ORIGINAL ARTICLE

Validation of content of guidelines for people with peripheral neuropathy due to diabetes

Validação de conteúdo de um guia de orientações a pessoas com neuropatia periférica por diabetes

Validación de contenido de una guía de orientaciones a personas con neuropatía periférica por diabetes

Uiara Aline de Oliveira Kaizer¹, Vanessa Soares de Araujo², Sonia Regina Perez Evangelista Dantas³

ORCID IDs

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Kaizer UAO () https://orcid.org/0000-0002-9115-8043 de Araujo VS () https://orcid.org/0000-0003-0570-9038 Dantas SRPE () https://orcid.org/0000-0002-9639-8900 Kaizer UAO; de Araujo VS; Dantas SRPE. Validation of content of guidelines for people with peripheral neuropathy due to diabetes. ESTIMA, Braz. J. Enterostomal Ther., 16: e2518. doi: 10.30886/estima. v16.582.

ABSTRACT

Objective: A quantitative methodological approach with the objective of elaborating and validating the content of an educational instrument with health promotion actions for self-care of people with peripheral neuropathy due to diabetes. **Methods:** A bibliographic survey was realized on the subject in the databases of the Virtual Health Library, SciELO and LILACS/ Database of Nursing (BDENF) and elaborated a guide of recommendations for health promotion of people with diabetes, with educational texts and original photos. Validation of the educational guide was performed by a judges' committee for clarity, relevance and comprehensiveness, and the content validity index (CVI) of all items and subitems was calculated. **Results:** The instrument obtained the CVI of 0.89. Items and subitems <0.8 were modified or excluded, and the appearance of the material was considered good. **Conclusion:** The educational instrument obtained adequate agreement between the judges and was validated.

DESCRIPTORS: Diabetic foot; Diabetic neuropathies; Foot ulcer; Validation studies; Stomatherapy.

¹Universidade Estadual de Campinas – Faculdade de Enfermagem – Programa de Pós-Graduação em Enfermagem – Campinas/SP – Brazil. ²Conjunto Hospitalar de Sorocaba – Comissão de Feridas Estomas e Incontinência – Sorocaba/SP – Brazil. ³Universidade Estadual de Campinas – Faculdade de Ciências Médicas – Curso de Especialização de Enfermagem em Estomaterapia – Campinas/SP – Brazil.

Corresponding author: Uiara Aline de Oliveira Kaizer | Universidade Estadual de Campinas – Faculdade de Enfermagem | Cidade Universitária Zeferino Vaz – Barão Geraldo | ZIP Code: 13083-970 – Campinas/SP – Brazil | E-mail: uiara_oliveira@hotmail.com Received: Mar. 30 2018 | Accepted: Sept. 10 2018



RESUMO

Objetivo: Estudo de abordagem metodológica quantitativa com objetivo elaborar e validar o conteúdo de um instrumento educativo com ações de promoção de saúde para autocuidado de pessoas com neuropatia periférica por diabetes. **Métodos:** Foi realizado levantamento bibliográfico sobre o tema nas bases de dados Biblioteca Virtual Saúde, SciELO e LILACS/Banco de Dados em Enfermagem (BDENF) e elaborado um guia de recomendações para promoção da saúde de pessoas com diabetes, com textos educativos e fotos originais. A validação do guia educativo foi realizada por um comitê de juízes quanto à clareza, pertinência e abrangência, e calculado o índice de validade de conteúdo (IVC) de todos os itens e subitens. **Resultados:** O instrumento obteve o IVC de 0,89. Itens e subitens < 0,8 foram modificados ou excluídos, e a aparência do material foi considerada boa. **Conclusão:** O instrumento educativo obteve concordância adequada entre os juízes e foi validado.

DESCRITORES: Pé diabético; Neuropatias diabéticas; Úlcera do pé; Estudos de validação; Estomaterapia

RESUMEN

Objetivo: Estudio de abordaje metodológico cuantitativo con el objetivo de elaborar y validar el contenido de un instrumento educativo con acciones de promoción de la salud para el autocuidado de personas con neuropatía periférica por diabetes. **Métodos:** Se realizó un relevamiento bibliográfico sobre este tema en las bases de datos de la Biblioteca Virtual Saúde, SciELO y LILACS/Banco de Datos en Enfermería (BDENF) y se elaboró una guía de recomendaciones para la promoción de la salud de personas con diabetes, con textos educativos y fotos originales. La validación de la guía educativa fue realizada por un comité de jueces en cuanto a la claridad, pertinencia y alcance, y calculado el índice de validez de contenido (IVC) de todos los ítems y subítems. **Resultados:** El instrumento obtuvo el IVC de 0,89. Ítems y subítems < 0,8 fueron modificados o excluidos, y la apariencia del material fue considerada buena. **Conclusión:** El instrumento educativo obtuvo concordancia adecuada entre los jueces y fue validado.

DESCRIPTORES: Pie diabético; Neuropatías diabéticas; Úlcera del pie; Estudios de validación; Estomaterapia.

INTRODUCTION

Diabetes Mellitus (DM) is a chronic disease caused by a heterogeneous group of metabolic disorders that result from malfunctioning in the secretion and/or action of insulin, leading to hyperglycemia and consequent alterations in the metabolism of carbohydrates, proteins and lipids, causing complications long-term¹.

The disease affects about 387 million people around the world and it is estimated to increase to 592 million until 2035². The frequency of DM is considered epidemic and attributed to growth, population aging, and lifestyle changes related to obesity, inactivity and food³.

The disease has an impact on quality of life (QoL), and education and health promotion measures are described as effective in preventing complications of the disease. Primary prevention refers to changes in lifestyle habits, with emphasis on food and physical activity, and secondary refers to metabolic control to minimize microangiopathic complications⁴⁻⁶.

Diabetic foot is one of the chronic complications of the disease, described as "soft tissue infection, ulceration and/ or destruction associated with neurological changes and various degrees of peripheral arterial disease in the lower limbs"⁴. Diabetic polyneuropathy is the main risk factor for ulceration and results in loss of protective sensitivity related to nerve fiber lesions due to endoneural ischemia of the microcirculation and metabolic changes due to prolonged exposure to hyperglycemia. Complications related to the motor nervous system are characterized by muscular atrophy and deformities of the foot (claw or hammer fingers, arch accentuation and metatarsal prominences), with the possibility of abnormal gait. Changes in the autonomic nervous system are characterized by decreased perspiration of the feet, dry skin, cracks and fissures that may result in an increased risk of bacterial or fungal infection^{1,5}.

Trauma, limited joint mobility and abnormal plantar pressure due to deformities associated with decreased sensitivity are the main risk factors for ulceration. People with DM have a 25% risk of developing foot ulcers throughout life, and diabetic foot complications account for 40% to 70% of non-traumatic lower limb amputations. Approximately 85% of the amputations are preceded by foot ulcerations. The estimated mortality after five years of ulceration is 50% and increases to 70% after five years of amputation^{4,7}. The risk and frequency of repeated amputations have significant regional differences associated with socioeconomic factors, availability of footwear and measures to prevent secondary complications⁴. Amputations have an impact on the health system, mortality and QoL, affecting self-image, self-esteem and the role of the individual in the family and in society^{8,9}.

The clinical evaluation for traceability and identification of persons at risk of ulceration covers the clinical history and examination of the feet for the identification of neurological dysfunctions and areas of plantar pressure^{7,10}.

Self-care education should involve clear guidelines on the disease and risks of complications, both for the client and its family members or legal guardians, in order to stimulate adherence to treatment and changes in lifestyle. Emphasis should be given to examination, care and signs of complications on the feet, guidance on shoes, nails and the necessity for glycemic control^{7,9}.

The difficulty and scarcity of physical, human, and material resources in many health services in Brazil puts diabetes education at risk, and educational materials have assumed an important role in the teaching-learning process and empowerment of this clientele, making it capable of understand the actions that influence its health, emphasizing the importance of self-care¹¹.

Printed information materials help the education process for self-care and the interaction between the client and the educator, facilitating the understanding of the disease, adapting to new concepts and overcoming difficulties¹²⁻¹⁴. Images and written guidelines allow a better understanding of the problem, reinforcing verbal information and serving as a guideline in case of doubt. Teaching and learning instruments in health should be developed for specific diseases, based on scientific evidence and with language accessible to the population at risk¹²⁻¹⁴.

In order to contribute to diabetes education, this study aimed to elaborate and validate the content of an educational instrument with health promotion actions for self-care of people with peripheral neuropathy due to diabetes.

METHODS

Study of methodological approach of quantitative type structured in two stages: elaboration of the educational instrument and validation of content.

The educational instrument was elaborated after a bibliographical survey realized in the databases Virtual Health Library, SciELO and LILACS/Database of Nursing (BDENF); the search terms were "diabetic foot", "diabetic neuropathy" and "foot ulcer", selected in the Medical Subject Headings (MeSH) and Health Sciences Descriptors (DeCS), with descriptors and keywords in English, Portuguese and Spanish. The images were obtained by photographs taken by the authors with consent for use of the image.

The information was written in a language accessible to the lay population, addressing the topic diabetes, prevention guidelines, signs and symptoms of primary and secondary complications of peripheral neuropathy, hygiene, moisturization and foot inspection, nail care and shoe suitability. The printed material was titled *Guidelines for People with Diabetic Peripheral Neuropathy* - Preventing Foot Wounds.

Validity of content

The educational instrument was submitted to the evaluation of a committee of six specialists (judges) composed of two stomatherapist nurses, a podiatry nurse, a vascular surgeon, an endocrinologist and a physiotherapist (orthotist and prosthetist). The material for validation was sent by correspondence after formal invitation to the specialists and signing of the free and informed consent form.

The instrument was evaluated for the comprehensiveness, pertinence and clarity of each item and subitem and also its general appearance. The evaluation form included spaces for comments and/or suggestions. The instruments were analyzed and the data organized, grouped and presented in the form of absolute numbers and percentages. The acceptable rate of concordance between the judges was considered 80%¹⁵.

The content validity score (CVI) score was calculated using the sum of agreement of the items scored by 3 or 4 by the specialists. Items that received scores 1 or 2 were reviewed or deleted. To perform this calculation, it was used Eq. 1:

$$CVI = \frac{\text{Number of answers 3 or 4}}{\text{Total number of answers}}$$
(1)

Following the definitive changes, the final artwork and diagramation were realized by specialized audiovisual technical assistance and the material was printed and reproduced on *couche* paper specifically for the printing of figures. The page size was half sheet (15×21 cm) in landscape format and finished with staple, trim and fold.

The research project was approved by the Research Ethics Committee of the Faculty of Medical Sciences of the State University of Campinas (UNICAMP) (opinion 1054/2010).

RESULTS

From the review, selection and adaptation of the contents to the composition of the educational material, the following contents resulted: introduction on diabetes, how to prevent complications of diabetes, health care, nail care, shoe choice and information of interest to the user.

As a result of the validation process, the educational instrument obtained a general CVI of 0.89. Table 1 specifies the items and subitems of the instrument evaluated by the judges and its respective CVI.

The modifications made in the material were established according to the suggestions and/or comment of the judges and it are described below:

Items modified by CVI <0.8

In the item "Talking about diabetes", it was suggested to broaden and detail the diseases caused by neuropathy. It has been added: "... it may evolve to heart disease, blindness, decrease or loss of function of the kidneys and amputations", as well as the expression "... loss of sensitivity to pain, pressure and temperature (cold and hot)."

In the item "Taking Care of Your Foot Health -Examine Your Feet," one of the judges questioned how a patient with impaired visual acuity would examine her feet. The questioning was considered valid, including: "Examine your feet daily; if you find it difficult to see them ask for help or use a magnifying glass or magnifying lens."

In the item "Nail Care - Nail Moisturizing", it was added, at the suggestion of one of the judges: "If you notice spots and deformities on the nails, consult a specialist." In the last paragraph of the same item, "a specialist" by "a specialized service".

In the item "Choosing the shoe", the suggested suggestion was accepted and the text became: "The most appropriate shoe is the one that comfortably accommodates your feet" and also "Look for information on therapeutic footwear." In the item "Information of interest", 33.3% of the judges considered the appointment of the "podologist" as the specialized nail care professional not relevant; also considered this information unclear and not very comprehensive, and it was decided to exclude the name of this professional. The term "orthopedic footwear" was replaced by "therapeutic footwear" at the suggestion of one of the judges.

Items modified with suggestions of judges and agreement of the authors, although CVI > 0.8

In the item "Introduction", it was suggested by one of the judges to add the phrase "... especially *heart*, *kidneys*, nerves and blood vessels". The authors found it pertinent and the guide was changed.

One of the judges suggested changing the title "Preventing Complications" to "Preventing foot wounds," focusing on complications. This alteration was deemed pertinent and realized.

In the item "Taking care of its health", the judges considered that the control of the blood pressure had no relation with the objective of the material. For this reason, its opted to maintain only emphasis on glycemic control.

In the same item, it was suggested to clarify how smoking interferes with diabetic health and, therefore, added that "... smoking increases the clogging of diabetic blood vessels."

Considering the suggestion of one of the judges to cite the importance of the risk assessment of this population, the term "his doctor" was replaced by "a specialist" and "at least once a year was added to assess his risk to develop a sore foot. "

In the item "Choosing the shoes," one of the judges suggested adding that the type of socks most indicated, as well as seamless cotton, should be "white".

Also excluded was the term "rigid insoles" and maintained only "silicone insoles are not indicated for neuropathy", so there would be no misinterpretation.

In the item "Information of interest", the phrase "The endocrinologist and the general practitioner are the professionals who can help him in the control of diabetes" was added by consensus among the authors, and was also replaced "the specialist in podiatry and stomatherapy" by " the nurse stomatologist and other specialists are best suited for the treatment of wounds and problems with the nails."

Table 1. Content validity index (CVI) results of the items and sub-items evaluated by the judges.

Evaluated items	CVI Results			
	Scope	Relevance	Clarity	General appearance
Introduction	1			1*
Talking about diabetes	0.84	1	0.5*	
Preventing complications	1	1	1*	
Caring for your health				
Blood glucose control		0.84*	0.84*	
Exercises		0.84	1	
Smoking		1	0.84*	
Food		1	1	
Medication		1	1	
Monitoring		1	1	
Caring for the health of your feet				
Watching the feet		0.84	0.84	
Hygiene		1	0.84	
Dry		1	1	
Moisturize		1	1	
Massage		0.84	0.84	
Prevent burn		1	0.84	
To examine		0.84	0.66*	
Caring for nail health		0.04	0.00	
Cut		0.84	0.84	
Moisturization		0.66*	0.66*	
To remove		1	1	
		0.84*	1	
Specialist		0.04"		
Choosing the shoe			1	
Barefoot		1	1	
Soft shoe		0.66*	0.66*	
To buy shoe		0.84	0.84	
Special shoes		0.84	0.84	
Socks		1	0.84*	
To examine shoe		1	0.84	
Comfortable shoes		0.84	0.84	
Useful Information	1			
Podologist		0.66*	0.5*	
Podiatrician or Stomatherapist		1	0.84*	
Orthopedic footwears		1	0.66*	
Doubts		0.84	0.84	
General appearance				
Diagramming				1
Preview				1
Understanding				1
Grouping				0.84
Sequence				1
Theoretical foundation				0.84

* Items modified, reformulated and/or withdrawn.

DISCUSSION

The process of preparing an educational booklet is of great importance, as it guarantees the continuity of care at home, aiming for adequate care, making people affected by diabetes responsible for the success of its treatment, actively participating in the behaviors proposed by the health team¹².

Educational strategies broaden teaching-learning possibilities and, when employed appropriately, help in the acquisition of knowledge, skills and attitudes in the management of diabetes¹¹. This was also demonstrated in a almost experimental study realized in Mexico, which compared the traditional method with participatory communication, proving that the participatory method favored learning and the choice of conduits for the care of the feet of people with diabetes¹⁴.

Another study corroborates that the use of educational material with images through simplified models, illustrative folders, serial albums, pamphlets, posters, leaflets, followed by guidelines by health professionals produces satisfactory results during teaching-learning¹³.

Services for preventing complications in the feet of people with diabetes should be structured according to national guidelines, minimizing variations in clinical practice and ensuring different levels of care organization for people with diabetes and feet problems¹. However, the organization and access to feet care services and the availability of skilled health professionals still present significant regional differences that interfere in the care of this population^{7,10}.

Several studies point out that a high percentage of lower limb amputations in people with DM is avoidable and that feet ulcerations represent the main risk factor^{4,16}. Educational approaches should emphasize the prevention of the occurrence of ulcerations based on daily and adequate care of the lower limbs and periodic examination of the feet, aiming to identify early changes, facilitating interventions and avoiding the development of complications^{10,17}.

Education should be directed to improve knowledge, behavior and motivate adherence to self-care¹⁰. Consensus on diabetes, with recommendations for prevention of feet ulcerations, emphasize metabolic control, risk classification, feet evaluation and shoe suitability as essential measures for care 4,6,7,10 .

Persistent hyperglycemia and time of diabetes are the primary primary risk factors for peripheral neuropathy. Glycemic control significantly reduces the chronic complications of the disease and, in addition to glycosuria and fasting glycemia dosages, several methods are currently available for this purpose, such as glycemic control in the long term by means of glycated hemoglobin tests and detection of fluctuations in glycemia by means of self-monitoring of capillary glycemia (SMCG) and continuous monitoring of glucose in interstitial fluid (MGII)^{7,10,17}.

Diabetic polyneuropathy is present in 50% of patients older than 60 years with type 2 DM, 30% of patients in hospital clinical care and 20% to 25% of patients in primary care¹⁸. The perception and recognition of symptoms such as paresthesia, burning sensation, needle or twinge in the plantar region or loss of sensation with decreased sensation of pain and temperature perception are essential for the prevention of secondary complications of the disease^{6,19,20}. Monitoring through insensitivity screening, evaluation of sensory, motor, vibratory, painful and reflex changes and observation of neuropathic deformities of the feet are also essential as a strategy to prevent ulcerations^{6,7,19}.

Neurological tests for sensitivity assessment, tendon reflexes, and blood pressure and heart rate measurements should be performed according to the risk classification or at least annually by a specialist as a measure of control and prevention of ulcerations⁴.

The suitability of footwear is part of both prevention and treatment of ulcers^{4,6}. The selection of footwear should consider the classification of risk of ulceration and be prescribed according to the Brazilian Association of Technical Standards (ABNT) and the National Institute of Metrology, Standardization and Industrial Quality (Inmetro), which have technical data for approval of footwear²¹. The user needs understanding and guidance on feet protection risks and measures related to the use of footwear, socks, insoles and orthoses to adhere to treatment¹⁰.

Early diagnosis of diabetic foot is the most effective measure for the prevention of ulcerations and amputations. The person with DM should be part of an interdisciplinary therapeutic plan that guarantees specialized treatment, provision of adequate footwear and education ^{6,7,10}.

A study on health education strategies used for teaching and learning of people with diabetes mellitus and peripheral neuropathy and another on risk assessment for diabetic foot²³ have shown that health education is paramount and guarantees efficacy of self-care, change of habits and improvement of QoL

CONCLUSION

The final instrument of this study obtained the CVI of 0.89, with adequate agreement among the judges, and was therefore validated. It has been shown to be comprehensive and pertinent, with clear and easy-tounderstand information, good appearance, informative texts and photographic illustrations that may contribute to the health education process of people with peripheral neuropathy due to diabetes and, consequently, to the prevention of primary and of the disease. The limitations of the study refer to the necessity to test the instrument with the target audience.

AUTHORS CONTRIBUTION

Conceptualization, Kaizer UAO and Araujo VS; Methodology, Kaizer UAO, de Araujo VS and Dantas SRPE; Investigation, Kaizer UAO and Araujo VS; Writing - First version, Kaizer UAO and Araujo VS; Writing - Review & Editing; Kaizer UAO and Araujo VS; Writing - Review and Editing, Dantas SRPE.

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