THEORETICAL AND METODOLOGICAL ASPECTS FOR THE CULTURAL ADAPTATION AND VALIDATION OF INSTRUMENTS IN NURSING

Flávia de Oliveira¹, Tatiane Prette Kuznier², Cristiane Chaves de Souza³, Tânia Couto Machado Chianca⁴

Abstract

Objective: to identify in the literature references about methodology used in studies of cultural adaptation and validation of instruments in Nursing.

Method: it is an integrative review of the literature based on a bibliographic survey in the LILACS, BDENF, IBECS, SciELO and PubMed databases, in August and September of 2016.

Results: a total of 28 articles were analyzed. The reference that has been used for the cultural adaptation of instruments with more frequency (22-78.57%) is the one proposed by Beaton, Bombardier, Guillemin and Ferraz (2007); Beaton, Bombardier, Guillemin e Ferraz (2000) and Guillemin, Bombardier, Beaton. (1993). These authors propose five steps: translation, synthesis, back-translation, committee of judges and pre-test. The validation is classified into three categories: content, criterion, and construct validity. This study has shown that the most used criteria for the validation of instruments have been the validation of content (18-64,28%), construct (13-46,43%) and face validation (9-32,14%).

Conclusion: it has been valued the judicious following of method with the use of reliable and valid instruments in the researchers developed in nursing. In this sense, the present study dealt with references used for the cultural adaptation and validation of measurement instruments. The most used references were about the types of validation applied. It was concluded that methods should be stimulated to guarantee the reliability and validity of the instruments were identified in the study.


ASPECTOS TEÓRICOS Y METODOLÓGICOS PARA LA ADAPTACIÓN CULTURAL Y LA VALIDACIÓN DE INSTRUMENTOS EN LA ENFERMERÍA

Resumen

Objetivo: identificar en la literatura las referencias metodológicas utilizadas en estudios de adaptación cultural y la validación de instrumentos en la Enfermería.

Método: se trata de una revisión narrativa de la literatura realizada a partir de un análisis bibliográfico en las bases de datos LILACS, BDENF, IBECS, SciELO y PubMed, en agosto y septiembre del 2016.

Resultados: se analizó un total de 28 artículos. El referente metodológico que ha sido utilizado para la adaptación cultural de instrumentos con mayor frecuencia (22-78,57%) es el propuesto por Beaton, Bombardier, Guillemin y Ferraz (2007); Beaton, Bombardier, Guillemin y Ferraz (2000) y Guillemin, Bombardier, Beaton. (1993). Esos autores proponen cinco etapas: traducción, síntesis, retrotraducción, comité de jueces y pretest. La validación es clasificada en tres categorías: validación de contenido, criterio y constructo. Este estudio señaló que los criterios más utilizados para la validación de instrumentos han sido la validación de contenido (18-64,28%), constructo (13-46,43%) y la validación de cara (9-32,14%).

Conclusión: en las investigaciones desarrolladas en la enfermería ha sido valorizado el seguimiento del método criterioso con el uso deinstrumentos confiables y válidos. En este sentido, el presente estudio trató de las referencias empleadas para la adaptación cultural y la validación de instrumentos de medida. Se identificaron en los trabajos los referentes metodológicos más empleados, los tipos de validación utilizados y los métodos que deben ser estimulados para garantizar la confiabilidad y validad de los instrumentos.

INTRODUCTION

In recent years, the development of researches to obtain valid and reliable instruments capable of measuring certain phenomena in the health area has been monitored. The need to assess constructs led Nursing to appropriate the concepts of Psychometrics and Cultural Adaptation for the elaboration, adaptation and validation of instruments that contribute simultaneously to the improvement of the care provided and to the quality of life.

It is true that, for an instrument to measure a construct, it must be valid, trustworthy and reliable. The process of constructing an instrument is often more expensive when compared to the cultural adaptation of another instrument previously known. It is known that the majority of instruments for measuring health-related psychosocial variables are published in English and are targeted to populations who speak this language.

Thus, in order to use an instrument considered valid, stable, with good internal agreement, which evaluates the phenomenon of interest studied, but is in another language, it is recommended that a cultural adaptation and validation is performed for the reality in which one wishes to apply it.

The process of cultural adaptation has two components: the translation of the material from the original language and its adaptation to the target language. The translation of the material from the original language is the literal translation of the sentences from one language to another. Then, the actual adaptation is done, which involves the steps of synthesis, back-translation, committee of judges and pre-test.

After the process of cultural adaptation of an instrument, its psychometric measures should be validated in order to verify if the characteristics of the original instrument were preserved through a content, criterion and construct validation. Maintaining the psychometric characteristics of the instrument means that it can be able to measure exactly what it proposes to measure in different cultures. In this sense, it is necessary for the researcher to use a methodological course that meets this objective.

Brazilian Nursing has developed studies with the purpose of performing translation, cultural adaptation and validation of the instruments developed in other cultures. However, there is still no consensus on the methodological framework for conducting the cultural adaptation and validation of instruments. It has been observed that studies designed to adapt and validate measurement instruments use different methodological paths, which raises doubts about which methodological reference is more reliable.

In view of the above, it is questioned: which are the methodological references most used in the studies of cultural adaptation and validation of instruments in Nursing? Thus, this research was designed with the objective of identifying, in the literature, the references about the methodology used in studies of cultural adaptation and validation of instruments in Nursing.

METHOD

It is a integrative review of literature constituted by the analysis of published literature, in the interpretation and critical analysis on the subject. The narrative review has a fundamental role for the continuing education, favoring the acquisition and updating of knowledge, including the methodological references used by researchers to carry out the cultural adaptation and validation of instruments of measures used in studies in Nursing.

The data were collected in August and September 2016. The search, considered the publications of the last ten years, in the LILACS (Latin American and Caribbean Health Sciences Literature), BDENF (Nursing Database), IBRACEN (Bibliographical Index of Health Sciences), SciELO (Scientific Electronic Library Online) and PubMed (U.S. National Library of Medicine) databases. In order to proceed with the search in the databases, controlled descriptors contained in the Descriptors in Health Science (DeCS) of the Virtual Health Library (VHL) and MeSH (Medical Subject Headings), keywords and Boolean operators combined were used, obtaining the search strategies shown in table 1:
The recovered studies were initially evaluated by title and abstract and those pertinent to the proposed objective were selected. The inclusion criteria used were: the articles made available in full, published in the last five years, in Portuguese or English, having as objective to adapt and validate instruments used in Nursing, and to explain the methodological framework adopted for cultural adaptation and validation. For the extraction of the data of interest of the study, an instrument was developed for the analysis and characterization of the selected articles containing information about the reference about methodological aspects used for the cultural adaptation and validation of the instruments.

**RESULTS**

There was an initial population of 118 publications that were submitted to the critical analysis of the researchers. A sample of 28 publications met the inclusion criteria of the study. Table 2 describes each publication according to author and year of publication, periodical of publication and the reference of the methodology used for cultural adaptation and/or validation of the instruments.

**Table 2 - Published articles that deal with the cultural adaptation and validation of instruments in Nursing and the methodological references used. Belo Horizonte, MG, 2016. (n=28)**

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<tr>
<th>Author and year</th>
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<td>Rev Bras Enferm</td>
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<td>Reichenheim ME, Moraes CL, 200711</td>
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<td>Guillemin F, Bombardier C, Beaton D, 19935</td>
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<td>Beaton DE, Bombardier C, Guillemin F, Ferraz MB, 20006</td>
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<td>Hirsch CD, Barlem ELD, Barlem JGT, Dalmolin GL, Pereira LA, Ferreira AG, 201613</td>
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<td>Rev Latino-am Enfermagem</td>
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<td>Beaton DE, Bombardier C, Guillemin F, Ferraz MB, 20006</td>
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<td>Silva MC, Peduzzi M, Sangaleti CT, Silva D, Agreli HF, West MA, et al., 201614</td>
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<td>Rev Saúde Pública</td>
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<td>Beaton D, Bombardier C, Guillemin F, Ferraz MB, 200715</td>
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<td>Cordeiro VS, Botelho SE, Silva FL, Turner NE, Pinheiro RV, Duarte CLM, 201616</td>
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<td>BMC Med Res Methodol</td>
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<td>Beaton D, Bombardier C, Guillemin F, Ferraz MB, 200715</td>
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<td>Zhao Y, Li Y, Zhang X, Lou F, 201523</td>
<td>Health Qual Life Outcomes</td>
<td>Brislin RW, 198624</td>
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<td>Almutary H, Bonner A, Douglas C, 201525</td>
<td>BMC Nephrol</td>
<td>Brislin RW, 197026</td>
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<td>Schardosim JM, Ruschel LM, Motta GCP, Cunha MLC, 201427</td>
<td>Rev Latino-am Enfermagem</td>
<td>Beaton D, Bombardier C, Guillemin F, Ferraz MB, 200715</td>
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<tr>
<td>Campos MCT, Marziale MHP, Santos JLF, 201332</td>
<td>Rev Esc Enferm USP</td>
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<td>Author and year</td>
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<td>Bernardino E, Dyniewicz AM, Carvalho KLB, Kalinowski LC, Bonat WH, 201335</td>
<td>Rev Latino-am Enfermagem</td>
<td>Guillemin F, Bombardier C, Beaton D, 19935</td>
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<td>Paschoalin HC, Griep RH, Lisboa MTL, Mello DCB, 201336</td>
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<td>Feijó MK, Ávila CW, Souza EM, Jaarsma T, Rabelo ER, 201240</td>
<td>Rev Latino-am Enfermagem</td>
<td>Guillemin F, Bombardier C, Beaton D, 19935</td>
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The analysis of table 2 allows to infer that, in some studies, more than one reference of the methodology was adopted for the cultural adaptation of the instruments. It should be highlighted that the main references used were Beaton, Bombardier, Guillemin and Ferraz, mentioned in 11 studies (39.29%), followed by Guillemin, Bombardier and Beaton, in six studies (21.43%) and Beaton, Bombardier, Guillemin and Ferraz in five studies (17.86%). Since it is a group of researchers that have been recognized in the accomplishment of studies employing this methodology, a total of 22 studies (78.57%) used some of their references to carry out the process of cultural adaptation of the instruments.

Regarding the validation of the instruments, a majority of 18 studies (64.28%) performed the validation of content, followed by 13 studies (46.43%) in which the validation of construct was used and nine studies (32.14%) that used the validation of face. The most mentioned methods for obtaining the validity of a measure by psychometrists are the construct validity, criterion validity and content validity. It was verified that the criterion validity was only performed in one study, however, authors refer to...
the impossibility of performing this validation in view of the scarcity of instruments that measure the studied variable, a fact that, although not mentioned in other studies of this sample, may have extended to other studies.

**DISCUSSION**

This study is limited to point out the main references about the methodology used by researchers to direct studies of cultural adaptation and validation of instruments in Nursing and, thus, to contribute to the direction of research correlated to the theme.

**Cultural adaptation of instruments in Nursing**

The cultural adaptation of a questionnaire, instrument or scale for use in a new country, culture or language requires an exclusive methodology in order to obtain equivalence between the source and target languages. This methodology is a complex task that requires a high degree of planning and scientific-methodological rigor regarding the maintenance of the original content, the psychometric characteristics and the validity for the population for which it is intended. The establishment of equivalence of measurement is a prerequisite for any comparisons between groups.

Although there is no consensus regarding the best method to be used to perform the cultural adaptation of instruments, in this study it was observed that most of the studies (22-78.57%) use, as a reference of the methodology, the steps proposed by Beaton, Bombardier, Guillemin and Ferraz; Beaton, Bombardier, Guillemin and Ferraz and Guillemin, Bombardier, Beaton. The steps indicated by these authors are: translation, synthesis, back-translation, committee of judges and the pre-test. Before initiating the process, you must obtain the authorization of the authors who own the copyright of the instrument to carry out the research.

The first step, the translation, aims to obtain a consensual version that preserves, to the maximum, the same meaning of each item from the source language to the language in which the instrument is to be applied. It is performed by, at least, two highly qualified independent translators with mastery of the language and culture of the source instrument, which are preferably native to the target language. The two translators should have different profiles, the first being informed about the purpose of the study. In contrast, the second translator should not be aware of the purpose of the study. At the end of this step, two translations are obtained, being described as T1 and T2.

After the two versions of the translations, the synthesis of T1 and T2 is performed by an observer/researcher and by the translators, giving rise to a common translation described as T12. All subsequent steps will be performed based on this synthesis version, the T12 consensus version.

Thus, the consensus version is back-translated back to the source language of the instrument, which is called back-translation. This is to verify if the meanings and/or contents between the original instrument and the translation into the target language contemplate the same meanings, thus guaranteeing quality and consistency to the translation.

Methodologically, this step must be performed from the same number of translators established for the translation, independently. The translators must be fluent in the source language of the instrument, that is, natives of the country of origin of the instrument, should not know the original version of the instrument being adapted and not know the objectives of the study. The purpose is to verify if the version made with the back-translation is similar to the original version.

At the end of the back-translation step, the original version and the translated version should be compared and the divergences discussed by the researcher with the translators. The objective is to correct possible errors that compromise the meanings of the items, as well as to review mistaken interpretations that could compromise the consistency of the instrument.

Recently, an experimental study sought to evaluate the contribution of the back-translation and the judges’ committee to the psychometric properties of translated and adapted instruments. The study showed that the back-translation has a moderate impact, while the multidisciplinary judges’ committee helps ensure content accuracy.

This study also recommends that for the translation and adaptation of “robust” instruments, there should be a multidisciplinary committee of judges composed of bilingual experts. In this case, the back-translation would not necessarily have to be performed, thus reducing the costs and time of the research. However, it is important to emphasize that this is a first experimental evidence, and other studies are necessary to verify if the back-translation could really be omitted without harming the process.

After the back-translation, the judges’ committee is responsible for consolidating all the versions
of the instrument and obtaining a linguistically adapted final version. Thus, the purpose of this step is to ensure that the entire content of the instrument is translated and adapted while preserving the instrument’s equivalences between the original version and the new version.\textsuperscript{5,6}

There are different types and procedures of equivalence proposed for the cultural adaptation of instruments, but the committee of judges must necessarily perform the analysis of conceptual and item equivalence, semantics, idiomatic and cultural. The conceptual and item equivalence has the purpose of exploring whether the different domains and/or concepts understood by the original instrument in defining the concepts of interest would be relevant and pertinent to the new context to which it is being adapted.\textsuperscript{11} That is, the relevance of the items within the domains and/or concepts is verified, since they can vary according to the culture studied.\textsuperscript{37}

The semantic equivalence correlates with the ability to transfer the meaning of the words from the original instrument to the new version, thus providing an analogous effect in both cultures. It is performed by comparing the original version and the consensus version, emphasizing the referential (denotative) and general (connotative) meaning of the instrument.\textsuperscript{37} Some authors use the methodology of collecting focal group data in this step to assess the comprehension of each item of the instrument in question.\textsuperscript{49-50}

The idiomatic equivalence assesses the colloquial expressions to ensure that the idiomatic expressions represent the same equivalence between the two languages (source and target). It should be highlighted that this step does not aim at deleting intra-linguistic differences, but at transposing barriers that impede the intercultural dialogue and the possibility of retrieving as many elements as possible from lexical meanings.\textsuperscript{51}

The cultural equivalence represents the situations observed in the version of origin that need to be adjusted to the cultural context in which the adaptation is objectified. It relates to all the expressions portrayed in the original version that should be consistent with the cultural context in the target language. Some items may be modified or even deleted.\textsuperscript{5}

After analyzing these equivalences, at the end of this phase will be obtained the pre-final version that will be submitted to the pre-test. This is performed from the application of the instrument of the pre-final version translated and adapted in a sample of 30 to 40 subjects, to verify the comprehensibility, pertinence and cultural relevance.\textsuperscript{6-52}

The subjects answer the questionnaire and then are interviewed to see if they understood the meaning of the questions and whether they answered properly. If there are doubts on the part of the respondents, it is possible to return to the committee of judges for changes in the questions. Questions that have 15\% or more cases of doubts, or that are not understood, should be reviewed by the judges’ committee and reapplied to the respondents.\textsuperscript{53}

In order to conclude the process of cultural adaptation of instruments, it is relevant to present all the reports and forms used during the process to the authors who hold the instrument’s copyright. However, it is not up to these authors to modify the content, since it is expected that, with all the steps of the process of cultural adaptation, a reasonable translation will have been achieved.

Validation of instruments in Nursing

After the process of translation and cultural adaptation of an instrument, the psychometric properties should be assessed in order to verify if the characteristics of the original instrument were maintained. It is considered that the translated and culturally adapted version should present similar performance to the original.\textsuperscript{2,6}

The process used to verify the instrument performance is the validation. The validation of instruments is about the robustness of the study, that is, if there is evidence that the methods will actually measure what was intended.\textsuperscript{52} That is, it involves a research process in which the validity evidences that support the adequacy, meaning and usefulness of the decisions made based on the inferences made from the scores obtained from the test are sought.\textsuperscript{54}

In 1954, the American Psychological Association (APA), with the American Educational Research Association (AERA) and the National Council on Measurement in Education (NCME), published the first version of the North American standards for tests. In this document, the validity was classified into three categories: content, criterion, and construct validity.\textsuperscript{54} In Nursing, these categories have been used to guide the process of validation of adapted instruments and demonstrate their validity.

The validity of content refers to how much a test can be a representative sample of the behaviors that are the expression of the latent trace in question, that is, if the items of the test constitute a representative sample of the universe of items of the construct.\textsuperscript{1} It is not determined by statistical measures and tends to be evaluated from the perception
of judges or experts who judge to what extent the instrument is representative of what one intends to measure. The judges will analyze the alignment of the instrument to the theoretical assumptions and it can be performed during the cultural adaptation at the judges’ committee step. It is fundamental in the process of defining the instrument, since all the statistical measures used in the other validation stages depend on this definition.⁵⁵-⁵⁶

Regarding the number of participants, the literature presents controversies. A study⁵⁷ recommends a minimum of five and a maximum of ten people participating in this process. Other authors suggest from six to 20 subjects, being composed of a minimum of three individuals in each group of professionals selected to participate.⁵⁸ However, the characteristics of the instrument, the training, the qualification and the availability of the required professionals should be taken into account. The judges should receive an explanatory letter and a questionnaire developed specifically for this evaluation.⁵⁹

In order to quantify the degree of agreement between the judges, they independently assess the objective relationship between the items and their relevance, using the agreement percentage calculation or the Content Validity Index (CVI).⁶⁰ The agreement percentage is the simplest measure of inter-observer agreement.⁶¹ The formula used is described below:

\[
\text{% agreement} = \frac{\text{Number of participants who agree}}{\text{Total number of participants}} \times 100
\]

To determine the CVI, the judges independently assess the objective relationship between the items and their relevance.⁶⁰ The proportion of judges who agree on a particular aspect of the instrument and its items is measured.⁶² A Likert-type scale of relevance is used: 1=not relevant, 2=little relevant, 3=relevant, 4=very relevant. The analysis is performed by the content validation index (CVI) defined by the proportion of items classified as relevant or very relevant by the judges. Items that score 1 or 2 should be deleted or reviewed.⁶⁰

\[
\text{CVI} = \frac{\text{number of answers 3 or 4}}{\text{total number of answers}}
\]

In order to evaluate the instrument as a whole, there is no consensus in the literature. It is necessary that the researchers describe, in the studies, the method used. Usually, there are three forms: the average of the proportions of the items considered relevant by the judges; the average of the values of the items calculated separately, that is, all the CVIs calculated separately and divided by the number of items considered in the assessment; divide the total number of items considered relevant by the judges by the total number of items.⁵²

Moreover, it is necessary to stipulate the acceptable rate of agreement between the judges. In the process of assessing the individual items, the number of judges must be considered, and with the participation of five or fewer subjects, a 100% agreement must be obtained. If there are six or more judges, an agreement of 0.90 or more is suggested.⁵²,⁵⁷

The next step, the criterion validity, represents the degree to which measures agree with other approaches that measure the same characteristic. In the criterion validity, it is sought to establish relations between the scores of the instrument in question with some external criterion.⁴,⁵² The criterion validity can be considered as the degree of effectiveness that the instrument has in predicting a specific performance.⁴⁵

Criterion validity tests evaluate whether scores are systematically related to one or more outcome criteria using measures and data independent of the scale in question. It is verified if the quality of the measurement method corresponds to another observation that correctly measured the same phenomenon.²,⁶²

It is necessary to have the availability of a reliable and valid criterion with which the measures of the instrument in question can be compared. Thus, a gold standard is sought, that is, a scientific evidence of a true and reliable measurement.⁶²

However, it is not always possible to find a gold standard. Thus, the criterion validity can be
verified through predictive validity, with which instruments can be tested for predicting some clinical outcome. Another form of evaluation in the absence of a gold standard, proposes the creation of a criterion group composed of ten participants, at random. The data extracted from this group will be compared with the data obtained in individual interviews, using the Pearson correlation.

The construct or concept validity is the most fundamental form of validity of the instruments, since it is the direct way of verifying the hypothesis of the legitimacy of behavioral representation. It is related to the degree to which an instrument measures what it was designed to measure. It is the property of the measurement method that correctly measures the underlying construct, which can contain several attributes.

The necessary evidence to succeed the construct validation is obtained by means of a series of interrelated studies aiming at the empirical verification of the theoretical constructions on the variables to be measured.

It is evaluated internally, checking the factorial validity, when the items used to measure the same attribute correlate better with each other than with items measuring other attributes (factorial analysis); and also by the internal consistency, when several items measuring the same attribute tend to provide the same information and thus closely correlate with one another.

Externally, the construct validity is evaluated by convergent validity and divergent validity. The convergence presupposes a significant correlation between the phenomenon measured by the instrument under study and other variables with which such phenomenon should be related. The divergence verifies the non-correlation of the variables with which it should differ. It can be said that the convergent would be equivalent to the concept of sensitivity, while the divergent, of specificity.

CONCLUSION

This review contributes to the unveiling of the references about the methodology used in the process of cultural adaptation and validation of instruments in Nursing. In the process of cultural adaptation of instruments, the study showed that the methodological reference that has been most frequently used (22-78.57%) is the one proposed by Beaton, Bombardier, Guillemin and Ferraz; Beaton, Bombardier, Guillemin and Ferraz; Beaton, Bombardier, Guillemin and Ferraz; Beaton, Bombardier, Guillemin and Ferraz; Beaton, Bombardier, Guillemin and Ferraz.

For the validation of instruments, the most used criteria have been the validation of content (18-64, 28%), validation of construct (13-46,43%) and the validation of face (9-32,14%).

It should be highlighted that, in the process of cultural adaptation, the back-translation step requires more scientific evidence that contributes to its effectiveness in the process. Regarding the validation, although the literature points out those different criteria are used to state that an instrument is valid, it is proposed, according to the criteria adopted by psychometrists, that it is minimally subject to content, criterion and construct validity.

This study does not intend to wear out the subject, but rather to be a guiding force for research involving this theme, considering the importance of following a judicious method in order to guarantee the reliability and validity of the instruments that are used in Nursing studies. The references about the methodology most used currently for the cultural adaptation that involves translation and the adaptation to the target language in different steps and then the validation with the analysis of the psychometric properties of the measurement instruments used in nursing research were presented.

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