

# Construction and validation of educational booklet content for fall prevention in hospitals

Construção e validação de conteúdo de cartilha educativa para prevenção de quedas no hospital  
Elaboración y validación de contenido de cartilla educativa para prevención de caídas en el hospital

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## Keywords

Health education; Accidental falls; Accident prevention; Validation studies

## Descritores

Educação em saúde; Acidentes por quedas; Prevenção de acidentes; Estudos de validação

## Descriptores

Educación en salud; Accidentes por caídas; Prevención de accidentes; Estudios de validación

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## Abstract

**Objective:** To construct and validate an educational booklet for fall prevention in hospitals.

**Methods:** A methodological study developed from the construction, validation and assessment of the booklet by 22 nurses and 22 patients hospitalized in a medical clinic. For the validation with judges, objective, structure/presentation and relevance of the material were assessed and, in assessment with patients, the Suitability Assessment of Materials (SAM) tool. Content Validity Index (CVI) was used to analyze each validation step, considering valid values equal to or greater than 0.80.

**Results:** The booklet titled "Careful not to fall for this" consists of 20 pages. In content validation, practitioners assigned the overall CVI of 1.0 for purpose, structure/presentation, and material relevance. In the assessment of patients, the overall CVI of the booklet was 0.98.

**Conclusion:** The educational booklet is considered valid regarding the content and understandable by patients in a way that has a viable use in health education for fall prevention in hospitals.

## Resumo

**Objetivo:** Construir e validar cartilha educativa para prevenção de quedas no hospital.

**Métodos:** Estudo metodológico desenvolvido a partir da construção, validação e avaliação da cartilha por 22 enfermeiros e 22 pacientes internados em clínica médica. Para a validação com juízes, avaliou-se objetivo, estrutura/apresentação e relevância do material e, na avaliação com pacientes, aplicou-se o instrumento Suitability Assessment of Materials (SAM). Utilizou-se o Índice de Validade de Conteúdo (IVC) para análise de cada etapa da validação, considerando válido os iguais ou superiores a 0,80.

**Resultados:** A cartilha intitulada "Cuidados para não cair nessa" é composta por 20 páginas. Na validação de conteúdo, os profissionais atribuíram o IVC global de 1,0 para objetivo, estrutura/apresentação e relevância do material. Na avaliação dos pacientes, o IVC global da cartilha foi de 0,98.

**Conclusão:** A cartilha educativa é considerada válida quanto ao conteúdo e compreensível pelos pacientes de forma que possui utilização viável na educação em saúde para prevenção de quedas no hospital.

## Resumen

**Objetivo:** elaborar y validar cartilla educativa para prevención de caídas en el hospital.

**Métodos:** estudio metodológico desarrollado a partir de la elaboración, validación y evaluación de la cartilla por 22 enfermeros y 22 pacientes internados en clínica médica. Para la validación con jueces, se analizó el objetivo, estructura/presentación y relevancia del material; y para la evaluación con pacientes, se aplicó el instrumento Suitability Assessment of Materials (SAM). Se utilizó el Índice de Validez de Contenido (IVC) para analizar cada etapa de validez, considerando válidos los iguales o superiores a 0,80.

**Resultados:** la cartilla llamada "Cuidados para no caer" se compone de 20 páginas. En la validación de contenido, los profesionales atribuyeron un IVC global de 1,0 para el objetivo, estructura/presentación y relevancia del material. En la evaluación de los pacientes, el IVC global de la cartilla fue de 0,98.

**Conclusión:** la cartilla educativa es considerada válida respecto al contenido y comprensible por los pacientes, de forma que posee utilización viable en la educación en salud para la prevención de caídas en el hospital.

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## Introduction

Falls are defined as events in which the individual is impacted by the soil, ground or other lower level, which are a public health problem and can cause severe or fatal injuries. It is estimated that 646,000 fatal falls occur each year. This makes them the second leading cause of death from unintentional injury. More than 80% of falls-related deaths occur in low- and middle-income countries.<sup>(1)</sup>

In the hospital setting, falling individuals have, on average, 12.3 days of hospitalization and the occurrence of such an adverse event can increase hospital costs by up to 61%.<sup>(2)</sup> Therefore, health professionals, especially nursing, need to carry out interventions aimed at coping with falls in hospitals. Among these interventions, we have health education as a strategy to prevent its occurrence.<sup>(3)</sup>

Effectiveness of educational interventions to prevent falls is observed in randomized trials in Australia with 3606 adult patients and 221 elderly, the results of which show that individualized patient education programs combined with training in basic prevention care are able to contribute to reduction of falls rates.<sup>(4,5)</sup>

During the health education process, professionals can use printed educational materials that favor the understanding of guidance from information organization and illustrations presence.<sup>(6)</sup> Among these printed materials, the booklet stands out as a useful tool for describing health issues and as a viable resource due to its low cost and practicality in the hospital application.<sup>(7)</sup>

Nursing is the largest professional category in the hospital environment. It is in a longer time of contact with the patient and has health education as inherent to its professional practice. It should be emphasized that the availability of the educational booklet on fall prevention in hospitals, built and validated by means of a scientific method, could contribute to the effectiveness of the educator's role of the nurse on the subject.

It is worth emphasizing that the availability of the booklet can favor improvements in care directed to hospitalized patients by facilitating the understanding about self-care behaviors to prevent

adverse events, such as falls. In addition, it makes possible the accomplishment of future studies that compare the effectiveness of educational resources in the knowledge of patients and in fall prevention in hospitals.

Moreover, this study aimed to construct and validate an educational booklet to prevent hospital falls.

## Methods

It is a methodological study, developed from February to September of 2018, through construction and validation of an educational booklet to prevent hospital falls.

For the construction of the booklet, the following steps were established: 1 - integrative review on the theme; 2 - storyboard drawing with the graphic designer to assist in the development of educational technology; 3 - material validation built by health professionals and booklet assessment by the target audience.

### Bibliographic survey

The data collection was performed in April 2018, for the selection of articles on hospital falls through the PubMed, LILACS, MEDLINE, BDeEnf, Scielo, SCOPUS, and CINAHL databases. The descriptors used in Portuguese and English were: “*Enfermagem/ Nursing*”; “*Acidentes por Quedas/Accidental Falls*”, “*Hospitalização/Hospitalization*”, “*Segurança do Paciente/Patient Safety*”. The search strategy used in Portuguese and English was: “*Enfermagem/ Nursing*” AND “*Acidentes por Quedas/Accidental Falls*” AND “*Hospitalização/Hospitalization*” AND “*Segurança do Paciente/Patient Safety*”. Inclusion criteria were articles made available in full in English, Spanish and Portuguese and published as of 2008. Editorials, reflective studies, repeated manuscripts that did not address the theme of the study were excluded.

98 publications were found and, after reading abstracts and articles in full, 16 articles were selected for reflective reading and synthesis of the most relevant points, which guided the elaboration of

the educational booklet content. Data were collected regarding the title, year of publication, country, language, objective, method, results, conclusion and level of evidence.

After compiling the data obtained with the articles selected in the integrative review, information was also included in the fall prevention protocols made available by the Ministry of Health, the Brazilian Health Regulatory Agency (ANVISA - *Agência Nacional de Vigilância Sanitária*) and the World Health Organization.<sup>(8,9)</sup>

### Construction of educational material

After listing the relevant content for the booklet, a script was elaborated with information, settings and texts that should be present in the material. Subsequently, there was adaptation of the scientific language, making it more appropriate to the public, regardless of the education degree.

Then the material was delivered to a specialist in the area of designer to develop the illustrations and carry out the layout of the material. The choice of the professional is justified by the experience in developing educational materials for the Graduate Program in Nursing at the *Universidade Federal do Ceará*, contributing to the construction of technologies related to dissertations and theses.

The layout and structure of the text/phrases were carried out by the designer through the researcher's follow-up and according to recommendations for educational technologies texts<sup>(10)</sup>. The colored illustrations were created in the program Corel Draw X7.

### Validation of content with judges

After being built, the validation of the booklet was performed by nurses with expertise in care in the hospital environment, patient safety or educational technologies. The sample size was defined from  $n = Z_{\alpha}^2 \cdot P(1-P)/e^2$  formula. The stipulated values were  $Z_{\alpha}$  (confidence level) = 95%,  $P$  (judges' agreement ratio) = 85%, and (accepted difference expected) = 15%, which resulted in 22 judges.<sup>(11)</sup>

The search for judges occurred among professors of nursing courses of public universities of Ceará State with expertise in patient safety, edu-

cational technologies and nursing. It was also requested, through "snowball" sampling, the indication of other professors with profile to participate in the validation. From the indication, the Lattes Curriculum was assessed to verify if the indicated professionals met the established inclusion criteria.

In the selection of professionals, the criteria of Jasper (12) were used, as well as knowledge/ability in the subject (dissertations and theses guidance related to patient safety or educational technologies); to have knowledge/ability through professional experience (have teaching experience in the clinical nursing area or have assistance experience in the hospital environment) and have expertise in a specific type of study (experience in the development of printed educational technologies, participation of assessment teams related to the subject, and to have published articles on patient safety or educational technologies). Thus, 45 professionals were invited, of which 23 did not return contact, which resulted in a sample of 22 judges.

In order to collect data, a form was created by Google Forms that was shared via email, along with the Free and Informed Consent Term (FICT). A 14-day deadline was set for booklet assessment and tool completion.

The booklet images were inserted in the form, along with the 18 items of the validation instrument that contained variables about the objective (purposes, goals or purposes of the booklet), structure/presentation (organization, structure, language, coherence, and text size) and material relevance (significance, impact, motivation and interest for reading the booklet).<sup>(13)</sup> Each of these topics on the tool contained affirmative sentences about the items and, after reading the material, judges could assess the item as adequate, partially adequate or inadequate.

It also included space for suggestions to be made by judges. All suggestions submitted by judges were organized and analyzed according to the tool variables (purpose, structure/presentation and relevance of the material), which were duly adhered to. Restatement of some sentences was requested to make it easier for the audience to understand, as well as to improve illustrations such as highlighting

vibrant colors and include images that are representative of best practices in the text.

### Assessment by the target audience

After content validation, the educational material was assessed by 22 patients hospitalized in a public hospital clinic in the city of Sobral, Ceará State, Brazil. The choice of this setting is justified by the fact that the booklet addresses fall prevention in hospitalized patients in the hospital ward, and the chosen sector bears similarity to the illustrations present in the educational material. For inclusion in the sample, the following inclusion criteria were adopted: being literate and clinically stable during reading of the material. Patients with visual and cognitive impairment were excluded.

The Suitability Assessment of Materials (SAM) was translated and validated into Brazilian Portuguese containing 30 items that includes the assessment of objectives, organization, language, appearance, and motivation of the printed material.<sup>(14)</sup> A topic containing clinical and epidemiological data was added to the patient and another topic where the patient classified the material as approved, approved with modifications, reproved with quality, and disapproved. In addition, they were also asked to indicate suggestions to improve the understanding or illustration of the material.

The participants were selected based on identification of inpatients and application of inclusion and exclusion criteria. After explaining the purpose of the study, patients who agreed to participate signed the FICT. Then the booklet and the data collection tool were delivered. Each participant was instructed to read the booklet, analyze the text and images, and then answer the form.

### Data analysis

A descriptive analysis of the data regarding the characterization of judges and patients was performed. In order to verify the content validity of the booklet, the Content Validity Index (CVI) was used. The I-CVI (Item-level Content Validity Index) was calculated for each item of the instrument and the overall CVI. The booklet was considered valid when

the item obtained CVI equal to or higher than 0.8. In addition, the binomial test was used in software R to verify statistically agreement equal or greater than 0.80 of judges and patients, separately. The level of significance adopted in the study was 5%.

### Ethical aspects

The project was approved by the Research Ethics Committee of the *Universidade Estadual Vale do Acaraú*, under Opinion 2,933,103 pursuant to Resolution 466/2012.

## Results

The booklet for fall prevention titled “Careful not to fall for this” was built with 20 pages, composed by cover, back cover, technical sheet, cover sheet and presentation page. The characters present in the educational material were a nurse named Ana, a patient named Mariah, a companion named Joseph and a mascot named Alert who interacts with the reader throughout the content exposed.

The content was divided into the following topics: “Risk situations” (presents definition and characterization of falls); “Factors associated with falls” (contemplates extrinsic and intrinsic risks); “How to avoid complications” (addresses prevention measures for the patient and companion); “Safe environment” (has tips for keeping the ward environment safer); “Exercises do well” (exercise guidelines for strengthening muscles); “Super team” (presents nursing team assignments, aimed at preventing falls, and the conduct of a fall situation); “Seven errors game” (list risk factors present in the hospital environment).

In order to make the textbook comprehensible, the approach to the theme was clear and objective, with highlighted titles and images, simple language, logical sequence of information, and speech balloons to ratify the content. Therefore, the information was expressed through dialogues between characters, in which the nurse interacts with the patient and the companion, presenting guidelines for fall prevention. It is noteworthy that the illustrated setting corresponded to the hospital clinical ward.

Some pages of the final version of the booklet are presented (Figure 1).



**Figure 1.** Pages of the Booklet on hospital falls “Careful not to fall for this!”

In the validation of content performed by 22 nurses, 11 were masters, six doctors and five had specialization. In relation to the area of performance, 12 worked in teaching, two in research, one in management and seven in care. As far as teaching experience was concerned, 14 had experience in the subject and 16 had participated in fall training or courses. The items assessed and the respective CVI values regarding objectives, structure/presentation and relevance are detailed in table 1.

As observed in table 1, the 18 items were assessed by judges as adequate, there was a 100% agreement level, agreement on the objectives of the educational material was unanimous, as well as its content and relevance to clinical practice. The overall CVI in validation with judges was equal to 1.0, which is considered gold standard. In view of this result, only one round of validation was conducted with judges since suggestions for modifications were minimal and would not invalidate the already assessed and validated material. Among the suggestions made by judges, it is worth highlighting in the title fall prevention in the hospital environment, highlighting the cover colors, review some terms difficult to understand, and add figures that illustrate the exam-

**Table 1.** Professionals' agreement regarding the items in the booklet

Variables	n(%)*	I-CVI	p-value †
<b>1. Objectives</b>			
1.2 Contemplates the proposed theme	22(100)	1	1
1.3 Information/contents are adequate to the process and teaching-learning	22(100)	1	1
1.4 Clarifies possible doubts about the topic addressed	22(100)	1	1
1.5 Provides reflection on the theme	22(100)	1	1
1.6 Encourages behavior change	22(100)	1	1
<b>2. Structure and Presentation</b>			
2.1 Messages are presented in language appropriate to the target audience	22(100)	1	1
2.2 Language appropriate to educational material	22(100)	1	1
2.3 Interactive language, allowing active involvement in the educational process	22(100)	1	1
2.4 Information is correct	22(100)	1	1
2.5 Information is objective	22(100)	1	1
2.6 Information is clarifying	22(100)	1	1
2.7 Information is necessary	22(100)	1	1
2.8 Ideas are in logical sequence	22(100)	1	1
2.9 Current theme	22(100)	1	1
2.10 Text size is adequate	22(100)	1	1
<b>3. Relevance</b>			
3.1 The booklet encourages learning	22(100)	1	1
3.2 Contributes to the knowledge in the area	22(100)	1	1
3.3 Awakens interest in the subject	22(100)	1	1

\*Percentage of agreement in the item; I-CVI = Item-Level Content Validity Index; †Binomial test.

ples of exercises to strengthen the muscles. All these modifications were adhered to and the designer was asked to make such changes. The final version of the booklet was assessed by the target audience represented by hospitalized patients, who were mostly men with a mean age of 28.7 years, single, with brown skin and complete high school. The mean time of hospitalization was 11.6 days due to automobile accidents, postoperative and complications such as infections. Most interviewees had a history of both domestic and hospital falls. The agreement of the patients in the assessment of the booklet is presented in table 2.

Of the 33 items assessed by patients, 24 indicated 100% agreement (CVI equal to 1.0). Another seven had CVI of 0.95 and two CVI equal to 0.90. The booklet's overall CVI in the validation with patients was 0.98. The adjustments suggested by patients were related to the increase in the source size and to exchange of the type of paper used for printing. Suggestions have been accepted for the final version of the booklet.

**Table 2.** Agreement of the patients hospitalized in medical clinic, regarding the items of the booklet

Variables	n(%)*	I-CVI	p-value †
<b>1. Objectives</b>			
1.1 Meets the goals of inpatients and helps them understand fall risks.	21(95.4)	0.95	0.972
1.2 Promotes reflection on the necessary precautions in fall prevention.	22(100)	1	1
1.3 Adequate for use by any healthcare professional.	22(100)	1	1
<b>2. Organization</b>			
2.1 The booklet's cover is attractive.	22(100)	1	1
2.2 The booklet's cover contemplates material information.	22(100)	1	1
2.3 Title size and topic content is suitable.	22(100)	1	1
2.4 Themes address important key aspects.	20(90.9)	0.90	0.863
2.5 There is consistency between information on the cover, presentation, summary and contents of the booklet.	22(100)	1	1
2.6 Paper of the printed material is appropriate.	22(100)	1	1
2.7 The number of pages is adequate.	20(90.9)	0.90	0.863
2.8 Material is of adequate size, that is, it is neither extensive nor tiring.	21(95.4)	0.95	0.972
<b>3. Language</b>			
3.1 Writing is in proper style.	22(100)	1	1
3.2 Text is vivid and interesting.	22(100)	1	1
3.3 Vocabulary is accessible in simple and common words.	22(100)	1	1
3.4 All important concepts are addressed clearly and objectively.	22(100)	1	1
3.5 There is an association between the theme of each session and the corresponding text.	22(100)	1	1
3.6 Text presents interaction with guidance between professional and target audience.	22(100)	1	1
3.7 Text is written in such a way that the target audience is the center of attention, that is, the patient is more important.	21(95.4)	0.95	0.972
<b>4. Appearance</b>			
4.1 Visual composition is attractive.	22(100)	1	1
4.2 Pages or sessions appear organized.	22(100)	1	1
4.3 The number of figures is sufficient.	21(95.4)	0.95	0.972
4.4 Figures are presented in an appropriate size.	22(100)	1	1
4.5 Figures are simple, appropriate and easily understood.	22(100)	1	1
4.6 Figures are self-explanatory.	21(95.4)	0.95	0.972
4.7 Figures are familiar to readers.	22(100)	1	1
4.8 Figures are integrated with the text (well located).	22(100)	1	1
<b>5. Motivation</b>			
5.1 The booklet is appropriate for your age, gender, and culture.	21(95.4)	0.95	0.972
5.2 The booklet presents a logical sequence on care to prevent falls.	22(100)	1	1
5.3 The booklet arouses interest and curiosity.	22(100)	1	1
5.4 The booklet promotes behavior change and attitude.	22(100)	1	1
5.5 The content of the booklet maintains the dynamics of reading.	22(100)	1	1
5.6 The content of the booklet motivates the reading to the end.	21(95.4)	0.95	0.972
5.7 The use of the booklet becomes relevant.	22(100)	1	1

\*Percentage of agreement in the item; I-CVI = Item-Level Content Validity Index; †Binomial test.

## Discussion

The dissemination of printed educational materials is effective in contributing to improvements in the health area, as verified in the results of a longitudinal study carried out during four years in southern Brazil, which showed an association between distribution of folders/posters and reduction of falls index.<sup>(15)</sup> It is therefore pertinent to develop methodological studies that contemplate the construction and validation of educational health materials to be made available in health services.

Contents addressed in the booklet contribute to the dissemination of important information advocated by the fall prevention protocol, part of the *Programa Nacional de Segurança do Paciente* (freely translated as Brazilian Patient Safety Program) of the Ministry of Health.<sup>(8)</sup> Moreover, from the layout of the contents in boxes of texts and topics and with illustrations of the text, the material becomes easier to be understood during the reading.

This is consistent with the proposal for other fall prevention education materials built by fall prevention and management organizations in Ireland and hospitals in Northern Ireland and Australia. These materials, printed in the form of a booklet, had the elderly target audience and addressed the main risk situations, as well as information related to fall prevention.<sup>(16-18)</sup> Furthermore, there is an international concern to disseminate information on printed technologies that contribute to health education on the subject.

During validation by professionals, the CVI was equal to 1.0 in all topics analyzed. This finding corroborates other methodological studies carried out in Brazil that have obtained satisfactory results in the validation of the booklet contents for children with hydrocephalus and their caregivers<sup>(19,20)</sup> who obtained CVI between 0.9 and 1.0 and a booklet for prevention of metabolic syndrome in adolescents<sup>(21)</sup> who obtained CVI of 1.0 in most of the analyzed items. Validation with assessment of items related to the objective, structure/presentation and relevance is important so that educational materials do not have misleading or incomplete information that may in-

duce the target population to error or make it difficult to understand the subject.

In addition to having correct information and valid content, health education materials must be understandable by the target audience. In this perspective, the professionals who carried out the validation of content suggested small adjustments related to language adequacy of the booklet in sentences that could make difficult the interpretation of patients.

This situation resembles the finding of Brazilian methodological studies on booklet validation for prevention of vertical HIV transmission and for patients with head and neck cancer submitted to radiotherapy. These patients evidenced the need to modify the language in order to clarify the content to the readers, according to the judges' suggestions.<sup>(22,23)</sup> Thus, it is observed that suggestions for adjustments in the text of educational technologies are recurrent and have relevance so that the material can be understood by as many people as possible.

After the proposed changes were made, it was possible to verify that the patients easily understood the information contained in the printed material, since all language-related topics had a CVI of 1.0, which indicates the clarity of the writing. These findings converge with study on educational materials printed in Texas. This study was about safety in the use of medicines with 300 patients. The results showed that the health education tool was easy to understand and language accessible to patients.<sup>(24)</sup>

In this way, educational materials, once understandable and attractive, are characterized as an alternative to sensitize the patient so that the latter can be active in their self-care. Regarding this, in the present study, it was possible to prove the feasibility to use the booklet, since patients expressed interest in reading the material and learning about fall prevention.

In the United Kingdom, a study on the use of a booklet for preventing falls in the elderly in the community also demonstrated good patient acceptability and practical applicability of the material.<sup>(25)</sup> Furthermore, it is important that studies involving

new educational technologies assess their applicability in the context in which they will be used.<sup>(26)</sup>

It is worth noting that the educational manual was not designed to replace the verbal guidance provided by the nurse during nursing care, but rather to reinforce the guidelines and solve doubts, since the patient can consult the material whenever they are interested.<sup>(25)</sup> It is suggested that nurses use the booklet during educational strategies and that, at that moment, this technology facilitates the construction of knowledge between nurse-patient-family, besides favoring clarification of doubts.

Constructing, validating and applying educational materials of the booklet type has presented positive results in national and international studies. Therefore, it is important that patient guidance instruments on falls be developed and validated for use in clinical practice in order to contribute to the safety culture of the patient in the hospital context. It is emphasized that one of the priorities in the reduction of falls in hospitalized patients is the multidisciplinary care with actions that promote education for patient and relatives.<sup>(8)</sup>

Therefore, the present study contributes to the scientific advance in nursing science by providing, for care and academic environment, a booklet with an educational focus that has been validated by judges and assessed by the target public (patients), and can be used in clinical practice.

It is believed that, after construction and validation, it is pertinent to verify the effectiveness of the educational material in guiding the patient in relation to prevention of falls in the hospital environment. This moment can be carried out individually or collectively with patients and caregivers.

This study presents limitations regarding generalization of the results considering that the booklet addresses prevention of falls in the hospital context, which made it difficult to discuss the findings with studies with the same theme. Another limitation is that the material was assessed only by SUS (*Sistema Único de Saúde* – Brazilian Unified Health System) users in the medical clinic sector, so that the results obtained may differ from the reality of patients assisted in the private healthcare network or hospitalized in other sectors.

## Conclusion

The educational booklet “Careful not to fall for this” was built based on a review of the scientific literature and literature on the subject (fall prevention protocols provided by the Ministry of Health, ANVISA and the World Health Organization). In content validation, it was considered valid by judges (nurses) in relation to the objectives, structure/presentation and relevance (CVI = 1.0) and assessed as comprehensible by patients admitted to a medical clinic (CVI = 0.98). It is appropriate that during the assessment of educational materials, the target audience can express their opinion on the content, language and appearance so that the material becomes suitable for the target population. Consequently, the material will achieve its purpose when applied during clinical practice. Therefore, it is recommended that in every methodological study the assessment stage be valued by the target audience. Viable educational material is available to be used in the hospital context, which may favor fall prevention by allowing patients access to knowledge of important care. Therefore, this material contributes to patient safety as well as the improvement of the quality of health care and education carried out by nursing.

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## Collaborations

Ximenes MAM contributed to the project design, data collection and interpretation, and article writing. Fontenele NAO, Bastos IB, Macêdo TS contributed to the data collection and interpretation. Galindo Neto NM, Caetano JÁ and Barros LM contributed to article writing, content critical review and final version approval

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