Translation, adaptation and validation of instruments or scales for use in cross-cultural health care research: a clear and user-friendly guideline

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Keywords
back-translation, cross-cultural validation, health care research, translation

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Accepted for publication: 3 February 2010
doi:10.1111/j.1365-2753.2010.01434.x

Abstract

Rationale, aims and objectives The diversity of the population worldwide suggests a great need for cross-culturally validated research instruments or scales. Researchers and clinicians must have access to reliable and valid measures of concepts of interest in their own cultures and languages to conduct cross-cultural research and/or provide quality patient care. Although there are well-established methodological approaches for translating, adapting and validating instruments or scales for use in cross-cultural health care research, a great variation in the use of these approaches continues to prevail in the health care literature. Therefore, the objectives of this scholarly paper were to review published recommendations of cross-cultural validation of instruments and scales, and to propose and present a clear and user-friendly guideline for the translation, adaptation and validation of instruments or scales for cross-cultural health care research.

Methods A review of highly recommended methodological approaches to translation, adaptation and cross-cultural validation of research instruments or scales was performed. Recommendations were summarized and incorporated into a seven-step guideline. Each one of the steps was described and key points were highlighted. Example of a project using the proposed steps of the guideline was fully described.

Conclusions Translation, adaptation and validation of instruments or scales for cross-cultural research is very time-consuming and requires careful planning and the adoption of rigorous methodological approaches to derive a reliable and valid measure of the concept of interest in the target population.

Introduction

Globalization and migration have contributed to an increasing diversity of the population in many countries, particularly in the USA, where the background of the population is extremely diverse regarding culture, language and ethnicity [1,2]. Therefore, there is a need for relevant cross-cultural research to addresses a number of problems among these multinational and multicultural populations. However, health care researchers conducting cross-cultural studies must have access to reliable and cross-validated instruments in other cultures and/or in other languages [3–6]. Findings from cross-cultural research may have great clinical implications for physicians, nurses and other health care professionals who provide care for diverse populations because the delivery of quality care depends on the accurate assessment and deeper understanding of an individual’s cultural, linguistic and ethnic background.

Background and significance

The increase in diverse populations worldwide and the need for cross-cultural and multinational research indicate a great need for clinicians and researchers to have access to reliable and valid instruments or measures cross-validated among diverse cultural segments of the population and/or in other languages [3,4,6]. This would enhance the validity, the generalization and the translation of cross-cultural health care research. Although there are well-established methodological approaches for translating, adapting and validating instruments for use in cross-cultural health care research [2–5,7–15], a great variation in the use of these approaches continues to prevail in the health care literature.

A recent review of 47 methodological studies focusing on the translation and validation of instruments for cross-cultural research reported that the quality and methodological approaches of the reviewed studies varied greatly [16]. There was no clear
consensus among researchers on how the approaches should be used or combined, a great variation on the qualifications of translators, and a lack of detailed information about the translation, back-translation, validation, testing, and revision and refinement of the instruments.

Corroborating these findings, another researcher [2] reported that, unfortunately, translating, adapting and cross-culturally validating research an instrument is treated as an unimportant step of study protocols. Furthermore, the most commonly used and reported methodological approach was the forward translation only, often using an unqualified translator. In addition, the same author [2] reported that only a few researchers have described the use of strategies and steps or processes for the adaptation and/or validation of the instruments, and emphasized that it is not sufficient to forward translate an instrument without carefully evaluating its adaptation and cross-cultural validation. The procedure should consist of a comprehensive process that involves not only translation of an instrument, but also thorough evaluation of its adaptation and cross-cultural validation.

These data suggest that despite the existing recommendations and guidelines to use a comprehensive multistep process for translating, adapting and cross-validating instruments, researchers have not been doing this. It may be that the methodological approaches are not clearly presented in a user-friendly format, which makes it difficult for researchers to adopt and follow the recommendations. Therefore, the objectives of this scholarly paper were to review published recommendations of cross-cultural validation of instruments and scales, and to propose and present the highly recommended methodological approaches for translating, adapting and validating instruments for cross-cultural health care research in a clear and a user-friendly guideline. This would lead to better understanding and use of these approaches by health care researchers, particularly nurse researchers worldwide.

Methodological approaches

Of the two main categories of translation (symmetrical and asymmetrical), the symmetrical category is the most recommended approach because it refers to faithfulness of meaning and colloquialness in both the source language (SL; original language of the instrument) and the target language (TL; desired language) and not to a literal translation [12]. The purpose of translation is to achieve equivalence between the instrument in the SL and the instrument in the TL [2]. The symmetrical translation is the only category that facilitates the comparison of responses from individuals of one culture to those of another [6,12,13] and the determination of the most relevant types of cross-cultural equivalence: the semantic, conceptual, content, technical and criterion [1,17]. In addition, the process known as centring [7], in which both the SL and the TL of an instrument are equally important, should be used.

The process of translation, adaptation and cross-cultural validation of an instrument for use in other cultures, languages and countries requires careful planning and adoption of comprehensive, rigorous and most established methodological approaches [2–5,7–15]. Because there are variations among these approaches, we have incorporated the most recommended ones in a user-friendly guideline to facilitate adoption, consistency and use.

Step 1: translation of the original instrument into the target language (forward translation or one-way translation)

The instrument in the source (original) language is forward translated to the TL (target language) by at least two independent translators, preferably certified, whose mother language is the desired TL of the instrument. The translators must be bilingual (i.e. fluent in the source and desired TL of the instrument) and preferably bicultural (i.e. having in-depth experience in the culture of the source and desired TL of the instrument). In addition, the two translators must have distinct backgrounds. The first translator must be knowledgeable about medical terminology and the content area of the construct of the instrument in the desired TL. The second translator must be familiar with health care terminology and the cultural nuances. Therefore, choosing well-qualified translators is the key to high-quality translations. If resources are available, translations can also be done by two teams of independent translators (each team of translators must have the same characteristics as the two individual independent translators described above), which may result in higher-quality translations by minimizing the introduction of personal idiosyncrasies when using only two independent translators.

Key points

1. Instrument in the SL \(\rightarrow\) translated to TL (TL1 and TL2) to produce two forward-translated versions of the instrument.
2. Use two bilingual and bicultural translators whose mother language is the desired TL, but who have distinct backgrounds:
   - One translator must be knowledgeable about health terminology and the content area of the construct of the instrument in the TL.
   - The other translator must be knowledgeable about the cultural and linguistic nuances of the TL.
3. Two independent teams of translators can also be used (each team of translators must have the same characteristics of the two individual independent translators).

Step 2: comparison of the two translated versions of the instrument (TL1 and TL2): synthesis I

The instructions, the items and the response format of the two forward-translated versions of the instrument (TL1 and TL2) and both the TL1 and the TL2 with the original version of the instrument in the SL are initially compared by a third bilingual and preferably bicultural independent translator regarding ambiguities and discrepancies of words, sentences and meanings. Any
ambiguities and discrepancies must be discussed and resolved using a committee approach. Consensus should be achieved with the participation of the third translator, the two translators from Step 1, and the investigator and/or other members of the research team. This process will generate the preliminary initial translated version of the instrument in the TL (PI-TL).

**Key points**

1. Use a third independent translator to compare the TL1 and TL2, and to compare both the TL1 and TL2 with the SL version of the instrument.
2. Use a committee approach (third independent individual or translator, translators who participated in Step 1, and investigator and/or other members of research team) to resolve ambiguities and discrepancies and derive the PI-TL.

**Step 3: blind back-translation (blind backward translation or blind double translation) of the preliminary initial translated version of the instrument**

The PI-TL is translated back into the SL by two other independent translators with the same qualifications and characteristics described above in Step 1. For this step, the translators’ mother language should be the SL of the original instrument, and they should be completely blind to the original version of the instrument (they had never seen the original version of the instrument). They will produce two back-translated versions of the instrument. Again, the first translator must be knowledgeable about health care terminology and the content area of the construct of the instrument in the SL, but no prior knowledge of the instrument being back-translated. The second translator must be familiar with colloquial phrases, health care slang and jargon, idiomatic expressions, and emotional terms in common in the SL. The first translator should not be knowledgeable about medical terminology and/or construct of the instrument and should have no prior knowledge of the instrument being back-translated as well. If resources are available, back-translation can also be done by two teams of translators, which may result in higher-quality back-translations by minimizing the introduction of personal idiosyncrasies when using only one independent back-translator to generate each initial back-translated version of the instrument. This process will result in two back-translated versions of the instrument in its original SL (B-TL1 and B-TL2). This step allows for clarification of words and sentences used in the translations. As noted in Step 1, choosing well-qualified translators is the key to high-quality back-translations.

**Key points**

1. The PI-TL $\rightarrow$ Back-translated to SL (B-TL1 and B-TL2) to produce two back-translated versions.
2. Use two bilingual and bicultural translators whose mother language is the SL, but who have distinct backgrounds:
   - One translator must be knowledgeable about health terminology and the content area of the construct of the instrument in the SL.
   - The other translator must be knowledgeable about the cultural and linguistic nuances of the SL.

3. Two independent teams of translators can also be used (each team of translators must have the same characteristics of the two individual independent translators).

**Step 4: comparison of the two back-translated versions of the instrument (B-TL1 and B-TL2): synthesis II**

Initially, the instructions, items and response format of the two back-translations (B-TL1 and B-TL2) are compared by a multidisciplinary committee with the instructions, items and response format of the original instrument in the SL regarding format, wording, and grammatical structure of the sentences, similarity in meaning, and relevance. It is highly recommended that the committee should include at least one methodologist (who can be the investigator and/or a member of the research team), one health care professional who is familiar with the content areas of the construct of the instrument, and all four bilingual and bicultural translators involved in Step 1 (forward translation of the instrument into the TL) and Step 3 (back-translation of the instrument from the TL into the SL). It is also recommended that the developer of the original instrument in the SL participated and provide insights on the construct of the instrument and clarify any questions that might arise. Having at least one monolingual committee member whose mother language is the TL of the instrument would enhance the quality of the pre-final version of the translated instrument. Any ambiguities and discrepancies regarding cultural meaning and colloquialisms or idioms in words and sentences of the instructions, the items, and the response format between the two back-translations (B-TL1 and B-TL2) and between each one of the two back-translations (B-TL1 and B-TL2) and the original instrument in the SL are discussed and resolved through consensus among the committee members to derive a pre-final version of the instrument in the TL (P-FTL).

If discrepancies cannot be resolved, it may be necessary to repeat Steps 1 though 4: two other independent bilingual and bicultural translators must be used to translate the original instrument (SL) again to generate two translations, and two other independent bilingual and bicultural translators must be used to back-translate the translated versions of the instrument (TL) following the same procedure described above (known as the repetition approach). Alternatively, only items that do not retain their original meaning are re-translated and back-translated. The evaluation of the translated and back-translated versions follows the same validation process described above. This process is repeated until no ambiguities or discrepancies are found.

These methodological approaches of Step 4 will establish the initial conceptual, semantic and content equivalence of the P-FTL. Conceptual equivalence refers to the degree to which a concept of the items of the instrument exists in both the source and target cultures. Semantic equivalence refers to sentence structure, colloquialisms or idioms that ensure that the meaning of the text or idea of the items of the instrument in the SL is present in the TL. Finally, content equivalence refers to the relevance and pertinence of the text or idea of the items of the instrument in each culture. The committee’s role is to evaluate, revise and consolidate the instructions, items and response format of the back-translated instruments that have conceptual, semantic and content equivalence and to develop the P-FTL for pilot and psychometric testing.
Key points
1 Comparison between the two back-translations (B-TL1 and B-TL2) of the instrument, and between both BTL1 and B-TL2 and the original SL instrument:
   • Evaluate similarity of the instructions, items and response format regarding wording, sentence structure, meaning and relevance.
2 Use a multidisciplinary committee:
   • One methodologist (researcher or a member of the research team).
   • One health care professional.
   • All four bilingual and bicultural translators used in Step 1 and Step 3: two translators whose mother language is the desired TL of the instrument and two translators whose mother language is the SL of the original instrument.
3 If possible, developer of the original instrument should participate in the discussions.
4 If ambiguities and discrepancies cannot be resolved, Steps 1 through 4 may be repeated as many times as necessary. Alternatively, only items that do not retain their original meaning are re-translated and back-translated.

Step 5: pilot testing of the pre-final version of the instrument in the target language with a monolingual sample: cognitive debriefing

The P-FTL is pilot tested among participants whose language is the TL of the instrument to evaluate the instructions, response format and the items of the instrument for clarity. Participants should be recruited from the target population in which the instrument will be used (e.g. if the instrument measures self-care among individuals with type 2 diabetes, then the sample must consist of individuals with type 2 diabetes). A sample size of 10–40 individuals is recommended [3,18]. Each participant is asked to rate the instructions and items of the scale using a dichotomous scale (clear or unclear). Participants who rate the instructions, response format or any item of the instrument as unclear are asked to provide suggestions as to how to rewrite the statements to make the language clearer. Instructions, response format and items of the instrument that are found to be unclear by at least 20% of the sample must be re-evaluated [19]. Therefore, the minimum inter-rater agreement among the sample is 80%. This step is used to further support the conceptual, semantic and content equivalency of the translated instrument and further improve the structure of sentences used in the instructions and items of the P-FTL to be easily understood by the target population prior to psychometric testing.

To further determine the conceptual and content equivalence of the items of the P-FTL, use of an expert panel, is highly recommended. The instructions, response format and the items of the instrument are evaluated for conceptual equivalence (clarity) by six to ten members of an expert panel [20,21] who are knowledgeable about the content areas of the construct of the instrument and the target population in which the instrument will be used and whose mother language is the TL of the instrument. When possible, a committee of 10 members is preferable [20,21]. Each member of the committee who rates the instructions, response format or any item of the instrument as unclear is asked to provide suggestions as to how to rewrite the statements and make the language clearer. Instructions, response format and items of the instrument that are found to be unclear by at least 20% of the committee members must be revised and re-evaluated [19]. The minimum inter-rater agreement among the experts panel is 80%. This process will further determine the conceptual equivalence of the translated instrument.

The expert panel is then asked to evaluate each item of the instrument for content equivalence (content-related validity [relevance]) using the following scale: 1 = not relevant; 2 = unable to assess relevance; 3 = relevant but needs minor alteration; 4 = very relevant and succinct. Items classified as 1 (not relevant) or 2 (unable to assess relevance) should be revised [20,21]. Content validity index at the item level (I-CVI) and at the scale level (S-CVI) should be calculated. There are three methods to calculate S-CVI [20–22], but the averaging calculation (S-CVA/Ave) method is preferred [22]. Using 10 experts, the I-CVI of 0.78 or above [20] and S-CVA/Ave of 0.90 or above [21] are the minimum acceptable indices. Items that do not achieve the minimum acceptable indices are revised and re-evaluated. New content validity indices are calculated. The process continues until acceptable indices of content-related validity or content equivalence are achieved. It is also recommended that the kappa coefficient of agreement be determined to increase confidence in the content validity of the instrument [23]. A kappa of 0.60 is generally the minimum acceptable coefficient to determine good agreement [24]. The purpose of Step 5 is to continue developing the P-FTL for pre-field test for preliminary and/or full psychometric testing.

Key points
1 Pilot test of the P-FTL among individuals whose language is the TL of the instrument:
   • Evaluate the instructions, items and response format clarity.
   • Use a sample size of 10–40 participants.
2 It is highly recommended to use an expert panel to further examine the instrument for:
   • Clarity of the instructions, items and response format.
   • Content equivalence (content-related validity) using I-CVI, S-CVI/Ave and Kappa coefficient of agreement.
   • Use a sample of 6–10 experts (10 experts are preferred).

Step 6: preliminary psychometric testing of the pre-final version of the translated instrument with a bilingual sample

This step is rarely used; however, when a bilingual population is accessible, it is recommended that the instrument be pre-field tested among bilingual individuals (fluent in the SL of the original instrument and the TL of the translated instrument). If this is not possible, skip this step and move to Step 7. In general, the recommendation is to use at least five subjects per item of the instrument to conduct the preliminary psychometric testing of a new instrument [25]. Ideally, the bilingual sample should be from the target population in which the instrument will be used (e.g. adult individuals with type 2 diabetes, African–American women with heart failure). However, in many instances, this may be difficult and unrealistic; thus other alternatives can be used such as sampling bilingual college students and faculty or workers in travel agencies, currency exchange agencies, international trade companies, embassies and consulates, and language schools.
Initially, participants are given the P-FTL and are asked to answer the items. The participants respond to the items of the P-FTL without seeing the original instrument in the SL. After completion of the P-FTL, participants are given the original instrument in the SL and are asked to answer the items. They may complete a demographic questionnaire and/or other instruments of interest. The order of the items of the original instrument must be mixed to be in a different order from that of the items of the P-FTL. Responses on both versions of the instrument are then compared (i.e., interpretation of scores is the same in both cultures) to establish criterion equivalence (a type of construct validity). Statistical analyses used for comparison purposes may consist of descriptive statistics, correlation coefficients, and paired t-test or one-way ANOVA. Scale and item analysis is also used to establish the initial preliminary psychometric properties of the instrument (internal consistency reliability) and to compare these properties of the P-FTL with the SL of the original instrument. When the instrument purpose is to serve as a diagnostic or screening testing, preliminary calculation of sensitivity and specificity is recommended. This Step 6 also determines initial technical equivalency (the method of assessment) and is useful to support the conceptual, semantic, content and construct validity of the P-FTL prior to conducting full psychometric field testing.

Key points
1. When possible, pilot test the P-FTL among bilingual individuals to:
   - Compare the P-FTL and the SL instrument in the SL.
   - Establish criterion equivalency and further support the conceptual, semantic, content and construct equivalency of the P-FTL.
2. Use at least five subjects per item of the instrument.
3. Subjects complete the P-FTL first without seeing the original instrument in the SL.
4. Subjects complete the original instrument in the SL in which items have been mixed in different order from the P-FTL.

Step 7: full psychometric testing of the pre-final version of the translated instrument in a sample of the target population

This last step is used to establish the initial full psychometric properties of the newly translated, adapted and cross-validated instrument with a sample of the target population of interest. The sample size for this step depends on the types of psychometric approaches that will be used. The more complete the psychometric approaches for evaluation of the translated instrument the more confidence will be generated in its reliability and validity properties. In general, per rule of thumb, it is highly recommended to use at least 10 subjects per item of the instrument scale and item analysis and exploratory factor analysis [25–28]. If there is a plan to use confirmatory factor analysis to test the factor structure of the instrument, the recommendation per rule of thumb is approximately 300–500 subjects per item of the instrument [28,29]. Power analysis based on the number of degrees of freedom, an alpha level (0.05 or 0.01), and a desired power (80% or above) can also be calculated [30,31].

The most recommended and commonly used psychometric approaches in this step are estimation of: (1) internal consistency reliability (or sensitivity and specificity); (2) stability reliability (test–retest reliability); (3) homogeneity; (4) construct-related validity such as convergent and/or divergent (discriminant) validity; (5) criterion-related validity such as concurrent and/or predictive validity; (6) factor structure of the instrument (dimensionality); and (7) model fit. Although, it is not the purpose of this user-friendly guideline to describe the many statistical approaches that can be used in Step 7, the most common statistical approaches are scale and item analysis, Pearson’s correlation analysis, exploratory factor analysis and confirmatory factor analysis. The purpose of the Step 7 is to revise and refine the items of the P-FTL as needed to derive the final psychometrically sound FTL consisting of adequate estimates of reliability, homogeneity, and validity and with a stable factor structure and/or model fit.

Key points
1. Full psychometric testing of the P-FTL among individuals from the target population to:
   - Revise and refine the items of the final version of the instrument in the TL.
   - Establish internal consistency reliability (or sensitivity and specificity), stability reliability, homogeneity, construct-related validity, criterion-related validity, factor structure and model fit of the instrument.
2. Use at least 10 subjects per item of the instrument for general psychometric approaches (scale and item analysis, Pearson’s correlations and exploratory factor analysis).
3. Use 300–500 subjects for confirmatory factor analysis or conduct a power analysis.

Example of a project to translate, adapt and validate a research instrument

A project to translate, adapt and cross-validate an instrument for cross-cultural research may take several years; and it is normally conducted using more than one study to adhere to the recommended methodological approaches described above. One study might set as its initial goal to translate, adapt and cross-validate a research instrument using Steps 1, 2, 3, 4 and 5 only. In a second study, the researchers might set a single goal to establish the preliminary psychometrics of the translated instrument with bilingual participants using Step 6. Then, in a third study, the researchers’ goal might be to establish the initial full psychometric properties of a translated instrument in a sample of the target population of interest using the approaches described in Step 7. Depending on the psychometric approaches used in this third study, other studies might be necessary to continue the development and psychometric evaluation of the translated instrument. To illustrate the use of the methodological steps to translate, adapt and cross-validate an instrument and to evaluate the preliminary and initial full psychometric properties of an instrument, we present an example of a project that used two studies to adhere to the recommended guideline.

Study one: cross-cultural equivalence and psychometric properties of the Portuguese version of the depressive cognition scale

In this study [6], the depressive cognition scale (DCS) was translated from English into Portuguese using Steps 1 and 2, and
back-translated from Portuguese into English and cross-culturally validated using Steps 3 and 4. Preliminary psychometric evaluation of the scale was conducted with a bilingual sample using Step 6. Note that Step 5, important to determine clarity of the instructions, response format and sentence structure of the items, was not done because the committee was comprised of three members whose mother language was Portuguese who were convinced that all those aspects of the scale were completely clear. The DCS was originally developed in English to measure depressive cognitions [32]. The theoretical basis for the development of the scale was Beck’s theory of depression and Erickson’s theory of psychosocial development. The DCS consists of eight items on a 6-point Likert-type scale ranging from 0 (strongly disagree) to 5 (strongly agree). Each item of the scale measures a specific cognition: hopelessness, helplessness, purposelessness, powerlessness, worthlessness, loneliness, emptiness and meaninglessness.

Using Steps 1 through 4, the DCS English version was translated into Portuguese by two bilingual translators who were fluent in both English and Portuguese languages to generate two versions of the translated scale. The Portuguese versions of the scale were blindly back-translated into English by two different translators who never saw the original version of the DCS in English. The two versions of the translated scale were compared with each other, and each one of these versions was compared with the original English version of the scale to determine its conceptual, semantic and content equivalence using a panel of three Brazilian bilinguals and an American monolingual expert in the content area with consultation with the translators who participated in the translation and back-translation of the versions of the scale. Ambiguities and discrepancies regarding conceptual and semantic equivalence on two items that measured emptiness and purposelessness were discussed and resolved by the committee members. A final version of the translated scale in Portuguese was derived and named ‘Escala Cognitiva de Depressão (ECD).’

As we stated previously, we skipped Step 5 and proceeded to Step 6 to evaluate the preliminary psychometrics of the Portuguese version of the scale (ECD), with a bilingual sample of individuals from the general population, mostly students and faculty members of a major Brazilian university. This sample was chosen because of the anticipated difficulty to approach and recruit individuals from the target population of interest (i.e. individuals with diabetes mellitus). We used the recommended sample size of at least 10 subjects per item of the scale. The sample consisted of 82 Brazilian adults with diabetes mellitus. The estimate of internal consistency reliability was a Cronbach’s alpha of 0.88. Scale and item analysis indicated that the inter-item correlation coefficients ranged from 0.37 to 0.69 and the item-to-correlation coefficients ranged from 0.51 to 0.71. Exploratory factor analysis indicated that the ECD was unidimensional, explaining 56.73% of its item variance, and had factor loadings ranging from 0.60 to 0.80 and communality values ranging from 0.36 to 0.67. In addition, the ECD total score was statistically significantly correlated with the Portuguese version of the Beck Depression Inventory ($r = 0.24$, $P < 0.05$). The study findings further supported the reliability, homogeneity and construct-related validity of the ECD among Brazilians with diabetes mellitus.

**Conclusions**

The diversity of the population worldwide shows a great need for cross-culturally validated instruments or scales. Translation, adaptation and validation of an instrument or scale for cross-cultural research is time-consuming and requires careful planning and adoption of rigorous methodological approaches to derive a reliable and valid measure of the concept of interest in the target population. This scholarly paper has reviewed and incorporated the highly recommended methodological approaches in a clear and user-friendly guideline. The adoption of symmetrical translation using centring process will lead to more accurate adaptation and cross-cultural validation of a translated instrument. The steps of the proposed guideline provide clear directions to cross-culturally validate research instruments or scales. Choosing the right translators and committee members is key aspect that must be considered to enhance the quality of the translation, back-translation and cross-validation of an instrument or scale. Pilot testing of a translated instrument or scale among participants whose language is the TL of the instrument to evaluate the instructions, the items and the...
response format of the instrument for clarity also enhances the quality of the final version of the translated instrument. Finally, using well-established approaches to test the preliminary psychometric properties of the translated instrument or scale among bilingual individuals and full psychometrics of the translated instrument or scale among individuals from the target population of interest will derive a reliable and valid scale in the TL of interest.

References