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CONSTRUCTION AND VALIDITY OF THE ADAPTATION LEVEL SCALE OF THE PERSON WITH OSTOMY

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ABSTRACT

Objective: To construct and validate the content of the scale for verifying the level of adaptation of the person with ostomy. **Method:** Methodological study involving two stages: construction based on two integrative literature reviews and qualitative study with people with stomas; and content validity with judges of the following criteria: behavioral, objectivity, relevance, clarity, simplicity, variety in relation to language; carrying out the pilot test with the target group; lexical and grammatical correction and resubmission to the content validity index. **Results:** in the first stage, thirteen items received suggestions for improvement, three items were unified by similarity and one was excluded. After the adjustments, a consensus was reached among the judges regarding the representativeness of the items and permanence in the modes based on the evaluated criteria. The target population judged the items as easy to understand, followed by grammatical and lexical correction. **Conclusion:** The scale presented evidence of content validity demonstrating consensus between the judges and the population.

DESCRIPTORS: Validation studies. Nursing. Ostomy. Adaptation, psychological. Models, Nursing. Enterostomal therapy.

CONSTRUÇÃO E VALIDADE DA ESCALA DO NÍVEL DE ADAPTAÇÃO DA PESSOA COM ESTOMIA

RESUMO

Objetivo: Construir e validar o conteúdo da escala de verificação do nível de adaptação da pessoa com estomia. **Método:** Estudo metodológico envolvendo duas etapas: construção baseada em duas revisões integrativas da literatura e estudo qualitativo com pessoas com estomia; e validade de conteúdo com juízes dos seguintes critérios: comportamental, objetividade, relevância, clareza, simplicidade, variedade em relação à linguagem; realização do teste-piloto com o grupo-alvo; correção léxica e gramatical e nova submissão para o índice de validade de conteúdo. **Resultados:** Na primeira etapa, treze itens receberam sugestões de melhoria, três itens foram unificados por similaridade e um foi excluído. Após os ajustes, alcançou-se consenso dos juízes quanto à representatividade dos itens e à permanência nos modos a partir dos critérios avaliados. A população-alvo julgou os itens como de fácil entendimento ocorrendo em seguida correção gramatical e lexical. **Conclusão:** A escala apresentou evidência de validade de conteúdo demonstrando consenso entre os juízes e a população-alvo.

DESCRITORES: Estudos de Validação. Enfermagem. Estomia. Adaptação Psicológica. Modelos de Enfermagem. Estomaterapia.

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CONSTRUCCIÓN Y VALIDEZ DE LA ESCALA DEL NIVEL DE ADAPTACIÓN DE LA PERSONA CON OSTOMIA

RESUMEN

Objetivo: Construir y validar el contenido de la escala de verificación del nivel de adaptación de la persona con ostomía. **Método:** Estudio metodológico que involucra dos etapas: construcción a partir de dos revisiones integrativas de la literatura y estudio cualitativo con personas con estomas; y validez de contenido con jueces de los siguientes criterios: conductual, objetividad, pertinencia, claridad, sencillez, variedad en relación al lenguaje; realización de la prueba piloto con el grupo objetivo; corrección léxica y gramatical y reenvío al índice de validez de contenido. **Resultados:** en la primera etapa, 13 ítems recibieron sugerencias de mejora, tres ítems fueron unificados por similitud y uno fue excluido. Luego de los ajustes, se llegó a un consenso entre los jueces respecto a la representatividad de los ítems y permanencia en las modalidades con base en los criterios evaluados. La población objetivo juzgó los ítems como fáciles de entender, seguidos de corrección gramatical y léxica. **Conclusión:** La escala presentó evidencias de validez de contenido demostrando consenso entre los jueces y la población.

DESCRIPTORES: Estudios de Validación. Enfermería. Estomía. Adaptación Psicológica. Modelos de Enfermería. Estomaterapia.

INTRODUCTION

After the creation of a stoma, several adaptive demands arise in the life of the individual, which include the need for physical, psychological and social adjustments that will directly impact their quality of life[1]. Despite the importance of the health professional in the process of adaptation to the new condition of the person with ostomy, nurses show a deficit of knowledge about the care of elimination intestinal stomas, which can result in divergences and inefficiency in the care provided[2].

Promoting the adaptation of the person from the understanding of the being in an integrative and humanistic way from a system able to adapt aiming at the four adaptive modes (physiological, self-concept, role function and interdependence) treated in the adaptation theory of Callista Roy is necessary in the clinical practice of the enterostomal therapist nurse[3]. Thus, during consultations, the relevance of assessing the level of adaptation of the person with ostomy is verified, favoring the identification of effective and ineffective behaviors, the focal, contextual and residual stimuli and the ways of coping with the health-illness process by reliable, accurate and precise instruments; as well as the relevance of assessing the testability, the applicability, the empirical adequacy and the pragmatics of the theoretical elements of Roy's adaptation model (MAR) in this population[4].

It is evident that there is a lack of nursing instruments capable of measuring and quantifying the adaptation to the new life condition that the stoma and its particular needs bring. Therefore, the elaboration of this resource may provide the professional with a systematized, operationalized, and standardized investigation in order to evaluate the person as a whole and help with the main difficulties encountered, collaborating in the adaptive process. To evaluate adaptation as a nursing goal, it is essential to construct and validate the content of the items contained in this instrument, in order to favor the planning and implementation of interventions considered adequate, efficient and effective for the promotion of effective behaviors[5].

Given the gap evidenced in the national and international literature, the construction and content validity by experts and the target population is a primary tool for providing significant contributions in the constitution of the items to be inserted into an assessment scale[5]. Thus, the following guiding questions were formulated: "Which items should be constructed to compose the The Scale for the Level of Adaptation of Ostomy Patients (SLAOP)?" and "Are the items that compose the SLAOP considered valid by expert and target population?"

The objective of this work was to construct and validate the content of the items that make up the SLAOP.

METHODS

Design

This is a methodological study represented in two stages, based on the psychometric model recommended by Pasquali[6], guided by the AGREE tool, which directs research on clinical practice guidelines. The first one was developed to build the instrument with the definition of the constructs based on the theoretical framework of MAR concepts; to consolidate it, two literature reviews and one qualitative study with people with intestinal stoma were carried out. The second stage checked content validity with judges. Figure 1 represents the steps developed in this study.

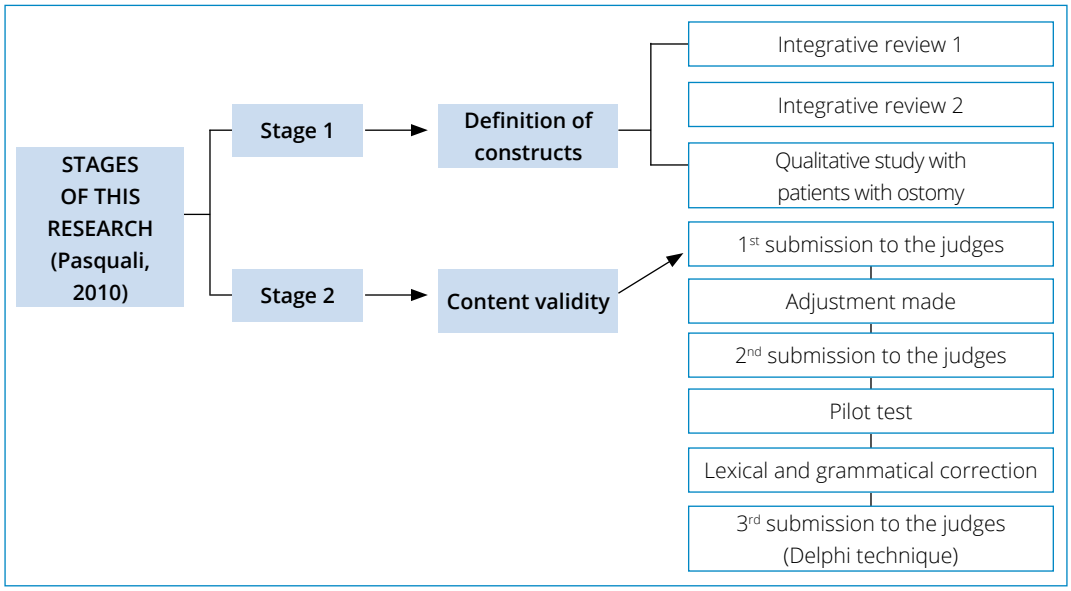

Figure 1. Flowchart of the steps of this research. Natal, RN, 2022.

First step: Definition of the constructs

Study protocol

The construction of the scale content, based on the concepts that comprise MAR, occurred through literature reviews and statements of people with ostomy, which were analyzed and distributed in the four adaptive modes. Figure 2 shows these steps and the quantity of indicators found.

Integrative review 1

The first literature review had as a guiding question, "What adaptive problems of MAR in people with ostomy are identified in the literature?" The search was conducted between the months of November and December 2015 in the following databases: Latin American Literature in Health Sciences (LILACS), Cumulative Index to Nursing & Allied Health Literature (CINAHL), Medical Literature Analysis and Retrieval System Online (MEDLINE), PUBMED and Web of Science.

Original articles, available in full, that mentioned at least one adaptive problem addressed in MAR were included in this review. Review articles, theses, dissertations, and editorials were excluded.

The review was produced as follows: in LILACS and MEDLINE databases, the search was performed by crossing the following Health Science Descriptors (DeCS): "estomia" AND ("adaptação" OR "ajustamento social" OR "adaptação psicológica" OR "transtornos de adaptação"). And in the international databases CINAHL, PUBMED and Web of Science,

the following descriptors identified in MeSH Terms were used: "ostomy" AND ("adaptation, psychological" OR "social adjustment" OR "adjustment disorders").

The analysis of the review data was based on the MAR and the list of adaptive difficulties contained in the model in order to classify the identified problems into the adaptive modes proposed by the framework.

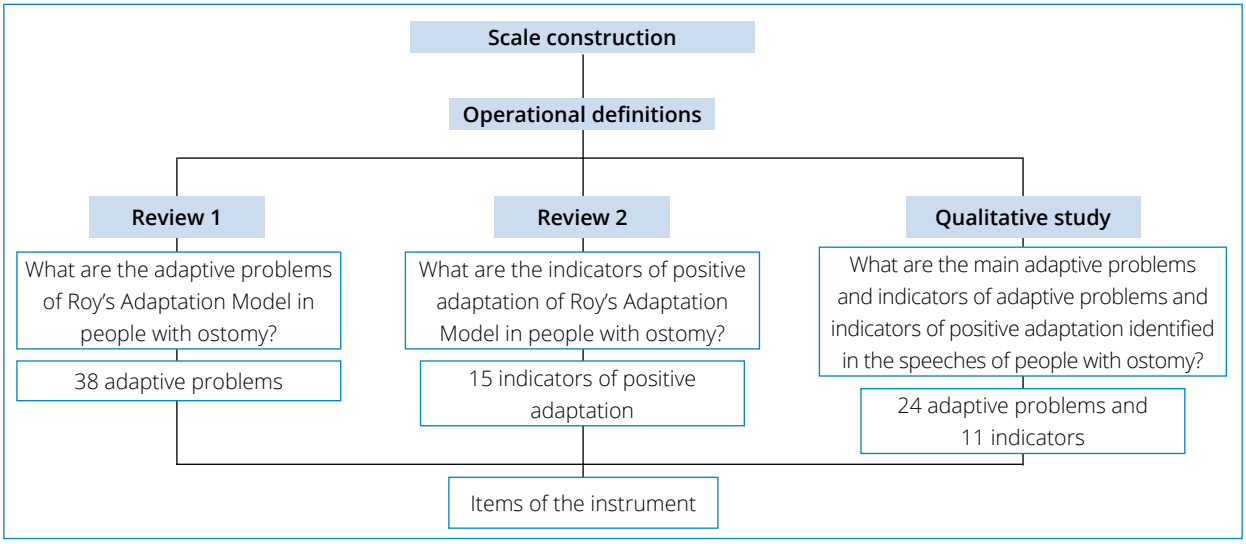

Figure 2. Flowchart with the steps for constructing the scale content. Natal, RN, 2022.

Integrative review 2

The second review was directed by the following research question: "What indicators of positive adaptation of MAR in people with ostomy are identified in the literature?" The collection of data in the literature was developed between May and June 2016 and included studies indexed in the LILACS, MEDLINE, CINAHL, Web of Science, and Scopus databases.

As criteria, original researches that referred to at least one indicator of positive adaptation evidenced by MAR or another element delimited by the model were selected.

The search was made using the following descriptors: "estomia" AND "adaptação psicológica" in the national databases. And the cross-referencing of the following English descriptors indexed in the MeSH Terms were used: "ostomy" AND "adaptation, psychological" in CINAHL, Web of Science and Scopus.

The data from this second review were analyzed according to the list of indicators of positive adaptation established by MAR. Furthermore, the description of the indicator of positive adjustment allowed the determination of references for the recognition of other indicators manifested by people with ostomy.

Qualitative research

The qualitative study was conducted to detect the main adaptive problems and indicators of positive adaptation of MAR in the reports of people with ostomy. The data was collected with 27 people in July 2016 at the Centro Especializado em Reabilitação e Habilitação do Rio Grande do Norte (CERHRN), a reference place for the assistance of the person with ostomy in the Brazilian state Rio Grande do Norte. The following criteria were adopted: to be registered in the Ostomy Association of Rio Grande do Norte, to be over 18 years old, to present a good health condition, and to have had an intestinal stoma for at least three months, due to the ease in getting these people in the care center and due to the fact of the initial adaptation to the impact that the stoma causes. Patients were excluded if they had any cognitive or speech deficits that prevented communication with the interviewer.

For execution, the selected participants were invited to participate in the research and clarified about the importance of the study and data safety, after confirmation and signing of the Informed Consent Form (ICF), the respondents answered

semistructured interviews, based on the four adaptive modes, with the following questions: "What changes do you perceive in your body and your organism after the ostomy?", "How do you see and feel after the ostomy?", "After the confection of the stoma, has your role at work, in the family, and in society as a whole changed?", "What is your day-to-day routine like?", "After the ostomy, has anything changed in your relationship with people?"

To enable the phase analysis, all the responses of the people with ostomy interviewed were recorded and transcribed. Subsequently, the data were verified by determining relative and absolute frequencies of the speeches referring to adaptive difficulties and indicators of positive adaptation of MAR, as well as in the face of new problems and impacts that emerged from the interview.

The interviews were conducted individually in a reserved room to ensure people's privacy and well-being, and all data were collected in a way that did not allow the identification of any respondent. At the end of this first stage, the instrument was made up of 45 preliminary items, which were submitted to the judges in the second stage of the study.

Second stage: Content validation with judges

After the construction of the instrument, we proceeded to the second stage of the research with the content validation, in which it was decided to use the Delphi technique of validation with judges. This step was based on the resumes identified in the Plataforma Lattes of the Conselho Nacional de Desenvolvimento Científico e Tecnológico (CNPq). Judges were contacted via email between September 26, 2016 through October 31, 2016 for subsequent contacts.

The selection was made by intentionality (people already known for productions in the area) and via authorship of articles, the Plataforma Lattes, and the snowball technique, in which the initial participants indicate other participants to compose the sample until the determined quantity is reached. For the selection of judges, the terms "estomia" and "ostomia" were searched in the Plataforma Lattes, after the application of the Fehring's criteria[7] (master in nursing: 4 points; master in nursing with dissertation in the area of interest: 1 point; published research on diagnosis or relevant content: 2 points; publication of articles on diagnosis in indexed journal: 2 points; doctorate in nursing with thesis in the area of interest: 2 points; recent clinical practice of at least one year in the topic of interest: 2 points; training in clinical area relevant to the diagnosis under study: 2 points). Among those who achieved a minimum score of 6 points in the predetermined requisites by Fehring, there were 83 judges, but only 9 returned the contact and participated in the research.

After clarifying the objectives and the importance of the research, agreeing to participate in the study, and signing the ICF, the experts had access to the instrument via e-mail. The following criteria were evaluated: behavioral, objectivity, relevance, clarity, simplicity, variety with regard to language, and with regard to the preferred scales. Each criterion was scored according to its representativeness: (1) Not representative; (2) Item needs major revision to be representative; (3) Item needs minor revision to be representative; (4) Representative[8].

The preliminary instrument contained 45 items and a field to recommend relevant changes to the items, add necessary items that were missing, or unnecessary items; as well as to insert comments regarding the evaluation of the items[8,9]. Apparent validation was performed on the presentation of the content, clarity and comprehension when reading the items.

The preliminary instrument went through three rounds of submission to the selected judges. The first round was conducted with nine judges and resulted in the pre-final version of the instrument. In the second round, after the adjustments requested by the judges in the first submission, eight of the nine judges participated. In this stage, a minimum agreement of 80% was expected for the instrument to be submitted to a pilot test for semantic analysis.

Pilot testing and lexical and grammatical correction

This last phase included ten people with ostomy, intentionally selected according to their level of education, with different levels of schooling. All participants were briefed about the research and agreed to participate by signing a two-part ICF.

The participants assessed whether they understood the items of the instrument by classifying them as A (easy to understand), B (medium understanding), and C (did not understand the item), which made it possible to identify whether

they were suitable for use with the various strata of the target population. For this, the Content Validity Index (CVI) was also used, dividing the number of patients who judged the item as easy or medium to understand by the total number of patients. After the pilot test, lexical and grammatical corrections were made with a Portuguese teacher. Following the adjustments and corrections, the third round of submissions to the judges took place.

Last round of submissions to the judges

To verify the level of agreement and consistency of the judges in relation to the permanence or not of the items that made up the instrument, the CVI was used, adopting a minimum agreement of 0.80. The index score was calculated by summing the agreement of the items that were scored by 3 or 4 by the judges, divided by the total number of responses[8,9]. To assess the content validity of the SLAOP, the Delphi technique was also used, which occurs in a systematized manner and should be performed as many times as necessary[10]. All data were analyzed and presented in such a way that no research judge could be identified.

Ethical aspects

The study was authorized by the Research Ethics Ctommittee of the Universidade Federal do Rio Grande do Norte under opinion number: 1,527,460 in the year 2016. The ethical aspects related to research with human beings were obeyed, with the request for authorization by signing the ICF after all the necessary explanations and confirmation of the safety of the data collected.

RESULTS

The first review resulted in 125 articles, and 23 were included as a result of the search. Figure 3 details the sample selection flowchart for review 1.

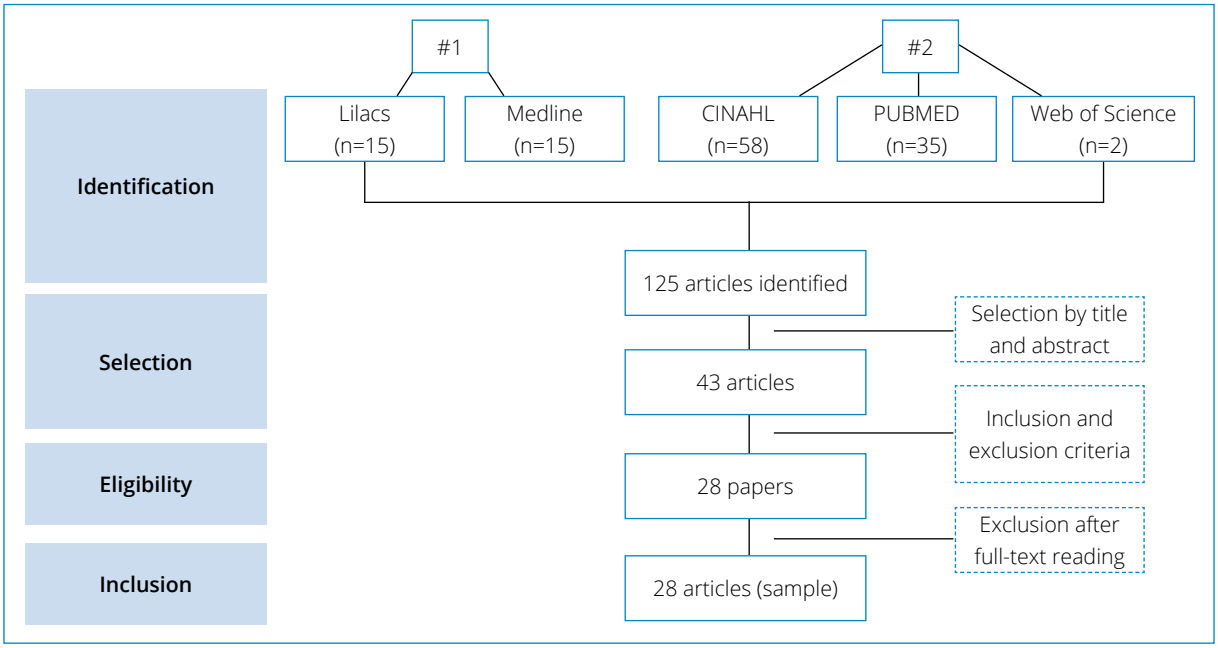

Figure 3. Flowchart of the integrative review 1. Natal, RN, 2022.

#1: "estomia" AND ("adaptação" OR "ajustamento social" OR "adaptação psicológica" OR "transtornos de adaptação"). #2: "ostomy" AND ("adaptation, psychological" OR "social adjustment" OR "adjustment disorders").

The second review detected 226 papers of which 19 were elected to constitute the final sample. Figure 4 presents the flow chart followed by the review study.

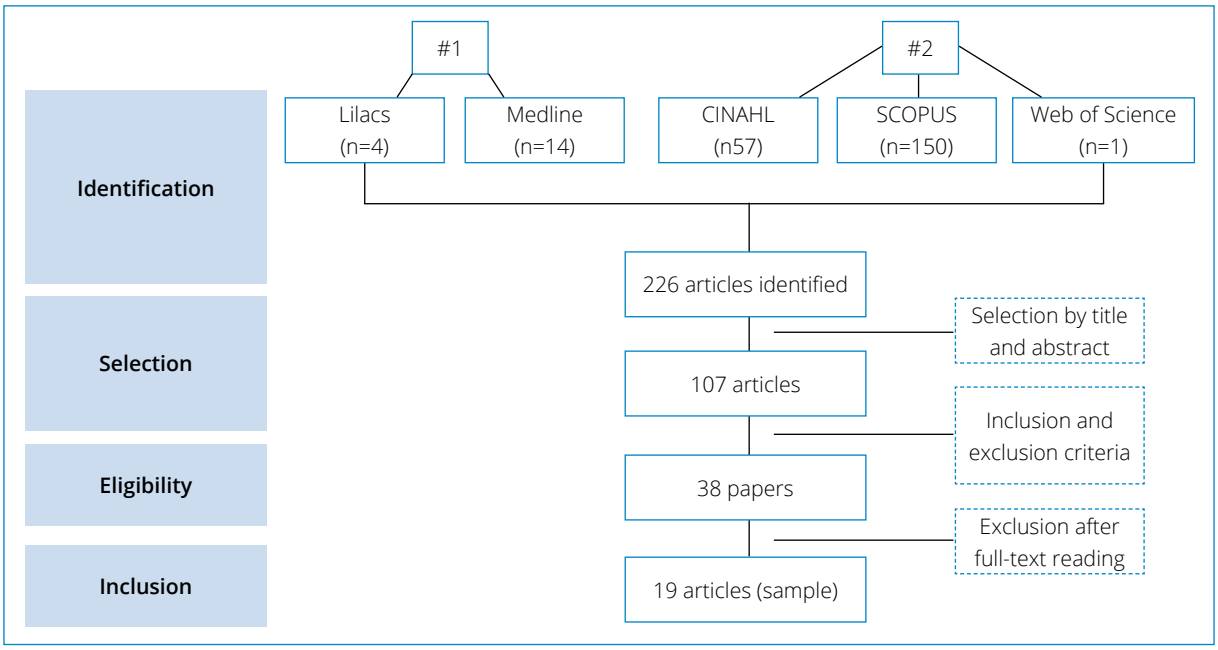

Figure 4. Flowchart of the integrative review 2. Natal, RN, 2022.
#1: "estomia" AND "adaptação psicológica". #2: "ostomy" AND "adaptation, psychological".

From these integrative reviews, 23 of the 78 adaptive problems presented in the model were identified, and 15 new ones evidenced in the literature were added. Furthermore, 6 of the 61 indicators of positive adaptation presented in the model were identified and 9 indicators were added.

Regarding the qualitative stage, 13 adaptive problems and 11 indicators of positive adaptation were identified in the speeches. Based on this, the constitutive and operational definitions obtained led to the elaboration of the 45 preliminary items of the instrument.

These 45 items from the preliminary instrument were arranged on a Likert type scale and then submitted to the first round of judges' appreciation. The content validity of the scale was performed by the evaluation of nine experts. Eight (88.9%) of them had the master's degree as their highest degree, four (44.4%) were graduated in the Northeast and six (66.7%) from public institutions, and the average time of graduation was 9.3 years. Five (55.6%) did not work in the field of enterostomal therapy, the average time working with people with ostomy was 7.1 years, and six (66.7%) said they studied and/or worked with ostomies due to affinity.

The preliminary instrument was sent and, after the judges' analysis in the first round of instrument submission, the physiological mode presented eight (50%) items with CVI above 0.80, as for the permanence of the item in the initially allocated mode, only three (18.7%) had 100% of responses favorable to the maintenance of the item in the mode. Regarding the aspects of representativeness and adequacy of the item to the adaptive mode, only four items showed a 100% adequacy percentage in more than 50% of the criteria.

In the validation of the physiological mode items, 11 (68.8%) items had as a majority response no suggestions for improvement and 11 (68.8%) had recommendations for removal from the instrument (Table 1). Considering the CVI, one item was removed in the instrument, two items were unified into one, and one item was relocated in the self-concept mode (Table 1).

Of the 17 items in the self-concept mode only four (23.5%) scored CVI above 0.8 and eight (47%) showed 100% responses in favor of keeping the item in the mode. Regarding the evaluation of the mode construction criteria, five (29.4%) items showed adequacy in all criteria, and 14 (82.4%) had a 100% adequacy percentage in more than 50% of the criteria. Regarding the options for withdrawal or suggestions for improvement of the self-concept mode items, two (11.8%) items had no suggestions and/or were recommended for deletion. The suggestions made for the items were about changes of terms and specification of some sentences. Given the CVI, the inadequacy of the criteria, and the recommendation for exclusion, three items were excluded from the instrument (Table 1).

Table 1. Final version of the instrument after lexical and grammatical correction of the SLAOP submitted to content validity by judges and target population. Natal, 2017.

Adaptive mode/Item	CVI 1st Round	CVI 2nd Round	CVI Target population
Physiological			
1. Not being able to control the elimination of intestinal gas bothers me.	1.00	1.00	0.90
2. The smell of feces coming from the collection bag bothers me.	0.89	1.00	1.00
3. I have no complications (allergies, prolapse, edema, bleeding, itching, leaks, pain, redness, and skin injuries) related to the ostomy.	0.89	1.00	1.00
4. It bothers me that I cannot perform the same activities after the ostomy.	0.89	1.00	1.00
5. The quality of my sleep got worse after the ostomy.	0.78	1.00	1.00
6. It bothers me to have constipation or diarrhea.	0.56	1.00	0.90
7. After the ostomy, I became more anxious.	0.67	1.00	1.00
Self-concept			
8. The ostomy has negatively affected my sex life.	1.00	0.89	1.00
9. I can adapt to the changes caused by the ostomy.	0.44	1.00	0.40
10. I am not satisfied with the way my body looks.	1.00	1.00	1.00
11. The stoma has negatively affected my self-esteem.	0.44	1.00	1.00
12. I feel ashamed because of the stoma.	1.00	1.00	1.00
13. I feel incomplete after the ostomy.	0.67	1.00	1.00
14. I feel that I am well informed about the stoma.	0.78	1.00	1.00
15. I feel powerless after the ostomy.	0.67	1.00	1.00
16. I accept the stoma.	0.78	1.00	1.00
17. I have difficulty looking at and touching the stoma.	0.89	1.00	1.00
18. I feel guilty for having a stoma.	0.33	1.00	1.00
19. I try to have good feelings about the stoma.	0.89	1.00	1.00
20. I would like to be able to reverse my ostomy.	0.78	1.00	1.00
21. I don't think I will ever get used to having a stoma.	0.89	1.00	1.00
22. My religious belief helps me to cope with my condition of having a stoma.	1.00	1.00	1.00
23. I don't like how I dress now because of the stoma.	0.67	1.00	1.00
24. I feel good after the construction of the stoma.	0.89	1.00	1.00
Role function			
25. I am not seen as before, in the family, at work, at school and in other places I go, after the ostomy.	0.89	1.00	0.90
26. I withdrew from my social activities because of the stoma.	1.00	1.00	1.00
27. After the ostomy, I changed my social role.	1.00	1.00	0.80
28. The costs with the stoma harm me.	0.89	1.00	1.00
Interdependence			
29. The ostomy caused me loneliness.	0.89	1.00	1.00
30. The stoma has not affected my relationship with other people.	0.78	1.00	1.00
31. The stoma causes me shame and that is why I hide it.	1.00	1.00	1.00
32. I participate in the support group for people with ostomy.	0.78	1.00	1.00

CVI: Content Validity Index

Therefore, in the adaptive mode role function, four (100%) items showed CVI above 0.8 and two (50%) items showed full permanence recommendation. As for the evaluation of the construction criteria, four (100%) showed adequacy in more than 50% of the criteria. About the observations made by the judges, four (100%) items had suggestions for improvement and two (50%) had recommendations for deletion (Table 1).

Finally, the judges evaluated items in the interdependence mode, of which three (42.9%) had CVI above 0.8 and four (57.1%) had all responses directed toward keeping the item in the mode. Thus, of the seven items evaluated, five (71.42%) had more than 50% of the criteria evaluated as adequate and one item had all criteria evaluated as inadequate. As for the observations made by the judges, of the seven items, four (57.1%) had suggestions for improvement. None of the interdependence mode items received suggestions for change, but taking into consideration the CVI, the inadequacy of the criteria, and the recommendation for exclusion, two items were removed from the instrument.

After all the adjustments were made, the instrument that initially contained 45 items, ended the first round with 34 items. After the first round of instrument submission and suggested adjustments, the second round with experts was carried out (Table 1).

The first adaptive mode (physiological) in the second round of judges' evaluation, in which all items presented CVI above 0.80, regarding the permanence of the item in the allocated mode, ten (91.0%) had 100.0% of favorable responses to the maintenance of the item in the mode and only one item had disagreement in the permanence in the mode. Of the eleven items evaluated, ten presented a percentage of adequacy above 87%; however, one item obtained a percentage of objectivity, simplicity, clarity, relevance, typicality, and credibility below this value. Of all the items analyzed by the judges, seven received suggestions for improvement. When considering the indices cited above, four items were unified for similarity of approach and one item was excluded because of similarity with another item of the self-concept mode (Table 1).

As for the self-concept mode, all 17 items in the adaptive mode obtained values above 0.8 and showed 100.0% responses favorable to keeping the item in the mode. About the evaluation of the construction criteria, nine (53.0%) items showed suitability in all criteria and eight (47.0%) showed a percentage of suitability of 100.0% in more than 50.0% of the criteria and the other criteria had a percentage of suitability above 87%. Regarding suggestions for improvement of the self-concept mode items, 64.7% of the items had no allusions to improvement. The suggestions made concerned changes in terms and specifications of some sentences. Taking into consideration the CVI, the suitability of the criteria, and the suggestions made, the items were kept in the instrument (Table 1).

Therefore, in the role function mode, all items scored maximum CVI and showed full recommendation to stay in the mode. As for the evaluation of the construction criteria, 100.0% showed adequacy in all criteria. The paper function mode items did not get any suggestions for improvement. Considering the CVI values, 100.0% adequacy to the construction criteria, and the absence of suggestions for improvement, all items were kept in the instrument (Table 1).

Finally, the judges evaluated the interdependence mode items, which reached maximum content validity index, there was unanimity in the judges' responses regarding the permanence in the mode, and all the construct criteria obtained a 100% adequacy percentage (Table 1).

After making the required adjustments, the version of the instrument after the second round of submission to the judges ended up with 32 items. The pilot test was then carried out with ten people with ostomy with ages ranging from 26 to 66 years old, and levels of education ranging from elementary school to incomplete high school. In this evaluation, 31 (96.9%) items obtained CVI above 0.8 and only one item was classified with a low CVI (0.4); however, it was decided to keep it, because it was an item considered important for the self-concept mode by the judges and the researcher. In this sense, this item was highlighted in the next step of lexical and grammatical correction with the Portuguese proofreader. Of the 32 items evaluated, 17 (53.1%) were modified for wording adequacy and item clarity (Table 1).

The instrument was once again sent to the judges to assess whether or not they agreed with the items. Of the eight judges who participated in the second round, seven responded. The same order of evaluation of the items was followed, and the judges agreed on the representativeness of the items and the permanence in the modes, obtaining a CVI of 1.00 in all items evaluated (Table 1).

DISCUSSION

From the stages performed it was possible to structure items according to the theoretical framework of adaptation modes proposed by Callista Roy and validate the content with experts. Thus, in the physiological mode, issues such as the discomfort of uncontrolled gas elimination, problems with unpleasant odor, stress, physical limitations, leaks, complications, pain, and changes in sexual activity were allocated.

It was verified that the uncontrolled elimination of gases causes embarrassment, culminating in social isolation and hindering the physiological adaptation and self-concept of the person with ostomy[11]. Foul odor is also a physiological problem and is related to the type of excreta eliminated and stored in the ostomy pouch[11]. Domain changes were necessary, as the item related to the stress caused by the stoma was allocated in the self-concept mode and this adaptive problem is related to moments of distress, doubts and anger that can make this experience very stressful[1].

Episodes of leakage are also common, mainly due to the lack of habit in the correct handling of the collecting equipment, making the experience of having a stoma even more negative, resulting in reduced participation in social events1. Regarding the incidence of complications, it is observed that dermatitis is the most frequent and is generally related to the inadequate use of the collection equipment[12].

Also, although items such as pain and body image disturbances are allocated in physiological adaptation, they may be associated with other modes, such as self-concept. As for pain, its presence negatively affects well-being and quality of life. It is noteworthy that, under normal conditions, the stoma should be painless, so its occurrence deserves to be highlighted[13]. In addition, body image disturbance related to leaking during sexual intercourse, social isolation and physiological changes in the sexual organs are present in both sexes, interfering with quality of life and the adaptive process[13,14].

About the items of the self-concept mode, those that dealt with dissatisfaction with the appearance of the body, the feeling of embarrassment about the stoma, the difficulty in looking at the stoma, the optimism in relation to the stoma, the feeling that you will never get used to the stoma, and feeling better after the construction of the stoma stood out. Body image disturbance is characterized by how individuals see, feel and behave after the change, directly interfering in expressions of approval or disapproval of themselves[15].

The scale items in the self-concept domain show that the embarrassment caused by the stoma is glimpsed in the constant report of the need to hide it. The social valorization of the body and the new standards of body aesthetics influence clothing, establishing a new relationship with the body[16]. The difficulty in looking at the stoma is reported mainly by the absence of orientation and clarification, causing feelings of rejection to the unknown. Some attempts to minimize this are being made with the preoperative demarcation of the ostomy site and the institution of teaching strategies[1,17]. The item that deals with optimism regarding the stoma approaches the attempts to visualize the positive aspects of its construction, which are fundamental in the process of acceptance and adaptation of the person with ostomy conferring a better quality of life, positive and hopeful feelings[18].

One of the items inserted in the scale is about the feeling that the individual will never get used to it, which clearly represents an inefficient adaptive process, in which the stoma is not accepted and the negative aspects overlap the positive ones. In these situations, nursing must act, providing information that can clarify the person with ostomy regarding their adaptive demands and effective coping strategies[19,20]. Regarding the feeling of improvement after the ostomy, this is often present when the condition before the ostomy caused a great impact on the person's health and well-being, and the creation of the stoma results in improved quality of life[1].

The items in the role function mode domain are about the interference of the stoma in work and/or school activities, detachment and/or change of the social role, and the financial costs of the stoma care. About the interference of the stoma in the labor activities, it is known that there are few restrictions regarding the exercise of the work, which must be analyzed, selected and adapted to the possibilities of the person with ostomy[21].

The main difficulties in returning to work activities include physical effort at work, difficulties inherent to the loss of sphincter control, the presence of odor, gas, volume and diarrhea, difficulties in sanitizing the stoma and inappropriate toilets[20,21]. These problems cause social withdrawal due to the discrimination suffered in the work environment, the

impossibility of returning to the activities performed before the ostomy[22], and the change and distancing of the social role. To minimize this, it is necessary the knowledge of the controlled and regulated functioning of the stoma, acceptance and adaptation to the condition of the person with ostomy and favorable conditions to return to the work activity[23]. The care with the stoma may demand financial resources for the dislocation to the place where the bags are distributed, participation in consultations, acquisition of collecting equipment and adjuvants, causing concern at the possibility of lacking some of these important materials for self-care[1].

Finally, there was the analysis of the interdependence mode items that dealt with social isolation after the ostomy, the need to hide the stoma, and the relationship with other people affected negatively after the ostomy. Social function is one of the domains affected in the quality of life of people with ostomy. It is expressed in involvement in family and social events, leisure activities, and also in participating in work activities and carrying out activities of daily living. Sociodemographic, psychological, and social factors can also influence aspects of quality of life[21].

Some reports from people with ostomy show possible causes for the social isolation, being the certainty of the incomprehension of other people in relation to what a stoma is and not wanting to explain what it is about13. The relationship with others negatively affected by the stoma is an adaptive problem involving multiple issues. Acceptance and adaptation to the stoma is not only a need of the person with ostomy, but of all those who are part of their support network[13].

The judges' consensus regarding the construct's representativeness and the items' agreement with the construct's criteria demonstrate the relevance of the scale's content validation based on elements of Roy's adaptation theory. The Delphi technique contributed to reaching the maximum level of agreement on the items of the instrument, allowing the critical judgment of the information from different perspectives inherent to each professional to build a consensus on a given topic[10].

As a limitation of the study, the delay of the judges and the small number of responses stand out as a delaying factor for data interpretation and development of results. It is expected that the use of this instrument contributes to the qualified and integral assistance to the person with ostomy, considering their real needs and the specific aspects of each individual in order to facilitate the adaptive process to the new condition of having a stoma.

CONCLUSION

Thus, the scale was constructed and presented content validity of the items through the consensus among the judges, represented by the maximum CVI and consequent achievement of the Delphi technique, regarding the representativeness of the items and permanence in the modes. The scale consisted of 32 items distributed over the four MAR adaptive modes, physiological mode (n = 7), self-concept (n = 17), role function (n = 4), and interdependence (n = 4). At the end, the scale was named as The Scale for the Level of Adaptation of Ostomy Patients (SLAOP).. It is expected that this scale makes it possible to evaluate the domains related to the adaptive process of the person with a stoma and to contribute to the planning and improvement of the quality of the care provided. Thus, the use of this tool is recommended in services that provide assistance to people with ostomy.

AUTHORS' CONTRIBUTION

Conceptualization: Costa IKF; Medeiros LP and Xavier SSM; **Methodology:** Costa IKF; Medeiros LP and Xavier SSM; **Investigation:** Medeiros LP; Xavier SSM; Freitas LS; Silva IP; Brito Do O L, Lucena SKP and Silva RA; **Writing - First Draft:** Medeiros LP and Xavier SSM; **Writing - Review & Editing:** Medeiros LP; Xavier SSM; Freitas LS; Silva IP; Brito Do O L, Lucena SKP and Silva RA; **Funding Acquisition:** Costa IKF; **Resources:** Costa IKF; **Supervision:** Costa IKF; Medeiros LP and Xavier SSM.

AVAILABILITY OF RESEARCH DATA

The data will be available upon request.

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