

Validity of an instrument on Nursing care for people with chronic wounds

Validade de instrumento sobre os cuidados de Enfermagem às pessoas com feridas crônicas

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ABSTRACT

Objective: to build and validate the content of an instrument to investigate changes in the Nursing care provided to people with chronic wounds. **Methods:** methodological study, consisting of the stages of development and content validity, according to the criteria of clarity and relevance, by six judges, using the Delphi technique in two rounds. A Coefficient of Content Validity ≥ 0.8 was considered adequate. **Results:** the first version of the instrument contained 15 questions and after the judges' evaluation it was reduced to 11, addressing the periods before and during the pandemic. In the second round of evaluation, it was verified that the instrument showed a total content validity coefficient equal to 0.96. **Conclusion:** the instrument showed evidence of content validity and can be used to investigate possible changes resulting from the pandemic of COVID-19 in the Nursing care of people with chronic wounds in Primary Care.

Descriptors: Coronavirus Infections; Primary Health Care; Wounds and Injuries; Nursing Care; COVID-19.

RESUMO

Objetivo: construir e validar o conteúdo de um instrumento para investigar mudanças nos cuidados de Enfermagem às pessoas com feridas crônicas. **Métodos:** estudo metodológico, constituído das etapas de elaboração e validade de conteúdo, segundo os critérios de clareza e pertinência, por seis juízes, utilizando a técnica Delphi em duas rodadas. Considerou-se adequado um Coeficiente de Validade de Conteúdo $\geq 0,8$. **Resultados:** a primeira versão do instrumento continha 15 questões e após avaliação dos juízes reduziu-se para 11, abordando os períodos antes e durante a pandemia. Na segunda rodada de avaliação, verificou-se que o instrumento apresentou coeficiente de validade de conteúdo total igual a 0,96. **Conclusão:** o instrumento mostrou evidências de validade de conteúdo, podendo ser utilizado para investigar possíveis mudanças decorrentes da pandemia da COVID-19 nos cuidados de Enfermagem de pessoas com feridas crônicas na Atenção Básica.

Descritores: Infecções por Coronavírus; Atenção Básica à Saúde; Ferimentos e Lesões; Cuidados de Enfermagem; COVID-19.

Introduction

The pandemic caused by the Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2) that began in early 2020, causing the coronavirus disease (COVID-19), has disorganized health care systems worldwide, changing the work process of Primary Health Care, known in Brazil as Primary Care, to meet the new demands of the population, including the care of suspected and confirmed cases of the disease⁽¹⁾.

The burden of COVID-19 on Primary Care can be explained by the presence of three waves: direct morbidity and mortality impacts of COVID-19; acute and chronic complaint demands secondary to resource restriction and/or no demand for health services; and impacts of these two waves on the mental health of the population⁽²⁾.

In the second wave, the repercussions of the pandemic on the management of chronic conditions are highlighted. Access restrictions or people's fear of seeking health services cause unassisted health care and tend to destabilize chronic conditions, leading to acute episodes⁽³⁾.

Among these conditions, chronic wounds, also called hard-to-heal wounds, are highlighted, mainly characterized by prolonged duration of treatment and frequent relapses⁽⁴⁾. Corroborating such issues, a study⁽⁵⁾ shows that the interruption of regular follow-up of people with diabetes mellitus during the pandemic had a deleterious effect on acute complications related to the diabetic foot, being associated with an increase in severe infections and a 10.8 times higher probability of suffering any level of amputation compared to the period before the pandemic.

In the context of care for people with chronic wounds, the nurse is responsible for the holistic assessment of the user, topical treatment of the injury and health education, performing the nursing consultation, guidance for self-care, collective educational activities, home visits, among others⁽⁶⁾. During the pandemic, the effectiveness of these practices may have been impaired by the interruption of procedures

wrongly classified as elective⁽⁷⁾.

Thus, the need to know the nursing care of people with chronic wounds in the face of the pandemic of COVID-19 and under what conditions these injuries developed emerges, enabling the knowledge of the actions taken by nurses for the continuity of care for this population. For this, it is essential to have a reliable instrument for data collection, i.e., capable of obtaining reliable information of what is proposed. However, we found a lack of validated instruments to analyze the nursing care of people with chronic wounds in the context of the pandemic.

Thus, the following guiding question for this study stands out: What is the evidence for the content validity of an instrument to investigate changes resulting from COVID-19 in the Nursing care of people with chronic wounds in Primary Care?

Considering the above, this study aimed to build and validate the content of an instrument to investigate changes in the Nursing care provided to people with chronic wounds.

Methods

This is a methodological study, developed between September 2020 and February 2021, following two stages, namely: instrument development and content validity. In the first stage, a literature search was conducted on the nursing care of people with chronic wounds seen in Primary Health Care, in the context of the COVID-19 pandemic. The literature review was performed in the Latin American and Caribbean Literature on Health Sciences (LILACS), Medical Literature Analysis and Retrieval System Online (MEDLINE), Cumulative Index to Nursing and Allied Health Literature (CINAHL) and Web of Science databases, using the health science descriptors (DeCS) "Wounds and Injuries" AND "Primary Health Care" and their respective translations in English and Spanish versions. Inclusion criteria were articles⁽⁶⁾ with freely available full content, written in Portuguese, English and Spanish and published in the years 2020 and 2021, to select

only studies published in the context of the pandemic.

The instrument was developed based on the practical experience of the researchers and on the database search, in which publications related to the nursing care of people with chronic wounds and the organization of Primary Care during the COVID-19 pandemic were identified.

Fifteen objective questions were developed, divided initially into two dimensions: before (questions 1 to 5) and during the pandemic of COVID-19 (questions 6 to 15). The questions addressed the following variables: main types of chronic wounds presented by the enrolled population (question 1), personal protective equipment (questions 2 and 7), materials and solutions for hand hygiene (questions 3 and 9), materials and dressings used in the care of people with chronic wounds (questions 4 and 10), actions performed by nurses (questions 5 and 11), amount of people with chronic wounds seen in primary care (question 6), training on the use of personal protective equipment (question 8), human resources after the beginning of the pandemic (question 12), removal of professionals because they are risk group (question 13) or because they contracted COVID-19 (question 14) and feeling of safety/ability to care for people with suspected or confirmed diagnosis of COVID-19 (question 15).

In the second stage, the content validation of the instrument was performed by judges with knowledge in Dermatologic Nursing or stoma therapy. The Delphi technique was used in two rounds to reach consensus in the judgment of the instrument⁽⁶⁾. The following criteria were considered for the selection of judges: undergraduate degree in Nursing, PhD in progress or completed, with at least two years of professional experience in assistance, teaching or research in wounds.

The judges were recruited through email contact with the coordinator of the Study and Research Group on Wound Care of the Federal University of Paraíba, who provided information (name, telephone contact and academic background) of the group members. It was decided to recruit the judges of this study

group because of the multiplicity of research carried out in wounds, using as reference a study previously conducted⁽⁹⁾. It is also justified that the research group is linked to the National Council for Scientific and Technological Development, has 15 years of existence, and brings together professionals in Dermatologic Nursing and Stoma Therapy.

The researchers made contact through social media (WhatsApp) with 13 eligible nurses, six of whom agreed to participate in the validity stage. The judges who agreed to participate received explanations about the research by e-mail, which included a letter of introduction, the Informed Consent Form, and the Electronic Form for validity of the instrument. Thus, we met the recommendation that defines as ideal sample those that contain between 6 and 10 evaluators⁽⁷⁾.

In the first round of evaluation (Delphi I), the judges were asked to evaluate the content of each item of the instrument, considering the criteria of pertinence (if the items are appropriate and relevant) and clarity (if the items are impartial, direct, practical, and clear). Each item was evaluated based on a Likert-type Scale, with the following scores: 1 (disagree), 2 (partially disagree), 3 (partially agree), and 4 (agree). A space was made available for suggestions for improvement and comments. In this process, the judges also had the opportunity to make suggestions for adjustments, inclusion, or exclusion of content.

A deadline of 15 days was set for the judges to perform the evaluation in both the first and second rounds, and if the data was not returned within this period, a new contact would be made, granting another 15 days for the return. The period of 15 days between the Delphi rounds was considered for the systematization of the data to be sent again to the specialists.

After returning the evaluations, the data were organized in an electronic spreadsheet and analyzed with the help of the SPSS version 21.0. The analysis was done by means of the Content Validity Coefficient (CVC). The calculation of the error (Sp) was also per-

formed, resulting in the calculation of the instrument's total content validity coefficient (CVCT)(7). Considering that the standard error calculated in the study had a very low value ($Sp=0.000021$), the CVCT was equivalent to the CVC.

A CVC ≥ 0.8 was considered adequate, and the questions that did not reach this value were modified⁽⁷⁾. The questions that obtained indexes below this value were excluded or reformulated, according to the judges' suggestions. The instrument with the pertinent adjustments was judged again (Delphi II) as to content, to validate the final version of the instrument.

The study met the ethical and legal aspects established by Resolution No. 466/2012, of the National Health Council and was approved by the Ethics Committee on Research involving Human Beings of the Center for Health Sciences, Federal University of Paraíba, through Opinion No. 4,432,653/2020.

Results

In the first stage, 140 publications were found, however, only 11 were used in the development of the instrument. In the second stage, six nurses evaluated the instrument and analyzed the adequacy of the proposed questions.

All judges were female (100%), aged between 36 and 54 years, with a mean age of 46.3 years (standard deviation (SD) ± 7.9). As for qualification, 66.7% were PhDs, 33.3% were studying for a doctorate, 50% were specialists in dermatologic nursing or stomal therapy and 50% worked in teaching. The time of training ranged from 14 to 29 years, with a mean of 22.17 years (SD ± 5.8). The judges participated in the activities developed by the research group and studies on nursing care to people with wounds. All of them have published works on the subject in the last five years.

In the first round of content validity, validity of the dimension of nursing care of people with chronic wounds before the pandemic was verified, with CVCT equal to 0.93, considered excellent. After the judges' analysis, it was suggested to add in question number

two the items "shoe cover" and "others". This suggestion was accepted as it would make it possible to obtain additional data.

Regarding the dimension of Nursing care during COVID-19, the CVCT was also considered excellent (CVCT ≥ 0.92). However, due to the judges' evaluation, two items ("soap" and "disposable towels") were reformulated as follows: "soap for hand hygiene" and "paper towel", to facilitate nurses' understanding.

Based on the CVCT, the instrument presented an index of 0.93 in the first round, and the recommendations proposed by the judges were fully accepted. Moreover, the judges considered in their comments that the instrument was extensive and suggested the union of some questions (2 and 7; 3 and 9; 4 and 10; 5 and 11), and that it was necessary to include in the alternatives a proper place for the professional, when answering the instrument, to mark the item used in the respective period of care (before and after the beginning of the pandemic), being able to mark more than one alternative, for example, if the nurse marks both alternatives in the item "alcohol gel" it means that he used this product both before and during the pandemic.

After the reformulations, the instrument now has 11 questions, which allow the evaluation of possible changes in the use of materials and performance of care actions, as well as the identification of other relevant aspects for nursing care, such as the reduction of the professional team. The division of the instrument into two dimensions was not used in the final version, because there was a union of questions that began to simultaneously approach the two periods. With the objective of ratifying the modifications suggested by the judges, a second round of validity of the instrument was carried out by the same group of judges. In the second round of evaluation, it was verified that the instrument presents evidence of content validity regarding the clarity and relevance of the items, which obtained CVCi ≥ 0.80 in both criteria evaluated and CVCT equal to 0.96 (Table 1).

Table 1 – Coefficient validity of the items after the second round (Delphi II), in relation to clarity and relevance (n=6). João Pessoa, PB, Brazil, 2021

Items	Clarity	Relevance
1) What are the main types of chronic wounds that are followed up in the Basic Health Unit that you work? Allow more than one alternative	1.00	0.96
1.1) Diabetic foot ulcer	1.00	1.00
1.2) Venous ulcer	1.00	1.00
1.3) Arterial ulcer	1.00	1.00
1.4) Pressure injury	1.00	1.00
1.5) Oncologic wound	1.00	1.00
1.6) Hansen's lesions	1.00	1.00
1.7) I don't remember the type of chronic wound	1.00	1.00
1.8) Other	1.00	1.00
2) After the beginning of the pandemic of COVID-19, the number of people with chronic wounds, regularly followed up by the Basic Health Unit: () Reduced; () Increased; () Maintained the same number	0.96	1.00
3) Before and after the onset of the COVID-19 pandemic, what Personal Protective Equipment did you use in performing care for people with chronic wounds? Allow more than one alternative	1.00	1.00
3.1) Surgical mask	1.00	1.00
3.2) N95 mask	1.00	1.00
3.3) Face shield or facial protector	1.00	1.00
3.4) Sterile glove	1.00	1.00
3.5) Procedure gloves	1.00	1.00
3.6) Protective Glasses	1.00	1.00
3.7) Disposable aprons	1.00	1.00
3.8) Disposable hats or caps	1.00	1.00
3.9) Propé	0.88	0.88
3.10) Others:	1.00	1.00
4) After the beginning of the pandemic did you receive any kind of training on the use of individual protection equipment in the Basic Health Unit? () Yes () No	0.96	1.00
5) Before and after the beginning of the pandemic of COVID-19, what materials/solutions were used in the Basic Health Unit to perform hand washing/hygiene?	0.96	1.00
5.1) Soap	0.96	1.00
5.2) 70% Alcohol	0.96	1.00
5.3) Gel Alcohol	0.96	1.00
5.4) Paper towel	0.96	1.00
5.5) Others:	0.96	1.00
6) Before and after the onset of the COVID-19 pandemic (March 2020), what materials and dressings did you use in performing care for people with chronic wounds?	1.00	1.00
6.1) 0.9% saline solution	1.00	1.00
6.2) Sterile forceps	1.00	1.00
6.3) Scalpel blades	1.00	1.00
6.4) 20 ml syringe	1.00	1.00
6.5) 40mmx12mm needle	1.00	1.00
6.6) Infectious material bag	1.00	1.00
6.7) degerming povidine	1.00	1.00
6.8) Alcoholic povidine	1.00	1.00
6.9) Chlorhexidine degerming agent	1.00	1.00
6.10) Alcoholic chlorhexidine	1.00	1.00
6.11) Solution or degerming agent based on Poly hexamethylene Biguanide	1.00	1.00
6.12) Gauzes	1.00	1.00
6.13) Compressas6.4) Seringa de 20 ml	1.00	1.00
6.14) Crepe bandages	1.00	1.00
6.15) Adhesive tape	1.00	1.00
6.16) Hypoallergenic adhesive	1.00	1.00
6.17) Silver sulfadiazine	1.00	1.00
6.18) Collagenase	1.00	1.00
6.19) Vegetable oil composed of essential fatty acid	1.00	1.00
6.20) Hydrogel	1.00	1.00
6.21) Calcium alginate	1.00	1.00
6.22) Hydrocolloid	1.00	1.00
6.23) Polyurethane film or film	1.00	1.00
6.24) Sterile non-adherent cover	1.00	1.00
6.25) Activated carbon	1.00	1.00
6.26) Coatings impregnated with silver	1.00	1.00
6.27) Polyurethane foams	1.00	1.00

(the Table 1 continue in the next page...)

Items	Clarity	Relevance
7) Before and after the beginning of the pandemic of COVID-19 what actions were performed by you in the care of people with chronic wounds, seen at the Basic Health Unit you work at? Allow more than one alternative	1.00	1.00
7.1) Scheduling of users for care	1.00	1.00
7.2) Nursing consultation	1.00	1.00
7.3) Dressing at the health unit	1.00	1.00
7.4) Home visit to perform bandages	1.00	1.00
7.5) Orientation for wound care at home	1.00	1.00
7.6) Delivery of materials to people with chronic wounds or family members/caregivers for home dressing	1.00	1.00
7.7) Collective educational activities (in groups)	1.00	1.00
7.8) Individual educational activities	1.00	1.00
7.9) Guidance for self-care	1.00	1.00
7.10) Use of telecare (by telephone, on-line chat or WhatsApp)	1.00	1.00
7.11) Hygiene of the environment before and after the consultations	0.96	1.00
7.12) Availability of material for hand hygiene	1.00	1.00
7.13) Mandatory use of mask by the user	1.00	1.00
7.14) Attendance in external areas	1.00	1.00
7.15) Others: _____	1.00	1.00
8) Has the pandemic of COVID-19 interfered in the number of professionals working in the Basic Health Unit? () Yes () No	0.92	0.83
9) In the Basic Health Unit that you work, have there been professionals on leave because they are in the risk group for COVID-19? () Yes () No. If yes, please specify	0.92	0.88
10) In your Basic Health Unit have there been professionals on leave because they contracted COVID-19? () Yes () No. If yes, please specify	0.92	0.88
11) In your opinion, are you able and do you feel safe to assist/care for people with chronic wounds that have a suspected or confirmed diagnosis of COVID-19? () Yes () No	0.96	0.96

Discussion

The limitations of this study include the small number of studies addressing wound care in the context of the pandemic of COVID-19, making it difficult to obtain a greater theoretical basis on the subject. Other limitations were: small number of specialists who agreed to participate in the research, greater academic experience and absence of judges from other regions of the country, so that the suggestions found may not represent the national reality.

Given the importance of the continuity of nursing care for people with chronic wounds during the pandemic, the proposal to build an instrument to investigate changes in the context of Primary Care was seen as an opportunity to recognize the potentialities and deficiencies in the actions developed by nurses in this period. The expectation is the dissemination of the instrument and its use in different locations, enabling the knowledge of important information about the assistance offered in basic health units, regarding the use of personal protective equipment, materials

and solutions used for hand hygiene, reduction of the professional team and actions performed by nurses.

In future studies, these findings will allow the recognition of operational and material adjustments made to ensure care to users, in order to give visibility to the role of Primary Care in combating health problems, the need to continue the assistance focused on chronic conditions in order to avoid complications, despite the difficulties faced during the pandemic, such as reduction of face-to-face care (nursing consultation, home visits, among others), use of telecare and withdrawal of professionals, allowing managers to know possible weaknesses in the care of people with chronic wounds.

In addition, the recognition of the organizational changes in Primary Care caused by the nurse's performance in the COVID-19 frontline will contribute to the theoretical framework that guides nursing work, enabling the creation of strategies that promote the quality of care provided to people with chronic wounds.

Regarding the characteristics of the participants, females prevailed, corroborating other studies on validation in the Nursing area⁽⁹⁻¹⁰⁾, a finding that highlights the historical prevalence of women in the profession. Moreover, the delimitation of the inclusion criteria of judges with doctoral or doctoral degrees and with experience in the theme of chronic wounds adds to the study the scientific knowledge of the judges and seeks to give greater accuracy to the instrument, since the level of qualification of the judges is related to the quality of validation⁽¹¹⁾.

In the first round of instrument evaluation, the suggestions presented by the judges were fully accepted and referred mainly to the grouping of similar questions to facilitate the understanding of the interviewee during data collection. Although there is no consensus about the ideal number of questions for an instrument, it is important that the researcher consider the number of questions so as not to discourage the participation of the respondent⁽¹²⁾. Given the suggestions made by the judges, it was perceived as a positive contribution to the reformulation of the instrument, making possible the adjustment of items considered inadequate and optimization of questions with similar items.

The judges also indicated the inclusion of the shoe cover in the question that refers to personal protective equipment. It is noteworthy that the shoe cover is not routinely used for dressings, especially in Basic Health Units⁽¹³⁾. However, we decided to keep this item, which had a validity coefficient greater than 0.8 (CVCi=0.88), since some health services started to make shoe covers available for patients with suspected or diagnosed COVID-19 outside of the surgical environment, justifying that the SARS-CoV-2 virus can be found on surfaces such as floors and shoes⁽¹⁴⁾. In summary, the item "shoe cover" will bring additional information about possible differences in the use of personal protective equipment before and during the pandemic.

To ensure a safe and quality care, it is important to use adequate Personal Protective Equipment

provided in sufficient numbers to health professionals and symptomatic individuals. This concern should be part of the daily routine of workers who make up the primary care teams because they are in direct contact with people and, consequently, are exposed to COVID-19, however, due to the scarcity of research, it is only possible to demonstrate the problem⁽¹⁵⁾.

In the second round of content validity, it was found that the instrument proved valid regarding clarity and relevance. The validity of instruments in scientific research is important to ensure the quality of the data collected, besides allowing their application in future research⁽⁸⁾. These results agree with other studies that considered the need for at least 80% agreement between the judges in the process of content validity⁽¹⁶⁻¹⁷⁾.

The nursing care of people with chronic wounds in primary care has gained notoriety with the pandemic of COVID-19, as experiences from this context have suggested that wound care services may be misclassified as elective care⁽⁷⁾.

Given the current pandemic context, it is necessary that Primary Care can organize its care flows to provide comprehensive care to users throughout the life cycle through preventive actions, health promotion, diagnosis, treatment, and rehabilitation, in addition to health surveillance and palliative care. After all, lives go on, needing care, some constant, such as those of people with skin wounds that require specific actions to prevent the worsening of health conditions unrelated to COVID-19⁽³⁾.

The formulation of strategies that enable the monitoring of people with chronic wounds in Primary Care are important in the current health scenario, because without proper care, injuries are at greater risk of evolving to infection, limb amputation and even death from sepsis. In this context, some actions are suggested, such as: screening of people with chronic wounds; scheduling appointments to avoid crowding; social distancing in the waiting line; availability of places for hand hygiene; home care in necessary cases; telecare with availability of materials to perform the dressing by the user and/or family⁽¹⁸⁾.

However, primary care teams may face difficulties in carrying out these actions, mainly due to the lack of Personal Protection Equipment, deficiencies in the operationalization of the call center, inadequate physical space, and risk of contamination by COVID-19, which has led to sick leave, disease, and death⁽³⁾.

Conclusion

The instrument showed evidence of validity as to content and may contribute to analyze possible changes arising from the COVID-19 pandemic in the Nursing care of people with chronic wounds in Primary Care.

Authors' Contribution

Conception and design, data analysis and interpretation, article writing, relevant critical review of the intellectual content, and final approval of the version to be published: Gonzaga MHHPOA, Felix LG, Mendonça AEO, Silva ACO, Oliveira SHS, Carvalho PS, Soares MJGO.

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