Promoção da Saúde
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Validation of educational materials for health promotion in fibromyalgia

Validação de material educativo para promoção da saúde na fibromialgia

Amanda Januário Lira[1], Letícia Assis Couto[1], Amélia Pasqual Marques[1], Mateus Dias Antunes[1*]

[1]Department of Physiotherapy, Speech Therapy and Occupational Therapy, School of Medicine, University of São Paulo, São Paulo (SP), Brazil

***Corresponding author**: Mateus Dias Antunes – *Email*: mateus_antunes03@hotmail.com

ABSTRACT
Fibromyalgia is a rheumatic syndrome that interferes with a person's functional capacity and quality of life. It is important to note that the initial non-pharmacological strategy should be patient education, focusing on the process of adaptation and coping with fibromyalgia and quality of life. The objective of this study was to validate educational material to promote health in fibromyalgia. The material was validated using the Delphi technique with 23 experts judges (professionals with experience in rheumatology, education, and health promotion) and 23 target audience judges (people with fibromyalgia). The groups evaluated the difficulty and convenience of the educational material. Content validation was performed using the Content Validity Index and the Kappa Coefficient. The educational material obtained the feasibility from the expert judges and the target audience, with mean values of all evaluated items of 0.78±0.03 and 0.91±0.06, respectively. Additionally, reliability also showed mean values of all evaluated items classified as good, excellent, and perfect for the expert judges (0.97±0.05) and the target audience (0.86±0.10). It is concluded that the educational material regarding content and language was validated and showed reliability, proving to be a relevant instrument for the target audience and expert judges.

Keywords: Fibromyalgia. Health Education. Self-care. Pain Education. Health promotion.

RESUMO
A fibromialgia é uma síndrome reumática ue interfere na capacidade funcional e qualidade de vida da pessoa. Destaca-se que a estratégia inicial não farmacológica deve ser a educação do paciente, centrada no processo de adaptação e enfrentamento da fibromialgia e na qualidade de vida. O objetivo deste estudo foi validar um material educativo para promover a saúde na fibromialgia. O material foi validado por meio da utilização da técnica Delphi com 23 juízes especialistas (profissionais com experiência nas áreas de reumatologia, educação e promoção da saúde) e 23 juízes público-alvo (pessoas com fibromialgia). Os grupos avaliaram a dificuldade e conveniência do material educativo. A validação de conteúdo foi feita com aplicação do Índice de Validade de Conteúdo e do Coeficiente Kappa. O material educativo obteve a viabilidade dos juízes especialistas e público-alvo, com valores da média de todos os itens avaliados de 0,78±0,03 e 0,91±0,06, respectivamente. Além disso, a confiabilidade também apresentou valores médios de todos os itens avaliados classificados entre bom, ótimo e perfeito para os grupos de juízes especialistas (0,97±0,05) e o público-alvo (0,86±0,10). Conclui-se que o material educativo quanto ao conteúdo e linguagem foi validado e apresentou confiabilidade, mostrando-se um instrumento de relevância junto ao público-alvo e juízes especialistas.

Palavras-chave: Fibromialgia. Educação em Saúde. Autocuidado. Educação em Dor. Promoção da Saúde.

INTRODUCTION

Fibromyalgia is a rheumatic syndrome that affects functional capacity and quality of life, causing mental distress, physical discomfort, and impairments in social relationships[1-2]. The prevalence of the disease in the general Brazilian population ranges between 2.4% and 6.8%, with a higher incidence in women[3]. In recent years, fibromyalgia has become a public health issue in Brazil due to its high prevalence in the adult population, poorly understood etiology and pathophysiology, and dissatisfaction among both the public and healthcare professionals regarding therapeutic approaches[4-7].

The recommendations revised by the European Alliance of Associations for Rheumatology (EULAR) for the management of fibromyalgia highlight the importance of combining pharmacological and non-pharmacological interventions. Moreover, these guidelines emphasize that the initial non-pharmacological strategy should focus on patient education centered around the process of adaptation and coping with fibromyalgia in relation to quality of life[8-9]. For the effectiveness of fibromyalgia treatment, the emphasis of interventions should be on the triad of: healthcare team, patient, and family, so that by interrelating these three units, it is possible to address the phenomenon more comprehensively by involving the family in the reality of the disease, clarifying doubts, providing guidance, and seeking to reorganize and strengthen family relationships to optimize pain management[10-11].

Regarding education, it is necessary for it to be continuous and to present to individuals the importance of active participation in treatment and understanding, in general, the symptoms and pathophysiology of fibromyalgia, aiming for acceptance, adherence, and, primarily, the development of self-care. The individual is the center of any change in their own life and health, being the one who knows their situation best and understands what is needed to feel well and what aids or hinders the process of change[12-17]. Furthermore, the educational process should also extend to those who are not directly affected by the problem, as fibromyalgia is a syndrome with no visible signs of disability or illness, leading to skepticism about the condition as a real affliction. Consequently, individuals may lose credibility regarding their complaints and limitations in performing tasks due to the lack of knowledge among friends, family, and society in general[13-14].

There is scientific evidence that written and printed materials are among the best and most effective ways to inform patients, families, and the community, and can be used as a strategy for promoting health education, as well as stimulating cognitive development[18]. Thus, it should be developed in a way that the content is easy to understand and meets the individual's needs. Additionally, the development of this tool should be in accordance with the guidance of professionals[19]. Considering all the points presented, especially regarding the importance of health education in fibromyalgia, there is a need to develop educational strategies that promote health in fibromyalgia, including general information, clarifications, and guidance for both individuals with the syndrome and the community, in order to popularize scientific knowledge on this topic. In this sense, the objective of the study was to validate an educational material to promote health in fibromyalgia.

METHODS

STUDY DESIGN

This is a methodological research conducted from July to September 2023. The study employed specific guidelines to develop and validate educational materials intended for health care[19].

ETHICAL ASPECTS

The study was approved by the Research Ethics Committee of the Faculty of Medicine of the University of São Paulo, with approval number 3,197,778. Participants were verbally and in writing informed about their participation in the study before consenting to the Free and Informed Consent Form.

DEVELOPMENT OF EDUCATIONAL MATERIAL

The educational material was developed in a preliminary study conducted by the research group responsible for the project. Its construction used an approach based on Paulo Freire's principles, starting with a significant identification of the participants' primary needs to be addressed, so that subsequently, the process of awareness could occur[20]. The researchers developed the educational material containing information identified by individuals with fibromyalgia and healthcare professionals from a Basic Health Unit in São Paulo, SP. The educational material was created in the format of a leaflet.

VALIDATION OF EDUCATIONAL MATERIAL

As the validity and reliability of the instruments are demonstrated, their quality is confirmed, potential random errors are ruled out, and usability credibility in practice is increased[21]. This stage requires the researcher to be open to criticism and genuinely willing to meet various expectations and interests[19]. It is recommended that the evaluation be conducted by healthcare professionals in the thematic area (experts) and by individuals affected by the condition (target audience), ensuring that the work was executed as a team, valuing different perspectives on the same focus[19]. Thus, the Delphi technique was used, which involves a questionnaire that can be repeatedly administered until a convergence of judges' responses, or consensus, is achieved, representing the consolidation of the group's intuitive judgment[22].

CONSULTATION WITH EXPERTS AND TARGET AUDIENCE

A calculation was performed to determine the required number of judges using the formula $n = \frac{Z_a^2 \cdot P(1-P)}{e^2}$. The values used were: Z_a (confidence level) = 95%, P (proportion of agreement among judges) = 85%, and e (acceptable difference from the expected) = 15%[23-24], resulting in a total of 22 judges. However, Vianna[25] emphasizes the importance of having an odd number of experts to avoid ties in opinions. Following a systematic search, as described below, the sample of judges consisted of 23 participants per group: the expert judges group (professionals with experience in rheumatology, education, and health promotion) and the target audience group (people with fibromyalgia).

The selection of expert judges in the area of interest was initially carried out through consultation on the Plataforma Lattes of CNPq (www.buscatextual.cnpq.br). The selection was as follows: after accessing the "Plataforma Lattes" site, in the "Currículo Lattes" window, the "Search curriculum" option was chosen. In the advanced search tab, by subject, the keywords "fibromyalgia" and "health promotion" were used. The search was conducted from July 1 to 20, 2023.

People with fibromyalgia (target audience) were invited to participate in the study through online support associations. Inclusion criteria were: individuals of both sexes, aged 18 years or older, with a medically confirmed diagnosis of fibromyalgia according to the International Classification of Diseases - ICD-10, using code M79.7. Additionally, the presence of fibromyalgia was confirmed by an evaluator following the American College of Rheumatology classification criteria, revised version of 2016[26].

Exclusion criteria included: individuals with other conditions that may cause chronic pain, such as neuropathies, rheumatoid arthritis, osteoarthritis, spinal stenosis, or neoplasms; those with severe mental disorders documented by a healthcare professional (such as schizophrenia, psychosis, bipolar affective disorder, or severe depression); and pregnant or breastfeeding women. All these criteria were reported by the participants themselves.

For the groups, a snowball sampling technique[27] was used. This approach is based on convenience sampling, which is often used when the population consists of individuals with characteristics that are difficult to find. In this context, a person who met the study's participation criteria was invited to refer other participants[22]. Contact with participants was made via email or WhatsApp during July and August 2023.

Through email, each group of judges received: an invitation letter, the Free and Informed Consent Form, and the initial version of the educational material in a portable document format (PDF). An initial deadline of 15 days was

established for submitting the evaluated material. If there was no return within this period, a new contact was made for additional clarifications and a new 15-day deadline was given. Participants who did not respond within the total period of 30 days were considered as having withdrawn.

EVALUATION INSTRUMENTS

Considering that each participant group had a specific focus in their evaluation, two instruments were used: the first for the expert judges and the second for the target audience[28]. The Suitability Assessment of Materials (SAM) was sent to the expert judges. This is a specific and widely used tool for evaluating the difficulty and convenience of educational materials. The instrument uses a Likert-type scale (0=unsuitable, 1=partially suitable, 2=suitable), with a checklist for attributes related to content, writing style, graphic illustration, presentation, motivation, and cultural appropriateness. For the material to be considered suitable, the percentage score obtained should be equal to or greater than 60%[28-29].

Additionally, a tool adapted from Galdino[30] was applied to individuals with fibromyalgia. The first part consisted of socio-economic profile information; the second part included items regarding the domains of organization, writing style, appearance, and motivation, requiring a minimum agreement of 75% on positive responses; and the third part provided an open space for participants to share their personal opinions[28-31].

MATERIAL SUITABILITY

After collecting all suggestions from both experts and individuals with fibromyalgia, the educational material was adjusted to meet the needs and expectations of the population. Subsequently, the material was sent for Portuguese language review by a professional linguistic advisor[19].

DATA ANALYSIS

Regarding the interpretation and analysis of data, the professional information of the judges, as well as the socio-demographic and clinical data of individuals with fibromyalgia, were organized using Microsoft Excel 8.0 for Windows, and a descriptive analysis was conducted. For the validation of the educational material content, the percentage of scores obtained was calculated by summing all the values marked and dividing by the total number of scores present in the instrument. For the educational material to be considered appropriate, this calculation must yield a result equal to or greater than 60%[29].

Initially, content validation was performed using the Kappa Coefficient to measure the level of agreement and consistency (reliability) of the judges regarding the inclusion or exclusion of items in the instruments[32]. The Kappa Coefficient is an adjusted agreement indicator that ranges from “minus 1” to “plus 1” - the closer to 1, the better the level of agreement between observers; its distribution and respective levels of interpretation are classified from poor to perfect[33] as follows: poor (<0.00), weak (0.00 to 0.20), fair (0.21 to 0.40), moderate (0.41 to 0.60), good (0.61 to 0.80), excellent (0.81 to 0.99), and perfect (1.00). For this analysis, responses “1” (totally unsuitable) were grouped with “2” (partially suitable). Similarly, responses “3” (suitable) and “4” (totally suitable) were grouped. The acceptance criterion was set at a Kappa value greater than 0.61 between the judges[32].

Furthermore, the Content Validity Index (CVI) proposed by Waltz and Bausell[34] was used. This method evaluates the degree of agreement among experts on different aspects of the material. To calculate the CVI, the number of responses marked with values "3" and "4" (agree and strongly agree) is divided by the total number of questions[35]. According to Lynn[36], the cutoff point for the CVI was set at 0.78, both for each item individually and for the questionnaire as a whole. All calculations were performed using the Statistical Package for the Social Sciences, version 22.0, serial number 10101151049.

RESULTS

Figure 1 illustrates the model of the educational material.

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Figure 1. Fibromyalgia Folder (front and back).
Source: The authors.

Table 1 shows the profile of the expert judges. Most were female (61%), married or living with a partner (61%), white (65%), with a length of professional experience of 1 to 10 years (48%), and holding a master's degree (43%). Regarding geographical distribution, the highest numbers were from the states of Paraná (26%), São Paulo (22%), and Rio de Janeiro (13%).

Table 1. Profile of Specialist Judges

Variables	n	%
Sexo Gender		
Female	14	61
Male	9	39
Age	37,8 ± 9,7	
Marital Status		
Married or living with partner	14	61
Divorced	1	4
Separated	-	-
Widowed	1	4
Single	7	30
Race/Ethnicity		
White	15	65
Brown	7	30
Black	1	4
Yellow	-	-
Indigenous	-	-
Profession*		
Physiotherapist	8	35
Rheumatologist	3	13
Nurse	3	13
Psychologist	3	13
Nutritionist	3	13
Occupational Therapist	3	13
Years of Experience		
1 to 10 years	11	48
11 to 20 years	9	39
More than 21 years	3	13
Highest Degree		
Specialization/Residency	8	35
Master's Degree	10	43
Doctorate	3	13
Postdoctoral	2	9

Caption: *Profession according to the Brazilian Classification of Occupations 2021.

Regarding the expert judges' evaluations of the educational material, all items had a Content Validity Index (CVI) greater than 0.78, indicating validity. Additionally, the Kappa Coefficient showed values categorized as good, excellent, and perfect (Table 2).

Table 2. Expert judges' judgment on the educational material.

Items	JUDGMENT									
	Totally inadequate		Partially inadequate		Adequate		Totally suitable		IVC	*Kappa*
	n	%	n	%	n	%	n	%		
1 – OBJECTIVES										
1.1 Innovation potential of care for people with fibromyalgia	-	-	1	4	8	35	14	61	0,95	1,00
1.2 Clarity of the folder's objective	-	-	-	-	5	22	18	78	1,00	1,00
1.3 Relevance of the theoretical framework	-	-	-	-	8	35	15	65	1,00	1,00
1.4 Basic premises capable of guiding people with	-	-	-	-	6	26	17	74	1,00	1,00

fibromyalgia to promote their health										
2 – PROPOSED THEMES AND ACTIONS										
2.1 The themes and actions listed provide support for promoting the health of people with fibromyalgia	-	-	-	-	13	57	10	43	1,00	1,00
2.2 The themes and actions listed are important for application to people with fibromyalgia in primary health care	-	-	-	-	9	39	14	61	1,00	1,00
3 – RELEVANCE										
3.1 Organization of content and actions	-	-	-	-	3	13	20	87	1,00	1,00
3.2 Clarity of the text	-	-	-	-	3	13	20	87	1,00	1,00
3.3 Vocabulary used	-	-	3	13	10	43	10	43	0,86	0,79
3.4 Length of the material	-	-	1	-	5	22	17	74	0,95	0,93
3.5 Complexity of the text	-	-	-	-	8	35	15	65	1,00	1,00
3.6 Common language for professionals	-	-	1	-	3	13	19	83	0,95	0.93
4 – WRITING STYLE										
4.1 Organization of content and actions	-	-	-	-	5	22	18	78	1,00	1,00
4.2 Clarity of the text	-	-	-	-	4	17	19	83	1,00	1,00
4.3 Vocabulary used	-	-	-	-	6	26	17	74	1,00	1,00
4.4 Length of the material	-	-	-	-	11	48	12	52	1,00	1,00
4.5 Complexity of the text	-	-	1	4	6	26	16	70	0,95	0,93
4.6 Common language for professionals	-	-	1	4	4	17	18	78	0,95	0,93
5 – PROGRAM STRUCTURE										
5.1 Number of pages	-	-	-	-	13	57	10	43	1,00	1,00
5.2 Structure of the material	-	-	-	-	8	35	15	65	1,00	1,00

Caption: CVI: Content Validity Index

The target audience judge group was composed entirely of women (100%), with 57% being married or living with a partner, 52% identifying as white, 74% having completed higher education, 43% with a monthly income of 1 to 2 minimum wages, 43% managing 3 or more medications per day, and 43% reporting regular health status (Table 3). Regarding geographical distribution, a higher number of target audience judges were from the states of São Paulo (39%), Minas Gerais (13%), Paraná (9%), and Bahia (9%).

Table 3. Profile of Target Judges

Variáveis	**n**	**%**
Gender		
Female		100
Male	-	-
Age (mean/standard deviation)	41,7 ± 10,5	
Marital Status		
Married or living with partner		57
Divorced	4	17
Separated	-	-

Widowed	-	-
Single	6	26
Race/Ethnicity		
White	12	52
Brown	8	35
Black	3	13
Yellow	-	-
Indigenous	-	-
Education Level		
Incomplete Elementary School	-	-
Completed Elementary School	-	-
Incomplete High School	-	-
Completed High School	4	17
Incomplete Higher Education	2	9
Completed Higher Education	17	74
No Formal Education	-	-
Monthly Income		
1 to 2 Minimum Wages	10	43
2 to 3 Minimum Wages	4	17
More than 3 Minimum Wages	9	39
Self-Perceived Health		
Poor	8	35
Fair	10	43
Good	5	22
Very Good	-	-
Number of Medications Used		
None	2	9
1 to 2 Medications	3	13
3 or More Medications	18	78
Other Diseases Besides Fibromyalgia		
None	5	22
1 or 2 Diseases	13	57
3 or More Diseases	5	22
Duration of Fibromyalgia Diagnosis		
1 to 5 Years	6	26
6 to 10 Years	12	52
11 Years or More	5	22
WPI	13, 9 ± 2,9	
SSS	10,5 ± 1,5	
FIQ-R		
Function	21,1 ± 4,7	
Global	16,3 ± 4,1	
Symptoms	38,3 ± 5,5	
Total Score	75,7 ± 11,4	
Pain	7,8 ± 1,3	

Caption: *Salário-mínimo baseado no ano de 2023 no valor de R$ 1.320,00 reais. WPI: Widespread Pain Index; SSS: Symptom Severity Scale; FIQ-R: Fibromyalgia Impact Questionnaire-Revised.

Regarding the target audience judges' evaluations of the educational material, all items had a Content Validity Index (CVI) greater than 0.78, indicating validity, and the Kappa Coefficient showed values categorized as good, excellent, and perfect (Table 4).

Table 4 - Assessment of the target audience regarding the organization, writing style, appearance and motivation of the educational material.

Items	Positive responses		Negative responses		Unbiased responses		CVI	*Kappa*
	n	%	n	%	n	%		
Organization								

Did the cover catch your attention?	23	100	-	-	-	-	1,00	1,00
Is the sequence of content appropriate?	20	87	-	-	3	13	0,86	0,79
Is the structure of the educational material adequate?	20	87	-	-	3	13	0,86	0,79
Writing Style								
Are the sentences (easy to understand/difficult to understand/don't know)?	20	87	3	13	-	-	0,86	0,79
Is the written content (clear/confusing/don't know)?	22	96	1	4	-	-	0,95	0,93
Is the text (interesting/uninteresting/don't know)?	22	96	1	4	-	-	0,95	0,93
Appearance								
Are the illustrations (simple/complicated/don't know)?	22	96	1	4	-	-	0,95	0,93
Do the illustrations complement the text?	19	83	-	-	4	17	0,82	0,74
Do the pages or sections seem organized?	23	100	-	-	-	-	1,00	1,00
Motivation								
In your opinion, will anyone who reads this educational material understand it?	20	87	-	-	3	13	0,86	0,79
Did you feel motivated to read the educational material until the end?	23	100	-	-	-	-	1,00	1,00
Does the educational material cover the necessary topics for people to learn how to promote the health of individuals with fibromyalgia?	19	83	-	-	4	17	0,82	0,74
Did the educational material motivate you to take action or think about self-care in fibromyalgia?	21	91	-	-	2	9	0,91	0,86

Caption: CVI: Content Validity Index

DISCUSSION

In this study, the objective was to validate an educational material to promote health in fibromyalgia. After this process, the Content Validity Index (CVI) from expert judges was greater than 0.78, indicating validity in line with other studies validating educational materials that achieved CVI $>$ 0.80[37]. This validation step by experts is crucial to ensure that educational materials do not contain incomplete or conflicting information that could hinder or complicate understanding for the target population, which the material aims to assist[38].

To ensure methodological rigor in the validation process, the participation of target audience judges is important, as their contributions are fundamental, given their daily experience with fibromyalgia. Thus, they were included in the analysis and validation of the material, consistent with other studies in the field[37]. Educational technologies, such as printed materials and videos, can be effective as health education strategies, as they facilitate the guidance and information provided to patients and families[39].

Overall, the opinions of the judges were consistent. Regarding the items related to the objective, theme, relevance, language, and structure of the material, the educational material was deemed valid, as it demonstrated high reliability and agreement in responses, with CVI greater than 0.95 and Kappa Coefficient values greater than 0.93. This indicates that educational materials are significant tools in the health education process, helping professionals, patients, and families understand the conditions and everything involved[40-41].

In the case of this educational material, it provides information about the syndrome and tips for improving health care, aiming to encourage autonomy in the development of self-management in health. Access to this material will help individuals with fibromyalgia adapt to their new life condition, overcome fears associated with the diagnosis, and improve their quality of life. The material was designed to cover basic knowledge on the subject with language that accommodates varying levels of education. The

target audience positively evaluated the material, showing valid agreement levels greater than 0.78. This evaluation was crucial for validating the material and contributing to the dissemination of accurate information for the daily care of individuals with fibromyalgia.

In this context, it is evident that health education plays a fundamental role for individuals with fibromyalgia, as demonstrated by a program conducted in Brazil called "Amigos do Fibro," which was developed[42] and validated[43] to promote the health of individuals with fibromyalgia. A study that received approval from 23 health professionals and 45 individuals with fibromyalgia showed that "Amigos do Fibro" presented adequate content validity and internal consistency, making it a valid tool for health professionals working with this target audience in primary health care, enabling them to act as health promoters. Its protocol is already published and available for other researchers and health professionals to use in practice[44]. As a result, the project's effectiveness is being evaluated, and the authors are enthusiastic about the development and initial results of this innovative proposal in Brazil[45-50].

The educational material is being distributed in an outreach event on Avenida Paulista, in the city center of São Paulo-SP, Brazil, through an extension project coordinated by the responsible researchers and students from the Physiotherapy course at the University of São Paulo, aiming to increase awareness and understanding of this condition, contributing to a more informed and supportive society regarding fibromyalgia.

CONCLUSION

The educational material has proven to be a valid and reliable tool for use, as it was validated for content, language, and relevance with both the target audience and expert judges. It is anticipated that this educational material will provide relevant information to aid in health education for the population, with the aim of promoting quality of life, strengthening individual autonomy, and understanding the health-disease process, with a focus on empowering decision-making. Furthermore, it is expected that this educational material will be used for health promotion and education for the target population and their families, highlighting the importance of comprehensive intervention and understanding of care for individuals with fibromyalgia.

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