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Original

Design, face and content validation of the instrument "family caregiver's role in medication administration"

Diseño, validación facial y de contenido del instrumento "rol del cuidador familiar en administración de medicamentos"

Projeto, face e validação do conteúdo do instrumento "papel do cuidador familiar no gerenciamento de medicamentos"

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Abstract

Objective: To design an instrument to measure the adoption of the role of the family caregiver in the administration of medications in people with chronic disease and to establish both its content and facial validity. ***Method***: Methodological study that included three phases: design of the instrument, determination of content validity with 9 experts and determination of facial validity through cognitive interviews with 14 caregivers and judgments of 30 caregivers of adults with chronic diseases. ***Results***: A questionnaire made up of 32 items distributed in 3 dimensions called tasks, organization and response to the role was obtained. The instrument presented adequate content validity since all the items exceeded the minimum CVI of 0.58, while for the total scale it was 0.97. For its part, facial validity showed that clarity was 99.6%, comprehension was 98.4%, and precision was 96.9%. ***Conclusion***: The instrument Adoption of the role in drug administration logically measures the construct and the items that comprise it adequately represent its domains.

Keywords: Medications; Chronic Disease; Family Caregiver; Instrument; Validation Study.

Resumen

Objetivo: Diseñar un instrumento para medir la adopción del rol del cuidador familiar en la administración de medicamentos en personas con enfermedad crónica y establecer tanto su validez de contenido como facial. ***Método***: Estudio metodológico que incluyó tres fases: diseño del instrumento, determinación de la validez de contenido con 9 expertos y determinación de la validez facial mediante entrevistas cognitivas a 14 cuidadores y juicios de 30 cuidadores de adultos con enfermedades crónicas. ***Resultados***: Se obtuvo un cuestionario conformado por 32 ítems distribuidos en 3 dimensiones denominadas labores, organización y respuesta ante el rol. El instrumento presentó una adecuada validez de contenido dado que todos los ítems superaron el CVI mínimo de 0,58, mientras que para la escala total fue de 0,97. Por su parte, la validez facial mostró que la claridad fue del 99,6%, la comprensión fue del 98,4% y la precisión fue del 96,9%. ***Conclusión***: El instrumento Adopción del rol en la administración de medicamentos mide de forma lógica el constructo y los ítems que lo con-

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forman representan adecuadamente sus dominios.

Palabras claves: Medicamentos; Enfermedad crónica; Cuidador familiar; Instrumento; Estudio de validación.

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Resumo

Objetivo: Projetar um instrumento para medir a adoção do papel do cuidador da família na administração de medicamentos em pessoas com doenças crônicas e estabelecer tanto seu conteúdo quanto sua validade facial. ***Método***: Estudo metodológico que incluiu três fases: desenho do instrumento, determinação da validade do conteúdo com 9 especialistas e determinação da validade do rosto através de entrevistas cognitivas com 14 cuidadores e julgamentos de 30 cuidadores de adultos cronicamente doentes. ***Resultados***: Foi obtido um questionário composto de 32 itens distribuídos em 3 dimensões chamadas trabalho, organização e resposta ao papel. O instrumento mostrou validade de conteúdo adequada, dado que todos os itens excederam o CVI mínimo de 0,58, enquanto que para a escala total foi de 0,97. A validade facial mostrou que a clareza era 99,6%, a compreensão era 98,4% e a precisão era 96,9%. ***Conclusão***: O instrumento de adoção do papel da Administração de Medicamentos mede logicamente a construção e seus itens representam adequadamente seus domínios.

Palavras-chave: Medicamentos; Doença crônica; Cuidador da família; Instrumento; Estudo de validação.

Introduction

The role of caregiver for chronically ill and dependent elderly people is largely assumed by a family member, who needs to develop cognitive, emotional and social skills that allow them to respond to a number of instrumental tasks for which them are not prepared, such as the administration of medications (1). This process of transition to the role of caregiver becomes more relevant as the number of people with chronic noncommunicable diseases (NCDs) with increasingly complex care needs has increased in recent years (2). The role of caregiver has become even more important as the number of people with chronic noncommunicable diseases (NCDs) has grown.

In this sense, for people suffering from an NCD, following hospitalization, there is a higher risk of complications at home related to the administration of medications, such as a higher incidence of adverse reactions, errors related to the dose, the medication, the route or the time of administration (3,4), to the point of even interrupting treatment. These situations lead to clinical exacerbations, physical and cognitive deterioration, hospital readmissions and higher costs to the health system (5,6,7).

Studies on the medication administration process have focused on evaluating the knowledge and skills of health professionals, prescribing errors and medication dispensing in hospital settings (8,9). However, the most extensive use of them occurs in patients' own homes, making it essential to have tools that comprehensively assess the medication administration process, in this case, aimed at family caregivers, who lack sufficient instrumental support for the organization, execution and response to the role. In this context, the support and education provided by nursing in the process of preparing patients and their caregivers is fundamental, especially when dealing with competencies related to the care of the elderly at home. By analyzing this context, it is possible to identify improvement actions oriented to an adequate adoption of the caregiver role at home.

Therefore, the objective of this research is to design, conduct the content validity and face validity of the instrument “Adoption of the role of the family caregiver in the administration of medications ROL-M”, carried out for family caregivers of people with NCD in condition of dependence. The role adoption construct is originally framed in the concept of transition, defined in the theory of transitions by Afaf Melis(10). Thus, this study responds to the need to make family caregivers co-participants in the process of safe medication admi-

nistration, so that with this study the effort to provide evidence to understand the complex world of caregivers is decanted and validated.

Metodología

The research was psychometric (11), and was conducted between March and June 2021 in the city of Bogota. The theoretical aspects proposed by the International Test Commission and guidelines to be followed for the application of tests (12) were followed, including the justification or purpose of the construction of the instrument, the conceptual and theoretical support of the construct to be evaluated, the construction and qualitative evaluation of items, content validity and face validity (Figure 1). With a non-probabilistic sample by convenience, with the participation of 9 experts, 44 family caregivers (14 cognitive interview and 30 item evaluation). Considering the above, three phases were considered for this research: justification and conceptual support, item writing, and content and face validation.

The following image shows the development phases of the study, to determine the design of the instrument, adoption of the role of family caregiver in the administration of medications (ROL-M) and its facial validation and content validation.

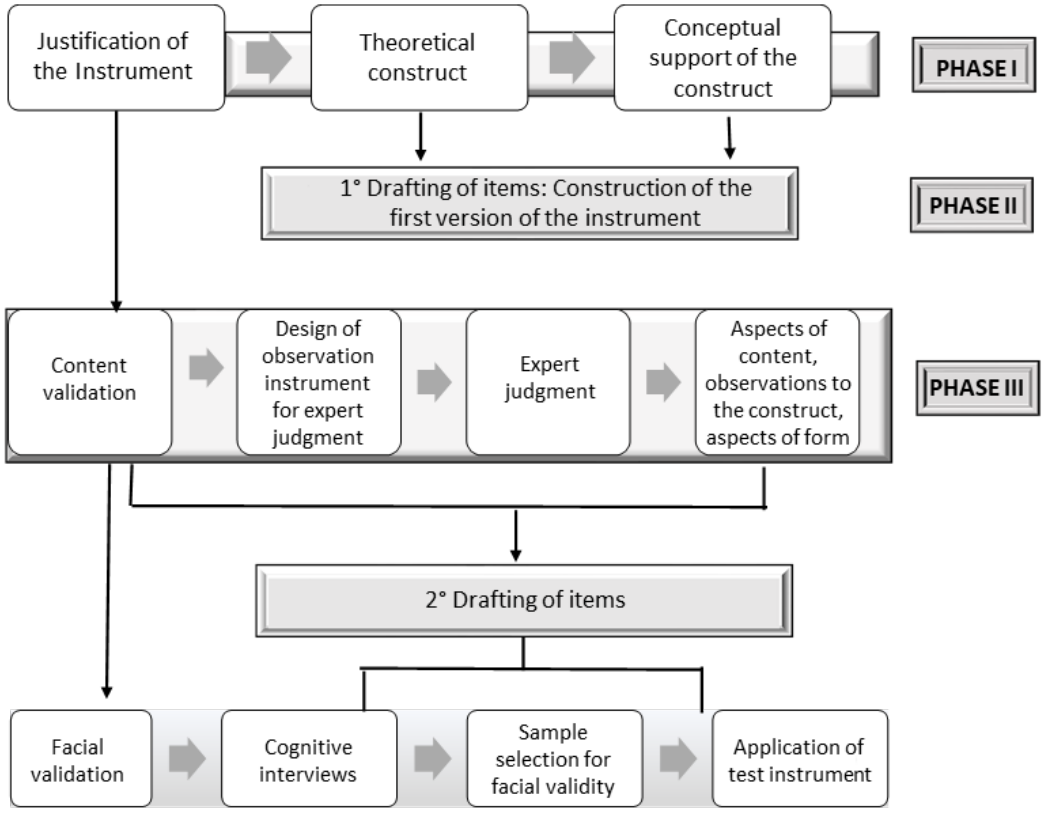

Figure 1. Steps for the development of the ROL-M instrument.
Source: Prepared by the authors

Phase I: Justification and conceptual support

The adoption of the caregiver role involves a transition that involves cognitive, behavioral and relational elements. As a dynamic process, such adoption should be evaluated periodically, so that role clarification, modeling and rehearsal interventions can be carried out (13), incorporating resources according to the needs of both the patient and the caregiver, in order to facilitate therapeutic adherence and treatment success (14). In this context, an instrument is required to assess the adoption of the role in the use of medications by family caregivers of elderly people with chronic disease, so that it can be used to demonstrate the changes and progress that are occurring in this process.

Thus, the construction of the ROL-M instrument emerged from the literature review and was based on the three dimensions of the original version of the instrument "Adoption of the caregiving role of the person with chronic illness" (13) combined with the experience of the researchers in the knowledge of the role of family caregivers of older adults in chronic condition.

The findings were organized according to common characteristics, relationships between them and the thematic affinity of the content. In addition, a process of continuous comparison was carried out in the search for patterns in order to subsequently assign a category to each of the groups that emerged with the selected results. Then, a theoretical review was made of the identified process corresponding to the caregiver's tasks, organization and responses, located within the theoretical and conceptual framework of transitions provided by Meleis, which allowed integrating the findings with the theoretical properties.

Phase II: Drafting of items

For the construction and qualitative evaluation of the items, so that they would have useful, uniform and important characteristics or attributes that would identify the role of the family caregiver who assumes the preparation and administration of medications in the elderly home and based on the review of the literature and the definition of the construct of the adoption of the role in the use of medications, a first version of the instrument was constructed with 26 items, with the participation of the research team and a linguist in order to align the items with simple language and grammatical order.

Phase III: Content validity and face validity

- **Content validity**

For content validity, 9 experts (5 men and 4 women) with master's (n=8) and doctoral (n=1) training, from Colombia, experts in the care of adults with chronic diseases, in making judgments and decisions based on evidence, recognition in the community and availability to participate in the process with impartiality, participated in the content validity. The agreement among the judges was determined by content validity as defined by Lawshe and modified by Tristán (15), while the evaluation of each item was carried out taking into account the criteria of redundancy, relevance and clarity.

With the results, the content validity ratio (CVR) was calculated to determine which items of the instrument were acceptable and should be maintained in the final version of the instrument. In addition, the content validity index (CVI) was established for the entire instrument. Subsequently, the researchers and a linguist with experience in the production of written texts and knowledge of health terminology consolidated the information on each item with the observations made by the experts and made decisions regarding the semantic, conceptual and content structure. From this process, those items that had an agreement index equal to or greater than 0.58 were left as definitive, which led to the elaboration of a second version of the instrument.

- **Facial validity**

Initially, 14 semi-structured cognitive interviews were conducted with caregivers of chronically ill adults by videoconference, each lasting approximately 40 minutes. For the collection of information, the verbal probing technique was used, which was oriented towards the judgment of the items in terms of comprehension/interpretation, recall and judgment (16). The data were collected concurrently through field notes and the interviews were recorded with prior consent of the participants.

In a second step, the items were evaluated by another group of 30 family caregivers of chronically ill older adults. For inclusion in the study, participants had to be over 18 years of age, have been caregivers for six months or more, and demonstrate mental capacity to answer or evaluate the instrument.

To validate the items of the instrument according to criteria of clarity (type of language or wording easy to understand), precision (expression in concise and exact language, leaving no doubts) and comprehension (understanding of what is understood when reading the item). The researchers established the percentage of agreement among the judges in each of the items and it was decided that values higher than 85% would be considered satisfactory, following the criteria proposed in the study by Villamizar and Laguado (17). Finally, the information provided by the participants and experts was consolidated in order to analyze the clarity, precision and comprehension of the items, which led to a final consensus and consolidation of the instrument.

Ethical considerations

The research was conducted within the framework of the ethical principles for research involving human subjects in Colombia (Res. 8430/93) and in accordance with the ethical guidelines established by the Council for Organizations of Medical Sciences (CIOMS). In addition, it complied with the current intellectual property regulations of the National University of Colombia (Agreement 035/2003) and obtained the ethical endorsements of the Ethics Committee of the National University of Colombia (Endorsement 012 of 2021).

Results

Phase I: Justification and conceptual support

Once the findings of 27 pieces of research had been selected, analyzed and grouped, the thematic grouping of the information made it possible to integrate the concepts most frequently addressed in the articles. From this, three main themes emerged: *role tasks, role organization and response to the role (Table I).*

Table 1. Main themes and findings emerging from the literature review

Topics	Findings
Work or execution of the role	Implementing actions to provide the drug.
	Establishing routines
Role organization	Organizing everything to comply
	Looking for support from others
	Delegating care
Response to the role	Feeling worried and anxious about the effect of the medicine
	Being ready to 'give
	Being connected to treatment
	Managing the burden of medication administration

Source: own elaboration

Regarding the t*asks or execution of the role*, this integrates the actions involved in the administration of the medication, which include the steps and procedures at the time of administering the medication to the chronically ill person. The *organization of the role* is defined as the previous actions taken to facilitate and anticipate the process of administering the medication to the person with chronicity, and the *response to the role* includes the perceptions or feelings associated with the effective adoption of the role, derived from the experience of administering the medication to the person with chronicity.

Phase II: Drafting of items

The construction and qualitative evaluation of the items allowed the elaboration of an initial questionnaire made up of 26 items that were organized and denominated under three domains. Domain 1, work or role performance (1-5 items), sought to make explicit the

instrumental activities in the use of medications. We chose to use the term "giving medications" instead of "administering medications", because it is a simple, general and culturally clearer term used by caregivers.

In domain 2, *role organization (6-14 items)*, emphasis was placed on actions involving behavior such as "asking for help", "sharing", "knowing what to do", "having taught" and the search for information on medications that complement the prescription indications.

Finally, in domain 3, *response to the role (15-26 items),* emphasis was placed on the manifestation of feelings with words such as "I feel" and the presence of positive or negative effects "I am", "I trust" or "overburdened". In all the items of the instrument, it was chosen to refer to the care recipient as "the family member I care for", taking into account that this is one of the roles that the caregiver may have among many others. This version was subjected to content validity by experts.

Phase III: Content validity and face validity

- **Validez de contenido**

Table II shows the results corresponding to content validity (CVR) according to the evaluations obtained for each item. Those items that obtained values lower than 0.58 should be revised. In addition, the overall validity index of the 26 items was 0.75, a value considered acceptable.

Table 2. Content validity by experts

Dimension	Item	Aspect of interest											
		No redundancy				Relevance				Clarity			
		%	CVR	CVR'	CVI	%	CVR	CVR'	CVI	%	CVR	CVR'	CVI
Responses to the role	1	89%	0,78	0,89		100%	1,00	1,00		33%	-0,33	0,33	
	2	89%	0,78	0,89		100%	1,00	1,00		44%	-0,11	0,44	
	3	100%	1,00	1,00		100%	1,00	1,00		78%	0,56	0,78	
	4	100%	1,00	1,00		89%	0,78	0,89		67%	0,33	0,67	
	5	100%	1,00	1,00		100%	1,00	1,00		78%	0,56	0,78	
Role organization	6	89%	0,78	0,89		100%	1,00	1,00		89%	0,78	0,89	
	7	100%	1,00	1,00		100%	1,00	1,00		100%	1,00	1,00	
	8	78%	0,56	0,78		100%	1,00	1,00		89%	0,78	0,89	
	9	100%	1,00	1,00		67%	0,33	0,67		67%	0,33	0,67	
	10	100%	1,00	1,00		100%	1,00	1,00		78%	0,56	0,78	
	11	78%	0,56	0,78		100%	1,00	1,00		100%	1,00	1,00	
	12	89%	0,78	0,89		78%	0,56	0,78		89%	0,78	0,89	
	13	89%	0,78	0,89		78%	0,56	0,78		89%	0,78	0,89	
	14	89%	0,78	0,89		89%	0,78	0,89		89%	0,78	0,89	

Role tasks	15	100%	1,00	1,00	100%	1,00	1,00	89%	0,78	0,89
	16	89%	0,78	0,89	89%	0,78	0,89	78%	0,56	0,78
	17	78%	0,56	0,78	100%	1,00	1,00	100%	1,00	1,00
	18	78%	0,56	0,78	89%	0,78	0,89	89%	0,78	0,89
	19	89%	0,78	0,89	89%	0,78	0,89	89%	0,78	0,89
	20	89%	0,78	0,89	100%	1,00	1,00	89%	0,78	0,89
	21	89%	0,78	0,89	78%	0,56	0,78	89%	0,78	0,89
	22	100%	1,00	1,00	100%	1,00	1,00	44%	-0,11	0,44
	23	89%	0,78	0,89	89%	0,78	0,89	89%	0,78	0,89
	24	100%	1,00	1,00	100%	1,00	1,00	89%	0,78	0,89
	25	33%	-0,33	0,33	89%	0,78	0,89	78%	0,56	0,78
	26	89%	0,78	0,89	89%	0,78	0,89	78%	0,56	0,78

Source: study data

As a consequence of these findings, items 8, 11, 17, 18 and 25 were qualified as redundant, items 9, 12, 13 and 21 were considered not relevant and it was determined that items 1, 2, 3, 4, 5, 7, 9, 10, 16, 22, 25 and 26 were not clear, so their wording was adjusted. After analyzing the results, the panel of experts decided to eliminate items 6, 11, 12 and 17 due to redundancy with other items and 21 due to relevance.

On the other hand, the dimensions and their respective items were reorganized. Thus, dimension 1 became work-role performance, because it was concluded that both experts (who are from the health area) and caregivers tend to think first about the instrumental activities of care, then go through aspects of the process (role organization) and finally understand the impact of the work. Meanwhile, role organization was retained as dimension 2. Finally, domain 3 of role response became the last one and was composed of 9 items.

Similarly, a heading was added to the instrument with open and closed questions that allowed the characterization of the number of medications, dosage, route and frequency of medication administration, the assessment of the presence or absence of gastrostomy and the use of other natural or homeopathic products as complementary treatment measures.

This second version was again evaluated by 7 of the 9 experts who participated in the first round of validation and, with the findings, the second version of the instrument was constructed. As a result of this review by experts, the adjustments required were minor, the CVI for the total scale was 0.97, all items had a CVR greater than 0.71 and, thanks to this, all items were kept except item 12, which obtained a CVR of 0.42, and was therefore definitively eliminated. In item 18, the term "register" was taken up again, since the experts expressed that it was simpler and more common than a calendar. In item 23, it was seen that it was more common to know the educational sessions or courses as "talks", so this term was incorporated. Finally, 32 items remained, which were subjected to face validity.

- **Facial validity**

The analysis and adjustments derived from the cognitive interviews are presented in terms of comprehension, judgment and approval. Regarding comprehension, some difficulties were identified related to terms such as "pillbox", "anus", "complement" or "ability". In this regard, other options were sought to replace these terms and the questions were adjusted to use more appropriate expressions. Similarly, comprehension difficulties were identified due to long statements (items 13 and 21), which were solved by simplifying them.

Regarding the trial, the observations were specific in item 5 when considering the use of the pill dispenser as a bad practice that conditions the caregiver, so it was decided to delete this term. Also, in item 9, not all possible routes of administration of medications are fully known, so it was suggested to include gastrostomy. Likewise, item 12 is perceived as a judgment and understood as an intentional action, so the word "involuntary"

was included.

Regarding approval, the ROL-M instrument was well accepted by the caregivers, the items were considered appropriate, important and also reflect the role they play on a daily basis in a structured way. Some caregivers expressed the importance of the item that asks about hand washing, especially at the time of the COVID-19 pandemic, since this context has led to it being understood as a daily activity, especially for the care of people with chronic diseases. It was stated that item 10 is very important because it allows identifying whether the patient is being over- or under-medicated. In general, the instrument was considered easy to complete and they consider it a useful tool to obtain a holistic view of the caregiver's situation that could be used as a basis for care planning.

Regarding the face validity performed by the group of 30 participants, 93% were women, with an average age of 52 years (minimum of 36 and the oldest of 81 years). In terms of schooling, 40% had completed high school, 23% had a technical-technologist degree and 20% had university education. Finally, in terms of stratum, 7% belonged to stratum one, 57% were from stratum two and 30% from stratum three. The percentage of agreement among the 30 participants in the criterion of clarity was 99.6%, in comprehension 98.4% and in precision 96.9%. In general, the participants had few observations or suggestions in terms of wording, clarity or lack of precision for each of the questions

Discussion

The purpose of this article is to describe the design process, content and face validity of an instrument that assesses the adoption of the caregiver's role in medication administration in older adults, in order to evaluate it and detect eventual improvement actions needed to avoid hospitalizations, achieve treatment goals, disease control and decrease medication-related adverse events (18).

Ensuring that the caregiver transition is carried out with high quality standards is especially important in people who live with geriatric patients with multiple chronic conditions, dependency and complex therapeutic regimens. These individuals, on average, receive five formulated and two over-the-counter medications, placing them in a greater state of vulnerability and risk for adverse events resulting from inadequate medication administration or noncompliance with therapy, as well as potential side effects, allergic reactions, and interactions with food or other medications (19). Medication administration error rates during the transition from the hospital to the home environment ranged from 19-80%, making it necessary to ensure continuity and safety of care at home, especially when the degree of dependency and pluripathology also increase (20).

Considering the negative consequences in terms of economic burden, loss of efficacy, possible toxicity and resistance, it is necessary to minimize the risk of harm from inadequate implementation, maintenance and persistence of the therapeutic regimen by caregivers (21). Thus, it has been determined that most caregivers understand that careful medication management contributes to a person's disease course with fewer complications and that caregivers must comply with a series of daily activities and responsibilities that involve processes of searching for and exchanging information, purchasing, storing, supplying, supervising, planning, using medications and making decisions to maintain, increase, decrease a dose or discontinue a medication completely(22-24). Therefore, it is necessary to organize the role so that it can respond and comply with the treatment in a timely manner.

Role performance during the medication administration process is a reflection of the experience, knowledge and preparation that caregivers have. However, studies have shown that most of them lack self-confidence, feel inadequately prepared and supported to administer medications at home (25,26), so as caregivers they need education to recognize the adverse effects of medications that may occur as their family member's condition changes, thus helping them to develop the critical thinking skills to manage these potential problems (27) and to respond appropriately to the task of administering medications by developing coping strategies that enable them to overcome and manage negative emotions such as fear, anxiety, stress and depression through recognition, evaluation and acceptance of their role as caregivers (28) .

However, most of the studies on medication administration have focused on studying patients' compliance or adherence to treatment, emphasizing the causes or reasons for non-adherence to medication and associa-

ted factors, such as prescription and dispensing errors in hospital settings (29). However, in the context of middle-income countries, family caregivers have been faced with performing treatment at home on many occasions orally even transcending to other routes for which they do not feel prepared.

In relation to role performance in family caregivers of older adults, instruments have been developed to measure their caregiving skills (30), to assess home caregiving readiness and competencies (31), family caregiver role adoption (13) and caregiver overload (32). However, there are no performance measures that capture the role of the geriatric patient's family caregiver in the actual experience during coordination, continuity of medication therapy and that allow objective assessment of role adoption to ensure safe home care and optimize therapeutic outcomes.

The instrument designed was based on the theoretical reference of transitions (33), consisting of 32 items distributed in 3 domains that were labeled as work, organization and response to the role, elements that are closely related and that have an impact on long-term health outcomes, since it has been shown that caregivers may have difficulties with the development of the role at the beginning, in its implementation or persistence of treatment (34).

It was observed that the experts and caregivers of the older adults supported the conceptual development of the instrument during the content and face validity, however, it should be noted that this is a first step in the validation process of the instrument, which should continue with the construct validity and reliability assessment. Some limitations can be identified in the study in the sense of including the convenience sample obtained for face validity, since it could be identified that it was relatively homogeneous (most of them were women with medium educational and socioeconomic level), so future research could include caregivers of different socioeconomic levels and expand to other regions of the country including, for example, the rural population.

Conclusión

The ROL-M instrument allows objective evaluation of three aspects: work, organization and response to the role during the process of medication administration by the caregiver. This tool showed acceptable content and face validity, so it is suggested to continue with its construct validity process.

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Conflicts of interest

The authors declare that they have no conflicts of interest.

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