaire were determined and made available for all members of the translation team.

Step 2: The Translation Process – Forward Translation

Checklist item 2a involved the recruitment of dual-language translators for forward translation. The two forward translators recruited were an Audiology doctoral student and a graduate student with a Medical Spanish minor. They were both U.S. residents and bilinguals with Spanish as their first language. One of the forward translators (the Audiology doctoral student) also led the translation process by overseeing the reconciliation of forward/backward translations and committee review. The next step, Item 2b, involved briefing the translators about the research project, PROMs being translated, target population, and the important concepts and definitions developed. Checklist item 2c involved instructions on the translation requirements. The main aim of forward translation was to ensure the Spanish questions carried exactly the same meaning regarding the important concepts. This was

achieved by identifying the words or phrases most commonly used by the U.S. Spanish population, and was especially important when multiple terminologies were available for a word. The next step, item 2d, involved the forward translators independently producing their own versions of the translations. These two versions were reconciled and yielded a single forward translation. The final step, item 2e, was to reconcile the forward translations between the translators. When compared, the main differences between the two forward translators were found for specific word choices. The lead translator discussed the discrepancies with the second translator and one of the committee members, who was a professor of Spanish language. The most commonly used words were selected.

Step 3: The Translation Process – Back Translation

Item 3a specified recruitment of two dual-language backward translators. They were Audiology doctoral students who were U.S. residents and bilinguals with Spanish as their first language. Both translators were briefed about the research project, PROM translation, and the target population. Back translators had not seen the original English version of the questionnaires at the time of translation. Item 3b involved both back translators working independently and producing separate versions of the translations. The final item (i.e., 3c) involved the translation team lead reviewing both back translations and comparing them against the source language. In addition, the original developer of THS, Dr. James Henry, reviewed the back translations and provided feedback. The comparative process examined the translation to determine the degree to which the backward translations preserved the meaning with adequate semantic equivalence. Notes regarding the classification of the translations were compiled and presented for committee review (see Tables 1 and 2). The good practice guidelines recommended the items be classified using an A-D scheme as follows: (A) perfect semantic equivalence; (B) satisfactory semantic equivalence; (C) preservation of the meaning of original item without satisfactory equivalence; and (D) items requiring further revisions. To simplify the process, the items were classified as: (a) perfect semantic equivalence; and (b) not a perfect semantic equivalence, instead of “satisfactory equivalence” as described above. Those items rated as “not perfect” required a more careful review.

Step 4: Committee Review

Item 4a involved appointing a multi-disciplinary review committee upon which four Spanish review committee members served. The team included two Audiology doctoral students, one Spanish professor, and an Audiologist. Three of the committee members were bilingual U.S. residents with Spanish as their first language. However, the fourth committee member did not speak Spanish, and English was his second language. The three bilingual members played a key role in the discussion regarding word choices and also cultural and linguistic equivalence. The fourth non-English speaking member focused on comparing the back translations to the original version of the questionnaire and offered additional comments about the project when necessary.

The next checklist item, 4b was a committee review of the translation report. The committee members were given detailed notes about each item of the PROM, which included each step of the translation (see Tables 1 and 2). The committee members reviewed the notes carefully

and discussed each item. The most time was spent on items lacking semantic equivalence. The committee discussion resulted in the creation of the final version of the items for pre-testing. The main issue noted during the translation process involved the choice of gender-neutral words. For instance, in Spanish, all nouns were classified as masculine or feminine, even nouns relating to places or things, a substantial difference from wording used in English. In the Spanish language, both verbs and adjectives needed to match in terms of singularity and plurality. In some cases, these did not match in one of the forward translator's translations. When this occurred, the Spanish professor determined the most appropriate choice of words.

Step 5: Field Testing

Checklist item 5a: Recruitment—Following the actual translation process, field testing of the committee review finalized version of the PROMs was required during step 5. Item 5a involved recruiting a small sample of patients from the target population for field testing of the committee-reviewed, finalized PROM version. A sample of 15 Spanish speaking adults with tinnitus were recruited through convenience sampling from the Audiology clinic at Lamar University. The literature did not offer consensus on the desired sample size for pilot testing (Acquadro et al., 2008). The good practice guidelines recommended using the sample size of eight during the pre-testing of the translated version to ensure the original instructions, items and scoring materials were clearly expressed (Hall et al., 2018), and correspondingly, adequate participant numbers were recruited. The characteristics of the sample are found in Table 3. All the participants had tinnitus for 3 months or longer. However, we did not gather any additional details about hearing loss and tinnitus as the main aim was to understand the comprehension of the translated measures by a sample rather than testing the psychometric properties of the questionnaires.

Checklist item 5b: Assess the acceptability and accessibility of the new translated versions—The study participants then assessed whether the new versions were acceptable and accessible during field testing, according to item 5b. The focus during the field testing was to ensure that the participants understood the PROM items and that none of the questions made the participants uncomfortable. The researchers asked participants whether any of the items caused confusion or misunderstanding. Participants' reactions and opinions, their difficulties in understanding the questions, and their remarks concerning the questions were noted, as required by item 5b.

To ensure a thorough process was followed, two different field-testing approaches were used, (Acquadro et al. 2008; Wild et al. 2005): cognitive debriefings with five adults, and pilot testing with 10 adults as outlined below. The study participants answered the questionnaires without a break during cognitive debriefings and pilot testing. None of the participants reported any tiredness or discomfort during this process. On an average, study participants took about 30 minutes to complete cognitive debriefings and about 20 minutes to complete pilot testing.

Cognitive Debriefing: Cognitive debriefing provided the process by which a PROM was actively tested among a representative sample of the target population, and target language

group, to determine whether respondents understood the PROM (i.e., instructions, items and scoring materials) as intended in the original version. This process involved face-to-face semi-structured interviews during questionnaire completion to determine how well the questions were understood and comprehended. The focus was thus on comprehension rather than eliciting numerical scores. The aim was to identify any deviations from the conceptual, item, semantic and operational equivalences (Hall et al., 2018). Five study participants completed the PROM while "thinking aloud" and explaining the reason for each of their responses. This was followed by the researcher asking more specific questions. These follow-up questions focused on; (a) identifying any difficult words or phrases, (b) Explaining the question in their own words, and (c) providing suggestions or any changes to the wording to make the questions clearer or more acceptable. Researchers also asked participants to determine whether other people with tinnitus could misinterpret the questions. Questions related to paraphrasing the survey item in their own words and was considered the most important part of the cognitive debriefing process (Hall et al., 2018) as it provided insight into how well the questions were understood by respondents.

Cognitive debriefing was most helpful when examining how participants understood the translated questionnaire items. No issues were found for THS and only a few minor misunderstandings for the TCQ and TQQ. When answering Item 12 on the TCQ one participant did not understand the word "abrumara" (overwhelm). When answering question 10 in the TQQ, the word "sensitive" was understood by one participant as having "better hearing" than most (as in being able to hear very soft sounds), instead of discomfort because of sound tolerance issues.

Pilot Testing: The second approach, pilot testing, focused on determining how the users interacted and completed the questionnaires. This process considered aspects such as comprehension regarding the wording of the instructions, items, and/or response scale. It also evaluated the suitability of the format, length, and the time required to complete the questionnaire by the target population. The participants were asked to rate how difficult it was to complete the questionnaire using a Likert-scale response format. The question was worded as: How difficult was it to complete the questionnaire? Response options included: 1 = very easy, 2 = easy, 3 = neutral, 4 = difficult, and 5 = very difficult. When the responses indicated "difficult" or "very difficult," the reasons for their ratings were explored by asking open ended questions.

Pilot testing indicated that study participants were generally able to answer the questionnaires with ease. The THS was rated as "very easy" by all 15 participants. TQQ was rated as "very easy" by 12 participants (80%), "easy" by two participants (13.3%) and "neutral" by one participant (6.7%). A few participants left the answers to Item 8 and 9 for the TQQ blank. Upon further questioning, one participant said he was not sure if his mood altered his tinnitus; he was therefore unsure of the answer. Two other participants reported they did not listen to loud sounds, thus leaving that answer blank. These observations highlight that some items of TQQ may not be relevant to all participants.

TCQ was rated as "very easy" by nine participants (60%), "easy" by two participants (13.7%), "neutral" by two participants (13.7%), and "difficult" by two participants (13.7%).

When questioned regarding the reason for rating “difficult”, participants reported the questionnaire was too long (i.e., 26 items) and some of its items were too difficult to understand.

Step 6: Review and Finalize the Translation

Item 6a involved carefully reviewing the results of the field testing by the lead translator and one of the committee members to create a final version of the PROMs. As the field testing revealed only a minor difficulty with 1–2 individuals, no further changes were made to translated questionnaires. Consistent with item 6b, the PROMs were proofread formatted to match the original measure. For item 6c, the notes and documents created during the translation process were archived for future reference. This step included providing the original developer with the final version of the Spanish THS. The final item 6d was used to generate a report regarding the translation process. The report facilitated sharing all the three translated PROMs with the wider community (see Appendices).

Discussion

The purpose of this study was to translate three tinnitus PROMs into Spanish. Essential to that goal, the translation approach ensured the PROMs were culturally and linguistically appropriate. In this way, the translations benefitted from the advantages of cross-cultural adaptations when used for purposes of evaluating interventions (Hall et al., 2016). When adapting existing questionnaires for a different culture, the process must consider not only language issues but additional elements, such as cultural context (Epstein, Santo, and Guillemin, 2015). To ensure translation of these questionnaires accounted for cross-cultural adaptations, a rigorous 6-step process was employed. Adhering to rigorous translation processes was shown to enhance the effectiveness of multilingual projects (Harkness et al., 2010). It also ensured linguistic equivalence of the translated measures when compared to the original questionnaire. The translation process itself did not ensure the success of the study, although incorrectly translated questionnaires could introduce measurement bias and may be incompatible with the normative data obtained in the source language (Harkness et al., 2010). To ensure a rigorous process for the present translations, best practice guidelines for translating hearing-related questionnaires developed by Hall et al. (2018) were followed. These guidelines were used in a recent project focused on multi-national standardization of questions used in the estimation of prevalence and severity of tinnitus and hearing disability in European countries (Biswas et al., 2019). The process, procedures followed, and practical issues encountered during the adaption and translating process were discussed in this manuscript to guide other researchers wishing to undertake similar translations.

As reported previously (e.g., Willgerodt et al., 2005), various aspects of the translation process were challenging. First, it was more resource intensive than anticipated. The process was also more time consuming than expected due to the numerous steps involved. Recruiting translators with the appropriate dialect to ensure the translations are suitable for Spanish speaking populations in the U.S was a further challenge. Identifying a study team member with expertise in both the source and target language to consider relevant linguistic and

cultural aspects was difficult. Securing funding a priori to pay for professional translators would have made this process easier.

Despite these challenges, a comprehensive translation process was achieved. Key elements to streamlining the process included pre-establishing guidelines for the translation process, such as deciding which dialect to use. Following a rigorous process such as forward/backward translation and a committee review also helped in identifying problems early on and ensured that no major revisions were required later on during the process. Including both cognitive interviews and pilot testing during field testing provided a crucial step in the translation process. This helped to ensure that sub-sets of the intended population were able to understand the translated questions in the intended way (Acquadro et al. 2008; Wild et al. 2005).

In summary, it is important to note that translations themselves do not guarantee equivalency or comprehension, although they increase a measurement tool's likelihood of being accurate. Good practice guidelines are helpful although not all projects may have the time and resources required to follow all the sub-steps. To aid future translations, it would be useful to establish consensuses on essential and desired steps by all stakeholders to make the translation process more manageable. Moreover, evaluation of the psychometric properties of these questionnaires *(i.e.*, construct validity, concurrent validity, predictive validity, internal consistency, reliability, and repeatability) should be completed before adopting the questionnaire for clinical use.

Conclusions

The objective of this study was to translate and adapt three English language PROMs

(i.e., THS, TCQ, and TQQ) to Spanish using the recently proposed international good practice guidelines. The steps indicated in the guidelines were followed consistently and were field tested. The adopted procedure produced thematic and/or conceptual equivalence, rather than a literal translation. Field testing revealed only minor issues noted by two participants suggesting the translated questionnaires were easily understandable by a sub-set of the intended population. The translated versions are provided for interested readers, along with detailed notes on the translation process employed. Psychometric evaluations of these questionnaires remain necessary to confirm functional equivalence before adopting them for clinical practice.

Supplementary Material

Refer to Web version on PubMed Central for supplementary material.

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Table 1:

Example of the Tinnitus and Hearing Survey translation item presented to review committee

Steps	Item
Original THS	Over the last week, sounds were too loud or uncomfortable for me when they seemed normal to others around me.
THS FT 1	Durante la última semana, los sonidos eran demasiado fuertes o incómodo para mí cuando parecía normal a los demás a mi alrededor
THS FT 2	Durante la última semana, los sonidos eran demasiado fuertes o incómodos para mí cuando parecía normal a los demás a mi alrededor
THS Reconciled FT	Durante la última semana, los sonidos eran demasiado fuertes o incómodos para mí cuando parecía normal a los demás a mi alrededor
THS BT 1	During the last week, the sounds were too loud or uncomfortable for me when it seemed normal for others around me.
THS BT2	During the last week, the sounds were too loud or uncomfortable for me when it seemed normal for others around me
THS Review of BT against source language	Item was back translated with satisfactory semantic equivalence.
Committee review notes	The words in question were "*incómodo*" (singular) and "*incómodos"* (plural). The plural word was kept since the source language talked about more than one sound. There was no incongruence during backward translation for this word. However, the word "*durante"* was translated back to "*during"* instead of the original "*over"*. The committee decided that the overall meaning was preserved, so no further changes were made.
THS Version 1 for field testing	Pienso, "El ruido hace que mi vida sea insoportable"

Note: THS=Tinnitus and Hearing Survey, FT=Forward translation; BT=Backward translation

Table 2:

Example of the Tinnitus Cognition Questionnaire translation item presented to review committee

Steps	Item (same incongruence was encountered for 13 other items)
Original TCQ	I think “The noise makes my life unbearable”
TCQ FT 1	Creo que “El ruido hace que mi vida sea insoportable”
TCQ FT 2	Creo que “El ruido hace que mi vida sea insoportable”
TCQ Reconciled FT	Creo que, “El ruido hace que mi vida sea insoportable”
TCQ BT 1	I believe that “ The noise makes my life unbearable”
TCQ BT2	I believe that “ The noise makes my life unbearable”
TCQ Review of BT against source language	Item was back translated with perfect semantic equivalence
Committee review notes	The word “*creo”* was chosen by both forward translators and translated back to “*believe*” by both back translators. The committee decided to completely change the word to “*pienso”* which directly translates back to “*think*”.
TCQ Version 1 for field testing	Pienso, “El ruido hace que mi vida sea insoportable”

Note: TCQ=Tinnitus Cognition Questionnaire, FT=Forward translation; BT=Backward translation

Table 3:

Demographic details of study participants (n = 15)

Factor	Mean (SD)	N (%)
Age (in years)	71.6 (20)	
Duration of tinnitus (in months)	53.1 (45)	
Gender		
■ Male		11 (73.3%)
■ Female		4 (26.7%)
Education		
■ Less than high school		7 (46.7%)
■ High school		3 (20%)
■ Some college		2 (13.3%
■ University degree		3 (20%)
Work		
■ Unskilled work		2 (13.3%)
■ Professional work		3 (20%)
■ Retired		1 (6.7%)
■ Not working		9 (60%)
Ethnicity		
■ Hispanic or Latino		15 (100%)
Race		
■ White		14 (93.3%)
■ Unknown		1 (6.7%)