Original article

Validation of a guide for nursing consultations to adults with Type 2 Diabetes Mellitus*

Validação de guia para consulta de enfermagem a adultos com Diabetes Mellitus tipo 2

Validación de una guía para consultas de enfermería con adultos con Diabetes Mellitus Tipo 2

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Abstract

Objective: to validate the guide for nursing consultations to adults with Type 2 Diabetes Mellitus (DM2) in Primary Health Care (PHC). **Method:** methodological study, including the validation stage of the guide for nursing consultations to adults with DM2, with specialists and the target audience, in terms of content and appearance. The Content Validity Index (CVI) was calculated. **Results:** In the first round of validation, some items did not reach a satisfactory CVI, and there were suggestions for improvements which were accepted and changed for the final version. In the second round, in terms of content, objective, structure and design, most of the items achieved a CVI of 1. The target audience evaluated all the items, receiving a CVI of 1. **Conclusion:** the guide was validated and considered suitable for use by nurses in nursing consultations with users with DM2. The guide could be replicated in other PHC settings and other regions of Brazil.
Descriptors: Office Nursing; Diabetes Mellitus; Nursing; Validation Study; Primary Health Care

Resumo

Objetivo: validar o guia para a consulta de enfermagem a adultos com Diabetes Mellitus tipo 2 (DM2) na Atenção Primária à Saúde (APS). **Método:** estudo metodológico, contemplando etapa de validação do guia

para a consulta de enfermagem a adultos com DM2, junto a especialistas e público-alvo, quanto ao conteúdo e aparência. Realizado o cálculo de Índice de Validade de Conteúdo (IVC). **Resultados:** na primeira rodada de validação alguns itens não alcançaram IVC satisfatório, havendo sugestões de melhorias que foram acatadas, tendo sido alterados para a versão final. Na segunda rodada, quanto ao conteúdo, objetivo, estrutura e design, a maioria dos itens alcançaram IVC 1. O público-alvo avaliou todos os itens, recebendo IVC 1. **Conclusão:** o guia foi validado, sendo considerado apto para utilização pelas enfermeiras na consulta de enfermagem a usuários(as) com DM2. Destaca-se a possibilidade de replicabilidade do guia em outros cenários da APS e outras regiões do Brasil.

Descritores: Enfermagem no Consultório; Diabetes Mellitus; Enfermagem; Estudo de Validação; Atenção Primária à Saúde

Resumen

Objetivo: validar la guía de consultas de enfermería con adultos con Diabetes Mellitus Tipo 2 (DM2) en Atención Primaria de Salud (APS). **Material y método:** estudio metodológico, incluyendo la fase de validación de la guía de consultas de enfermería con adultos con DM2, con especialistas y público objetivo, en cuanto a contenido y aspecto. Se calculó el Índice de Validez de Contenido (IVC). **Resultados:** en la primera ronda de validación, algunos ítems no alcanzaron un IVC satisfactorio, y hubo sugerencias de mejora que fueron aceptadas y modificadas para la versión final. En la segunda ronda, en términos de contenido, objetivo, estructura y diseño, la mayoría de los ítems alcanzaron un IVC de 1. El público objetivo evaluó todos los ítems, recibiendo un IVC de 1. **Conclusión:** la guía fue validada y considerada adecuada para su uso por enfermeros en consultas de enfermería con usuarios con DM2. La guía puede ser replicada en otros contextos de APS y en otras regiones de Brasil.

Descriptores: Enfermería de Consulta; Diabetes Mellitus; Enfermería; Estudio de Validación; Atención Primaria de Salud

Introduction

Primary Health Care (PHC) is characterized by being the first level of care, with the capacity to solve most public health problems, and is the gateway for users to the Unified Health System (SUS). The Family Health Strategy (FHS) was adopted with a view to changing the care model in PHC and is the main strategy for consolidating its guidelines.[1]

In this sense, a strong PHC should solve most of the population's health problems, including the control of Chronic Non-Communicable Diseases (CNCDs) and long-term care. Fortified PHC generates an increase in the efficiency of the health system and promotes a reduction in unnecessary hospitalizations, which end up producing a high cost for the public health system.[2]

In the context of PHC, CNCDs are present and have become a global concern, responsible for 63% of global deaths. In Brazil, they account for 72% of the causes of death. CNCDs include diseases of the circulatory system, Diabetes Mellitus (DM), cancer and chronic respiratory diseases. DM is among the ten leading causes of death worldwide and is one of the biggest global health

emergencies of the century.[3]

In PHC, nurses are part of the multi-professional team and play a fundamental role in working with service users who have CNCDs, especially DM, as they develop actions and practices of education, disease prevention and health promotion, searching for a better quality of life, critical and constructive empowerment. These elements are essential for caring for people's health, as health promotion actions provide an insight into the disease and prevent possible complications.[4]

In PHC, nurses work to prevent and manage chronic conditions. These actions are effective if operationalized scientifically and comprehensively through the Nursing Process (NP) and, in Brazil, when carried out in the context of PHC, usually correspond to what is known as the Nursing Consultation (NC).[5]

Nurses are supported by Law No. 7,498, of June 25, 1986, which regulates the practice of nursing, and the development of NC is private.[6] And the National Policy of Primary Health Care (PNAB, in Portuguese) also considers NC to be one of the specific and private attributions of nurses within the scope of primary care.[7]

To systematize care during NC, it is essential to use technologies such as protocols, instruments, forms, guides to conduct the consultation, as these tools help to promote safety for professionals and users, improve decision-making, broaden the nurse's view of the health/disease process in the context of primary care, qualifying the care provided to the population.[8]

Thus, considering the prevalence of DM and the importance of using guides/instruments for NC in PHC, a literature search was carried out, through a study of trends, in the Catalog of Theses and Dissertations of the Coordination for the Improvement of Higher Education Personnel and a Narrative Review in national and international databases, showing a gap, due to the lack of validated technologies to be used as a guide during NC aimed at users with DM2.

Therefore, manuals,[9] educational booklets,[10-11] care protocols,[12] self-care assessment tools[13] were found, and for NC,[14-15] it was found that there was no guide for conducting NC for users with DM2. This highlights the need to develop technologies and research on this subject to strengthen assistance, standardize care, ensure scientificity and fill the gap in this area.

It should be noted that the guide in this study is part of a matrix research project, in which the participants were asked to create a guide for use during NE for users with DM2. The method used in this study was Convergent Care Research (PCA, in Portuguese). The guide was designed and built by the thesis project researcher and the master's student, together with the nurses who

took part in the matrix study.

Therefore, this study aims to validate the guide for NC for adults with DM2 in PHC.

Method

This is a methodological study with a quantitative approach, including the validation stage of the guide for NC for adults with DM2, by specialists in the field of nursing and the target audience, made up of nurses. Validation took place through agreement between nursing specialists and the target audience, by validating content and appearance. The study participants were nursing specialists and the target audience was made up of nurses.

The Adapted Fehring Model was used to select possible nursing specialists,16, and those with a score of 6 or more were chosen. Pasquali suggests that the number should vary from six to 20 specialists, so this study was based on Pasquali's,[17] with a minimum of six specialists.

The experts' scores were analyzed by consulting their CVs on the Lattes Platform, where 46 experts were selected and analyzed. An invitation letter was sent via e-mail and 15 of them agreed to take part, sending the Informed Consent Form (ICF), the first version of the Guide and the Validation Tool. However, only nine completed Validation Instruments were received, which made up the study sample. It is worth noting that several attempts were made to contact them so that the instrument would be returned within the specified time.

Validation with the target audience was carried out with professional nurses who worked in PHC in the Municipality of Santiago/Rio Grande do Sul (RS), and who took part in the matrix research and the drafting of the Guide, since the matrix research was a PCA that involved the participation of the subjects involved in the practice. The exclusion criteria were nurses who were on vacation or away from their job. Thus, three nurses did not agree to take part in the study because two were on vacation and one was away from her job. The exclusion criteria for nursing specialists were those who requested a subsistence allowance and who remained for more than 30 days without returning the validation instrument and without communicating with the researcher after three attempts to contact them.

The sample consisted of eight nurses, who were given the invitation letter, the ICF, the first version of the Guide and the Validation Instrument.

Participants were given a maximum of 30 days to return the Validation Tool duly completed, from the moment the material was handed over for analysis. With seven days to go until the

deadline, the participants were contacted to remind them of the deadline. After receiving the material, the researcher had 15 days to resend the Guide with the changes suggested by the nursing specialists and the target audience, for another round of evaluation with the same evaluators.

Data were collected from December 2022 to March 2023, online and in person, using an adapted Likert Scale Validation Instrument from Wild,[18] with a score of 1 to 4: 1- Yes, 2- Partly, 3- No, 4- No opinion.

For the quantitative analysis of the data, the Content Validity Index (CVI) was calculated, which measures the percentage of experts who agree on certain aspects of the instrument and its items. This method uses a Likert-type scale. For greater accuracy and reliability of the results, items that reached a CVI of 0.80 or more, that is, 80%, as described in the literature, were considered valid. Items with lower-than-expected averages were modified, considering the comments and suggestions of the experts.[19]

For the quantitative analysis, independent double entry was made and, after checking for possible typing errors, the data was stored in a Microsoft Office Excel spreadsheet and analyzed using the Statistical Package for the Social Sciences. Based on descriptive statistical analysis, with simple frequency distribution.

The ethical precepts of Resolution no. 466/2012 of the National Health Council were followed. The proposal was assessed and approved by the Research Ethics Committee of the Federal University of Santa Maria (UFSM), under CAAE: 58903922.0.0000.5346, on June 15, 2022. Potential participants were sent an invitation letter by email or in person, and were given the ICF and, once the signed terms had been returned, the fieldwork stage began.

Results

As for the characterization of the specialists, 88.9% (8) were female, and the highest percentage ranged in age from 26 to 40, 44.4% (4). Regarding qualifications, the majority (77.8% - 7) had a doctorate. The majority, 44.4% (4), had a degree in Public Health. 77.8% (7) had been trained for between three and 20 years and 44.4% (4) worked in care, teaching, and research. The majority had worked for between 1 and 26 years. The specialists covered four regions of Brazil, with the Northeast region predominating, accounting for 44.4% (4).

Regarding the profile of the target audience, all were female, the age ranged from 41 to 60 years 62.5% (5), only 12.5% (1) had a master's degree and 87.5% (7) had a specialization. The

majority, 37.5% (3), had a degree in Public Health and Public Health, with an emphasis on Family Health. All of them worked exclusively in care and, in terms of length of service, the majority, 62.5% (5), had worked for between 10 months and seven years and five (62.5%) had worked for between 8 and 17 years.

In the first round of evaluation, the responses of the experts and target audience were analyzed in relation to the content and objective. The results shown in Table 1 correspond to the order of the validation instrument, with the responses obtained for each item, according to the frequency of the variables, that is, the number of times each rating appeared and the CVI result per item.

Table 1 - Validation of the content and objective of the Guide according to the experts. Santa Maria/RS, 2023.

CONTENT AND PURPOSE	1-Yes n (%)	2 - In parts n (%)	3 -No n (%)	4 - No opinion n (%)	CVI
1.1 The information/content is or is consistent with the needs for conducting the nursing consultation.	8 (88.9)	1 (11.1)	-	-	0.88
1.2 The content of the Guide is appropriate for nurses to use during the consultation.	8 (88.9)	1 (11.1)	-	-	0.88
1.3 The amount of content in the Guide is adequate.	7 (77.8)	2 (22.2)	-	-	0.77
1.4 The Guide is suitable for use in your Primary Health Care practice.	8 (88.9)	1 (11.1)	-	-	0.88
1.5 The Guide covers subjects necessary for the nursing consultation.	7 (77.8)	2 (22.2)	-	-	0.77
1.6 The Guide covers the purpose of the nursing consultation.	8 (88.9)	1 (11.1)	-	-	0.88
1.7 The information in the Guide is scientifically correct.	7 (77.8)	1 (11.1)	-	1 (11.1)	0.77
1.8 The content is presented in a clear, comprehensible, appropriate, and objective manner.	6 (66.7)	3 (33.3)	-	-	0.66
1.9 There is a logical sequence to the proposed content.	8 (88.9)	1 (11.1)	-	-	0.88
1.10 The information is well structured in terms of concordance and spelling.	7 (58.3)	2 (22.2)	-	-	0.77
1.11 The Guide is practical for use during nursing consultations with adults with Type 2 Diabetes Mellitus.	7 (77.8)	1 (11.1)	1 (11.1)	-	0.77

As shown in Table 1, of the 11 items relating to the content and purpose of the Guide, five were considered valid (1.1, 1.2, 1.4, 1.6 and 1.9) once they reached a CVI of 0.88. However, items 1.3, 1.5, 1.7, 1.8, 1.10 and 1.11 achieved a CVI of 0.77 and received suggestions for improvement.

In the suggestions for improvement relating to items 1.1 and 1.8, the experts suggested removing the acronyms. In item 1.3, it was recommended that the "Framingham Global Risk Score (GRS)" be removed. In item 1.5, it should be emphasized that subjective questions permeate all phases of NC and that in subjective evaluation there is no sequence to be followed, the topics should be more detailed." And finally, item 1.10 suggested using punctuation in some parts of the text and revising the wording, as well as other punctuation.

Regarding the validation of the target audience in relation to the content and objective of the Guide, the data is shown in Table 2.

Table 2 - Validation of the content and objective of the Guide according to the target audience. Santa Maria/RS, 2023.

CONTENT AND OBJECTIVE	1-Yes n (%)	2 - In parts n (%)	3 -No n (%)	4 - No opinion n (%)	CVI
1.1 The information/content is or is consistent with the needs for conducting the nursing consultation.	7 (87.5)	1 (12.5)	-	-	0.87
1.2 The content of the Guide is appropriate for nurses to use during the consultation.	7 (87.5)	1 (12.5)	-	-	0.87
1.3 The amount of content in the Guide is adequate.	7 (87.5)	1 (12.5)	-	-	0.87
1.4 The Guide is suitable for use in your Primary Health Care practice.	6 (75)	1 (12.5)	1 (12.5)	-	0.75
1.5 The Guide covers subjects necessary for the nursing consultation.	7 (87.5)	1 (12.5)	-	-	0.87
1.6 The Guide covers the purpose of the nursing consultation.	8 (100)	-	-	-	1
1.7 The information in the Guide is scientifically correct.	7 (87.5)	1 (12.5)	-	-	0.87
1.8 The content is presented in a clear, comprehensible, appropriate, and objective manner.	7 (87.5)	1 (12.5)	-	-	0.87
1.9 There is a logical sequence to the proposed content.	7 (87.5)	1 (12.5)	-	-	0.87
1.10 The information is well structured in terms of concordance and spelling.	8 (100)	-	-	-	1
1.11 The Guide is practical for use during nursing consultations with adults with Type 2 Diabetes Mellitus.	6 (75)	2 (25)	-	-	0.75

According to the target audience's assessment of the content and purpose of the Guide, in the first round of validation, as shown in Table 2, seven items, 1.1, 1.2, 1.3, 1.5, 1.7, 1.8 and 1.9, were considered valid by the target audience, achieving a CVI of 0.87. Items 1.6 and 1.10 were also validated, achieving a CVI of 1. However, items 1.4 and 1.11 achieved a CVI of 0.75, a parameter seen as not suitable for validation.

As for the experts' and target audience's assessment of the structure and design, items 2.2,

2.3, 2.5 and 2.6 were considered valid, with a CVI of 0.88. Item 2.4 had a CVI of 0.66 and items 2.1, 2.7 had a CVI of 0.77, not reaching the desired CVI (Table 3).

Table 3 - Validation of the Guide's structure and design according to experts. Santa Maria/RS, 2023.

DESIGN AND STRUCTURE	1-Yes n (%)	2 - In parts n (%)	3 -No n (%)	4 - No opinion n (%)	CVI
2.1 The Guide is coherently organized.	7 (77.8)	1 (11.1)	-	1 (11.1)	0.77
2.2 The structure of the Guide is appropriate.	8 (88.9)	1 (11.1)	-	-	0.88
2.3 The size of the title and topics is appropriate.	8 (88.9)	1 (11.1)	-	-	0.88
2.4 The illustrations are expressive and sufficient.	6 (66.7)	2 (22.2)	-	1 (11.1)	0.66
2.5 The number of pages is appropriate.	8 (88.9)	1 (11.1)	-	-	0.88
2.6 The colors are appropriate.	8 (88.9)	1 (11.1)	-	-	0.88
2.7 The layout is comprehensible, clear, and didactic.	7 (77.8)	2 (22.2)	-	-	0.77

The suggestion for improvement regarding item 2.4 was to add figures and, for item 2.1, to reorganize the sequence of information. Considering the target audience's assessment of the structure and design, described in Table 4, items 2.1, 2.2, 2.3, 2.4, 2.7, which achieved CVI 1, and items 2.5 and 2.7, with CVI 0.87, were all considered valid in the first stage.

Table 4 - Validation of the structure and design of the Guide according to the target audience. Santa Maria/RS, 2023.

DESIGN AND STRUCTURE	1-Yes n (%)	2 - In parts n (%)	3 -No n (%)	4 - No opinion n (%)	CVI
2.1 The Guide is coherently organized.	8 (100)	-	-	-	1
2.2 The structure of the Guide is appropriate.	8 (100)	-	-	-	1
2.3 The size of the title and topics is appropriate.	8 (100)	-	-	-	1
2.4 The illustrations are expressive and sufficient.	8 (100)	-	-	-	1
2.5 The number of pages is appropriate.	8 (100)	-	-	-	1
2.6 The colors are appropriate.	8 (100)	-	-	-	1
2.7 The layout is comprehensible, clear, and didactic.	7 (87.5)	1 (12.5)	-	-	0.87

Considering the experts' suggestions regarding the content and objective, the material was reworked to take on board the suggestions, and then validated once again by all the participants.

After the first round of validation by the experts and the target audience, the suggested changes were made, and the validation process began again in the same way. In the second round of validation with the experts regarding content and objective, items 1.2, 1.3, 1.4, 1.5, 1.6, 1.7, 1.8, 1.9 achieved CVI 1, and items 1.1, 1.10 and 1.11 obtained CVIs of 0.87. Regarding structure and design, items 2.1, 2.2, 2.3, 2.4, 2.5, 2.6, 2.7, in the second round, all achieved CVI 1. The target

audience, in the second round, evaluated items 1.1, 1.2, 1.3, 1.4, 1.5, 1.6, 1.7, 1.8, 1.9, 1.10 and 1.11 as totally adequate, achieving a CVI of 1, considered valid. Similarly, in relation to structure and design, the target audience considered all items 2.1, 2.2, 2.3, 2.4, 2.5, 2.6 and 2.7 to have a CVI of 1, making them valid. Figure 1 shows the Guide in the final version of the booklet.
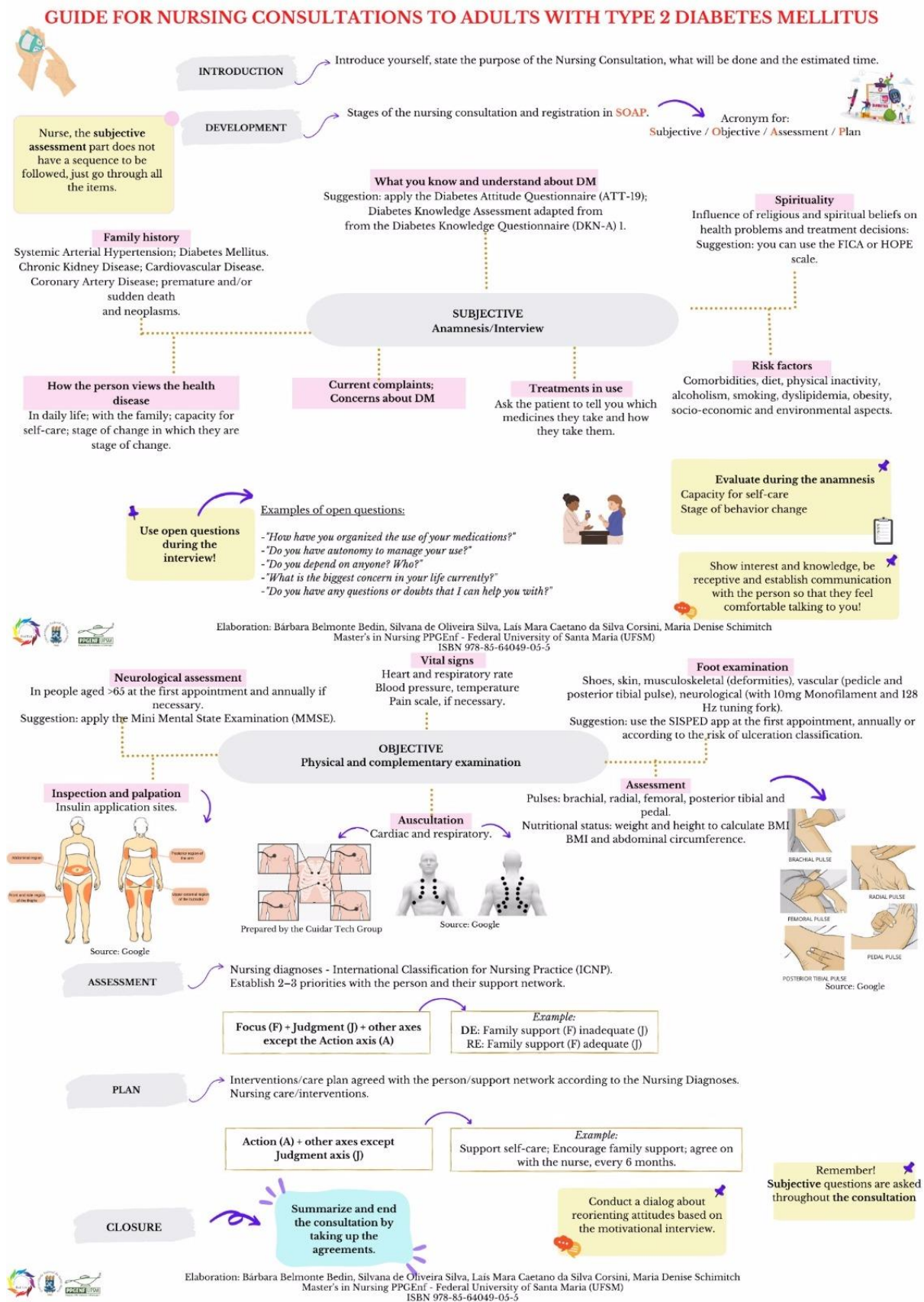
Figure 1 - Guide for nursing consultations to adults with type 2 diabetes mellitus.

Discussion

NC must be based on a theoretical framework that guides the entire process of nursing

care, data collection, the establishment of nursing diagnoses, the planning of nursing interventions and the evaluation of expected results. One of the difficulties of nurses' work in PHC is the lack of specific instruments capable of providing scientific support to guide care.[20]

In this way, the development of instruments is considered a strategy aimed at improving the quality of care and can promote autonomy and independence for professional nurses. However, for new materials and instruments to be used, they need to be classified as safe and reliable, and this is only possible through validation.[21]

The Guide was organized in a clear way so that it could be used to conduct CE, and was divided into the items introduction, development, evaluation, plan, and closure, addressing all the stages of NC in PHC, focusing on care for adults with type 2 DM, in addition to promoting comprehensive care throughout NC. In this sense, for NC to be effective, a plan should be used for each user so that care is personalized for each person.[22]

Most of the target audience and specialists were female, which is in line with a methodological study developed to validate an instrument on Self-Care Assessment for patients with type 2 DM, which mentions that the material was validated by specialists who were predominantly female (71.5%).[13] This prevalence of female participants in nursing research is supported by the fact that 90% of the nursing workforce is still made up of women and that, historically, nursing has been an area of activity built up and carried out mainly by women.[23]

Regarding qualifications, most of the specialists had a doctorate, the majority had been trained for between 3 and 20 years, and worked in care, teaching, and research, which may contribute to a better evaluation of the Guide. It is essential to use specialists with doctoral or master's degrees who have experience in care, research, and teaching in the validation process, as they help to standardize the terms, making the items more explicit and easier to understand, offering a standardized instrument for conducting NC in PHC.[24]

In this study, the target audience participated from the start of the matrix study, in which they helped and suggested the development of the Guide, so it was clear that, as the target audience was involved and developed the material according to their reality, from the first round of validation, the items achieved satisfactory CVIs and presented few suggestions for adaptation.

The participation of the target audience in methodological research is an important gain for the study, as it guarantees an adequate approach to the population that will be using the material, and they can directly point out what was missing to improve the material and make it usable for

their reality in PHC during NC for users with DM2.[25]

In this context, the target audience has the chance to validate the material by transforming it according to local and regional demand, meeting the health needs of the population, using their experiences in care, and being significant for nursing care. It is important to emphasize the importance of the language used in technological materials so that it is understandable by the target audience and can be of practical relevance.[26]

Experts are essential in the validation process, but there was a difficulty in accepting their participation and returning the completed instrument, a difficulty also reported in other validation studies. In three studies on validation with experts, this lack of feedback was addressed.[8,11,18]

Research shows that content-valid technologies are based on the judgment of a group of experts in the field, or target audience, who will be responsible for analyzing whether the content is correct and appropriate for what is proposed, and these valid materials subsidize the development of care practice. Regarding the validity of the appearance, it is the aesthetic representation made up of lines, shapes, colors, and movement of the images, which must harmonize with the content of the information.[18]

To validate the Guide, an instrument adapted from Wild[18] was used, which relies on a Likert scale, which, as described in the literature, is the most suitable for assessing agreement and relevance between specialists and the target audience.[27] A study aimed at validating an instrument for nursing consultations in PHC with pregnant women with DM also used a Likert scale.[15] In another study, an instrument that relied on a five-point Likert scale was used to assess the specialists.[28]

Therefore, to identify whether the Guide would be suitable for use in NC for adults with type 2 DM in PHC, the CVI was used, which requires agreement from 80% or more of the respondents.[19] According to the results found in a narrative review study on ways to validate an instrument for nursing consultation, three methodological studies used the CVI for agreement between specialists and the target audience.[28]

One of the limitations of this study is that the matrix study was a PCA, so the participants suggested the development of the guide, which may have led to a lack of possible suggestions for improving the Guide, a situation that needs to be better understood by the researchers involved in this research. Regarding the experts, there was little acceptance from them to participate, which resulted in a small sample of respondents.

As for the study's contributions to the field of nursing, we would highlight the availability of a face and content-validated instrument to be used in NC for people with type 2 DM seen in PHC.

Conclusion

The Guide was validated in two rounds of evaluation by experts and the target audience. In the second round, all the items evaluated reached a satisfactory CVI, proving to be understandable, accurate, valid, and suitable for use in NC in PHC. Thus, the validated material made it possible to collaborate with the practice and demands of PHC health professionals regarding NC to adults with type 2 DM.

In the future, we hope to evaluate the effectiveness of using this Guide in the care process in this SUS context, and to improve the management of this chronic condition and the reduction of complications related to DM, which can have a biological, psychological, social, and spiritual impact on people's lives. Also, to evaluate the usability of the Guide with nurses in Santiago/RS, and to highlight the possibility of replicating the Guide in other PHC settings and other regions of Brazil.

This research is relevant because it validates a Guide to improve the management of NC for adults with type 2 DM, to improve the work of professional nurses and improve the management of this chronic condition. Thus, to publicize the material, the Guide was registered online and in print at the UFSM Central Library, under ISBN 978-85-64049-06-2 and ISBN 978-85-64049-05-5 (printed resource) and will be made available on the Nursing Postgraduate Program website, in the Technical-Technological Products selection.

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