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ORIGINAL ARTICLE / *ARTIGO ORIGINAL*

Transcultural adaptation of Patient-Reported Outcomes in Obesity (PROS) questionnaire for Brazil

Adaptação transcultural do questionário Patient-Reported Outcomes in Obesity *(PROS) para utilização no Brasil*

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ABSTRACT: *Objective:* To perform a cross-cultural adaptation and validation in the Brazilian cultural context of questionnaire Patient-Reported Outcomes in Obesity (PROS). *Methods:* The cross-cultural adaptation process involved the translation from original English language into Brazilian Portuguese by two qualified and independent translators. The back-translation was performed by two English language teachers who were native speakers, without any medical knowledge of the original scale. An expert committee was created with researchers to assess semantic, idiomatic, experiential and conceptual equivalence. The pre-test of the Brazilian version, named PROS-Br, was carried out with ten adults with obesity. To assess the psychometric properties of the instrument, a cross-sectional epidemiological study was carried out. The population consisted of 120 Brazilian adults with obesity who went to the appointment at a school-clinic. The Item Response Theory and Factor Analysis with Principal Component Extraction was used for the psychometrics analysis. To measure reliability, the α-Cronbach indicator was used. *Results:* In the reliability analysis, α-Cronbach was 0.82. Two factors explained 58.3% of the total variance in the principal component analysis, involving behavioral and physical aspects. Item Response Theory curves showed that all questions have discriminatory characteristics, pointing to the adequacy of the proposed version. *Conclusion:* The Brazilian version was proven valid and reliable to measure the quality of life of individuals with obesity, allowing one to develop intervention strategies, plan and execute actions at services and for public health policies.

Keywords: Obesity. Quality of life. Factor analysis.

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RESUMO: *Objetivo:* Realizar a adaptação transcultural e a validação, no contexto cultural brasileiro, do instrumento de impacto da obesidade Patient-Reported Outcomes in Obesity (PROS). *Métodos:* O processo de adaptação transcultural contou com a tradução do idioma original, inglês, para o português, executada por dois tradutores qualificados e independentes. A retrotradução foi realizada por dois professores de inglês, nativos, sem qualquer conhecimento médico nem da escala original. Um comitê de especialistas foi composto de pesquisadores para avaliar as equivalências semântica, idiomática, experiencial e conceitual. O pré-teste da versão brasileira, denominada PROS-Br, foi realizado com dez indivíduos adultos com obesidade. Para a avaliação das propriedades psicométricas, foi realizado um estudo epidemiológico de delineamento transversal. A população foi composta de 120 indivíduos adultos com obesidade, brasileiros, presentes para consulta médica em ambulatório-escola. Para análises psicométricas, foram utilizadas a Teoria de Resposta ao Item e análise fatorial com extração de componentes principais. Para aferição da confiabilidade foi utilizado o indicador α-Cronbach. *Resultados:* Na análise de confiabilidade, o PROS-Br apresentou α-Cronbach de 0,82. Dois fatores explicaram 58,3% da variância total na análise de componentes principais, envolvendo aspectos comportamentais e físicos. As curvas da Teoria de Resposta ao Item mostraram que todas as perguntas apresentam características discriminatórias, apontando para a adequação da versão brasileira proposta. *Conclusão:* A versão brasileira mostrou-se válida e confiável para aferir a qualidade de vida de indivíduos com obesidade, possibilitando desenvolver estratégias de intervenção, planejamento e execução de ações nos serviços e na política pública de saúde.

Palavras-chave: Obesidade. Qualidade de vida. Análise fatorial.

INTRODUCTION

Considered by the World Health Organization as a worldwide epidemic, obesity is defined as abnormal or excessive accumulation of adipose tissue[1,2]. This condition, malnutrition and climate change together are a Global Syndemic and share underlying social factors, besides contributing to the increase of chronic diseases worldwide[3]. Thus, Jaacks et al.[4] proposed a conceptual model of transition to the stages of obesity epidemic, with the aim of guiding researchers and policymakers in identifying the current stage and anticipating subpopulations that have the potential to develop it to facilitate the adoption of measures to mitigate it, taking into account local factors.

Obesity is an increasingly prevalent condition in developed and developing countries, including Brazil, where its prevalence declined among high-income women from 1989 to 1998, but continued to grow among low-income women and all income groups among men[4,5]. In the last four decades, the number of obese individuals aged between 5 and 19 years has increased ten times worldwide. In 2016, 13% of the adult population, equivalent to 650 million people, were obese, and it is estimated that, in 2022, this number will surpass that of malnourished people for the first time[5]. In Brazil, the prevalence of obesity increased by 67.8%between 2006 and 2018, reaching 19.8% of the Brazilian population[6].

Changes in the Brazilian pattern of food consumption, favoring ultra-processed products, food that is rich in sodium, sugars and fats and poor in nutrients, along with the concomitant

decrease in physical activity and increased screen time, are factors that contribute to this situation in the country[7]. Also important to note that the increase in consumption of these products is related to the high production of greenhouse gases and climate change, which also worsen health in general[3].

Excess weight impairs quality of life, as affected individuals are exposed to the high risk of developing cardiovascular disease, difficult-to-control hypertension, obstructive sleep apnea and hypopnea syndrome, degenerative joint disease, and type 2 diabetes mellitus[8]. In addition, people with obesity face social discrimination and stigmas that can also impact their psychological well-being and lead them to depression, eating disorders, body image distortion, and low self-esteem[9,10].

Although obesity and some common mental disorders have similar symptoms, such as sedentary behavior, sleep disturbances, and poorly controlled food intake, they are often treated as separate illnesses. However, full attention to this association and monitoring of the mood, well-being and quality of life of individuals with obesity are recommended as preventive measure and early detection; not to mention the treatment for those at risk[11], since psychological changes interfere with the treatment of obesity and can linger after weight loss[12,13].

Improving quality of life should be a goal of the treatment of obesity and, for that, factors involved in the patients' perception of the disease and the impact it causes on their well-being must be acknowledged. Several health services are implementing a patient-reported outcome monitoring with a clinical feedback system (PRO/CFS) to record physical and mental symptoms and quality of life. This data system was designed to meet individual needs, guiding therapies and following the patient's evolution to mainly impact chronic and refractory diseases such as obesity. In addition, the service provider has an easy access to the information that they need to promote improvements in care[14,15]. In this way, valid and specific questionnaires for the obese population contribute to the standardization of this system, whose objective is to increase the efficiency of treatments, care and, consequently, the quality of life[14].

With this in mind, Aasprang et al.[16] developed the questionnaire Patient-Reported Outcomes in Obesity (PROS), a simple and comprehensive tool that can be used in clinical and scientific research. The instrument has eight items, and it was originally developed in Norwegian and English with the aim to find out to what extent an individual feels bothered by their weight or body shape in different categories such as common physical activities, body discomfort, social interaction, self-esteem and sex life based on a scale from 0 (not bothered) to 3 (considerably bothered). The total score is obtained by adding the value of each category and dividing the number obtained by eight. Higher total scores indicate greater discomfort[16].

PROS is relevant because, unlike other questionnaires created exclusively for research use[17], it does not require calculations, so it provides an objective way for the clinician to assess the impact of obesity on the patient's quality of life. Its good applicability makes it possible to improve the therapeutic approach to bring benefits to the quality of life of

individuals, that is, it is an instrument for data collection that can highlight the importance of adopting effective public policies for the prevention of obesity. It has, therefore, the potential to contribute to the reduction of the socioeconomic impact related to the disease, since many of its causes and consequences are preventable and reversible, psychological changes included[3,15].

However, the tool was developed in Norway and is suited to that sociocultural scenario. In order for it to be used in Brazil, a cross-cultural adaptation to the Brazilian sociocultural characteristics must be performed. So, the objectives of this study were to cross-culturally adapt questionnaire PROS on the impact of obesity to the Brazilian cultural context and to assess the psychometric properties of the new proposed version.

METHODS

The methodological course of this study had different steps. The first involved a cross-cultural adaptation of PROS[16] in its original English version. Then, an epidemiological study was made to assess the psychometric properties of the proposed Brazilian version.

TRANSCULTURAL ADAPTATION

The cross-cultural adaptation of PROS for Brazil (PROS-Br) met the methodological criteria proposed by The Professional Society for Health Economics and Outcomes Research (ISPOR)[18]. It involved translation, back-translation, analysis by an expert committee, pretest, and proposal of the Brazilian version, named PROS-Br.

TRANSLATIONS AND SYNTHESIS

The translation was performed by two qualified independent translators, one being a Brazilian and the other being a native speaker of English language. Based on both translations, the researchers synthesized a Brazilian Portuguese version.

BACK-TRANSLATION

The Portuguese synthesized version was back-translated into English by a third independent translator who was also a native speaker of English language with proficiency in Brazilian Portuguese.

EXPERT COMMITTEE

An expert committee, composed of researchers and health professionals with experience in the area of obesity, analyzed translation and back-translation, as well as the linguistic equivalences, creating a pre-final version.

PRE-FINAL VERSION TEST

The pre-final version was tested on ten adult individuals whose body mass index (BMI) was equal to or greater than 30 kg/m^2 and who were being assisted at the Specialty Medical Outpatient Clinic of Universidade do Sul de Santa Catarina. Participants were asked to give their opinion on the understanding of questions and adequacy of the writing. The researchers evaluated possible difficulties in interpretation or understanding, any constraints caused by the questions, and inadequacies in the answers given. With no need for adjustments, the Brazilian version was proposed (PROS-Br).

OUTLINE OF EPIDEMIOLOGICAL STUDY

A cross-sectional study was developed to assess the psychometric properties of PROS-Br.

DATA SAMPLING AND COLLECTION

The sample was formed by 120 obese individuals, which corresponds to the appropriate proportion according to the scale items[19,20].

The sample selection method was consecutive, at the Adult Health outpatient clinic. Thus, selection was non-probabilistic among all patients who were eligible for the study. Inclusion criteria were: adult individuals aged 20 years and older, Brazilians, who could read and write in Brazilian Portuguese, with a BMI equal to or greater than 30 kg/m^2, being assisted at the Specialty Medical Outpatient Clinic of Universidade do Sul de Santa Catarina. Besides application of PROS-Br questionnaire, data regarding age and educational level were collected.

DATA ANALYSIS

Data were entered into Microsoft Excel spreadsheets and exported into the Statistical Package for the Social Sciences (SPSS) for Windows (SPSS) 18.0, where they were analyzed. To measure the scale reliability, its stability was evaluated with the α-Cronbach indicator, calculated for the general analysis and for each question on the scale. Face validity was

assessed by the opinion of the experts involved in the study. For the test-retest, the instrument was applied for the second time to 25% of the sample (n=30) after one week for the analysis of stability using the Spearman's correlation coefficient. In addition, the correlation of differences between both applications and the averages of results were checked by the Bland-Altman plot.

To verify the construct validity, we performed an analysis of Item Response Theory (IRT)[21] and an exploratory factor analysis (EFA)[22]. The IRT, based on the Rasch[23] model using the R programming language in JAMOVI 2.0 software (https://www.jamovi.org/), allowed us to assess response probability, standard error, and test information graphs. These were also examined based on characteristics of discrimination and difficulty.

The EFA was performed after checking for the suitability of the data set obtained, using the linear correlation matrix, the Kaiser-Meyer-Olkin (KMO) and the Bartlett's sphericity test. The Kaiser criterion for eigenvalues greater than or close to one and the scree plot were used to define the number of factors extracted. To minimize the number of questions with high loads on each factor, these were extracted using the main components rotated by the Varimax method, and their commonalities were analyzed.

ETHICAL ISSUES

The project was submitted to and approved by the Ethics Committee of Universidade do Sul de Santa Catarina, under opinion no. 4132363. All participants signed an informed consent form after being invited to participate in the study.

RESULTS

After the translation, back-translation and synthesis were carried out, the semantic, idiomatic, experiential and conceptual equivalences were discussed by the expert committee. Then, the pre-final version was formed and applied to ten patients with obesity, who gave feedback about not having difficulties in answering it. After this process, the researchers approved the proposed Brazilian version (PROS-Br), whose questions are presented in Table 1.

In total, 120 people answered to PROS-Br. The age of the participants ranged from 20 to 90 years, with mean of 54.3±16.0. Educational level ranged from 0 to 17 years of study, with mean of 8.5±4.8. Among participants, 99 (82.5%) were women and 21 (17.5%) were men.

The test-retest results included 30 respondents. The lowest Spearman correlation coefficient found was 0.56 in item 1, while the highest was 0.86 in item 4. For all items, correlations were statistically significant, with $p<0.001$. The Bland-Altman plot with dispersion of response means is shown in Figure 1. The overall α-Cronbach index was 0.82. The values of corrected item-total correlation and α-Cronbach were excluded if items did not significantly alter the overall index.

As for IRT, the Pearson's reliability test of 0.71 (p=0.08) and the level of correlation between items lower than 0.40 showed that data fit the Rasch model used in the analysis. The lowest degree of difficulty was related to item 2, followed by item 1. In turn, items 5 and 6 were found to be the most difficult ones to be answered.

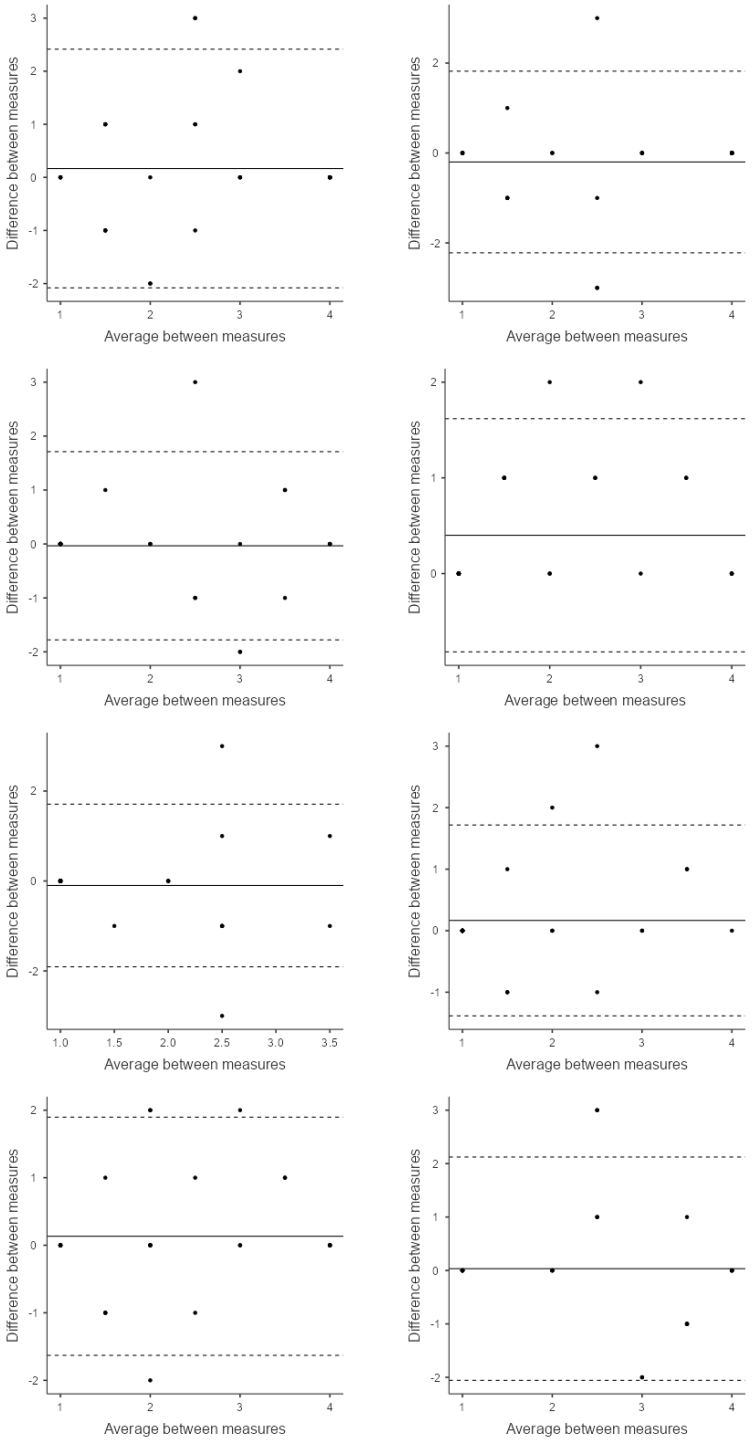
The characteristic curves of items are shown in Figure 2. The ones referring to item 1 have a z-score of 2.5, which represents 99% of normal Gaussian probability of answering "strongly agree". The curves for the other items are shown right after, in the same figure.

The distribution of curves for possible answers to questions is shown in Figure 3. All questions have discriminatory characteristics.

For the EFA, a correlation matrix with eight items was put together, showing $p<0.001$ for most questions. The KMO measure of sampling adequacy was 0.84. Bartlett's sphericity test showed $p<0.001$. Such results allowed to proceed mathematically with the analysis of commonalities. This revealed that all items had variance above 0.30 with the defined factors. The extraction of the main components was based on factors corresponding to eigenvalues greater than 1 ($\lambda \geq 1$) or very close to 1, which meant that none of the questions were deleted from the Brazilian version. Thus, the closely distributed factors explained 58.3% of the variance. The same behavior was observed in the escarpment graph (Figure 4).

Table 1. PROS-Br rotating component matrix (n=121).

Items	Factor loading	
	Factor 1	Factor 2
3. What is the level of discomfort caused by your weight or body shape when it comes to discrimination or unkind treatment/attitude?	0.77	
5. What is the level of discomfort caused by your weight or body shape in your sex life?	0.76	
8. What is the level of discomfort caused by your weight or body shape in your self-esteem?	0.70	
4. What is the level of discomfort caused by your weight or body shape in your sleep?	0.59	
6. What is the level of discomfort caused by your weight or body shape in normal social relationships?	0.58	
1. What is the level of discomfort caused by your weight or body shape in common physical activities (walking, climbing stair and others)?		0.82
2. What is the level of discomfort caused by your weight or body shape when it comes to pain in different body parts?		0.80
7. What is the level of discomfort caused by your weight or body shape at work, in the school and in other daily life activities?		0.59



Order of graphs: question 1 in upper left vertex following the line to question 8 in lower right vertex.

Figure 1. Correlation between differences and averages of results between applications. PROS-Br scale. Test-retest (n=30).

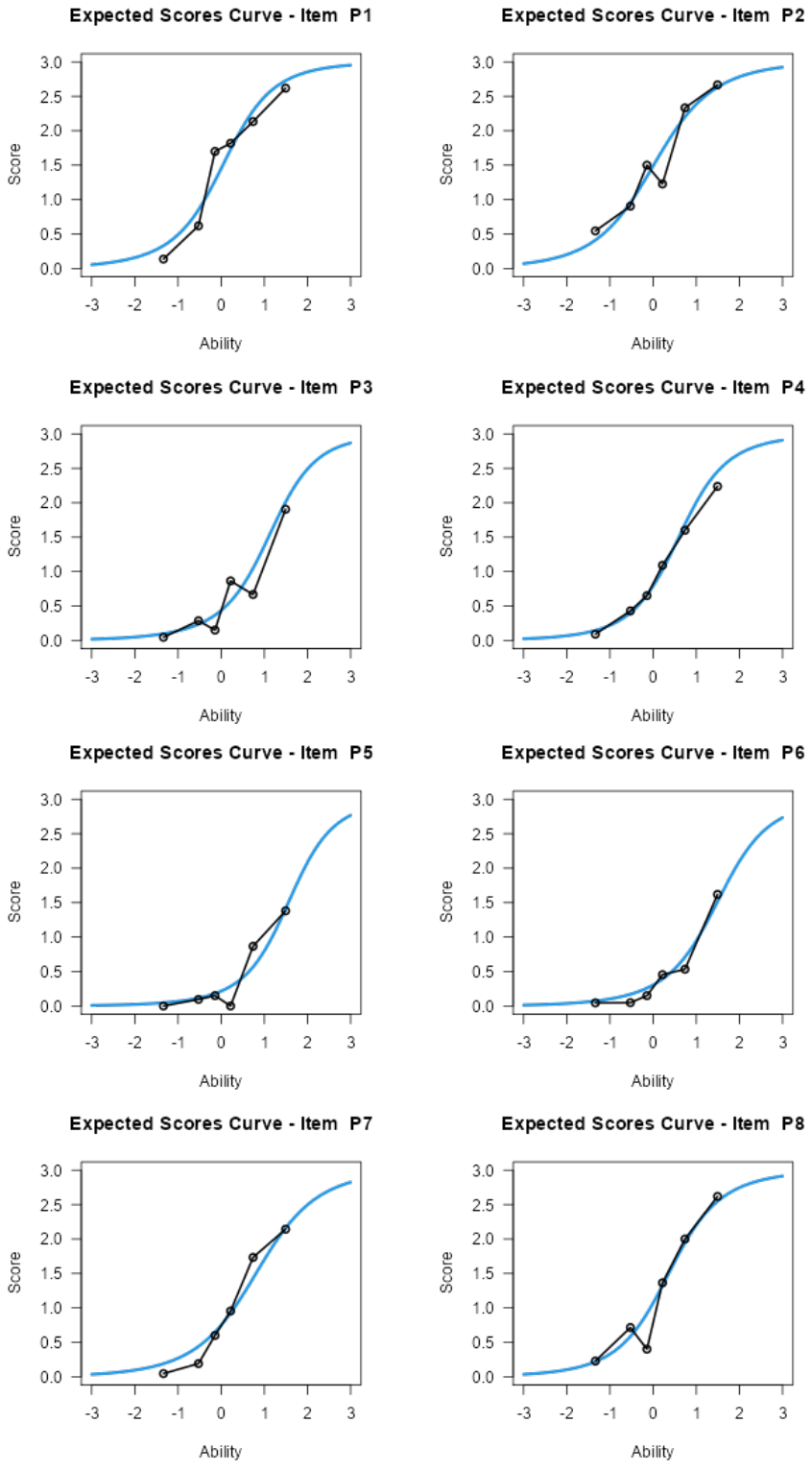


Figure 2. Characteristic curves for each PROS-Br question (n=121).

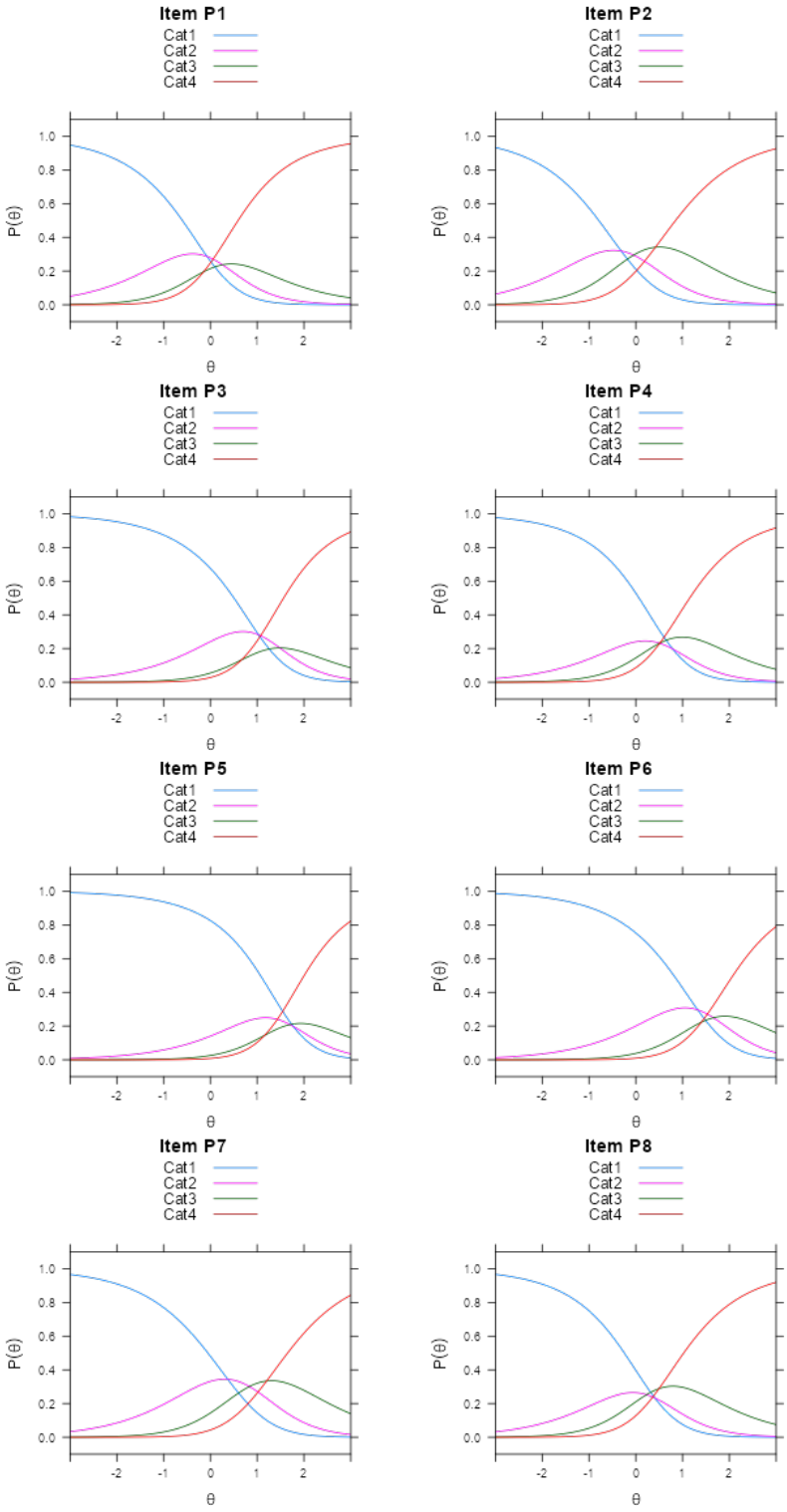


Figure 3. Distribution curves for possible answers to PROS-Br questions (n=121).

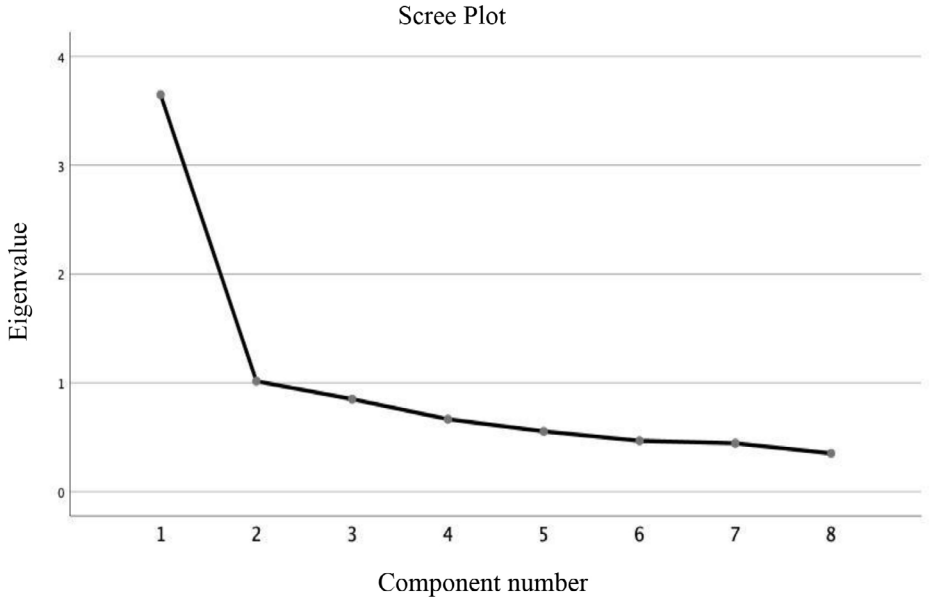


Figure 4. Values of latent factors. PROS-Br scale (n=121).

Factor rotation by the Varimax method minimized the number of variables with high loads in a factor and maximized the variation between the weights of each main component, shown in Table 1.

DISCUSSION

This study sought to carry out the cross-cultural adaptation of PROS to Brazil, proposing the PROS-Br. For this purpose, an internationally accepted methodology[18] was used and the proposed version was applied to 120 patients, an adequate sample size[19,20]. The results showed that the new tool is valid and reliable for the Brazilian cultural context.

It is important to mention that PROS questionnaire, developed by a team of Norwegian researchers and validated in two versions (English and Norwegian), was proven reliable to assess the specific quality of life related to obesity in clinical practice and in research. In addition, it demonstrated a high degree of validity compared to the Impact of Weight on Quality of Life – Lite (IWQOL-Lite)[17], considered the gold standard to assess quality of life among people with obesity[16]. The questionnaire was created with the involvement of 204 individuals with obesity, in response to the lack of tools that would allow physicians to obtain accurate information about the quality of life of individuals with this condition during the consultation, without the need for the calculations commonly required by similar questionnaires. The initiative aimed to provide obese patients and their physicians with

a simple and objective way of accessing individual needs, in a way they could be addressed in the treatment plan[16].

Regarding the characteristics of the sample, in the development of the original questionnaire, patients from the bariatric surgery service were included in the preoperative period or after surgery within up to five years. In contrast, our study included obese patients treated for different reasons at the Adult Health outpatient clinic with focus on individual's integral health. A higher prevalence of females was identified in the evaluated population, which is in line with epidemiological data from the IBGE, which states that adult women with obesity are predominant in all age groups[24].

In the psychometric analysis of reliability, the PROS-Br presented an overall α-Cronbach of 0.82, similar to the original scale, which was 0.90[16]. The α-Cronbach values if each PROS-Br question was excluded revealed that they all contribute to the homogeneity and stability of the indicator.

In the validity analysis, similarly to the original instrument, PROS-Br factors were very closely distributed and explained 58.3% of the variance, compared to 58.4% of the original in English[16]. The component matrix, after orthogonal rotation, aimed to extreme loads so that each variable was associated with only one factor, simplifying the interpretation. The evaluation of factor loadings showed that all PROS-Br items should be considered because they have good factor loadings. Two factors resulted from the orthogonal rotation. The first one grouped questions 3, 4, 5, 6 and 8, which pointed to a factor related to behavioral aspects. The second grouped questions 1, 2 and 7, which were related to physical aspects.

The IRT helped to understand the behavior of PROS-Br. For example, in question 1, at zero theta, respondents had the same probability of answering any categories, which gives the question a low level of information; or it could be interpreted as a very easy question to answer, with a very obvious answer. This also occurred with question 8. In question 6, the behavior of the curves pointed to a more complex issue, but with a good input of information—from a theoretical point of view, the greater the ability of respondents to understand, the greater the probability of responding to category 4. In turn, the shape of curves in question 7 would point to a question with greater discriminatory power, as they are more separated, with no specific point of respondent's ability to respond to any categories.

In general, the polygons are adjusted, which identifies the question as a contributor to the instrument's ability to measure. The item curves have discriminatory characteristics, thus contributing to the adequacy of the Brazilian version, with relevant information.

Although some studies use generic instruments to measure quality of life, such as the SF-36[12], to assess interventions in individuals with obesity, these are not designed to measure specific health conditions associated with obesity[25]. As a result, many questionnaires on this disease were developed and validated. The instrument presented by Kolotkin et al.[17], IWQOL-Lite, is used in clinical trials[25], but the number of items and their score make it

difficult to use during a consultation. On the other hand, The Moorehead-Ardelt Quality of Life Questionnaire II[26] is succinct, but restricted to clinical practice.

In order to meet this need, the PROS[16] questionnaire was proposed as usable both in clinical practice and in research, having been inspired by the Obesity-Related Problem Scale[27]. The authors added questions related to physical activity, pain, sleep, discrimination and self-esteem, characteristics also related to the quality of life of these patients[16]. The same instrument was used in a recent study[15], which applied a PRO/CFS with the proposal to introduce a structured assessment of quality of life related to physical and mental health in consultations before and after bariatric surgeries.

One of the main limitations of the present study is the non-probabilistic selection of the sample, which could introduce selection bias by not using a population-based sample. However, all eligibility criteria were strictly followed and effort was made to achieve representativeness of the population assisted at the service where patients were recruited. Another limitation was the non-application, for logistic reasons, of an instrument that contained an analogous construct, preventing the assessment of its external validity. Such limitations impose caution in the analysis of results presented and imply the need for further studies with such attributes.

The practicality and simplicity of PROS-Br can encourage health professionals to apply it, resulting in a better assessment of individuals with obesity. This tool also involves the patient in the process, and this allows recognizing and finding solutions for their own reality, impacting the chances of significant changes[3]. Another advantage is that the instrument can be applied at different times of the treatment, helping to perceive the results and provide positive reinforcement and contributions to the engagement to treatment and its success[15].

Other studies similar to this one expand the options of health professionals to use different instruments that seek, quickly and easily, to measure subjective constructs that are more difficult to be evaluated in patients' history and by traditional anamnesis.

In addition, questionnaires such as PROS-Br have the potential to be part of future research that seeks to implement a new technological vision of clinical monitoring, such as the PRO/CFS, which make it possible not only to evaluate the effects on treatment but also to develop intervention strategies, action planning and execution for public health services and policies[14].

Based on the results achieved, it is suggested that the Brazilian version was proven valid and reliable to assess the impact of obesity from the patient's perspective. Consequently, the availability of an instrument such as PROS-Br can facilitate the management of individuals with obesity, since the damage to mental health and quality of life must be considered in the treatment. It is also important to point out that obesity should not be seen as an alteration in which the individual is responsible for their condition, but rather consider the influence of the environment they belong to, since it helps to perpetuate and worsen their relationship with weight[3,28]. Therefore, tools for proper assessment are essential to achieve effective goals in the fight against obesity.

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