TEXTO & CONTEXTO ENFERMAGEM
TEXT & CONTEXT NURSING TEXTO & CONTEXTO ENFERMERÍA

VALIDATION OF AN EDUCATIONAL TECHNOLOGY FOR CAPECITABINE-INDUCED HAND-FOOT SYNDROME

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ABSTRACT

Objective: to validate an educational folder on guidance, prevention and treatment of capecitabine-induced hand-foot syndrome (HFS) using validation from professional specialists in the area.
Method: this is a methodological study that analyzed the validity of the folder, characterized as an educational technology. The elaboration and validation process of the content occurred between June and December 2022 in an Oncology Outpatient Unit of a Tertiary Hospital in the interior of São Paulo State, Brazil. The construction and validation phases of the folder contents were subsequently conducted with professional specialists. The validation criteria are based on a Content Validity Index greater than or equal to 0.90.
Results: seven oncology specialists, including five nurses and two pharmacists, were invited to participate in the study. Two validation rounds were conducted, and the folder was validated in the second round, achieving an overall content validation index of 1.0.
Conclusion: the educational folder was validated by specialists and demonstrated to be a tool with great potential to assist in the prevention and treatment of patients presenting capecitabine-induced hand-foot syndrome.

DESCRITORS: Nursing. Oncology. Educational technology. Education in health. Validation study.

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VALIDAÇÃO DE TECNOLOGIA EDUCACIONAL PARA SÍNDROME MÃO-PÉ INDUZIDA POR CAPECITABINA

RESUMO

Objetivo: Validar um *folder* educativo sobre orientações, prevenção e tratamento da síndrome mão-pé induzida por capecitabina, utilizando a validação de profissionais especialistas na área.
Método: Estudo metodológico que analisou a validade do referido *folder*, caracterizado como uma tecnologia educacional. O processo de elaboração e validação do conteúdo ocorreu entre junho e dezembro de 2022 em um Ambulatório de Oncologia de um Hospital Terciário no interior de São Paulo. Foram seguidas as fases de construção e validação de conteúdo do *folder* com profissionais especialistas. Os critérios para validação baseiam-se em um Índice de Validade de Conteúdo maior ou igual a 0,90.
Resultados: Foram convidados a participarem do estudo sete especialistas em oncologia, incluídos cinco enfermeiros e dois farmacêuticos. Foram realizadas duas rodadas de validações, nas quais se validou o *folder* na segunda rodada, atingindo um índice global de validação de conteúdo de 1,0.
Conclusão: O *folder* educativo foi validado por especialistas e demonstrou ser uma ferramenta com grande potencial para auxiliar na prevenção e tratamento de pacientes que apresentam a síndrome mão-pé induzida pela capecitabina.

DESCRITORES: Enfermagem. Oncologia. Tecnologia educacional. Educação em saúde. Estudo de validação.

VALIDACIÓN DE TECNOLOGÍA EDUCATIVA PARA EL SÍNDROME MANO-PIE INDUCIDO POR CAPECITABINA

RESUMEN

Objetivo: Validar una carpeta educativa sobre pautas, prevención y tratamiento del síndrome mano-pie inducido por capecitabina, utilizando la validación de profesionales especialistas en la materia.
Método: Estudio metodológico que analizó la validez de la carpeta antes mencionada, caracterizada como una tecnología educativa. El proceso de desarrollo y validación del contenido tuvo lugar entre junio y diciembre de 2022 en un Ambulatorio de Oncología de un Hospital Terciario del interior de São Paulo. Las fases de construcción y validación de contenido de la carpeta fueron seguidas con profesionales especialistas. Los criterios de validación se basan en un Índice de Validez de Contenido mayor o igual a 0,90.
Resultados: Se invitó a participar en el estudio a siete especialistas en oncología, entre ellos cinco enfermeros y dos farmacéuticos. Se realizaron dos rondas de validaciones, en las que la carpeta fue validada en la segunda ronda, alcanzando un índice general de validación de contenido de 1,0.
Conclusión: La carpeta educativa fue validada por expertos y demostró ser una herramienta con gran potencial para ayudar en la prevención y tratamiento de pacientes con síndrome mano-pie inducido por capecitabina.

DESCRIPTORES: Enfermería. Oncología. Tecnología Educacional. Educación para la salud. Estudio de validación.

INTRODUCTION

Cancer is one of the main causes of global deaths and a significant obstacle to increasing the population's life expectancy. It is estimated that by 2040 there will be 28.4 million new cases of cancer worldwide, accentuated by an increasing prevalence of risk factors. The forecast in Brazil is approximately 704 thousand new cases of cancer annually for the three-year period 2023–2025, or 483 thousand if cases of non-melanoma skin cancer are excluded[1–2].

Chemotherapy, which uses antineoplastic drugs to destroy cancer cells through their systemic effect, is one of the main cancer treatment strategies. This therapy is administered at regular intervals according to specific protocols for each type of cancer. Due to its lack of specificity and action on rapidly proliferating cells, this treatment presents significant toxicity and side effects[3–4].

Capecitabine is an antimetabolite and cytotoxic chemotherapy agent, mainly indicated for treating neoplasms of the breast, stomach, pancreas, colon and rectum, whether localized or metastatic. It is a fluoropyrimidine carbamate that is enzymatically converted in tumor tissues into 5-fluorouracil, which reduces toxicity due to less exposure of healthy tissues to the cytotoxic agent[5–7].

The main adverse reactions to capecitabine include gastrointestinal changes (diarrhea, nausea, vomiting), dermal changes (palmoplantar erythrodysesthesia and mucositis), myelosuppression (reduction in platelet and white and red blood cell counts), paresthesias, edema and neuromuscular and skeletal weakness[8].

Palmar-plantar erythrodysesthesia, known as hand-foot syndrome (HFS), can be observed in approximately 22–77% of patients treated with capecitabine. The mechanisms that lead to the emergence of HFS are still unknown, however this medication causes the cell death of keratinocytes and reduces the stratum corneum[5].

According to the National Cancer Institute, HFS can be classified into three degrees of severity. In grade one, the patient has minimal skin changes, such as erythema, edema or hyperkeratosis. In grade two, peeling, blistering, bleeding, fissures, edema or hyperkeratosis occur, accompanied by pain that interferes with instrumental daily living activities, such as handling objects, cooking and dressing. In grade three, serious skin changes appear, such as peeling, blisters, bleeding, with pain and daily self-care limitations. This adverse event is characterized by the clinical appearance of the lesions ranging from erythema, edema, fissures to blisters, with the palms of the hands generally being more affected than the soles of the feet[9].

Early recognition of the signs and symptoms of HFS, implementing preventive measures and adopting interventional strategies for its management can prevent major complications and improve patients' quality of life. Pharmacological and non-pharmacological strategies have been investigated to alleviate symptoms and prevent HFS. A systematic review and meta-analysis of oral and topical preventive medications revealed that despite the development of new medications, studies and prevention strategies for HFS are still needed. Depending on the severity of the condition, HFS may require a reduction in the medication dose, or even its interruption or replacement[5,7,10].

Therefore, the objective of this study was to validate an educational folder that contains guidelines for preventing and treating HFS. Therefore, this material can optimize diagnosis and treatment, and improve the quality of life of patients and their families who use capecitabine as a form of treatment.

METHOD

This is a methodological study which analyzed the evidence validity of an educational technology in the form of a folder. It was developed between June and December 2022, in an Outpatient Oncology Unit of a tertiary service located in the interior of São Paulo State, Brazil. The service is linked to the Regional Health Directorate VI, and is recognized by the Ministry of Health as a High Complexity

Unit in Oncology. The study was divided into two phases: the construction and validation of the folder with experts.

The methodology for validating educational technology was adapted[11], and the proposed model guides the development and construction of the material based on three criteria: the importance of the care activity to be dimensioned, its potential for improvement, and the degree of control over it. The model includes three procedures: theoretical, empirical and analytical. Taking into account the educational purpose of the technology for this study, theoretical validation procedures were applied. These involve selecting the care aspect to be assessed, the selection of indicators in the respective area, the development of a reliable and valid measure, and subsequent submission to experts to verify the clarity and relevance of the items[11–12].

This project was approved by the institution's Research Ethics Committee, and is in accordance with Resolution 466/2012. All participants signed the Informed Consent Form in two copies.

The first stage of the project aimed at building an educational technology in the form of a folder, which was executed in a previous study[13]. It was then decided to advance to the second validation phase involving experts in the nursing and oncology pharmacy areas.

The literature presents divergences regarding the number of judges required, however it was decided to follow a minimum of five and a maximum of ten judges[14] for the validation process. Thus, seven specialized professionals were selected to validate the study.

The chosen professionals, nurses and pharmacists linked to the chemotherapy outpatient clinic of the involved institution were invited for validation. The criteria for selecting specialists considered the training and experience of these individuals, meaning nurses and pharmacists with experience in teaching, research or care in oncology, handling chemotherapy drugs and association with care institutions. These professionals were responsible for monitoring adverse events related to antineoplastic therapy at the institution in question.

The criteria for inclusion established points according to the candidates' qualifications: Master's degree (four points); specialized in oncology (four points); publications in the field of oncology (two points); minimum of one year of experience in the area (one point); and certificate of relevance in clinical practice in the area (two points). Participants who did not complete the instrument provided to validate the material were excluded.

Data collection began with a face-to-face meeting with professionals who met the inclusion criteria at which the objectives, participation structure and guidelines for completing the instrument were presented. After accepting participation, a link with the Informed Consent Form was sent by email. By signing the term and confirming participation, participants were able to access the folder and validation form online. The time to complete the instrument was approximately 20 minutes, with exclusion of the specialist who did not respond to the instrument within 15 days after sending it.

The data collection instrument was structured in two parts. The first covered data and sociodemographic characteristics of the participants. The second focused on understanding the first stages of validating educational material[15]. The analysis of the structure and content of the material included domains such as content, language, relevance, layout and motivation of the material, providing space for comments and suggestions at the end.

Next, a second validation round with participation of the same experts was carried out two months after the first to adapt the material to the experts' guidelines and suggestions. They reviewed the educational folder and filled out the data collection instruments in an online format. The second round took place from August to September 2022, with the material being considered validated when it reached the minimum level of agreement.

For content validation, the Content Validity Index (CVI), the Content Validity Index per Item (CVII) and the Overall Content Validity Index were calculated. These are methods frequently used in

the health field to assess agreement between experts regarding a specific topic. It is recommended to use a Likert-type scoring scale that varies from one to four for this purpose[16].

The following classification was used in this study: 1 = totally disagree, 2 = disagree, 3 = agree, 4 = totally agree. The CVI score was determined by the proportion of items that received a score of 3 or 4 by experts. Items that received a score of "1" or "2" were subject to review or deletion. Therefore, the calculation formula used was based on the number of responses 3 and 4, divided by the total number of responses from experts[16].

Items that obtained a minimum agreement of 0.90 among experts were considered valid in this study[17].

RESULTS

The study included the participation of seven experts, of which five (71.4%) were nurses and two (28.6%) were pharmacists. The majority were female (71%), with an average age of 38 years. All were specialists in the field of oncology, with an average of six years of experience in the field.

Two evaluation rounds were conducted by experts. In the first round, the item "relevance" reached a CVI of 0.94. Based on these results, it was necessary to review other items: objective (0.85), content (0.88), language (0.85), layout (0.80) and motivation (0.79) (Table 1). The overall validation index of the folder in the first round was 0.85. The first version of the folder is shown in Figure 1.

Table 1 – Result of the Content Validity Index according to objectives, content, language, relevance, layout and motivation and average agreement rate. Botucatu, SP, Brazil, 2022. (n=7).

Domains	1st round	2nd round
1. Objectives	**CVI***	**CVI***
1.1 The objectives are consistent with the needs of individuals using capecitabine and capecitabine-induced hand-foot syndrome	1	1
1.2 This folder is a possibility in the health education process for patients with capecitabine and capecitabine-induced hand-foot syndrome	0.86	1
1.3 The folder is capable of promoting reflection on care to prevent the recurrence of hand-foot syndrome induced by capecitabine	0.86	1
1.4 The information contained in the folder promotes changes in user behavior and attitude	0.71	1
CVII**	**0.85**	**1**
2. Content		
2.1 The folder is appropriate for patients subject to capecitabine-induced hand-foot syndrome	1	1
2.2 The folder offers information on care to prevent the recurrence of capecitabine-induced hand-foot syndrome	0.86	1
2.3 The text is presented in a clear and objective way	0.86	1
2.4 The presented information is scientifically correct and in accordance with the service routine	0.86	1
2.5 There is a logical sequence of the content presented	0.71	1
2.6 It is valid to keep the sector's telephone number available for possible doubts and queries	1	1
CVII**	**0.88**	**1**

Table 1 – Cont.

Domains	1st round	2nd round
3. Language		
3.1 The information presented is clear and understandable	1	1
3.2 The writing style corresponds to the knowledge level of the target audience	0.71	1
3.3 The information is well structured	0.86	1
3.4 The writing used is attractive	0.71	1
3.5 The title of the folder is interesting and appropriate	1	1
CVII**	**0.85**	**1**
4. Relevance		
4.1 The themes portray points that should be reinforced during consultations and care	1	1
4.2 The folder enables the transfer of care between hospital and home	0.86	1
4.3 The folder proposes that the learner acquire knowledge to perform self-care	0.86	1
4.4 The folder is suitable for use by any healthcare professional	1	1
4.5 The topic is current and relevant	1	1
CVII**	**0.94**	**1**
5. Layout		
5.1 The presentation of the folder is attractive	0.43	1
5.2 The presentation of the folder is organized logically	0.86	1
5.3 The content is presented in suitable font and size for reading	1	1
5.4 The font used makes the material easier to read	1	1
5.5 Contrast with different colors was done appropriately	0.71	1
CVII**	**0.8**	**1**
6. Motivation		
6.1 The title is attractive and arouses interest in reading	0.71	1
6.2 The content sparks interest in reading	0.71	1
6.3 The content is motivating and encourages the reader to continue reading	0.86	1
6.4 The font used makes the folder easier to read	1	1
6.5 Contrast with different colors was done appropriately	0.71	1
CVII**	**0.79**	**1**
Overall Content Validity Index	**0.85**	**1**

*= Content Validity Index; **= Content validation index by item.

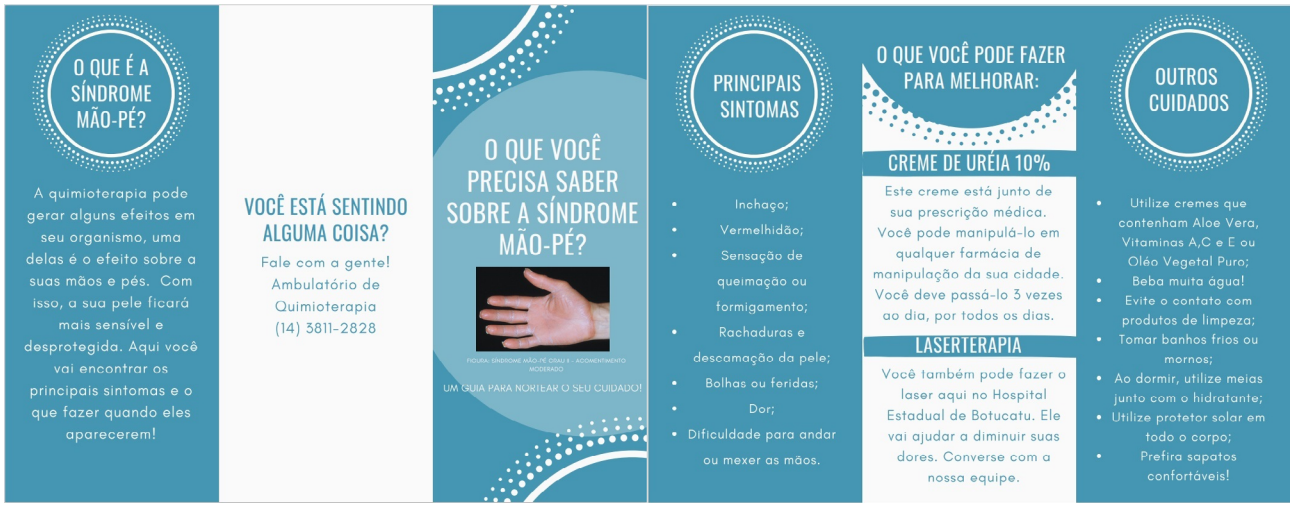

Figure 1 – First version of the educational folder on capecitabine-induced hand-syndrome[13]. Botucatu, SP, Brazil, 2022.

Experts proposed changes or comments in the instrument's descriptive fields in the first validation round, aiming to improve the material (Chart 1). Most of the suggestions focused on the use of language and layout aspects, which obtained CVI of 0.85 and 0.8, respectively. These results highlight the need to make such changes.

The final validation of the material took place in the second round, in which all items presented an CVII of 1.0, maintaining an overall validation index of 1.0. Despite the validation of the folder, experts suggested improvements to the material. These improvements involved correcting the language in a specific sentence and including images depicting hyperemic hands and feet, with both suggestions accepted.

Chart 1 – Suggestions from professional experts in the first validation round. Botucatu, SP, Brazil, 2022.

Suggestions from professional experts	Modifications made
Increase the amount of information related to the subject	Added new information about HFS
I suggest changing the order – what is hand-foot-first syndrome	Changed to chronological order
Prevention must be highlighted separately from other care	Separate item prepared for prevention
The institution's logo is missing	Added the logo for oncology, state hospital and multidisciplinary residency program
Which professional should I look for if the syndrome occurs and refer who will provide care (nurse, pharmacist and medical team)	It is specified that the patient must contact the nurse and/or pharmacist of the unit
Change the title to "Hand-foot syndrome: possibility of including dry hands and feet"	We chose to maintain the name hand-foot syndrome because it involves more symptoms than only dry hands and feet
Enlarge figures in text	Added more illustrative figures about HFS

After reviewing the material and considering the suggestions proposed by the experts, a second version of the folder was prepared. This version guaranteed both adjustments to the content and appearance of the material, as shown in Figure 2. The final folder and validation instrument were then sent back to the participants for new analysis.

Figure 2 – Second version of the educational folder on capecitabine-induced hand-foot syndrome. Botucatu, SP, Brazil, 2022.

DISCUSSION

The educational material aimed at patients with capecitabine-induced hand-foot syndrome achieved content validity in the second evaluation round with the collaboration by experts on the subject and obtaining an overall CVI of 1.0. This material arose from the need identified in the field of clinical practice of nurses and pharmacists to provide adequate guidance to oncology patients. Providing well-managed education to chemotherapy patients has been proven to improve treatment adherence, increase patient satisfaction, alleviate treatment anxiety and reduce healthcare costs[18–19].

Proper patient education is essential, as the patient must be completely integrated into their care, enabling them to understand and manage their health and stay up to date with suggested care plans. Patient education is more effective when supported by educational material that helps patients remember the necessary care. Instruction methods may vary, including individual, group, video or printed materials such as brochures and booklets, normally carried out at the beginning of treatment, when changing treatment or at the request of another healthcare professional[19–23].

Patients undergoing oral chemotherapy have less contact with healthcare professionals, consequently patient safety, adherence and therapy monitoring may be compromised. Therefore, the pharmacist plays a crucial role in educating cancer patients, as an excellent opportunity arises to promote health education during medication provision[21].

As part of the multidisciplinary team, the pharmacist is a professional with extensive knowledge about the medications used by the patient and their implications for treatment. They are often one of the few team members who has comprehensive understanding of the safety, efficacy, pharmacological and financial components of the care for cancer patients[22,24–26].

Oncology pharmacists play a significant role in educating other healthcare providers because of their specialized knowledge of chemotherapy drugs, and can provide intervention and guidance to patients and other professionals[20,22–24].

A study revealed that the vast majority of pharmacists evaluate the effectiveness of patient guidance through questions, ensuring that the information has been properly assimilated. In the first meeting with the patient, pharmacists cover topics such as medication administration, side effects, prevention and treatment, and drug interactions. Increased comorbidities, complexity of drug therapies, and greater awareness of clinically significant drug interactions contribute to an environment in which pharmacists become uniquely qualified to provide and/or facilitate medication management in the oncology population[19–23,25].

Therefore, the educational folder can be used during the pharmaceutical consultation. Counseling about chemotherapy medications improves knowledge and adherence to chemotherapy treatment, increases quality of life and reduces anxiety in cancer patients. Continuous guidance enables patients to effectively manage their adverse effects and remain on treatment for longer, without the need for dose reduction or interruption of therapy[22–26].

The dynamic healthcare landscape and progressive approach to cancer treatment (e.g., oral therapies, targeted therapies, personalized medicine) further reinforce the importance of the oncology pharmacist in the oncology healthcare team[24,25]. In this context, the validation of the educational folder is considered a valuable contribution, providing professional training to improve cancer care and management, especially for patients and/or family members dealing with HFS, aiming to improve quality of life and minimize treatment interruption.

As a limitation of the study, there is a lack of validation with the target audience, which can be addressed in future research.

CONCLUSION

In this study, an educational folder on capecitabine-induced hand-foot syndrome was validated by the contribution of specialist professionals. This material can be used as an educational tool both in hospital and out-of-hospital settings. The objective is for the folder to serve as an effective means of communication and education between the multidisciplinary team and the patient, providing important support for the treatment and prevention of this adverse event.

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NOTES

ORIGIN OF THE ARTICLE

Extracted from the Residency Completion Work "*Educação em saúde: Validação de Material Educativo para síndrome mão-pé*", presented to the Multidisciplinary Residency Program in Adult and Older Adult Health at the Faculdade de Medicina de Botucatu in 2023.

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APPROVAL OF ETHICS COMMITTEE IN RESEARCH

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CONFLICT OF INTEREST

There is no conflict of interest.

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