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CONSTRUCTION AND VALIDATION OF A BROCHURE ON DIABETIC FOOT CARE

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ABSTRACT

Objectives: To develop and validate a folder on diabetic foot prevention aimed at patients and their families. **Method:** Methodological study carried out in two stages. The first one was bibliographic review for the construction of the folder through the search of articles and manuals on the diagnosis, problems faced, self-care, prevention and the main interventions of the diabetic foot in the database at the National Library of Medicine. The second stage was related to the validation process, with the participation of 23 stomatherapist nurses. The content validity index (CVI) was used to assess the validity of the folder and Kappa as an indicator of agreement. **Results:** The technology's global CVI in the first evaluation showed an overall CVI = 0.91, and an overall Kappa index = 0.81. After reformulating the material based on the judges' suggestions, a second validation cycle indicated CVI = 0.99 and Kappa CVI = 0.98. **Conclusion:** The proposed technology was considered validated by specialists in terms of objectives, content, relevance, figures, writing style and content, presenting high scores in the CVI and Kappa index, suggesting that the material can be used to work on the prevention of diabetic foot with the patients and their families.

DESCRIPTORS: Diabetic foot. Educational technology. Validation study. Enterostomal therapy.

CONSTRUÇÃO E VALIDAÇÃO DE FÔLDER SOBRE CUIDADOS PARA PREVENÇÃO DO PÉ DIABÉTICO

RESUMO

Objetivos: Desenvolver e validar um fôlder sobre prevenção do pé diabético direcionado a pacientes e seus familiares. **Método:** Estudo metodológico realizado em duas etapas. A primeira envolveu revisão bibliográfica para a construção do fôlder por meio de busca de artigos e manuais sobre diagnóstico, problemas enfrentados, autocuidado, prevenção e as principais intervenções do pé diabético na base de dados da Biblioteca Nacional de Medicina dos Estados Unidos. A segunda etapa foi referente ao processo de validação, com participação de 23 enfermeiros estomaterapeutas. Utilizaram-se o índice de validade de conteúdo (IVC) para avaliar a validade do fôlder e o de Kappa como indicador de concordância. **Resultados:** O IVC global da tecnologia na primeira avaliação apontou IVC geral = 0,91 e índice de Kappa geral = 0,81. Após reformulação do material mediante sugestões dos juízes, um segundo ciclo de validação apontou IVC = 0,99 e Kappa = 0,98. **Conclusão:** A tecnologia proposta foi considerada validada por especialistas quanto aos objetivos, ao conteúdo, à relevância, às figuras, à forma de escrita e de conteúdo, apresentando altas pontuações no IVC e índice Kappa, sugerindo que o material pode ser utilizado para trabalhar prevenção do pé diabético com pacientes e seus familiares.

DESCRITORES: Pé diabético. Tecnologia educacional. Estudo de validação. Estomaterapia.

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CONSTRUCCIÓN Y VALIDACIÓN DE UNA CARPETA DE CUIDADOS PARA LA PREVENCIÓN DEL PIE DIABÉTICO

RESUMEN

Objetivo: Desarrollar y validar una carpeta sobre prevención del pie diabético dirigida a pacientes y sus familias. **Método:** Estudio metodológico realizado en dos etapas: revisión bibliográfica para la construcción de la carpeta a través de la búsqueda de artículos y manuales sobre el diagnóstico, problemas enfrentados, autocuidado, prevención y las principales intervenciones del pie diabético en la base de datos de la Biblioteca Nacional de Medicina - PubMed. La segunda etapa estuvo relacionada con el proceso de validación, con la participación de 23 enfermeros estomaterapeutas. Se utilizó el Índice de Validez de Contenido para evaluar la validez de la carpeta y Kappa como indicador de acuerdo. **Resultados:** El índice de validez de contenido global de la tecnología en la primera evaluación mostró un CVI general de 0,91, un índice Kappa general de 0,81. Luego de reformular el material con base en las sugerencias de los jueces, un segundo ciclo de validación indicó un CVI de 0.99 y el CVI fue de 0.98. **Conclusión:** La tecnología propuesta fue considerada validada por especialistas en cuanto a objetivos, contenido, pertinencia, cifras, estilo de redacción y contenido, presentando altos puntajes en el CVI y el Índice Kappa, sugiriendo que el material puede ser utilizado para trabajar en la prevención de la diabetes. pie con los pacientes y sus familias.

DESCRIPTORES: Pie diabético. Tecnología educacional. Estudio de validación. Estomaterapia.

INTRODUCTION

Diabetes *mellitus* (DM) is characterized as a multifactorial metabolic syndrome in which there is a persistent increase beyond normal blood glucose levels, and can occur for two reasons: the body cannot produce enough insulin, or it becomes unable to properly perform its function[1].

Chronic complications related to DM are divided into two classifications—microvascular and macrovascular—and result in numerous problems. In the scope of these classifications, there is a condition that substantially impacts the lives of individuals: the diabetic foot[2].

The Brazilian Diabetes Society states that diabetic foot is a set of alterations that occur in the lower limb of people with diabetes, which may present infections and destruction of soft tissues as a consequence of the neurological and vascular problems generated[3].

DM has a deleterious action on the blood vessels, also affecting the peripheral nerves. These effects generate symptoms such as burning pain or numbness, reduced pain, thermal and vibrational sensibility, and anatomical deformities. These conditions may predispose to the occurrence of corns, blisters, cuts, and burns, which cause diabetic foot ulcers[4]. Among the recommendations for the prevention of diabetic foot are: inspect, sanitize, and moisturize the feet daily, cut the nails in a straight line, do not remove calluses, never walk barefoot, use appropriate shoes, and perform a daily foot examination[3].

The literature points out that DM is one of the main causes of lower limb amputations with evolution to death[5]. If pre-ulcerative alterations are detected and treated in a timely manner, this may prevent the occurrence and recurrence of foot ulcers[6].

The high risk for the development of diabetic foot is associated with the deficit of knowledge regarding self-care, especially those related to the prevention of diabetic foot development[7]. Therefore, health promotion and harm prevention become a primordial part in reducing the complications of DM and its consequences. Thus, the health team must have at hand tools that promote the patient as an active agent of their health and self-care[8].

Thus, the technology allied to health education appears as an excellent tool to help the insertion of the patient in their own care, because it unites the needs of individuals to existing scientific knowledge, with great potential to encourage the patient and their family[9]. However, such educational technologies must be evaluated as to their content, appearance,

and application by previously selected evaluators, since it is considered that new validated technologies offer greater ease, efficiency, and advantage to the access of information[10].

From this perspective, it can be seen how promising the development and validation of a brochure addressing key points concerning foot care for people with DM can be, with the purpose of assisting self-care practices and improving well-being. In view of the above, an educational technology was created in the form of a brochure, with the purpose of promoting health promotion in diabetic people.

The objectives of the study were to develop and validate a brochure on diabetic foot prevention aimed at patients and their families.

METHODS

Methodological study on technology production and validation conducted from June to July 2021. The methodological study concerns research on methodology, organization and data analysis, which aims to develop, validate and evaluate research instruments and techniques[11].

The development of the study occurred in two major phases. The first referred to the construction of the educational technology, in which a literature review on diabetic foot and its care was performed, followed by the construction of guidelines and creation of a bank of illustrations to generate the brochure, which was entitled "Care for diabetic foot prevention."

The literature review was done by searching for articles and manuals that guided the identification of the main problems faced by people with DM in self-care for the prevention of diabetic foot and the main interventions. The searches were made in the United States National Library of Medicine (PubMed). After listing the main care procedures inferred from the literature studied, the construction of the brochure on diabetic foot prevention proceeded, through the interlocution of the content with illustrative images of the indicated care procedures. For the final production of the brochure, a graphic design professional provided assistance.

The second phase involved the validation process, carried out in the following moments: research of the data about the experts, creation of the database with the experts, sending the technology for evaluation, analysis of the judges' evaluation data, and final production of the technology[11,12].

Initially, the experts' data were collected through the Lattes platform, available from the Coordination for the Improvement of Higher Education Personnel (Capes), selecting the "Advanced Search" with the descriptor "Enterostomal Therapy" and the filters "Doctors" and "Masters." A total of 410 doctors and 413 masters were found. To select the professionals that would compose the database of specialists, the adapted Fehring scale was used with the following indications:

- To have a master's degree in nursing: 4 points;
- A master's degree in nursing, with a dissertation in the area of interest: 1 point;
- Having published research on the topic under study or relevant content: 2 points;
- Having a doctorate in the field of study: 2 points;
- Have a published article on the subject: 2 points;
- Recent clinical practice of at least one year in the subject: 2 points;
- Have training (specialization) in the clinical area of interest: 2 points.

The professional who totaled 5 points or more was considered a judge. A total of 225 specialists was identified with these aspects, who composed a database in Microsoft Excel, containing the collected information, such as name, e-mail, identified these professionals' articles, and the score according to Fehring's scale.

To define the sample, the final proportion of subjects related to a dichotomous variable and the maximum accepted difference of this proportion were considered (Eq. 1):

$$n = Z\alpha^2 \times P \times (1 - P)/d^2 \quad (1)$$

In which: Z_{α} = significance/confidence level, here set at 95%; P = the proportion of participants who agreed with the relevance of educational technologies for self-care, where the proportion of 85% agreement was adopted for the items evaluated; d = the proportion difference considered acceptable, 15%, totaling 22 judges for appearance and content validation[13].

The initial sample selected for participation in the survey was 70 professionals. The survey was conducted online, through Google Forms. An e-mail containing the brochure on diabetic foot prevention, the assessment instrument, and the informed consent form was sent to these professionals, and a response was obtained from 23 judges.

The technology was evaluated regarding six criteria: objective, content, relevance, pictures, writing style and organization, and the judges were responsible for evaluating whether these aspects were very adequate, adequate, not very adequate, or totally inadequate, according to an evaluative instrument with responses on a Likert scale[14]. In addition, a space was provided for suggestions and criticisms about improvements in the brochure.

The data obtained in the evaluation were verified using the Kappa index to assess the level of agreement and consistency in the judgment of the judges regarding the persistence of the items present in the brochure. The Kappa index is an indicator of agreement ranging from 0 to 1: the closer it is to 1, the better the level of agreement among the raters. For the item to be accepted as adequate and without the need for change, a level of agreement above 0.61 was adopted[15].

Similarly, the content validity index (CVI) was used to assess the judges' agreement with the representation of the items and the content of the study. The number of judges who rated the items as very adequate/adequate divided by the total number of raters was calculated. The overall CVI of the brochure was measured by the following calculation: the ratio of the sum of all CVIs evaluated alone to the total number of items. The index greater than or equal to 0.75 for the judgment of each item was considered as the overall judgment of the technology[11-15].

The Delphi technique was adopted as a systematized method to obtain consensus among the judges. After the first cycle of analysis, the items that did not present CVI and/or Kappa were observed to consider the technology validated, as well as the suggestions made by the judges, and the brochure was modified. Soon after, the second cycle of evaluations was carried out, in which 16 judges reevaluated the changes.

The study respected all the ethical precepts of research conducted with human beings according to Resolution No. 466/12, of the National Health Council, with approval from the Research Ethics Committee under Opinion No. 4,026,647.

RESULTS

The brochure, entitled "Diabetic Foot Care," had its final form with six-page parts (front and back), including the cover, and dimensions of 29.7 cm wide and 21 cm high. Such parameters were chosen to facilitate the printing of the technology in health services, and, in all, 15 illustrations were made.

The literature review phase guided the construction of the technology, and the following subjects were listed:

- What is diabetes?
- What is diabetic foot?
- Foot care.

These topics guided the content present in the brochure.

The content inserted in the technology took into consideration a language that would reach all people at risk for diabetic foot, and the items were worked on in a clear, objective, and accessible way.

The images were built in a graphic design program, in accordance with the instructions written in the brochure, with the pictures suitable for the reader's easy understanding and arranged close to the related cautions.

Regarding text formatting, the font used was Times New Roman, size 16 for texts and 18 for titles. For contextualization of DM and diabetic foot, the focus was on short texts. As for the instructions to prevent diabetic foot, it was preferable to focus on images and informative points (Fig. 1).

Figure 1. Image of the first version of the educational brochure. Fortaleza, Ceará, 2021.
Source: Elaborated by the authors.

For the validation of the technology, 23 judges answered about it, of which 21 (91.3%) were women, with ages ranging from 28 to 65 years (mean 42.9 years). The average time of graduation was 17.7 years, all of them were enterostomal therapists, with time in the specialty between one and 20 years. Regarding academic degrees, 14 (60.8%) had a master's degree and five (21.7%) had a doctorate.

Regarding the evaluation process of the items, all criteria reached CVI greater than 0.75, as shown in Table 1. Five of the 23 subitems presented perfect agreement index (CVI and Kappa = 1), and three obtained values lower than the minimum agreement of the Kappa index (< 0.61)—"Can it circulate in the scientific environment?" (item 1.3), "Do the figures complete the information in the text?" (item 4.4), and "Are the figures clear enough?" (item 4.5). The aspects that had the lowest evaluation points compared to the others were those related to the figures (item 4) and the objectives (item 1).

The relevance criterion received the best evaluation, with the maximum score of agreement in all items. Other criteria scored close to 1: content, writing style, and organization.

The suggestions of improvements pointed out by the experts to improve the technology were consolidated and are presented in Table 1. The evaluators' observations and the reformulation performed are exposed.

Table 1. Reformulation of the items according to the judges' suggestions. Fortaleza, Ceará, Brazil, 2021.

Items	Suggestions	Reformulations
Content	"The description about what is diabetic foot re-ports one symptom, numbness, as the cause. Di-abetic foot is because of neuropathic, circulatory, and orthopedic changes. Therefore, it has several symptoms. It is suggested that the cause be better adapted, maintaining a language that meets the target audience's needs." "Include foot hydration." "I suggest adding that, whenever necessary, to look for the basic health unit closest to your resi-dence, instead of 'when necessary' and 'your health unit,' since many patients are not linked to any health team, whether for lack of interest, mis-information, or any other reason."	Adaptation of terms to the audience, reformu-lation of concepts, and addition of guidelines.
Figures	"I suggest changing the photo of the hand in the item about cutting nails and inserting, for exam-ple, a photo of the hallux to better exemplify; I suggest inserting a photo of cracks on the feet." "Image of feminine feet and hands, young, well cared for, white. They totally escape my reality in the enterostomal therapy outpatient clinic. I think that patients who do not fit this pattern will not feel included and may lose interest in the infor-mation." "The figure for nail clipping and proper footwear is unclear. Illiterates must be considered."	Modification of the im-ages, inclusion of de-tails in the images, in-troduction of the dy-namics of the figures, adaptation of the image to the patients' reality.

Source: Elaborated by the authors.

After changes in the items suggested by the judges and that did not obtain minimum Kappa values, the second version was sent for a new evaluation cycle (Fig. 2).

Figure 2. Final version of the educational brochure. Fortaleza, Ceará, 2021.
Source: Elaborated by the authors.

In the first evaluation, the overall CVI was 0.91 and the overall Kappa index was 0.81, but, due to suggestions, the technology was reformulated and sent back to the judges for a new evaluation, and the new overall CVI = 0.99 and the new Kappa index = 0.98, as Table 2 shows[11].

Table 2. Content validity index (CVI) and kappa index in the two cycles regarding the criteria: objectives, content, relevance, pictures, writing style, and organization. Fortaleza, Ceará, 2021.

Criteria	1st Cycle		2nd Cycle	
	CVI	Kappa	CVI	Kappa
1. Objectives				
1.1 The information/content presented in the brochure is consistent with the everyday needs of the person living with diabetes.	0.91	0.83	1	1
1.2 They invite and/or instigate changes in behavior and attitude.	0.87	0.77	1	1
1.3 They can circulate in scientific environments.	0.78	0.57	0.94	0.88
1.4 They meet the objectives of professionals and insti-tutions that work with patients with diabetes.	0.86	0.74	1	1
2. Content				
2.1 The content hits the topic precisely.	0.95	0.92	1	1
2.2 The content is arranged in a complete and compre-hensive way.	0.91	0.83	1	1
2.3 The information presented is correct.	0.91	0.83	1	1
2.4 The simulations are consistent with reality.	0.95	0.92	0.94	0.88
2.5 The content is suitable for working with patients with diabetes on diabetic foot prevention.	0.95	0.92	1	1

continue...

Table 2. Continuation...

Criteria	1st Cycle		2nd Cycle	
	CVI	Kappa	CVI	Kappa
3. Relevance				
3.1 The items illustrate important aspects of nursing practice for diabetic foot prevention with people who have diabetes.	1	1	1	1
3.2 The brochure presents key aspects that should be reinforced with patients with diabetes.	1	1	1	1
3.3 The brochure proposes the construction of knowledge.	1	1	1	1
4. Figures				
4.1 The figures can attract the attention of patients with diabetes.	0.82	0.66	1	1
4.2 The information is exemplified by the figures.	0.82	0.66	1	1
4.3 The figures are simple.	0.91	0.83	1	1
4.4 The figures complete the information in the text.	0.78	0.57	1	1
4.5 The pictures are clear enough.	0.78	0.57	0.94	0.88
5. Writing style				
5.1 The writing is in proper style.	1	1	1	1
5.2 The text is interesting; the tone is friendly.	1	1	1	1
5.3 The vocabulary is accessible.	0.95	0.92	1	1
5.4 The style of the writing corresponds to the level of knowledge of the target audience.	0.95	0.92	1	1
6. Organization				
6.1 The cover is attractive and indicates the content of the material.	0.91	0.83	1	1
6.2 The size of the title and content in the topics is ade-quate.	0.95	0.92	1	1

Source: Elaborated by the authors.

The educational brochure was thus considered validated after modifications.

DISCUSSION

The self-care of patients with DM symbolizes a great challenge, since the level of adherence to treatment may be related to the improvement or worsening of the effects of the disease, but, for this, they must overcome socioeconomic, clinical, and psychological barriers to face the disease[16,17]. The health professional should pay attention to these problems and use strategies that facilitate this process.

One study pointed out that educational interventions to promote self-care in patients with DM generated significant changes in their behavior, especially in foot care8. The educational technologies are a considerable tool, because they improve the process of self-management and coping with illnesses, especially in people with chronic diseases[18].

In this context, the production of an educational brochure on diabetic foot prevention care emerged from the importance of new technologies for health education that promotes self-care for patients with diabetes from a methodological and scientific perspective, and can thus serve as a framework for a safe professional practice[10].

Regarding the first evaluation of the brochure, the items that had the best scores, perfect or almost perfect, were the content, relevance, writing style, and organization. Research carried out in a basic unit showed that patients with DM mentioned lack of information about the performance of self-care activities, such as proper nutrition and physical exercises19. In this circumstance, educational technologies evaluated by expert judges in the area can generate a reliable educational intervention, improving the exchange of information between health professionals and patients[20].

Item 1 (Objectives) in Table 2 had a subitem (1.3 – Can it circulate in the scientific community?) in which the Kappa index was less than 0.61 and the CVI = 0.78, demonstrating that the judges' responses were divergent, with the validity index being lower than the others. It was observed that the lowest score was in subitem 1.3. This result is in line with other validation studies of educational technologies[21], probably due to the more colloquial writing style present in the technology to the detriment of scientific terms present in academia. As the product will be indicated for use by the population, even with some adjustments in the information provided, it was decided to keep the simple and colloquial language directed to its target audience.

Studies show that the population most affected by DM are elderly people with low education, which can generate less understanding and consequent difficulty in adhering to treatment and the necessary care. Educational materials, when not adapted to the reality of these patients, can cause low strategy in their use, due to the difficult understanding of the information contained in them[22].

The subitems on item 2 (Content) (Table 2), despite having had a good rating, were one of the points with more suggestions from the judges and, along with the figures, the main points that were modified in the first round of evaluation. This is because some information and figures, in the judges' view, were not consistent with the reality of patients who go to the health service. Therefore, these modifications were accepted, and it is important to adapt these points to the experience[23]. In this context, it is important that the educational materials have understandable language and illustrations, sensitive to the reality of the user, thus achieving the property of facilitating the perception about the guidelines related to health education given by professionals, helping to promote the understanding of self-management of health activities and adherence to them[24].

The indexes reached at the end of the validation process of the educational material indicate a high level of confidence for the use of this material in educational interventions for people with diabetes. In addition, the brochure shows to be useful, because it can work as a guide for the maintenance of self-care of the patient regarding the prevention of diabetic foot in the home environment, also helping the people in the support network to assist in this type of care.

As for the limitations of the study, the lack of representation of the target audience directly in the validation process was identified. Therefore, there is a need for future studies that evaluate the application of this educational instrument with diabetic patients.

CONCLUSION

The brochure about diabetic foot care was considered validated. All aspects evaluated—objectives, content, relevance, pictures, writing form and content—presented high CVI and Kappa index scores. In the global evaluation after the second validation cycle, the CVI was 0.99 and the Kappa index = 0.98. Moreover, the judges' suggestions guided improvements for the development of the brochure construction, generating a better panorama regarding the understanding, clarity, and applicability of the information that constitutes it.

AUTHORS' CONTRIBUTION

Substantive scientific and intellectual contributions to the study: Menezes TAC and Coelho MMF; **Conception and design:** Menezes TAC, Coelho MMF and Cavalcante VMV; **Data collection, analysis and interpretation:** Menezes

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AVAILABILITY OF RESEARCH DATA

Data will be made available upon request.

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