



# CROSS-CULTURAL ADAPTATION AND ASSESSMENT OF THE MEASUREMENT PROPERTIES OF THE OSTOMY SELF-CARE INDEX IN THE BRAZILIAN CULTURE

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#### **ABSTRACT**

**Objective:** to adapt and evaluate the measurement properties of the Ostomy Self-Care Index in the Brazilian culture.

**Method:** methodological study carried out in a public hospital in Campinas, Brazil. For cross-cultural adaptation, the following stages were followed: translation and synthesis; back-translation; evaluation of content validity; pre-testing and evaluation of the final version by the author of the original instrument. The Content Validity Index, Modified Kappa coefficient, and Content Validity Ratio were used for content validity. The evaluation of the measurement properties followed the recommendations of the Study Design checklist for Patient-reported outcome measurement instruments. Reliability was tested through internal consistency and construct validity through confirmatory factor analysis and the testing of three hypotheses. Six specialists and 160 patients participated in the study. Data collection took place between October 2020 and June 2022.

**Results:** the stages of cross-cultural adaptation were carried out without difficulty. The internal consistency assessment obtained values within the established range. The confirmatory factor analysis of Sections A, B, and D of the OSCI (Brazilian version) showed satisfactory results after excluding two items. The hypothesis test partially corroborated one of the hypotheses and confirmed the other two. Section C could not be evaluated as it was intended only for patients with complications (n=66).

**Conclusion:** Sections A, B, and D of the Brazilian version of the OSCI demonstrated evidence of structural construct validity and reliability and can be used in both clinical and scientific practice.

**DESCRIPTORS:** Translation. Validation study. Ostomy. Self care. Nursing. Enterostomal therapy.

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# ADAPTAÇÃO TRANSCULTURAL E AVALIAÇÃO DAS PROPRIEDADES DA MEDIDA DO OSTOMY SELF-CARE INDEX NA CULTURA BRASILEIRA

#### **RESUMO**

**Objetivo:** adaptar e avaliar as propriedades da medida do *Ostomy Self-Care Index* na cultura brasileira. **Método:** estudo metodológico, realizado em um hospital público de Campinas, Brasil. Para a adaptação transcultural, seguiram-se os estágios: tradução e síntese; retrotradução; avaliação da validade de conteúdo; pré-teste e avaliação da versão final pelo autor do instrumento original. Para a validade de conteúdo foi utilizado o Índice de Validade de Conteúdo, coeficiente Kappa Modificado e *Content Validity Ratio*. A avaliação das propriedades da medida seguiu as recomendações do *Study Design checklist for Patient-reported outcome measurement instruments*. Foram testadas a confiabilidade, através da consistência interna, e a validade de construto, por meio da análise fatorial confirmatória e teste de três hipóteses. Participaram da pesquisa seis especialistas e 160 pacientes. A coleta de dados ocorreu entre outubro de 2020 a junho de 2022.

**Resultados:** os estágios da adaptação transcultural foram realizados sem dificuldades. A avaliação da consistência interna obteve valores dentro do estabelecido. A análise fatorial confirmatória das Seções A, B e D do OSCI (versão brasileira) apresentou resultados satisfatórios após a exclusão de dois itens. O teste de hipóteses corroborou parcialmente uma das hipóteses e confirmou as outras duas. A Seção C não pode ser avaliada pois era destinada somente a pacientes com complicações (n=66).

**Conclusão:** as Seções A, B e D da versão brasileira do OSCI demonstraram evidências de validade de construto estrutural e confiabilidade e podem ser utilizadas na prática clínica e científica.

**DESCRITORES:** Tradução. Estudos de validação. Estomia. Autocuidado. Enfermagem. Estomaterapia.

# ADAPTACIÓN TRANSCULTURAL Y EVALUACIÓN DE LAS PROPIEDADES DE MEDICIÓN DEL OSTOMY SELF-CARE INDEX EN LA CULTURA BRASILEÑA

#### **RESUMEN**

**Objetivo:** adaptar y evaluar las propiedades de medición del *Ostomy Self-Care Index* en la cultura brasileña. **Método:** estudio metodológico realizado en un hospital público de Campinas, Brasil. Para la adaptación transcultural se siguieron las siguientes etapas: traducción y síntesis; retrotraducción; evaluación de la validez de contenido; pre-test y evaluación de la versión final por el autor del instrumento original. Para la validez de contenido se utilizaron el Índice de Validez de Contenido, el Coeficiente Kappa Modificado y el Coeficiente de Validez de Contenido. La evaluación de las propiedades de medición siguió las recomendaciones del *Study Design checklist for Patient-reported outcome measurement instruments*. La fiabilidad se comprobó mediante la consistencia interna y la validez de constructo mediante el análisis factorial confirmatorio y la comprobación de tres hipótesis. Seis especialistas y 160 pacientes participaron en el estudio. Los datos se recogieron entre octubre de 2020 y junio de 2022.

**Resultados:** las etapas de la adaptación transcultural se realizaron sin dificultad. La evaluación de la consistencia interna obtuvo valores dentro del rango establecido. El análisis factorial confirmatorio de las secciones A, B y D del OSCI (versión brasileña) mostró resultados satisfactorios después de excluir dos ítems. La prueba de hipótesis corroboró parcialmente una de las hipótesis y confirmó las otras dos. La sección C no pudo ser evaluada por estar destinada solamente a pacientes con complicaciones (n=66).

**Conclusión:** las secciones A, B y D de la versión brasileña del OSCI han demostrado evidencia de validez de constructo estructural y fiabilidad y pueden ser utilizadas en la práctica clínica y científica.

**DESCRIPTORES:** Traducción. Estudio de validación. Estomía. Autocuidado. Enfermería. Estomaterapia.

#### INTRODUCTION

Surgery for an elimination ostomy, whether intestinal or urinary, is a complex process in which patients have to face a number of challenges. Initially, in the preoperative period, they will have to deal with the suffering and fear after being diagnosed with a serious illness and, after surgery, with the radical changes to their self-image and activities of daily living related to the presence of the stoma<sup>1–2</sup>, with consequent impairment of their quality of life (QoL)<sup>1–3</sup>.

It is precisely at this delicate moment that patients and their families, in addition to managing their emotions, need to begin an adaptation process<sup>2–3</sup>. Some patients, depending on the characteristics of their stoma and possible complications, in addition to learning how to handle the main equipment involved in stoma management, will also have to use adjuvant products to help with their care<sup>3</sup>. Therefore, in order for the individual to be able to safely handle all these technologies, it is necessary to develop new skills related to self-care<sup>2–3</sup>.

Self-care can be described as the practice of activities that individuals initiate and perform on their own behalf to maintain their life, health and well-being<sup>4</sup>. In relation to the ostomy, it can be understood as the person's ability to apply care management skills to the stoma<sup>2</sup> and the teaching and learning process is fundamental for self-care to be developed<sup>2–5</sup>. In this context, guidelines shared by qualified professionals, who are usually stoma nurses or nurses trained by them, are essential for patients to acquire knowledge about their stoma and the skills needed to maintain them<sup>2–6</sup>.

Well-guided individuals with a support network feel more empowered and secure to care for themselves and their ostomy and lead independent and autonomous lives<sup>7,8</sup>. It is also important to note that knowledge about possible complications leads to better prevention, early detection of complications, and a more agile search for a referral service<sup>2–3</sup>. To this end, the use of valid and reliable instruments to evaluate patients' level of self-care is essential so that professionals can formulate the appropriate diagnosis and interventions<sup>2</sup>.

The Ostomy Self-Care Index (OSCI) is an instrument developed in Italy in 2018 with the aim of evaluating the self-care of people with intestinal and urinary elimination stomas<sup>5</sup>, through 32 items distributed into four sections: A - Self-Care Maintenance, with nine items (1 to 9); B - Self-Care Monitoring, eight items (10 to 17); C - Self-Care Management, with five items (18 to 22) and D - Self-Care Confidence, with ten items (23 to 32). Each section has a standardized score from 0 to 100, with higher scores indicating greater self-care<sup>9</sup>. According to self-care scales used in other populations, a score ≥70 is considered adequate self-care<sup>9</sup>.

The construct validity of the original instrument was evaluated using exploratory factor analysis and testing the following hypothesis: the higher the self-care scores, the higher the QoL scores. This construct was measured using the Stoma Quality of Life Questionnaire (STOMA-QoL)<sup>5–10</sup>. The results showed a positive and statistically significant correlation between each of the OSCI subscales and QoL scores<sup>5</sup>. In terms of reliability, all the subscales achieved Cronbach's alpha values above 0.93, ranging from 0.93 to 0.96<sup>5</sup>.

The OSCI was constructed with recognized methodological rigor, and the evaluation of its measurement properties showed that it has evidence of validity and reliability and can therefore be used in clinical practice. In the Brazilian culture, there is no instrument to measure the self-care of individuals with elimination stomas. It is believed that the availability of the OSCI in our culture will help professionals to adequately evaluate the level of self-care of patients with elimination stomas and, based on this, design better care and educational strategies for each of them, with a positive impact on their QoL.

The aim of this study was to adapt and evaluate the measurement properties of the Ostomy Self-Care Index in the Brazilian culture.

#### **METHOD**

The cross-cultural adaptation and validation process of the OSCI for the Brazilian context was authorized by the author of the original instrument and the study was approved by the Research Ethics Committee of the State University of Campinas.

This is a methodological study carried out between October 2020 and June 2022. The research was structured into two phases: cross-cultural adaptation and evaluation of the measurement properties.

# 1st phase - Cross-cultural adaptation

For the cross-cultural adaptation process, six stages were followed: 1) translation, 2) synthesis, 3) back-translation, 4) evaluation by a committee of experts, 5) pre-test, and 6) evaluation of the final version by the author of the original instrument<sup>11–12</sup>.

The first stage was Translation, in which the original version of the instrument was translated by two Brazilians fluent in Italian. Only one of the translators was aware of the objectives of the study and, at the end of this stage, two translations were obtained (T1 and T2)<sup>12</sup>. The second stage, Synthesis (T12), was carried out by the researchers.

The T12 version was sent to two Italian translators fluent in Portuguese for the third stage, called backtranslation (BT)<sup>12</sup>. None of the translators were aware of the purpose of the study and, as a result, BT1 and BT2 were obtained<sup>12</sup>.

In the fourth stage, after signing the informed consent form, a Google® form was sent via email for evaluation of semantic equivalence (meaning of words), idiomatic equivalence (colloquial expressions), cultural equivalence (reflects whether the terms used in the original version are consistent with the experiences of the target population) and conceptual equivalence (reflects whether the items actually evaluate the construct to be measured), clarity, representativeness, and relevance, by a committee of experts.

Six experts, selected by convenience, participated in the committee. Five of them were health professionals with at least three years of clinical experience with patients with elimination stomas and four had published at least two papers in the field of ostomies or validation studies. One of the experts had had a stoma for three years and four months.

A Likert scale was used to assess equivalence, clarity, and representativeness, ranging from one (not equivalent, not clear, and not representative) to four points (equivalent, clear, and representative).

For relevance, the evaluation scale used ranged from one (unnecessary) to three points (essential). If the experts gave a score of 1 or 2 for equivalence, clarity, and relevance, or 2 points (useful, but not necessary) for relevance, they were asked to submit suggestions for changes<sup>13</sup>. All analyses were carried out using Statistical Analysis Software® (SAS), version 9.4.

After the experts' analysis, a quantitative stage began with the calculation of the Content Validity Index (CVI), the Modified Kappa coefficient, and the Content Validity Ratio (CVR), the latter being calculated based on assessments of relevance. Values above 0.80 for the CVI and 0.74 for the Modified Kappa coefficient were considered acceptable<sup>13,14</sup>. For relevance, the CVR was calculated, where a value above 0.78 was established as acceptable<sup>15</sup>.

Subsequently, a qualitative stage began, in which the suggestions made by the committee were analyzed for the items that did not reach the minimum scores established for the tests carried out. After the changes had been made, a new round of evaluation was carried out to reach a consensus<sup>12,13</sup>.

In the fifth stage, called pre-test, the pre-final version, already translated and with its content validated by the committee, was applied to 30 patients with elimination stomas to check the clarity and ease of understanding of the items and practical aspects of applying the instrument<sup>12</sup>.

The inclusion and exclusion criteria for the pre-test and evaluation of the measurement properties were the same. Participants were patients attending a public teaching hospital in the state of São Paulo, selected by convenience, aged 18 or over, who had elimination ostomies and were admitted to the surgical wards or being treated at the institution's surgery and/or stomatherapy outpatient clinics. Those who were totally dependent on family members or caregivers for the care of their stoma were excluded.

The patients were approached in person. Each patient was given an informed consent form and the pre-final version of the instrument, produced after evaluation by the expert committee. The time needed to fill in the questionnaire was measured to check its feasibility, based on the time it would take to complete the questionnaire <sup>16</sup>.

To assess usability, they were asked to answer two questions at the end of the instrument: 1) "Was it easy to understand the items in the instrument?" and 2) "Was it easy to understand and mark the answers in the instrument?" 16. For the answers, the patients had to mark an alternative on a four-point Likert scale: 1) Strongly Disagree, 2) Partially Disagree, 3) Partially Agree, and 4) Strongly Agree.

In the sixth and final stage, called Evaluation of the final version, the Brazilian version of the instrument was sent to the author of the original instrument for approval of the process carried out.

# 2<sup>nd</sup> phase - Assessment of measurement properties

The assessment of the measurement properties was carried out in a public hospital in Campinas, Brazil. This assessment followed the recommendations of the COSMIN Study Design checklist for Patient-reported outcome measurement instruments<sup>17</sup>.

After the pre-test, the final Brazilian version of the OSCI was applied to a sample of 160 patients (considering a minimum of five respondents for each item of the instrument for the factor analysis)<sup>18</sup> made up using the same criteria described in the pre-test. At this stage, the participants filled in a sociodemographic characterization form, the Brazilian version of the OSCI, and the Brazilian version of the Stoma Quality of Life Questionnaire (Stoma-QoL)<sup>1</sup>.

Patients were approached in two ways: in person and by telephone. Patients who were listed in the institution's Stomatherapy Center database were contacted by telephone. Consent to participate in the study was recorded using the Call Master® cell phone call recording software, which is free to use. Participants who were contacted by telephone and agreed to participate received a copy of the informed consent form according to their preference: by mail, or in digital format, by e-mail or via na instant message application for mobile phones.

Cronbach's alpha coefficient and composite reliability were calculated to assess reliability and values equal to or greater than 0.70 were considered satisfactory<sup>18</sup>.

For construct validity, confirmatory factor analysis was carried out and three hypotheses were tested<sup>17</sup>: 1) The higher the self-care score, the higher the quality of life score; 2) The longer the stoma, the higher the self-care score; 3) The presence of an informal caregiver reflects lower self-care scores.

Confirmatory factor analysis was carried out using structural equation models considering Partial Least Squares (PLS)<sup>19</sup> as the estimation method. Smart PLS 3.3.5 software was used to carry out these analyses.

Initially, to analyze the proposed model, the results obtained from the average variance extracted (AVE) for each of the factors in the model were evaluated. This measurement assesses the proportion of the variance of the items that is explained by the factor to which it belongs<sup>19</sup> and values greater than 0.50 indicate that the model converges to an acceptable result<sup>19</sup>.

The Fornell-Larcker criterion was then adopted, which compares the square roots of the AVE with the correlation values between the factors<sup>20</sup>. The model can be considered to have satisfactory results if the square roots of the AVE are greater than the correlations between the factors<sup>20</sup>. Cross-

loadings were also analyzed, which verify whether the factor load of a given item is higher in the factor in which it was initially allocated<sup>20</sup>. The minimum factor load considered was 0.40<sup>19</sup>.

For the hypothesis test, the distribution of the data was checked using the Shapiro-Wilk test. The correlation between the scores of the two instruments (Brazilian versions of the OSCI and the Stoma-QoL) and between the self-care scores and length of time with a stoma was checked using Spearman's correlation coefficient. The magnitude of the correlation coefficients was classified as follows: 0.1 to 0.29 (weak correlation), 0.30 to 0.49 (moderate correlation), and greater than or equal to 0.50 (strong correlation)<sup>21</sup>. The Mann-Whitney test was used to compare self-care scores with the presence or absence of an informal caregiver. Statistical Analysis Software® version 9.4 was used for all these analyses and a 5% significance level was considered.

#### **RESULTS**

# **Cross-cultural adaptation**

The translation, synthesis, and back-translation stages did not require any major changes, as there were no significant differences between the versions. In the fourth stage, in the assessment of the instrument's content validity, in the first round of evaluation by the expert committee, all the items achieved a CVI and modified Kappa coefficient within the established range, varying from 0.82 to 1.00.

However, 18 items did not reach the CVR established for the assessment of "Relevance", but only item 27 received suggestions for change by the committee. Therefore, this item was changed from "Persisting in keeping under control the condition of your stoma and surrounding skin even if it is difficult" to the version "Persisting in observing the condition of your stoma and surrounding skin even if it is difficult". After this change, the item was submitted to a second round of evaluation by the committee and achieved 100% agreement. The pre-test version was then created.

In the pre-test, the average time spent by individuals answering the questionnaire ranged from 4 to 30 minutes, with a mean of 9.06 (SD=7.16) and a median of 6.00. When assessing the instrument's usability, 93.3% (n=28) of the patients indicated that they agreed that the items and answers in the instrument were easy to understand and answer.

In the sixth and final stage, the Brazilian version of the Ostomy Self-Care Index was sent to the author of the original instrument, who approved the process with the suggestion of keeping the English name (Ostomy Self-Care Index (OSCI) - Brazilian version). The comparison between the synthesis and the final version is shown in Chart S1.

## Assessment of measurement properties

Once the cross-cultural adaptation process was complete, the evaluation of the measurement properties began with a sample of 160 patients with elimination ostomies.

The mean age of the participants was 56.8 years old (SD=14.1) and they had 7.9 years (SD=4.3) of schooling. Most were men (n=83; 51.9%), married or in a stable union (n=89; 55.6%). On average, the participants had had stomas for 2.9 years (SD=5.2), most of which were ileostomies (n=84; 52.5%), temporary (n=92; 57.5%), or associated with a diagnosis of colorectal cancer (n=98; 61.2%).

Most patients (n=90; 56.2%) stated that they had a caregiver to help with the care of the stoma, and that this role was played more by the spouse/partner (n=37; 41.1%). Regarding the presence of complications related to the stoma or peristomal skin, 66 (41.2%) patients reported that they had already had some kind of complication.

# Structural construct validity and reliability

Domains A (Self-Care Maintenance), B (Self-Care Monitoring), and D (Self-Care Confidence) of the instrument were answered by 160 participants, but domain C (Self-Care Management), which addresses any complications related to the stoma or surrounding skin, was answered by only 66 patients. Therefore, following the sample calculation, only domains A, B, and D were analyzed for their structure.

The initial model showed AVE values of less than 0.50 only for domain B (0.48). To adjust the AVE, item 16 of domain B (Self-care monitoring) was excluded, as it had the lowest factor load in this dimension (0.39). With the exclusion of this item, the AVE for domain B reached the established level (0.53).

Despite the change made, the domains had the same values and so the evaluation of the Fornell-Larcker criterion was not satisfactory. In order to adjust the criterion, item 9 of domain A (Self-care Maintenance) was excluded, as it was the item with the lowest factor load between domains A and B (0.46).

After excluding this item, the evaluation was satisfactory, as shown in Table 1.

In the evaluation of cross-loadings, the distribution reached the expected results with the exclusion of the two items (9 and 16), as shown in Table 2.

After excluding the two items (9 and 16), the AVE, composite reliability, and Cronbach's alpha values for each domain of the Ostomy Self-Care Index - Brazilian version are shown in Table 3.

# Construct validity - hypotheses testing

To test the hypotheses, we analyzed the correlation between the scores of the Brazilian versions of the Ostomy Self-Care Index and the Stoma-QoL for domains A, B, and D, as shown in Table 4.

**Table 1** - Discriminant validity according to the Fornell-Larcker Criterion of domains A, B, and D after exclusion of items 9 and 16 of the Ostomy Self-Care Index (Brazilian version). Campinas, SP, Brazil, 2022.

Domains		Domains	
	Α	В	D
A	0.82		
В	0.72	0.73	
D	0.48	0.56	0.80

**Table 2** - Factor load of the items that make up domains A, B, and D of the Ostomy Self-Care Index (Brazilian version). Campinas, SP, 2022.

Items	Domain A	Domain B	Domain D
1	0.75	0.56	0.46
2	0.69	0.54	0.48
3	0.85	0.62	0.39
4	0.86	0.60	0.32
5	0.92	0.68	0.41
6	0.83	0.54	0.31
7	0.81	0.52	0.30
8	0.87	0.67	0.48
10	0.46	0.69	0.36
11	0.30	0.62	0.41
12	0.71	0.83	0.41
13	0.75	0.83	0.39
14	0.37	0.70	0.45
15	0.42	0.74	0.44
17	0.56	0.68	0.43
23	0.36	0.45	0.84
24	0.41	0.44	0.87
25	0.43	0.48	0.87
26	0.43	0.48	0.91
27	0.47	0.50	0.92
28	0.50	0.57	0.80
29	0.34	0.39	0.60
30	0.25	0.35	0.64
31	0.25	0.34	0.71
32	0.30	0.43	0.72

**Table 3** - Average variance extracted, composite reliability, and Cronbach's alpha for domains A, B, and D, after excluding items 9 and 16 from the Ostomy Self-Care Index (Brazilian version). Campinas, SP, 2022. (n=160).

OSCI* domains	Initial model		
(Brazilian version)	AVE†	Composite reliability	Cronbach's alpha
A) Self-care maintenance	0.58	0.94	0.93
B) Self-care monitoring	0.53	0.89	0.85
D) Self-care confidence	0.63	0.94	0.93

<sup>\*</sup>OSCI: Ostomy Self-Care Index; †AVE: Average Variance Extracted

**Table 4** – Correlation between the scores of domains A, B, and D of the Ostomy Self-Care Index (Brazilian version) and the Stoma Quality of Life Questionnaire. Campinas, SP, 2022.

OSCI* domains (Brazilian version)	Correlation (Stoma-QoL‡,)		
Castion	0.0068		
Section A	0.9318*		
Section B	-0.0447		
	0.5746*		
Section D	0.2788		
	0.0004*		

<sup>\*</sup> p-value obtained by Spearman's correlation coefficient.;† OSCI: Ostomy Self-Care Index; ‡ Stoma-QoL: Stoma Quality of Life Questionnaire

The correlation between the time the patient had an elimination stoma and the scores of domains A, B, and D of the OSCI (Brazilian version) proved to be statistically significant, as shown in Table 5.

The comparison between the scores for domains A, B, and D and the presence of a caregiver also proved to be statistically significant, as shown in Table 6.

**Table 5** – Correlation between the scores of domains A, B, and D of the Ostomy Self-Care Index (Brazilian version) and the length of use of the elimination stoma. Campinas, SP, 2022.

OSCI* domains (Brazilian version)	Time in months		
Continu A	0.3844		
Section A	< 0.0001*		
Section B	0.3904		
Section B	< 0.0001*		
Section D	0.2919		
Section D	0.0002*		

<sup>\*</sup> p-value obtained by Spearman's correlation coefficient.;† OSCI: Ostomy Self-Care Index

**Table 6** – Comparison between the scores of domains A, B, and D of the Ostomy Self-Care Index (Brazilian version) and the presence of an informal caregiver. Campinas, SP, 2022.

OSCI* domains (Brazilian version)	Presence of a caregiver	n	Mean	Standard deviation	p-value*
Section A	No	70	38.3	2.87	< 0.0001
	Yes	90	25.24	12.19	
Section B	No	70	34.33	1.41	< 0.0001
	Yes	90	29.26	7.46	
Section D	No	70	46.41	5.77	0.0001
	Yes	90	40.76	11.52	

<sup>\*</sup> p-value obtained by Mann-Whitney test; † OSCI: Ostomy Self-Care Index

After evaluating the measurement properties of sections A, B, and D of the OSCI (Brazilian version), we obtained the final version of the instrument with 25 items, as shown in Versão final - Ostomy Self-Care Index (Versão brasileira).

#### DISCUSSION

The cross-cultural adaptation of an instrument is a rigorous process that aims to achieve equivalence between the original version and the adapted version<sup>13</sup>. All the steps recommended by the international literature were followed in the OSCI adaptation process, in a similar way to recent studies<sup>22–23</sup>.

The CVR calculation has been used in current research involving content validation<sup>24,25</sup>, however, there are some differences in the literature regarding the minimum value that should be reached<sup>15,26</sup>. Although the value recommended for the present study was not reached by most of the items, it was decided to keep them unchanged, considering that these items received no suggestions for modification from the expert committee and obtained satisfactory values for the CVI and modified Kappa coefficient. It should be noted that the use of the CVR in smaller samples<sup>26</sup> is excessively rigorous and less reliable, as it can differ significantly from the values presented by other coefficients, such as the CVI and modified Kappa.

Most content validation studies use only one indicator to evaluate this measurement property. Despite this and the caveat highlighted with regard to the CVR, we opted to use three measures (CVI, modified Kappa, and CVR) in order to better evaluate whether the translated and adapted content was suitable for use in the Brazilian population.

The only item that underwent a change after the expert committee stage relates to self-care confidence. The expression "Persisting in keeping under control the condition of your stoma and peristomal skin even if it is difficult" was replaced by "Persisting in observing the condition of your stoma and peristomal skin even if it is difficult", because the committee understood that the verbs "persist" and "keep under control" are very strong and show a certain demand that the patient may not be able to meet.

The verb "persist" can be defined as "to show constancy, insistence; to persevere" and the verb "keep under control" as "to exercise restrictive action over; to contain, regulate". In many cases, the person with the stoma may not be able to persist and keep all the conditions of their stoma and peristomal skin under control without a support network and an adequate orientation program for learning self-care<sup>7–8</sup>.

Factor analysis and internal consistency assessment showed evidence of validity and reliability for domains A, B, and C. In the test of hypothesis 1, only section D showed evidence of validity, perhaps because QoL is a complex and multifactorial aspect<sup>27–28</sup>, which involves physical, social, emotional, material, and even environmental issues<sup>27</sup>. In this sample, these different aspects may have been more relevant than the presence of the elimination ostomy.

The results obtained corroborated the second hypothesis. Time (combined with appropriate professional support and guidance) can be an essential factor in learning self-care<sup>3-6</sup>. A person who has had an elimination stoma for many years certainly has much greater self-care skills than a recently post-operative individual. As an example, an Italian study applied the original instrument in this study to a sample of patients and repeated the application six months later<sup>6</sup>. In the second evaluation, all the patients had higher self-care scores compared to the first test<sup>6</sup>.

The third hypothesis was also confirmed, as in other previous studies with the same objective<sup>2</sup>. This result can be explained by taking into account that people who have caregivers generally have less ability to carry out their self-care<sup>29</sup>. However, depending on the relationship that the caregiver has with the person with the stoma, the caregiver may carry out much more care than necessary, making it difficult for the patient to develop self-care<sup>29</sup>.

Still on this topic, another international publication showed that the presence of the caregiver can be positive when it comes to carrying out practical tasks, such as cleaning and replacing the

collection equipment, but may be insufficient in more subjective issues involving observation of the ostomy, changes in the effluent, and care in relation to the patient's diet<sup>30</sup>.

A limitation of this study is the fact that it was not possible to assess the construct validity and reliability of Section C (Self-Care Management) of the instrument, as this dimension could only be answered by patients who had undergone some kind of complication and, fortunately, this was the situation of the minority of the sample studied (41.2%; n=66).

By making the three domains of this tool available for the Brazilian culture, we hope that the self-care of individuals with elimination stomas can be properly evaluated by health professionals. As a result, more effective teaching-learning strategies and important indicators for the management of healthcare services for people with ostomies can be generated. Scientific research can also use this tool in studies evaluating the effectiveness of new interventions for developing self-care in this population.

#### CONCLUSION

The process of cross-cultural adaptation of the OSCI followed all the stages recommended by the international literature and its Brazilian version showed evidence of content validity for all the dimensions of the instrument. The evaluation of its measurement properties showed evidence of construct validity and reliability for domains A, B, and D and, therefore, this study makes available, for the Brazilian culture, a tool that can be used to evaluate self-care maintenance, monitoring, and confidence of Brazilian people with elimination ostomies, who have not suffered complications.

As a recommendation for future studies, we can suggest expanding this sample of patients to evaluate the measurement properties of this domain, as well as using this tool in longitudinal, correlational studies and clinical trials.

### REFERENCES

- Oliveira AL, Netto LLMMP, Leite ICG. Cross-Cultural Adaptation and Validation of the Stoma Quality of Life Questionnaire for Patients with a Colostomy or Ileostomy in Brazil: A Cross-Sectional Study. Ostomy Wound Manag [Internet]. 2017 [cited 2023 Aug 20];63(5):34-41. Available from: https://www.hmpgloballearningnetwork.com/site/wmp/article/cross-sectional-study-nutritionalstatus-diet-and-dietary-restrictions-among-persons
- Pinto IES, Santos CSVB, Brito MAC, Queirós SMM. Propriedades Psicométricas do Formulário Desenvolvimento da Competência de Autocuidado da Pessoa com Ostomia de Eliminação Intestinal. Rev Enf Ref [Internet]. 2016 [cited 2023 May 20];4(8):75-84. Available from: https://doi.org/10.12707/RIV15044
- 3. Wound Ostomy and Continence Nurses Society. WOCN Society Clinical Guideline: Management of the Adult Patient With a Fecal or Urinary Ostomy-An Executive Summary. J Wound Ostomy Cont Nurs [Internet]. 2018 [cited 2024 Apr 10]45(1):50-8. Available from: https://journals.lww.com/jwocnonline/abstract/2018/01000/wocn\_society\_clinical\_guideline\_\_management\_of\_the.9.aspx
- 4. Orem DE. Nursing Concepts of Practice. 6th ed. Louis S, editor. Saint Louis, STL(US): Mosby; 2001.
- 5. Villa G, Vellone E, Sciara S, Stievano A, Proietti MG, Manara DF, et al. Two New Tools for Self-Care in Ostomy Patients and Their Informal Caregivers: Psychosocial, Clinical, and Operative Aspects. Int J Urol Nurs [Internet]. 2019 [cited 2023 Jun 9];13:12117. Available from: https://onlinelibrary.wiley.com/doi/abs/10.1111/jjun.12177

- 6. Giordano V, Nicolotti M, Corvese F, Vellone E, Alvaro R, Villa G. Describing Self-Care and Its Associated Variables in Ostomy Patients. J Adv Nurs [Internet]. 2020 [cited 2023 Jun 22];76:2982-92. Available from: https://onlinelibrary.wiley.com/doi/10.1111/jan.14499
- 7. Liu H, Gu J, Gu J, Dai G, Hu Y. Exploration of the Effect of Continuous Nursing Mode on the Health of Patients with Permanent Enterostomy. Acta Medica Mediterr [Internet]. 2019 [cited 2022 Jun 16];35:579-86. Available from: https://doi.org/10.19193/0393-6384\_2019\_1s\_88
- 8. Seo H-W. Effects of the Frequency of Ostomy Management Reinforcement Education on Self-Care Knowledge, Self-Efficacy, and Ability of Stoma Appliance Change Among Korean Hospitalised Ostomates. Int Wound J [Internet]. 2019 [cited 2022 Sep 16];16(Suppl):21-8. Available from: https://doi.org/10.1097/NCC.00000000000000762
- 9. Riegel B, Lee CS, Dickson VV, Carlson B. An Update on the Self-Care of Heart Failure Index. J Cardiovasc Nurs [Internet]. 2009 [cited 2023 Jan 19];24(6):485-97. Available from: https://doi.org/10.1097/JCN.0b013e3181b4baa0
- 10. Prieto L, Thorsen H, Juul K. Development and Validation of a Quality of Life Questionnaire for Patients with Colostomy or ileostomy. Health Qual Life Outcomes [Internet]. 2005 [cited 2022 Jun 9];3:62. Available from: https://doi.org/10.1186/1477-7525-3-62.
- 11. Polit DF, Beck CT. Fundamentos de pesquisa em enfermagem: avaliação de evidências para a prática da enfermagem. 9th ed. Porto Alegre, RS(BR): Artmed; 2019.
- 12. Beaton DE, Bombardier C, Guillemin F, Ferraz MB. Recommendations for the Cross-Cultural Adaptation of the DASH & QuickDASH Outcome Measures. Inst Work Heal [Internet]. 2007 [cited 2022 Aug 18]; Available from: https://www.dash.iwh.on.ca/sites/dash/files/downloads/cross cultural adaptation 2007.pdf
- 13. Alexandre NMC, Coluci MZO. Content Validity in the Development and Adaptation Processes of Measurement Instruments. Cienc Saude Coletiva [Internet]. 2011 [cited 2022 Aug 18];16(7):3061-68. Available from: https://doi.org/10.1590/S1413-81232011000800006
- 14. Polit DF, Beck CT, Owen SV. Is the CVI an Acceptable Indicator of Content Validity? Appraisal and Recommendations. Res Nurs Heal [Internet]. 2007 [cited 2022 Sep 16];30:459-67. Available from: https://doi.org/10.1002/nur.20199
- 15. Rutherford-Hemming T. Content Validity Ratio. In: The SAGE Encyclopedia of Educational Research, Measurement, and Evaluation [Internet]. Thousand Oaks, CA(US): SAGE Publications; 2018 [cited 2022 Sep 20]. p.397-8. Available from: https://doi.org/10.4135/9781506326139
- 16. Alexandre NMC, Coluci MZO. Development of a Questionnaire to Evaluate the Usability of Assessment Instruments. Rev Enferm UERJ [Internet]. 2009 [cited 2022 Sep 20];17(3):378-82. Available from: http://www.revenf.bvs.br/pdf/reuerj/v17n3/v17n3a14.pdf
- Mokkink LB, Prinsen CAC, Patrick DL, Alonso J, Vet HCW, Terwee CB. COSMIN Study Design Checklist for Patient-Reported Outcome Measurement Instruments [Internet]. Amsterdam, (NL): COSMIN; 2019 [cited 2022 Sep 20]. Available from: https://www.cosmin.nl/wp-content/uploads/ COSMIN-study-designing-checklist\_final.pdf
- 18. Hair JF, Black WC, Babin BJ, Anderson RE, Tathan RL. Análise multivariada de dados. 6th ed. Porto Alegre, RS(BR): Bookman; 2009.
- 19. Hair JF, Hult GTM, Ringle CM, Sarstedt M. A Primer on Partial Least Squares Structural Equation Modeling (PLS-SEM). Los Angeles, CA(US): SAGE; 2014.
- 20. Fornell CLD. Evaluating Structural Equation Models with Unobservable Variable and Measurement Error. J Marketing Res [Internet]. 1981 [cited 2022 Sep 20];18:39-50. Available from: https://doi.org/10.1177/002224378101800104
- 21. Cohen J. A Power Primer. Psychol Bull [Internet]. 1992 [cited 2022 Sep 20];112(1):155-9. Available from: https://doi.org/10.1037/0033-2909.112.1.155



- 22. Dias FCP, Baitelo TC, Toso BRGO, Sastre-Fullana P, Oliveira-Kumakura ARS, Gasparino RC. Adaptation and Validation of the Advanced Practice Nursing Competency Assessment Instrument. Rev Bras Enferm [Internet]. 2022 [cited 2022 Jun 8];75(5):e20210582. Available from: https://doi.org/10.1590/0034-7167-2021-0582
- Santos CJ Jr, Costa PJMS. Cross-Cultural Adaptation and Validation for Brazilian Portuguese of the Parent Attitudes About the Childhood Vaccine (PACV) Questionnaire. Cienc Saude Coletiva [Internet]. 2022 [cited 2022 Jun 8];27(5):2057-70. Available from: https://doi.org/10.1590/1413-81232022275.11802021
- Rocha MR, Vale HS, Moreira TMM, Borges JWP, Machado ALG, Silva RV. Validation of an Educational Booklet: Effect on the Knowledge About Prevention of Metabolic Syndrome in Adolescents. Texto Context Enferm [Internet]. 2022 [cited 2022 Jun 08];31:e20210074. Available from: https://doi.org/10.1590/1980-265X-TCE-2021-0074.
- 25. Fabriz LA, Oliveira VC, Zacharias FCM, Valente SH, Ferro D, Pinto IC. Construction and Validation of a Matrix for Normative Evaluation of the Integrated Health System of the Borders. Rev Latino-Am Enferm [Internet]. 2021 [cited 2022 Jun 8];29: e3433. Available from: https://doi.org/10.1590/1518-8345.4141.3433.
- 26. Ayre C, Scally AJ. Critical Values for Lawshe's Content Validity Ratio. Meas Eval Couns Dev [Internet]. 2014 [cited 2022 Jun 15];47(1):79-86. Available from: https://doi.org/10.1177/0748175613513808
- Estoque RC, Togawa T, Ooba M, Gomi K, Nakamura S, Hijioka Y, et al. A Review of Quality of Life (QOL) Assessments and Indicators: Towards a "QOL-Climate" Assessment Framework. Ambio [Internet]. 2019 [cited 2023 Jan 10];48:619-38. Available from: https://doi.org/10.1007/ s13280-018-1090-3
- 28. Haraldstad K, Wahl A, Andenae R, Andersen Jr, Andersen MH, Beisland E, et al. A Systematic Review of Quality of Life Research in Medicine and Health Sciences. Qual Life Res [Internet]. 2019 [cited 2023 Jan 10];28(10):2641-50. Available from: https://doi.org/10.1007/s11136-019-02214-9
- Altschuler A, Liljestrand P, Grant M, Hornbrook MC, Krouse RS, McMullen CK. Caregiving and Mutuality Among Long-Term Colorectal Cancer Survivors with Ostomies: Qualitative Study. Support Care Cancer [Internet]. 2018 [cited 2023 Jan 15];26(2):529-37. Available from: https://doi.org/10.1007/s00520-017-3862-x
- 30. Giordano V, Iovino P, Corvese F, Vellone E, Alvaro R, Villa G. Caregiver Contribution to Self-Care and its Associated Variables Among Caregivers of Ostomy Patients: Results of a Cross-Sectional Study. J Clin Nurs [Internet]. 2021 [cited 2023 Jan 10];31:99-110. Available from: https://doi.org/10.1111/jocn.15851

#### NOTES

#### **ORIGIN OF THE ARTICLE**

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#### **CONTRIBUTION OF AUTHORITY**

Study design: Perissotto S, Silva VA, Villa G, Gasparino RC.

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## **SUPPLEMENTARY MATERIAL**

The following online material is available for this article

Chart S1 – Síntese das traduções (T12) e versão após Adaptação Transcultural do *Ostomy Self-Care Index*. Campinas-SP, Brasil, 2021.

Versão final – Ostomy Self-Care Index (Versão brasileira). Campinas, SP, Brasil, 2023.