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Editorial

Strategies to enhance the profession of nursing as a key partner in improving primary care across the hemisphere

For years now, the World Health Organization (WHO) has called for improved primary health care to solve patient needs and for an increase in more qualified health care practitioners to deliver this care (Lawn, et al, 2008). Nurses deliver 90 percent of all healthcare services worldwide, and make up over 80 percent of the global healthcare workforce (Benton, 2015; Davis, 2017). In Latin America and the Caribbean (LAC) primary health care is greatly needed especially in rural and underserved areas (PAHO, 2014). The Nursing Now campaign is built up on the Triple Impact Report which found that as well as improving health globally, empowering nurses will improve gender equality (since the vast majority of nurses are still women) and support stronger economies (All Party Parliamentary Group on Global Health, 2016; ICN, 2018).[1-14]

The Pan American Health Organization (PAHO) in a 2013 declaration called for nurses with advanced training to help meet these primary health care needs (PAHO, 2013) and most recently reiterated this focus in a new publication, *Expanding the roles of nurses in primary health care* (PAHO, 2018). These nurses must be educated as must nursing schools begin to prepare nurses in these advanced roles. One has to ask, what are the barriers to educate nurses to fill these needs in LAC? Zug, Cassiani, Pulcini and others (2016) surveyed key informants in LAC and found that the role of the APN has just begun or is not yet well implemented or understood in Latin America. While many know about Advanced Practice Nursing roles, others have less knowledge and could benefit from more information and advocacy strategies. Strategies for implementing the APN role have been suggested using to the PEPPA framework by Bryant-Lukosius. (Oldenburger, Cassiani, Bryant-Lukosius, et al, 2017).[5,7,14]

In Latin America, nurses in many areas have sustained low wages and subsequent low status compared to other health care professionals such as physicians. Physician programs have many applicants and many young women often choose this field over nursing. Another issue is the relative lack of status for clinical roles vs administrative roles. Clinical ladders are common, so when a nurse becomes more educated, she or he is likely to move into administration or teaching rather than advanced clinical practice. Physicians tend to dominate in the health professions so nurses do not enjoy the same status. While administrative roles and teaching provide an

important basis for improved nursing practice, clinical practice also needs to be valued in order to raise the status of the profession.

In the U.S., universities and other academic institutions have faced a similar growing challenge to provide primary care to patients in rural and underserved areas (Bodenhemer & Bauer, 2016). But, in the US, part of the solution is to increase the number of highly qualified Advanced Practice Nurses (APNs) to meet the complex primary health care needs of diverse populations. In addition, many higher education institutions have responded to an increasing need to shift from hospital-based, specialty nursing education to preparing staff nurses for primary care nursing roles (Macy Foundation, 2016). These changes call for nursing education programs to expand their curricula and incorporate innovative educational approaches to facilitate experiential learning, build skills and enhance knowledge for basic and advanced practice nursing within the context of a global community.[9,10]

Over the years since the APN roles were introduced in the U.S. the status of nurses at all levels has risen as have wages for nurses. Nursing has been the most trusted profession for many years in the U.S. Many young men and women choose nursing over medicine acknowledging the value of the nursing profession. While clinical ladders exist, more and more nurses choose to stay at the bedside or in primary care practices with more education as opposed to moving into higher administrative roles. Faculty shortages in educational institutions educating nurses are well known (AACN, 2017) and salaries of faculty tend to be lower than those of highly skilled clinicians in hospitals and primary care. The IOM Report published in 2011, *The future of nursing: Leading change, advancing health,* called for a rise in the educational level of all nurses in the U.S. from technical nurses to doctorally prepared nurses as well as increased scope of practice for nurses.[6,10]

One solution to improve clinical nursing in Latin America is to increase the exchange of information across the hemisphere. Currently, an unprecedented interest exists in transnational Academic Global Partnerships in which U.S. schools of nursing are creating institutional partnerships with universities and affiliated teaching hospitals overseas. These international academic partnerships offer unique opportunities for students to engage with peers, health professionals, experts and local citizens in shared learning environments, evidence-based clinical practice, and research. Students and faculty mutually benefit from shared expertise, resources and collaboration with international educators and nursing leaders, which advance nursing practice globally.

The concept of collaborative institutional partnering is not new. Many colleges and universities may lack the resources and expertise to achieve "global reach" and therefore, seek to establish linkages with overseas institutions. Public Private Partnerships (PPP) is another example in which institutions of higher education in wealthy countries have partnered with institutions in low and middle-income countries in various parts of the world.

Given the importance of addressing the unmet needs in primary care, faculty and nursing programs must examine how they can specifically use

collaborative academic partnerships with overseas institutions to prioritize advanced nursing education and within the context of a global community. What is needed is a framework for the development of sustainable international partnerships with measurable, defined objectives, goals and impact.

Another strategy is to partner with key nursing and political leaders to begin to implement the *Nursing Now* campaign in LAC. Engaging key partners beyond nursing such as Ministries of Health and Education as well as political leaders to advocate for this valuable profession can parallel the success that the *Future of Nursing* report effected in the U.S. The Pan American Health Organization has begun this work by its 2013 declaration and by bringing together nurses and others from across the continent to solve the problems of primary care for LAC (PAHO, 2013). Stakeholders across the continent can be mobilized to move the profession forward in dynamic ways. Nurses are a key part of the solution in solving the primary health care needs of populations. Their power and influence should be unleashed so that nursing talent can be maximally utilized across Latin America and the Caribbean.[12]

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Original Article

Elaboration and validation of a reader on childhood diarrhea prevention

Elaboração e validação de cartilha para prevenção da diarreia infantil

Elaboración y validación de libreta para la prevención de la diarrea infantil

Leidiane Minervina Moraes de Sabino[1]
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Keywords
Diarrhea, infantile; Self efficacy; Health promotion; Validation studies; Mother-child relations

Descritores
Diarreia infantil; Autoeficácia; Promoção da saúde; Estudos de validação; Relações mãe-filho

Descriptores
Diarrea infantil; Autoeficacia; Promoción de la salud; Estudios de validación; Relaciones madre-hijo

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Abstract
Objective: Elaborate, validate and evaluate an educational reader to promote maternal self-efficacy in the prevention of childhood diarrhea.
Method: Methodological study, developed based on the elaboration, validation and evaluation of educational material by 30 content judges and three technicians. For the validation, the clarity of the language, practical pertinence and theoretical relevance were considered, calculating the Content Validity Index for each item; and the tool *Suitability Assessment of Materials* (SAM) was applied to evaluate the reader.
Results: The reader was titled "You can prevent diarrhea in you child" was elaborated in the framework of Self-Efficacy Theory. The content judges attributed a global Content Validity Index (CVI) of 0.88 for language clarity, 0.91 for practical pertinence and 0.92 for theoretical relevance; and the technical judges attributed CVI of 0.96, 1.00 and 1.00 for the same items assessed, respectively. The assessment of the content and technical judges based on the SAM tool classified the material as "superior", with average coefficients of 88.7% and 90.1%, respectively.
Conclusion: The reader was considered appropriate in terms of face and content validation to promote maternal self-efficacy in the prevention of childhood diarrhea.

Resumo
Objetivo: Elaborar, validar e avaliar uma cartilha educativa para a promoção da autoeficácia materna na prevenção da diarreia infantil.
Método: Estudo metodológico, desenvolvido a partir da elaboração, validação e avaliação do material educativo por 30 juízes de conteúdo e três técnicos. Para validação, avaliou-se clareza da linguagem, pertinência prática e relevância teórica, calculando-se o Índice de Validade de Conteúdo para cada item; e aplicou-se o instrumento *Suitability Assesment of Materials* (SAM) para avaliação da cartilha.
Resultados: A cartilha teve como título "Você é capaz de prevenir a diarreia no seu filho!" e foi elaborada tendo como referencial a Teoria da Autoeficácia. Os juízes de conteúdo atribuíram Índice de Validade de Conteúdo (IVC) global de 0,88 para clareza da linguagem, 0,91 para pertinência prática e 0,92 para relevância teórica; e os juízes técnicos atribuíram IVC de 0,96, 1,00 e 1,00 para os mesmos itens avaliados, respectivamente. A avaliação dos juízes de conteúdo e técnicos a partir do SAM classificou o material como "superior", com média de 88,7% e 90,1%, respectivamente.
Conclusão: A cartilha apresenta conteúdo e aparência adequados para a promoção da autoeficácia materna na prevenção da diarreia infantil.

Resumen
Objetivo: Elaborar, validar y evaluar una libreta educativa para la promoción de la Autoeficacia materna en la prevención de la diarrea infantil.
Método: Estudio metodológico desarrollado partiendo de la elaboración, validación y evaluación del material educativo por 30 expertos en contenido y tres técnicos. Para la validación se evaluó claridad del lenguaje, adecuación práctica y relevancia teórica, calculándose el Índice de Validez de Contenido para cada ítem; y se aplicó el instrumento *Suitability Assessment of Materials* (SAM) para evaluación de la libreta.
Resultados: La libreta se tituló "¡Tú eres capaz de prevenir la diarrea de tu hijo!", y fue elaborada sobre el referencial de la Teoría de la Autoeficacia. Los expertos en contenido le otorgaron Índice de Validez de Contenido (IVC) global de 0,88 a la claridad del lenguaje, 0,91 a adecuación práctica y 0,92 a relevancia teórica; y los técnicos puntuaron con IVC de 0,96, 1,00 y 1,00 a los mismos ítems evaluados, respectivamente. La evaluación de los expertos en contenido y técnicos a partir del SAM clasificaron al material como "superior", con promedio de 88,7% y 90,1%, respectivamente.
Conclusión: La libreta ofrece contenido y apariencia adecuados para promoción de Autoeficacia materna en la prevención de la diarrea infantil.

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Introduction

Diarrhea is considered a global public health problem with high morbidity and mortality rates, mainly in developing countries.[1] In Brazil, the State of Ceará, located in the Northeast, is one of the states with the worst environmental and health conditions, favoring the presence of risk factors for the disease, especially in children.[2] In 2016, 3,711 cases of diarrhea in children under five years of age were registered in the city of Fortaleza, CE.[3]

Considered as a multifactorial disease, diarrhea can be prevented by adopting measures to protect against infectious agents.[4] The need for prevention strategies is highlighted, aimed at families of children under five years of age, which can improve knowledge and maternal confidence in preventive care for childhood diarrhea.[5]

Thus, an educational video based on Bandura's Theory of Self-Efficacy titled "Childhood Diarrhea: you can prevent it", applied to mothers of children under five years old, permitted enhancing maternal self-efficacy to prevent childhood diarrhea and reducing the cases of diarrhea up to two months after this intervention. After this period, however, the mothers' self-efficacy decreased, suggesting the need to develop and use other technologies in this area to keep up the implementation of interventions to prevent this condition.[5,6]

Thus, it was decided to elaborate an educational reader the promotion of maternal self-efficacy in the prevention of childhood diarrhea, using the Theory of Self-Efficacy as a reference framework. Readers are printed materials useful to describe health-related subjects, and can be used as a tool for health promotion, which facilitates the educational process.[7]

The use of this reader can contribute to improve educational activities for the prevention of childhood diarrhea performed by nurses, and will help the mothers in their childcare behaviors in the care of their child, increasing their confidence and influencing the reduction of cases of morbidity and mortality in children under five years of age due to diarrhea.

Therefore, the objective was to elaborate, validate and evaluate an educational reader for the promotion of maternal self-efficacy in the prevention of childhood diarrhea.

Methods

It is a methodological study, in which an educational reader was developed to promote maternal self-efficacy in the prevention of childhood diarrhea, based on the elaboration, validation and evaluation of that educational material.

Initially, the educational reader was elaborated, whose content was based on the items of the Maternal Self-Efficacy Scale for Prevention of Childhood Diarrhea (EAPDI) and the scenes of the educational video "Childhood Diarrhea: you can prevent it". Therefore, the reader was constructed in the light of Bandura's Theory of Self-Efficacy.[6] It is highlighted that both the EAPDI and the video mentioned were validated and had their reliability proven.[8,9]

In this construction stage of the reader, it is worth noting that theoretical and methodological references have been used which emphasize elements that should be considered in the elaboration of printed educational materials with a view to improving the readers' comprehension.[10-13]

Initially, the script of the reader was developed and the Flesch Readability Test was applied to ensure easy reading. The test classifies the textual comprehension as follows: very easy, easy, difficult and very difficult; also classifying the sentences in the active and passive voice.[14] Afterwards, a qualified design professional developed the illustrations and layout of the reader.

The reader was then submitted to validation, involving content and technical judges, to enhance the credibility of the material elaborated.[15] Thirty content judges, who were specialists in the thematic area of the reader; and three technical judges, graphic design experts, participated in this validation stage. They were recruited and selected according to the criteria described by Jasper.[16] The number of judges followed the recommendations suggested by the authors regarding the number of evaluators for this type of study.[17,18]

The instrument used for the validation was a five-point Likert scale, ranging from "very low" to

"very high", which permits evaluating each page of the reader based on: clarity of language, practical pertinence and theoretical relevance. In addition, space was provided for the judges' suggestions.[19]

The judges also evaluated the educational material using SAM. This tools makes it possible to evaluate the material in the following areas: content; language fit for the population; graphical illustrations, lists, tables and graphs; layout and type; stimulation for learning and motivation; cultural appropriateness.[10]

After validation and evaluation of the educational reader by content and technical judges, their suggestions were analyzed and the technical professional responsible for the illustration and diagramming of the reader was again contacted to modify and adapt the material according to the judges' recommendations.

The data obtained were organized, processed and analyzed using the Statistical Package for the Social Sciences (SPSS), version 20.0. As far as the data analysis was concerned, for the textual evaluation of the reader based on the application of the Flesh Readability test, the following indices were adopted: 100-75: very easy; 74-50: easy; 49-25: difficult; 24-0: very difficult.[14] To analyze the content validation of the educational reader, the CVI was calculated. Items were considered valid if the inter-rater agreement corresponded to CVIs equal to or greater than 0.80.

The data obtained by the application of the SAM questionnaire were organized in Excel. The obtained scores were processed using percentage analysis, as follows: 70% to 100% of the scores, "superior" educational material; from 40 to 69%, "adequate"; and 0 to 39%, "not suitable".[10]

The study received approval from the Research Ethics Committee of the Federal University of Ceará (UFC), under opinion 1.116.855, in compliance with Resolution 466/12.[22]

Results

The reader titled "You Can Prevent Diarrhea in Your Child!" was organized into eight sub-topics: 1. How to know if your child has diarrhea; 2. How to take care of your child's hygiene; 3. Learn how to take care of your hygiene; 4. Cleaning the environment helps prevent disease; 5. Let's learn how to wash the fruits and vegetables; 6. See how to take care of your child's nutrition; 7. Know the importance of vaccination for your child; 8. How to care for the child with diarrhea.

In relation to the elaboration of the material, the main characters present in the pages of the reader were portrayed on the cover. We sought to use simple and direct language to favor the population's understanding. In the illustrations, we sought to approach the cultural reality of the reader's target audience. In the layout, we used Arial font, size 16 points for the body of the text and 18 points for the subtitles.

Based on the script, the Flesch readability test was applied to the 44 paragraphs of the reader. Of these, 34 (77%) were considered very easy and 10 (23%) were easy. In the analysis of the complete reader, the test revealed a score of 91, classifying the material as very easy to read, with all phrases written in the active voice.

The first version of the reader consisted of 32 pages, 21 pages for content, eight pre-textual and post-textual pages and three blank pages the mothers can use to make notes.

Thirty content and three technical judges validated the first version of the reader. The 30 content judges were nurses, 24 of whom held a specialization degree, 20 an M.Sc. and 15 a Ph.D. Of these, 17 judges were teachers and 13 were active in care practice. As for the training of the technical judges, two were advertising agents and one was a musician. In addition, two had completed a specialization course in graphic design, two judges were working in the area of graphic design and one in art direction.

The CVI of each page of the reader was calculated considering the clarity of the language, the practical pertinence and the theoretical relevance; and later the global CVI, which is represented in table 1.

For most pages in the reader, the CVI was superior to 0.80. For pages 7, 21 and 23, the CVI was lower than 0.80 with regard to clear language. Changes were made in the language based on the judges' recommendations.

Table 1. Distribution of CVIs for each page according to the content and technical judges' analysis

Page/Theme	Clear language		Practical relevance		Theoretical relevance	
	Judges					
	C*	T**	C*	T**	C*	T**
Cover	0.9	1	0.93	1	0.9	1
Presentation	0.9	1	0.93	1	0.93	1
Page 7/ Definition of childhood diarrhea	0.76	1	0.93	1	0.93	1
Page 8/ Care with child hygiene	0.86	1	0.9	1	0.93	1
Page 9/ Care with child hygiene	0.83	1	0.9	1	0.9	1
Page 10/ Care with child hygiene	0.83	1	0.9	1	0.9	1
Page 11/ Care with maternal hygiene	0.8	1	0.9	1	0.9	1
Page 12/ Environmental cleaning	0.96	1	0.96	1	0.93	1
Page 13/ Environmental cleaning	0.93	1	0.86	1	0.93	1
Page 14/ Environmental cleaning	0.96	1	0.96	1	0.96	1
Page 15/ Environmental cleaning	0.86	1	0.9	1	0.86	1
Page 16/ Washing fruit and vegetables	0.93	1	0.93	1	0.96	1
Page 17/ Washing fruit and vegetables	0.86	1	0.9	1	0.93	1
Page 18/ Food	0.9	1	0.9	1	0.96	1
Page 19/ Food	0.83	1	0.93	1	0.9	1
Page 20/ Food	0.8	1	0.86	1	0.83	1
Page 21/ Food	0.9	0.66	0.9	1	0.9	1
Page 22/ Food	0.86	1	0.86	1	0.9	1
Page 23/ Vaccination	0.96	0.66	1	1	1	1
Page 24/ Diarrhea management conducts	0.96	1	0.96	1	0.96	1
Page 25/ Diarrhea management conducts	0.93	1	0.83	1	0.9	1
Page 26/ Closure	0.96	1	1	1	1	1
Global CVI	0.88	0.96	0.91	1.00	0.92	1.00

*Content Judges **Technical Judges

In addition, the judges gave relevant suggestions on the readers, mainly: update how long the fruit and vegetables should be left to soak for the sake of hygiene; and change the scenario on some pages (type of refrigerator and stove, foods shown in the refrigerator and on the meal table), recovering the population's reality. In addition, the inclusion of a new page was requested to discuss care for the child with diarrhea and signs of alert for diarrhea. All of these recommendations were accepted after the researchers' analysis.

The judges also evaluated the reader using the tool SAM (Table 2).

According to the analysis of the judges' evaluation, they considered the educational reader to be "superior", reaching an agreement percentage of 88.7% among the content judges and 90.1% among the technical judges. The judges also assigned a score of zero to ten concerning the recommendation to use the reader, averaging 9.26 by the content judges and 9.66 by the technical judges.

After the judges' analysis, the final version of the reader consisted of 32 pages, 22 pages of content, eight pre-textual and post-textual pages and two blank pages for notes.

Table 2. Assessment of educational reader by content and technical judges

Domains	Higher		Appropriate		Inappropriate		Total – Mean agreement (%)	
	C*	T**	C*	T**	C*	T**	C*	T**
1.Content								
a) Clear objective	23	3	7	-	-	-	88.3	100
b) Content discusses behavior	28	3	2	-	-	-	96.7	100
c) The proposal is limited	24	3	6	-	-	-	90	100
d) Abstract or review	16	-	5	2	9	1	61.7	33.3
2. Language fit for the population								
a) Level of reading	22	3	8	-	-	-	86.7	100
b) Active voice style	25	2	5	1	-	-	91.6	83.3
c) Vocabulary uses common words	23	3	7	-	-	-	88.3	100
d) Context first	26	2	4	1	-	-	93.3	83.3
e) Learning mediated by advanced signs	27	3	3	-	-	-	95	100
3. Graphical illustrations, lists, tables and graphs								
a) Cover	24	2	6	1	-	-	90	83.3
b) Type of illustrations	28	3	2	-	-	-	96.7	100
c) Relevance of illustrations	28	3	1	-	1	-	95	100
d) Lists, tables, graphs and forms	26	3	1	-	3	-	88.3	100
e) Captions are used	23	3	4	-	3	-	88.3	100
4. Layout and type								
a) Layout factors	24	2	6	1	-	-	90	83.3
b) Type	26	3	4	-	-	-	93.3	100
c) Subtitles are used	23	3	7	-	-	-	83.3	100
5. Stimulation for learning and motivation								
a) Interaction is included in the text and/or figures	15	-	13	3	2	-	71.7	50
b) Desired behavioral standards are modeled or shown in specific terms	26	2	4	1	-	-	93.3	83.3
c) Motivation/self-efficacy	23	3	7	-	-	-	88.3	100
6. Cultural Appropriateness								
a) Cultural game – logic, language and experience (LLE)	22	3	8	-	-	-	86.7	100
b) Cultural Image and Examples	27	2	2	1	1	-	93.3	83.3
Total							88.7	90.1

*Content Judges **Technical Judges

Discussion

As a limitation of the study, the validation of the readers only by content and technical judges is highlighted. Its clinical application to the mothers who will use this material in practice is important.

The use of this reader will support the practice of nurses and other health professionals who carry out educational activities, being an important tool to promote maternal self-efficacy in the prevention of childhood diarrhea.

The educational reader "You Can Prevent Diarrhea in Your Child!" was developed using Bandura's Self-Efficacy Theory as a framework because, as self-efficacy is developed, people intensify their efforts to achieve or even exceed the desired result.[6]

The reader was divided into eight topics to facilitate the understanding and organization of the content, so as to make it more interactive, so that the reader is motivated to follow the message addressed.[23] Simple language was used, so that individuals with a low level of education can read and understand the material, enhancing the reader's motivation.[10,24] The reality of the families' daily life was portrayed in the reader, as individuals who participate in educational approaches become more prone to adopt new behaviors when there is a relationship of trust and closeness to their reality.[15]

After the preparation of the first version of the reader, it was validated by content and technical judges, achieving a minimum CVI of 0.8, which is the recommended value in the literature.[9,21,25] It is emphasized that validation is essential after the elaboration of educational materials, as judges knowledgeable on the subject need to be able to evaluate the material and suggest improvements.[15,26,27] In addition, it is recommended that there should also be a group of judges knowledgeable in the field of graphic design in material validation studies.[28]

As to the judges' requests, changes were made in the time that fruits and vegetables should remain submerged in water with sodium hypochlorite;[29] and in some illustrations, the aim was to improve the socio-cultural adaptation, acknowledging the need to portray the contextual reality of the reader in the elaboration of the educational materials.[24]

The overall evaluation of the reader, based on the sum of the average SAM scores among the items of the six domains, revealed that the technical judges considered the material to be "superior". The SAM instrument can reveal weaknesses in the instruction of a material, which could reduce its suitability for use by the target audience.[10]

In the content domain, the content and technical judges rated the abstract or review item as "adequate" and "not suitable", respectively. Although some judges considered it pertinent to include this item in the reader, it was decided not to insert it; because it was elaborated in eight topics, according to authors' recommendations, who indicate that the division of the material into topics presents the subjects dynamically, allowing the closing of each subject; and the figures in each page of the reader were intended to aid in the textual review, contributing to knowledge acquisition.[23,24]

In the field of stimulation for learning and motivation, although the technical judges considered the item "interaction is included in the text and/or pictures" as "adequate", it is known that the reader is intended to encourage the reader to adopt the same behavior as the character, motivating the performance of responses similar to those of the character. Thus, the importance of inserting the Theory of Self-Efficacy in the elaboration of the material is emphasized, as can allow the reader to feel able to perform the care portrayed in the booklet.[5,6]

The domains language; graphical illustrations, lists, tables; layout and type; and cultural appropriateness were evaluated as "superior". The adequacy of these domains is fundamental in the communication of health education, and it is important that the materials are creative to attract the public's attention and more likely to achieve positive results.[30] In addition, it is essential that the population's living and cultural conditions be pictured in the reader, as it encourages the target audience to visualize its own reality, alluding to the fact that, if the character is able to prevent diarrhea in her child, so will the mothers living in similar situations.[15]

The content and technical judges' evaluation classified the educational reader as appropriate in terms of language clarity, practical pertinence and theoretical relevance. The reader was considered "superior" based on the application of the SAM tool, considering content; language fit for the population; graphical illustrations, lists, tables and graphs; layout and type; learning stimulation and motivation; and cultural appropriateness.

Conclusion

The educational reader "You can prevent diarrhea in your child" was considered valid educational material in terms of content and face validation to promote maternal self-efficacy in the prevention of childhood diarrhea.

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Collaborations

Sabino LMM, Ferreira AMV, Joventino ES, Lima FET, Penha JC, Lima KF, Nascimento LA and Ximenes LB participated in the project design, data interpretation, relevant critical review of the intellectual content and approval of the final version for publication.

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Original Article

Anthropometry versus subjective nutritional assessment in cancer patients

Antropometria versus avaliação subjetiva nutricional no paciente oncológico

Antropometría versus evaluación subjetiva nutricional en el paciente oncológico

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Neoplasms; Anthropometry; Nutritional status; Malnutrition; Edema

Descritores
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Abstract
Objective: Compare the results of anthropometry and subjective nutritional assessment applied to cancer patients.
Methods: Cross-sectional study with patients undergoing chemotherapy between March and June 2017. The instruments applied were anthropometry (body mass index, body fat percentage, muscle mass and edema) and the Patient-Generated Subjective Global Assessment (PG-SGA). Data were entered into a Microsoft Excel® spreadsheet. Statistical analyses were performed using SPSS® version 21.0. Central tendency (mean and standard deviation), absolute frequency and corresponding percentages were measured. The analyses used the t-test and Pearson correlation, considering a significance level of 5%.
Results: Of all 99 participants and based on the body mass index, 60.6% were healthy, 24.2% presented fat depletion, 51.5% had severe or moderate muscle depletion, and 87.9% had edema. According to the Patient-Generated Subjective Global Assessment, 31.3% were well-nourished participants, 37.4% moderately malnourished and 31.3% severely malnourished. Incompatibility of nutritional diagnosis was observed when comparing the body mass index and the Patient-Generated Subjective Global Assessment due to the high frequency of edema in the participants.
Conclusion: The results indicated that the body mass index should not be considered as the only assessment for cancer patients, requiring a complete anthropometric evaluation associated with the Patient-Generated Subjective Global Assessment.

Resumo
Objetivo: Comparar os resultados da antropometria e avaliação subjetiva nutricional aplicadas ao paciente oncológico.
Métodos: Estudo transversal com pacientes em tratamento de quimioterapia entre março e junho de 2017. Os instrumentos aplicados foram a antropometria (Índice de Massa Corporal, percentual de gordura corporal, massa muscular e edema) e a Avaliação Subjetiva Global Produzida pelo Próprio Paciente. Os dados foram digitados no programa Microsoft Excel®. As análises estatísticas foram realizadas no programa SPSS® 21.0. Realizaram-se medidas de tendência central (média e desvio-padrão), frequência absoluta e percentual. As análises ocorreram por meio do Teste *t* e *Correlação de Pearson*, adotando-se um nível de significância de 5%.
Resultados: Dentre os 99 participantes, 60,6% apresentaram eutrofia, segundo o Índice de Massa Corporal, 24,2% com depleção de gordura, 51,5% com depleção muscular grave ou moderada e 87,9% com edema. A categorização da Avaliação Subjetiva Global Produzida pelo Próprio Paciente foi de 31,3% participantes bem nutridos, 37,4% desnutridos moderadamente e 31,3% desnutridos graves. Houve incompatibilidade do diagnóstico nutricional proveniente do Índice de Massa Corporal e Avaliação Subjetiva Global Produzida pelo Próprio Paciente, em decorrência da alta frequência de edema nos participantes.
Conclusão: Os resultados apontaram que o Índice de Massa Corporal não deve ser considerado um indicador único de avaliação do paciente oncológico, necessitando-se de avaliação antropométrica completa associada à Avaliação Subjetiva Global Produzida pelo Próprio Paciente.

Resumen
Objetivo: Comparar resultados de antropometría y evaluación subjetiva nutricional aplicados al paciente oncológico.
Métodos: Estudio transversal con pacientes en tratamiento quimioterápico entre marzo y junio de 2017. Se aplicaron los instrumentos Antropometría (Índice de Masa Corporal, porcentaje de grasa corporal, masa muscular y edema) y la Evaluación Subjetiva Global Producida por el Propio Paciente. Datos introducidos en planilla Microsoft Excel®. Los análisis estadísticos fueron realizados con el programa SPSS® 21.0. Se aplicaron medidas de tendencia central (promedio y Desvío Estándar), frecuencia absoluta y porcentual. Análisis realizados mediante Test de t y Correlación de Pearson, adoptándose nivel de significatividad del 5%.
Resultados: De los 99 participantes, 60,6 presentó eutrofia según el Índice de Masa Corporal, 24,2% con depleción de grasa, 51,5% con depleción muscular grave o moderada, y 87,9% con edema. La categorización de la Evaluación Subjetiva Global Producida por el Propio Paciente fue de 31,3% participantes bien nutridos, 37,4% moderadamente desnutridos y 31,3% gravemente desnutridos. Existió incompatibilidad del diagnóstico nutricional derivada del Índice de Masa Corporal y Evaluación Subjetiva Global Producida por el Propio Paciente, determinada por la alta frecuencia de edema en los participantes.
Conclusión: Los resultados expresan que el Índice de Masa Corporal no debe considerarse indicador único de evaluación del paciente oncológico, precisándose de evaluación antropométrica completa asociada a la Evaluación Subjetiva Global Producida por el Propio Paciente.

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Introduction

Cancer is an abnormal (malignant) cell growth that can invade or spread to tissues and organs. This process involves metastasis when it spreads through the body. This evolution can happen quickly, leading to the formation of tumors (accumulation of cancer cells) or malignant neoplasms. If the tumor is classified as benign, it is rarely considered a life-threatening condition, a local mass of cells that is similar to the original tissue.[1]

Cancer has no symptoms in its early stage; however the first signs appear with the disease evolution and can be very distinct based on the neoplasm location. Symptoms may be classified as local effects (ulceration), systemic symptoms (weight loss, fever, excessive tiredness, epithelial changes), symptoms of metastasis (lymphadenopathy, hepatomegaly or splenomegaly, pain or fracture of affected bones), and neurological symptoms.[2]

Chemotherapy, which aims to control and treat cancer, has an impact on the patients' nutritional status. Symptoms such as nausea, vomiting, diarrhea, constipation and anorexia are possible consequences. Although some drugs can minimize the effects of this procedure, the symptoms are still a major obstacle for patients.[3]

Nutritional status is a very important aspect, as it has a direct influence on the evolution of cancer patients. Malnutrition is very frequent in these individuals, which may be a result of changes in metabolism caused by the disease and treatment, as well as reduced total intake and increased energy demand for tumor evolution.[4]

One of the evaluation instruments to determine the nutritional status is anthropometry, which includes the evaluation of weight, height, edema, skin folds and circumferences. This instrument indicates the presence of malnutrition, eutrophy or obesity. As its method of analysis, the reference values should be compatible with the population evaluated to identify and quantify the nature and severity of nutritional diseases.[5]

As an instrument for cancer patient screening, the Patient-Generated Subjective Global Assessment (PG-SGA) has 98% sensitivity and 82% specificity. It was translated into Portuguese and validated in Brazil in 2010, demonstrating its usefulness. Its use consists in the categorization of the nutritional status and screening of the degree of required professional intervention.[6]

In order to promote the recovery of cancer patients, several health areas should be supported. Nutrition professionals should conduct a nutritional assessment and define an intervention for the resulting diagnosis.[7]

Therefore, the objective of this study was to compare the results of the anthropometric assessment and the PG-SGA applied to cancer patients.

Methods

This is an observational cross-sectional quantitative study with 99 patients in outpatient chemotherapy in the Triângulo Mineiro region, Minas Gerais. Data collection was conducted from March to June 2017.

The inclusion criteria were: cancer patients undergoing chemotherapy in the third cycle or after, of both sexes, adults over 20 years old, elderly patients who knew how to read and write for the self-applied instrument. Individuals who presented mental confusion were excluded from the study, since the instrument required patient collaboration for data collection.

According to the procedures requested by the Research Ethics Committee, formal contact with the institution and participants occurred only after approval by the committee no. 1.974.551. Data collection started after the signature of an informed consent form. Guidance was provided on the benefits of the scientific study to the society.

Participants were contacted in the outpatient clinic and after agreement with the study terms; each participant was individually taken to a private room so that the instruments were applied by a qualified professional, spending on average 60 minutes.

The following methods were used to collect data: anthropometry (BMI, body fat percentage, muscle mass and edema) and PG-SGA.

The procedures were applied according to the Anthropometry Manual.[8] Height was measured with a stadiometer (WCS®, 2016, Paraná, Brazil), weight was measured with a wireless digital scale (Bioland®, 2016, São Paulo, Brazil), a caliper (CESCORF® Innovare, 2016, Porto Alegre, Brazil) was used to measure skin folds, and a meter tape (WCS®, 2016, Paraná, Brazil) was used to measure the circumference of limbs.

The BMI classification was based on cut-off points, according to the World Health Organization (WHO)[9] which is considered appropriate for healthy adult subjects. For the elderly, the reference values were those proposed by Lipschit.[10]

For the participants who were unable to walk, calculation formulas were used to estimate their height and weight.[11,12]

Regarding body composition, the Petroski Protocol was used[13], which evaluated four skin folds: medial axillary, supra iliac, medial calf and thigh for female participants, and subscapular, triceps, supra iliac, and medial calf for male participants. Data were calculated by providing the body density value. This value was applied to a final formula that determined the fat percentage. The ideal fat percentage was classified according to sex and age of each participant.[14]

Mid-arm circumference (MAC) and mid-arm muscle circumference (MAMC) (triceps fold) were considered in the analysis of muscle mass, whose values were used in a formula that provides the percentage of muscle mass (without bone correction), according to the percentile by age and sex.[15,16]

Godet signal was used for edema assessment, which consists of palpation with intense pressure for one or two seconds, classifying the degree according to a scale.[17]

PG-SGA is divided into two parts; the first is answered by the patient. Issues such as weight changes, gastrointestinal symptoms and changes in food intake were addressed. The results provided two types of classification: nutritional status and scores that identify four levels of nutritional risk, allowing different interventions for each of them.[6]

Participants were taken to a nutrition clinic in the Triângulo Mineiro region, Minas Gerais, according to the nutritional status diagnosed.

Data obtained from the application of both instruments were carefully described and analyzed with the development of a database in Microsoft Excel®, in a double-typing process to avoid inconsistency. Then, the variables were submitted to statistical analyses and testing using the Statistical Package for the Social Sciences - SPSS Statistics® 21.0.

In the statistical analysis, absolute frequency and percentage measurements were used. The t-test was performed for the bivariate analysis of categorical variables, considering a significance level of 5%.

Pearson correlation was performed for the quantitative variables, considering ρ=1 perfect positive correlation between the two variables, ρ=-1 perfect negative correlation between the two variables, and ρ=0 meaning that the two variables do not linearly depend on one another. The level of significance was 5%.

Results

Of the 99 cancer patients undergoing chemotherapy, 56.6% were male. The age group of 20 to 60 years included 40.4% of the participants. Regarding the types of cancer, gastrointestinal cancer presented a higher frequency (36.4%), and 24.2% presented metastasis.

Of all participants, 60.6% were healthy, that is, proper total body weight in relation to height, followed by 30.3% of overweight and 9.1% of underweight participants. Regarding body fat percentage, 57.6% were classified as adequate, 24.2% presented depletion and 18.2% were above the recommended level. For the percentage of muscle mass, 51.5% had severe or moderate depletion, 44.4% presented mild and 4% adequate depletion. The edema classification was as follows: 37.4% of the patients with mild edema, 27.3% with moderate edema, 23.2% had severe edema, and 12.1% were free from this condition (Table 1).

Table 1 shows the nutritional status categorized according to PG-SGA. About 31.3% were classified as 'well nourished,' 37.4% identified as 'moderately malnourished,' and 31.3% as 'severe-

Table 1. Nutritional status according to anthropometry and the Patient-Generated Subjective Global Assessment

Variables	Classifications	n(%)
BMI	Underweight	9(9.1†)
	Healthy	60(60.6†)
	Overweight	30(30.3†)
Body fat %	Depletion	24(24.2†)
	Adequate	57(57.6†)
	Over	18(18.2†)
Muscle mass %	Mild depletion	44(44.4†)
	Adequate	4(4†)
	Moderate or severe depletion	51(51.5†)
Edema	No presence	12(12.1†)
	Mild	37(37.4†)
	Moderate	27(27.3†)
	Severe	23(23.2†)
Categorization of nutritional status	Well-nourished	31(31.3†)
	Moderately malnourished	37(37.4†)
	Severely malnourished	31(31.3†)
Degree of professional intervention	Not required	29(29.3†)
	Nutritional education	21(21.2†)
	Nutritional intervention	25(25.3†)
	Important intervention	24(24.2†)

†Each relative frequency was calculated using the total sample (99 subjects)

ly malnourished.' Regarding the degree of professional intervention, 29.3% did not need nutritional intervention at the moment, but reassessment was required, 21.2% lacked individual and family nutritional education, 25.3% required nutritional intervention, and 24.2% required significant nutritional intervention to control symptoms.

Table 2 shows the comparison of mean values from the results of anthropometry and PG-SGA according to the variables of sex, age group, type of cancer and metastasis. For BMI, and percentage of fat and muscle mass, the lowest mean values were for males, individuals aged over 60 years, with gastrointestinal cancer and the presence of metastasis. Regarding the edema severity and the PG-SGA scores for the categorization of the nutritional status and degree of intervention, higher mean values were obtained for men, elderly, with gastrointestinal cancer and metastasis.

Table 3 shows the correlation between anthropometry and the PG-SGA. The percentage of muscle mass (ρ=0.68, p=0.001) and presence of edema (ρ=0.61, p=0.003) can be considered as moderately positive. The percentage of body fat (ρ=0.41,

Table 2. Comparison of mean values from the results of anthropometry and the Patient-Generated Subjective Global Assessment, according to the variables of sex, age group, type of cancer and metastasis

Variables	Mean	SD*	p-value
BMI			
Sex			
Male	21.4	0.61	0.004‡
Female	23.0	0.55	
Age group			
20 to 60	20.8	0.60	0.001‡
> 60	19.5	0.56	
Cancer type			
Gastrointestinal	21.7	0.56	0.002‡
Other	22.4	0.61	
Metastasis			
Yes	21.3	0.53	0.004‡
No	22.4	0.61	
Body fat %			
Sex			
Male	18.4	0.68	0.003‡
Female	20.7	0.59	
Age group			
20 to 60	20.1	0.65	0.004‡
> 60	17.3	0.60	
Cancer type			
Gastrointestinal	17.8	0.54	0.004‡
Other	20.3	0.69	
Metastasis			
Yes	19.2	0.71	0.003‡
No	19.5	0.63	
Muscle mass %			
Sex			
Male	64.6	0.53	0.002‡
Female	66.0	0.62	
Age group			
20 to 60	65.8	0.59	0.003‡
> 60	63.8	0.49	
Cancer type			
Gastrointestinal	65.2	0.61	0.001‡
Other	65.3	0.50	
Metastasis			
Yes	64.8	0.52	0.002‡
No	66.7	0.70	
Edema			
Sex			
Male	2.05	0.89	0.004‡
Female	2.46	0.99	
Age group			
20 to 60	2.26	0.98	0.003‡
> 60	2.35	0.89	
Cancer type			
Gastrointestinal	2.37	1.02	0.003‡
Other	2.14	0.83	
Metastasis			
Yes	2.31	0.97	0.003‡
No	2.21	0.93	
Categorization of nutritional status			
Sex			
Male	2.09	0.81	0.004‡
Female	1.88	0.76	

Continue...

Continuation.

Variables	Mean	SD*	p-value
Age group			
20 to 60	1.93	0.77	0.001 t
> 60	2.19	0.84	
Cancer type			
Gastrointestinal	2.05	0.79	0.003 t
Other	1.92	0.80	
Metastasis			
Yes	2.02	0.80	0.004 t
No	2.00	0.78	
Degree of professional intervention			
Sex			
Male	2.55	1.19	0.003 t
Female	2.30	1.10	
Age group			
20 to 60	2.34	1.12	0.003 t
> 60	2.73	1.21	
Cancer type			
Gastrointestinal	2.51	1.16	0.004 t
Other	2.33	1.14	
Metastasis			
Yes	2.48	1.16	0.004 t
No	2.33	1.12	

*SD – Standard deviation; t-test

Table 3. Correlation between anthropometry and the Patient-Generated Subjective Global Assessment

Variables	Categorization of nutritional status	
	ρ	*p-value*
BMI	0.06	0.003 ρ
Body fat %	0.41	0.001 ρ
Muscle mass %	0.68	0.001 ρ
Edema	0.61	0.003 ρ

ρ – Pearson correlation

p=0.001) presented a weak positive correlation. BMI presented the lowest positive correlation (ρ=0.06, p=0.003), which shows a low degree of correlation between the methods.

Discussion

This study had a predominance of male participants (56.6%), which is similar to a study with 70 subjects (54.3%).[18] Regarding nutritional status, male participants presented higher severity. This representativeness may be associated with their resistance to seeking health services, a behavior rooted in our society and still frequent.[19,20]

Regarding age, 40.4% were aged 20 to 60 years, in disagreement with most studies. The inclusion criterion of knowing how to read and write was determinant, since most illiterates correspond to the elderly. In this study, the higher the age group, the worse their nutritional status. According to the literature, about 70% of deaths caused by cancer occur among elderly people aged 65 or over.[21]

Regarding the type of cancer, gastrointestinal cancer presented a higher frequency (36.4%) and the most severe results in anthropometry and the PG-SGA. This type of cancer causes inappetence, malabsorption and poor digestion, leading to complications in the nutritional situation, such as malnutrition, anemia and changes in body composition.[22]

Another study used the PG-SGA with gastrointestinal cancer patients, and 98% of the cases required intervention, with improved nutritional status in 54% of these individuals.[23]

As for metastasis, 24.2% of the participants presented this condition, predisposing them to a greater nutritional risk, thus indicating greater attention and care required in this aspect.[24]

Some researchers have reported that insufficient food intake, type of cancer, disease progression, and chemotherapy are responsible for the loss of fat and muscle mass.[18]

This study found 24.2% of patients with body fat depletion and 51.4% with severe or moderate muscle mass depletion, in agreement with the estimated prevalence of malnutrition in cancer patients from 40 to 80%.[7] Another study detected malnutrition in 60% of patients based on arm circumference, and 73.3% using muscle circumference.[25]

The presence of edema affects the accuracy of nutritional diagnosis through BMI. Only 12.1% of the patients did not present the condition: 37.4% were mild, 27.3% moderate, and 23.2% severe. Chemotherapy increases the occurrence of edema, so a positive correlation was observed in more advanced stages of the disease.[26]

In the BMI assessment, most participants were classified as healthy (60.6%). In a study with 50 breast cancer patients, about 50% of the sample presented obesity according to the BMI.[27]

In the PG-SGA categorization, 31.3% were classified as 'well-nourished,' 37.4% as 'moderately malnourished,' and 31.3% as 'severely malnourished. In a prospective study with 416 cancer patients, 47%

were 'well-nourished,' 29% were 'moderately malnourished,' and 24% were 'severely malnourished,' with higher mortality in these individuals.[28]

Discrepancies were observed in the nutritional status evaluated by both instruments, 9.1% were considered malnourished according to the BMI, but 37.4% as 'moderately malnourished' and 31.3% as 'severely malnourished' according to PG- SGA.

In a study with 96 elderly individuals, the BMI indicated 29.2% of underweight individuals, while with PG-SGA, the percentage of malnutrition (moderately and severely malnourished) reached 43.8%.[29]

The inconsistent prognosis between the BMI and PG-SGA methods for cancer patients undergoing chemotherapy is due to the presence of edema, body composition assessment, and calculation of involuntary weight loss, underestimating the BMI diagnosis.[30]

One of the limitations of this study was its sample size, which is associated with the inclusion criterion of knowing how to read and write, a factor that was required for the self-applied part of the PG-SGA.

Conclusion

The results of this study showed an incompatibility in the nutritional diagnosis from the BMI and the PG-SGA, due to the high frequency of edema in the participants. Finally, BMI should not be considered as a single indicator of cancer patient evaluation, requiring a complete anthropometric evaluation associated with the PG-SGA.

Collaborations

Milani J participated in the study design and project, and data analysis and interpretation. Pereira EMS and Barbosa MH collaborated with the relevant critical review of its intellectual content. Barichello E collaborated with the study design and project, data analysis and interpretation, and final approval of the version to be published.

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ACTA 30 YEARS 1988 - 2018

Original Article

Evaluation of prenatal care process for habitual-risk pregnant women

Avaliação do processo na assistência pré-natal de gestantes com risco habitual

Evaluación del proceso en la atención prenatal de embarazadas con riesgo normal

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Descritores
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Abstract

Objective: Assess the quality of care in the prenatal care process for habitual-risk pregnant women.
Methods: Evaluation research, undertaken between May 2015 and January 2016 at the Natural Birth Center (CPN) Lígia Barros Costa in Fortaleza, Ceará. The sample consisted of 560 histories of pregnant women who received prenatal care at the CPN. The data collection instrument included sociodemographic, clinical and obstetric aspects, as well as process indicators of prenatal care. The criteria adopted to assess the process were the prenatal care quality indicators. The data were stored and processed in Statistical Package for the Social Sciences version 20.0. Descriptive statistical analysis was applied.
Results: As for the prenatal care quality indicators, 42.3% (n=237) complied with the appropriate number of appointments, have attended seven or more. Only 26.3% (n=147) started prenatal care early. Regarding the quality indicators of the clinical and obstetric procedures, it was verified that 55% (n=309) was appropriate. When the quality indicators were analyzed for the laboratory tests, only 25.4% (n=142) were appropriate.
Conclusion: The quality of prenatal care is appropriate in a minority of the study population. Managers and professional should pay greater attention to the planning of actions to improve the indicators, related to the number of appointments, early start of prenatal care, clinical and obstetric procedures and execution of laboratory tests.

Resumo

Objetivo: Avaliar a qualidade do cuidado quanto ao processo no pré-natal de gestantes com risco habitual.
Métodos: Pesquisa avaliativa, realizada no período de maio de 2015 a janeiro de 2016, na Casa de Parto Natural (CPN) Lígia Barros Costa em Fortaleza, Ceará. A amostra totalizou 560 prontuários de gestantes que realizaram pré-natal na CPN. O instrumento de coleta dos dados contemplou aspectos sociodemográficos, clínicos e obstétricos, e indicadores de processo da assistência pré-natal. Os critérios adotados para avaliar o processo foram os indicadores de qualidade do pré-natal. Os dados foram armazenados e processados no programa estatístico *Statistical Package for the Social Sciences* versão 20.0. A análise utilizou a estatística descritiva.
Resultados: Quanto aos indicadores de qualidade do pré-natal, observou-se que 42,3% (n=237) atenderam ao número adequado de consultas, realizando sete ou mais consultas. Apenas 26,3% (n=147) iniciaram precocemente o pré-natal. Referente aos indicadores de qualidade dos procedimentos clínicos e obstétricos verificou-se que 55% (n=309) estava adequado. Quando analisados os indicadores de qualidade referentes aos exames laboratoriais, apenas 25,4% (n=142) estavam adequados.
Conclusão: Conclui-se que a qualidade do pré-natal é adequada na minoria da população estudada, devendo existir maior atenção de gestores e profissionais para o planejamento de ações em prol da melhoria dos indicadores relacionados aos números de consultas, início precoce do pré-natal, procedimentos clínicos e obstétricos e realização dos exames laboratoriais.

Resumen

Objetivo: Evaluar calidad del cuidado respecto del proceso en el prenatal de embarazadas con riesgo normal.
Métodos: Investigación evaluativa, realizada de mayo 2015 a enero 2016, en la Casa de Parto Natural (CPN) Lígua Barros Costa en Fortaleza, Ceará. Muestra totalizando 560 historias clínicas de embarazadas que realizaron prenatal en la CPN. El instrumento de recolección de datos contempló aspectos sociodemográficos, clínicos y obstétricos, e indicadores de proceso de atención prenatal. Los criterios adoptados para evaluar el proceso fueron los indicadores de calidad del prenatal. Datos almacenados en programa estadístico *Statistical Package for the Social Sciences* versión 20.0. Análisis realizado mediante estadística descriptiva.
Resultados: Respecto a los indicadores de calidad del prenatal, se observó que 42,3% (n=237) respondieron al número adecuado de consultas, realizando siete o más. Solamente 26,3% (n=147) iniciaron precozmente el prenatal. Respecto a indicadores de calidad referentes a exámenes laboratoriales, solamente 25,4% (n=142) resultaron adecuados.
Conclusión: Se concluye en que la calidad del prenatal es adecuada en la minoría de la población estudiada, debiendo brindársele mayor atención de gestores y profesionales al planeamiento de acciones en pro de la mejora de los indicadores relativos al número de consultas, inicio precoz del prenatal, procedimientos clínicos y obstétricos y realización de exámenes laboratoriales.

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Conflicts of interest: *article taken from the thesis entitled "Evaluation of prenatal care for habitual-risk pregnant women".

Introduction

Women's Health care during pregnancy and postpartum represents a challenge for health authorities around the world regarding the quality of care provided and conceptual frameworks. The pregnancy cycle needs to be monitored satisfactorily in its three phases: pregnancy, childbirth and postpartum, so that the woman receives comprehensive and high-quality care.

In Brazil, prenatal monitoring (PN) aims to ensure the development of the pregnancy, favoring a healthy birth, with the least possible negative impact on maternal and fetal health, mainly addressing psychosocial aspects, educational and preventive activities.[1]

In that sense, Brazilian studies show that the health levels of mothers and unborn babies are closely intertwined with the quality of PN care, with a direct correlation between appropriate PN and lower maternal and perinatal morbidity and mortality rates.[2-4] Thus, the importance of managers and professionals' implementation of strategies is underlined with a view to guaranteeing access to health, as well as the quality of the service provided.

Over the last three decades, studies on the quality of health services have been based on one or more categories proposed by Donabedian (1991), who defines the quality of health services as health services' extent of accommodation of the population's needs, expectations and care standard.[5]

According to Donabedian (1988, 1991),[5,6] information, from which conclusions can be drawn on the quality of care, need to be based on three components of health care: structure, process and outcome analysis. The process corresponds to the activities developed in the relationship between professionals and patients, according to technical-scientific standards, as well as activities related to the use of resources in their quantitative-qualitative aspects, including the recognition of problems, diagnostic methods, diagnoses and care provided.

The same author still considers that the evaluation of the process is a fundamental component to investigate the quality of care. Therefore, through the application of quality criteria to evaluate the PN care process, service performance and care quality evidenced can be identified, which is one of the conditions to guarantee the effectiveness of care to pregnant women.[5,6]

The objective was therefore to evaluate the quality of care regarding the process offered to habitual-risk pregnant women.

Methods

Evaluation study, carried out from May 2015 to January 2016, at the Natural Birth Center Ligia Barros Costa (CPN), which is part of the Pro-Rectory of Community Services at *Universidade Federal do Ceará* (UFC).

The evaluation consisted of the analysis of all medical records as from January 2011, a period corresponding to the formulation of the Stork Network Strategy, until June 2015, during which 695 medical records were found.

The inclusion criteria were the files of women who received prenatal care at CPN and medical records in the archives sector. The exclusion criteria adopted were: files of women in PN monitoring at the time of data collection (56), who were referred to high-risk PN (21), and for whom only one consultation was registered (24). Therefore, the sample totaled 560 files.

In order to evaluate the process, Coutinho (2010) proposed: prenatal care indicators, clinical and obstetric evaluation indicators and complementary test indicators.[7]

Regarding the prenatal indicators, compliance is considered as having started within 12 weeks of pregnancy and women who had seven or more appointments. Non-compliance is considered when the PN started after the 27th week of pregnancy or the woman had two or less visits. The quality of PN is considered intermediate when situations between compliant and non-compliant are present. It is emphasized that the criterion was adapted, adopting, instead of six appointments and start of PN up to 14 weeks of pregnancy, seven consultations and start of PN up to 12 weeks of gestational age (GI), following the recommendation of the Stork Network Strategy.[8]

Regarding the indicators related to clinical and obstetric procedures, compliance is considered when there were five or more records of uterine height (UH), GI, weight, blood pressure (BP) and Body Mass Index (BMI); and four or more records of Fetal Heart Rate (FHR); and two or more records of fetal presentation and edema; Non-compliance: two or less records of UH, GI, BP, edema, weight and FHR, or no record of fetal presentation; and Intermediary: all intermediary situations between compliance and non-compliance.

Regarding the quality indicators for the complementary tests, the toxoplasmosis and HBsAg tests recommended by the Stork Network Strategy were evaluated, but the number of one serum test was adopted for each, according to a study carried out in 2012.[8,9] Compliance was considered when the pregnant woman underwent an ABO-Rh typing, two hematocrit, two hemoglobin, two fasting glucose, two VDRL, two anti-HIV tests, two type I urine, one HBsAg and one serology for toxoplasmosis throughout the prenatal period. Non-compliance was considered when there was no record of laboratory tests; and intermediary when any basic test was performed, regardless of the type.

In order to enhance the credibility of the collection instrument, three expert judges performed a face and content evaluation.

Data were stored and processed in the Statistical Package for the Social Sciences (SPSS), version 20.0. Absolute, relative frequencies and central trend measures were calculated. The results were presented in the form of tables and discussed according to relevant literature.

The ethical principles for research involving human beings present in Brazilian National Health Council Resolution 466/12 were respected. This study received approval under protocol 1.292.616.

Results

The first quality indicators presented refer to the number of appointments and the gestational age at the start of prenatal care, as shown in table 1.

Table 1. Prenatal care characteristics of pregnant women attended in Habitual-Risk Prenatal Care

Prenatal Care	n(%)	Median ± SD
No. of Appointments (n=560)		
2 – 3	155(27.7)	6.00 ± 2.82
4 – 6	168(30.0)	Min.: 2
≥ 07	237(42.3)	Max.: 14
Early start of PN (n=560)		
≤ 12 weeks	147(26.3)	
> 12 weeks	413(73.8)	
Start term of PN (n=560)		
1st Term (8 – 14 weeks)	209(37.3)	
2nd Term (15 – 27 weeks)	296(52.9)	
3rd Term (> 27 weeks)	55(9.8)	
Exit Term from PN (n=560)		
1st Term (8 – 14 weeks)	5(0.9)	
2nd Term (15 – 27 weeks)	76(13.6)	
3rd Term (> 27 weeks)	479(85.5)	
Final Appointment ≥ 37 weeks (n= 479)		
Yes	283(50.5)	
No	277(49.5)	
Compliance of PN as to 7 or more appointments		
Compliant	237(42.3)	
Intermediary	168(30.0)	
Non-compliant	155(27.7)	
Compliance of PN as to early start of appointments		
Compliant	147(26.3)	
Intermediary	349(62.3)	
Non-compliant	64(11.4)	

In this study, the mean number of PN appointments was 5.83 (median 6.00). Most pregnant women, 73.8% (n=413) started PN after the 12th week of pregnancy, with the highest prevalence of the start of PN monitoring occurring in the 2nd term of pregnancy in 52.9% (n=296). When the compliance of PN with seven or more appointments was analyzed, it was observed that little less than half (42.3%) took part in seven or more appointments, being considered compliant. What the early start of the consultations is concerned, only 26.3% (n=147) were considered compliant.

Table 2, the data on the quality indicators of the clinical and obstetric procedures offered to the pregnant women at the CPN are displayed.

Considering the clinical and obstetric procedure, compliance was observed in 309 (55%) cases of prenatal care that took place at the service analyzed. Despite the prevalence of favorable outcomes, the number of prenatal care cases with a smaller number of records in the files cannot be ignored.

Table 3, the compliance with the complementary tests the pregnant women attended at the CPN can be observed.

Table 2. Clinical and obstetric procedures offered to pregnant women attended in Habitual-Risk Prenatal Care

Obstetric Clinical Procedures	n(%)
Two fetal presentation records	
Yes	510(91.1)
No	45(8.0)
Not informed	5(0.9)
Five records of gestational age calculation	
Yes	353(63.0)
No	204(36.5)
Not informed	3(0.5)
Five records of UH evaluation	
Yes	343(61.3)
No	215(38.4)
Not informed	2(0.3)
Five records of BP verification	
Yes	345(61.6)
No	210(37.5)
Not informed	5(0.9)
Four records of FHR auscultation	
Yes	392(70.0)
No	166(29.7)
Not informed	2(0.3)
Five records of weight/BMI evaluation	
Yes	340(60.7)
No	216(38.6)
Not informed	4(0.7)
Two records of edema evaluation	
Yes	517(92.3)
No	40(7.2)
Not informed	3(0.5)
Anti-tetanus vaccination (n=439)	
None	59(10.5)
Only 1 dose	267(44.7)
≥ 2 doses	113(20.1)
Not informed	21(21.7)
Compliance of clinical and obstetric procedures	
Compliant	309(55.0)
Intermediary	112(20.0)
Non-compliant	140(25.0)

Table 3. Compliance with complementary tests by pregnant women in Habitual-Risk Prenatal Care

Test details	n(%)
ABO-Rh*	
Compliant	504(90.0)
Non-compliant	56(10.0)
Hb/Ht	
Compliant	189(33.8)
Non-compliant	345(61.6)
Not informed	26(4.6)
Fasting glucose	
Compliant	179(32.0)
Non-compliant	325(58.0)
Not informed	56(10.0)
VDRL	
Compliant	203(36.2)
Non-compliant	240(42.9)
Not informed	117(20.9)
HIV	
Compliant	173(30.9)
Non-compliant	253(45.2)
Not informed	134(23.9)
Urine type I	
Compliant	193(34.4)
Non-compliant	319(57.0)
Not informed	48(8.6)
HBsAG*	
Compliant	369(65.9)
Not informed	191(34.1)
Toxoplasmosis*	
Compliant	429(76.6)
Not informed	131(23.4)
Compliance with complementary tests	
Compliant	142(25.4)
Intermediary	208(37.1)
Non-compliant	210(37.5)

*Considered compliant when only one test was taken

When assessing compliance with the complementary tests, it was observed that most of the pregnant women did not perform the tests as recommended by the Federal Health Department. A percentage of 25.4% (n = 142) had performed all complementary tests considered appropriate in the study, namely: an ABO-Rh typing, two hematocrit, two hemoglobin, two fasting glucose, two VDRL, two anti-HIV tests, two urine tests, one HbsAg and one serology for toxoplasmosis.

Analyzing the table above, it was observed that only three of them showed compliance superior to 50%. These were: blood typing / Rh factor (90%), HBsAg (65.9%) and Toxoplasmosis (76.6%). These were the only tests considered compliant with only one test taken.

Discussion

The limitations of the study are related to the use of secondary sources (process evaluation), due to the under-registration, which affects the generalization power of the results.

Nevertheless, the results help nurses and health managers by presenting the weak points in the prenatal care offered, considering the components of the process, and can support decision making in order to formulate coping strategies for problems that affect the quality of care for women during this period. It is also worth noting that it is an innovative study, as it intended to verify the compliance of the prenatal process, in the framework of the Stork Network, a recent policy that brings valuable contributions to the Brazilian midwifery context.

It was observed that 147 (26.3%) pregnant women started PN care until the 12th week of pregnancy and 237 (42.3%) had seven or more PN visits. In a cohort study carried out in São Luiz / MA, considering the content of PN care, it was evidenced that the main damage was related to the small number of GI consultations, indicating the importance of surveillance at the end of pregnancy to identify risk situations and guarantee specific interventions.[10]

These results may have different determinants though, related to the characteristics of pregnant women regarding the difficulty to diagnose the pregnancy and access barriers.[2] In the service evaluated, there is a lack of a support network, especially of Community Health Agents (CHA) who recruit these women early. In addition, the pregnant woman only initiates the PN consultation and the opening of the medical record through the test results, in order to identify whether or not there is a need for referral to high-risk PN. These aspects may hinder the early start of PN monitoring.

The implementation of high-quality PN includes the early recruitment of pregnant women to start specialized care. The Federal Health Department (2012) stresses the importance of starting within 12 weeks, which was not achieved in the study.[11]

Another worrying finding is related to the higher proportion of women, 296 (52.9%), starting PN in the second term, contributing to a reduction in the period of care and a consequent increase in maternal and infant morbidity and mortality. These data reveal difficulty in accessing PN, as evidenced in earlier studies.[12,13]

The *Nascer Brasil* survey points out that the main barriers for compliance with PN or for the early start of monitoring are related to the persisting social inequalities in the country, with lower access of indigenous and black women, those with lower levels of education, more pregnancies and resident in the North and Northeast.[2]

It is also noticed that some professionals do not record the data of the pregnant women equally in both sources (pregnant woman's card and institutional charts). Comparing the number of PN consultations recorded in the medical records and collected on the pregnant women's cards revealed more consultations registered on the latter, which can contribute to erroneous evidence of low PN quality coverage in existing studies.[14]

It is also important to evaluate not only the GI at which the woman started PN, but also the GI at exit. In this study, the GI of the last visit was considered as the exit date. Thus, only 283 (42.5%) performed the last visit at 37 weeks or more, the mean GI of pregnant women considered ideal for the final care visit.[15]

It can be inferred from the results obtained that the late onset of PN and the inappropriate number of consultations contribute, among other factors, to an unfavorable outcome, as the accomplishment of this procedure is essential for the early discovery of situations that put maternal and fetal health at risk.[9]

Regarding clinical and obstetrical procedures, the cut-off point with two or more fetal presentation records was considered appropriate, in line with a cross-sectional study performed in Santa Maria/RS.[7] Such a parameter is followed because the fetal presentation is more easily identified as from the third term of pregnancy.[16]

Studies consider PN care as compliant when there are more than five records of GI. These surveys present a prevalence of 67%, 71.5% and 79.7% of compliant GI records in their findings.[7,9,13] These findings are similar to those found in this study, which obtained 63% of records. Calculating the GI during PN is an essential tool to evaluate fetal growth and wellbeing, providing parameters that indicate developmental changes.[13]

Regarding the UH measures, a procedure indicated as from the 12th week of pregnancy, with the purpose of assessing fetal growth as well as changes that may occur during this period,[17] it is noted that some authors differ on the number of records, considering compliance when this variable was registered in six or more or in five or more consultations.[7,18] These studies found a prevalence of 85.1% and 83.3%, respectively. In this study, the prevalence of the compliance of this record was 61.5%, being lower than that verified in the aforementioned studies.

A cross-sectional study carried out with 1,947 pregnant women's cards, aiming to evaluate the

compliance and prenatal monitoring of pregnant women with arterial hypertension and with habitual risk, considered BP records in all prenatal consultations as compliant, showing a prevalence of 95% compliance in its sample.[19]

Another study, in turn, considered five or more BP records as compliant, verifying compliance in 83.9% of the sample. In this study, using the same parameters, compliance was found in 62.2% of the sample, lower than the level verified in the above study. This result may have been influenced by the under-registration of this information in the medical records, as well as by the percentage of women who took part in at least five consultations.[7]

Regarding the auscultation of FHR, a fundamental procedure for the evaluation of fetal vitality, the research used as a reference considered four or more records as compliant, with a prevalence rate of 86.7%, a finding superior to that found in the present study, which evidenced 70.3% of compliance in the sample records.[7]

Another important parameter is the measuring of the pregnant woman's weight. It is known that obesity is associated with a higher frequency of dystocia, diabetes and hypertension, and a higher risk of cesarean section. On the other hand, in low-weight pregnant women, there is an increased risk of preterm birth.[1,20]

Studies consider that weight verification should be performed in all PN visits or in five or more visits.[7,9,12] In this study, using five or more records as a parameter of compliance, the prevalence was 61.2%, inferior to the rates found in the studies cited, with 96.3%, 83.5% and 71%.

Regarding the record about the presence of edema, it was observed that 92.3% of the files contained at least two records. Despite the low valuation and underreporting of this variable,[21] in this study, the results were good regarding the recording of this aspect.

Although the evaluation of edema was removed from the diagnostic triad of preeclampsia, this signal remains an important parameter to be evaluated, especially when there is a sudden increase in weight that may be related to increased blood pressure and renal failure.[22]

Tetanus immunization is a requirement of the Federal Health Department, and the pregnant woman has to receive the complete regimen or at least two doses of the vaccine. In this study, only 113 (25.6%) pregnant women received two or more doses. Like in the present study, in a survey that evaluated the vaccination coverage of 151 pregnant women enrolled in the Family Health Strategy in the South of Montes Claros / MG, important gaps were shown in the vaccination coverage of this population, in which 40.4% did not receive the vaccination schedule. Other studies present a similar reality in Rio de Janeiro, which points to the need to develop strategies aimed at improving coverage against neonatal tetanus.[23,24]

Another worrying factor, verified in this study, is the underreporting of clinical and obstetrical records. Registration is a way to ensure care continuity, serving as a parameter for the clinical and diagnostic evolution of care, as well as being a secondary source for research, which will foster knowledge about the reality.

The performance of laboratory tests during the prenatal period is relevant, as it permits more specific and detailed monitoring of the pregnant woman's health conditions.[1]

Laboratory tests should be requested at the first visit, being executed during the first trimester of pregnancy; and VDRL, HIV, urine type 1, glucose and complete blood count should be repeated in the third trimester. It is observed, however, that the primary concern is related to the recording of results, and not to the pregnancy period when the test was offered or performed.[1]

As for routine exams, Brazilian protocols recommend two serum tests for syphilis and HIV, as well as the repetition of blood and urine tests. For the control of syphilis and HIV, serum screening for syphilis and HIV is recommended for more than 90% of pregnant women. Based on these parameters, it is observed that most of the pregnant women did not perform the laboratory tests appropriately.[25]

Failure to perform these tests is directly related to high rates of vertical transmission of syphilis and HIV infection and the occurrence of preventable perinatal deaths, appointing problems in the quality of care provided.[26,27]

In view of the above results, it can be inferred that there is a considerable number of women with medical records without notes and uncompleted monitoring cards. In addition, only the tests that were considered compliant if performed only once (blood typing / Rh Factor, toxoplasmosis and HBsAg) revealed compliance rates superior to 50%. Hence, the results could be different if compliance corresponded to the accomplishment of only one test during the pregnancy.

In view of this implication, there are some factors that may explain that the women underwent the tests only once during pregnancy, such as: difficulty in accessing laboratories in the public network, long waiting time for the release of reports and the lat start of PN, delaying the request for tests.

Studies indicate that the evaluation of the prenatal care process contributes to the improvement of service quality, as well as to the reduction of maternal and perinatal morbidity and mortality rates. [14]

Thus, the evaluation of the process should not consider prenatal quality only based on the number of visits or the gestational age at the start of PN monitoring, but also compliance with the content of the care offered.

There is still no consensus on the minimum behaviors health professionals should adopt during care for women in the pregnancy and postpartum cycle. In this study, the recommendations of the Stork Network Strategy were followed though, to perform seven or more consultations for a full-term pregnancy, with the start of follow-up within 12 weeks, clinical and obstetric procedures and laboratory tests.[8]

In addition, the results reported here show that, despite the increase in prenatal care coverage in the country, few women receive appropriate care, according to the minimum procedures recommended by the Federal Health Department, with similar results being found in earlier studies.[2,12,14]

Regarding the analysis of prenatal quality, comparisons with other studies should be made with caution. As with the findings of the current study, other studies have observed differences in the classification of prenatal care according to the index used. This is justified because the indices use different algorithms to define their prenatal compliance categories. Such differences may result in different conclusions about the actual prenatal situation, leading to misinterpretations.[28]

Conclusion

The evaluation of the process evidenced low compliance of PN regarding the start of PN monitoring, number of consultations during pregnancy, clinical and obstetric procedures and laboratory tests recommended by the Federal Health Department. Therefore, the compliance level of the process in this service needs to be planned for the sake of meeting the quality indicators. It is concluded that there is a need to improve care regarding the process indicators in the service. Managers and health professionals should pay further attention to this, including investment in training and action planning to improve these indicators. In addition, a monitoring program needs to be implemented for the evaluation of prenatal care, in order to guarantee the effectiveness of the actions and the quality of care.

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Collaborations

Balsells MMD, Oliveira TMF, Bernardo EBR, Aquino PS, Damasceno AKD, Castro RCMB, Lessa PRA and Pinheiro AKB contributed to the project design, data analysis and interpretation, relevant critical review of the intellectual content and approval of the final version for publication.

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ACTA 30 YEARS 1988 - 2018

Original Article

Sexual activity of people with spinal cord injury: development and validation of an educational booklet

Atividade sexual na lesão medular: construção e validação de cartilha educativa

Actividad sexual en la lesión medular: construcción y validación de libreta educativa

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Spinal cord injuries; Sexuality; Health education; Teaching materials; Validation studies

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Descriptores
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Abstract
Objective: To describe the process of development and validation of an educational booklet about the sexual activity of people with spinal cord injury.
Methods: Methodological study performed in four steps: documentary search in blogs, integrative review, development of the educational booklet, and face and content validation, namely content validation with 11 referees, technical face validation with three referees, and face validation with 37 people from the target audience. The minimum value established for the content validity index (CVI) was 0.80.
Results: The booklet presented a global CVI of 0.91 after evaluation by healthcare professionals, 0.87 after inspection by graphic designers, and 0.94 after examination by members of the target audience. Despite the significantly high indexes, referees and people from the target audience proposed suggestions to improve the booklet, which were accepted and incorporated into the final version of the material.
Conclusion: The booklet showed content and face adequate to promote healthy and satisfactory sexual activity of people with spinal cord injury.

Resumo
Objetivo: Descrever o processo de construção e validação de uma cartilha educativa sobre atividade sexual de pessoas com lesão medular.
Métodos: Estudo metodológico em quatro etapas: pesquisa documental em blogs, revisão integrativa, construção da cartilha educativa, validação de conteúdo com 11 juízes, validação de aparência técnica com 3 juízes e validação de aparência com 37 pessoas do público-alvo. Considerou-se o Índice de Validade de Conteúdo (IVC) mínimo de 0,80.
Resultados: A cartilha apresentou IVC global de 0,91 pelos juízes profissionais de saúde; 0,87 pelos juízes designers gráficos; e 0,94 na validação de aparência pelo público-alvo. Entretanto, os juízes e público-alvo propuseram sugestões de melhorias da cartilha, que foram acatadas e modificadas para versão final do material.
Conclusão: A cartilha apresentou conteúdo e aparência adequados para promoção da atividade sexual saudável e satisfatória da pessoa com lesão medular.

Resumen
Objetivo: Describir el proceso de construcción y validación de una libreta educativa sobre actividad sexual de personas con lesión medular.
Métodos: Estudio metodológico en cuatro etapas: investigación documental en blogs, revisión integrativa, construcción de la cartilla educativa, validación de contenido con 11 expertos, validación de apariencia técnica con 3 expertos y validación de apariencia con 37 personas del público objetivo. Se consideró un Índice de Validez de Contenido (IVC) mínimo de 0,80.
Resultados: La libreta obtuvo IVC global de 0,91 de los jueces profesionales de salud; 0,87 de los jueces diseñadores gráficos; y 0,94 en validación de apariencia del público objetivo. Expertos y público objetivo sugirieron mejoras en la libreta, acatadas y aplicadas para la versión final del material.
Conclusión: La libreta presentó contenido y apariencia adecuados para promoción de actividad sexual saludable y satisfactoria en portadores de lesión medular.

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Conflicts of interest: article extracted from the doctoral thesis "Educational technology on sexual activity of people with spinal cord injury; construction and validation", presented to the Nursing graduate course of the Federal University of Ceará, Fortaleza, CE, Brazil.

Introduction

Spinal cord injury is one of the most severe health problems which may affect human beings. The physical changes caused by this condition impact on the life of people who have the trauma directly, including the aspect of sexual satisfaction, thus interfering with the psychological and social components as a consequence of an altered self-perception.[1,2]

The worldwide incidence of spinal cord trauma is from 15 to 40 new cases per year per one million people. In Brazil, the estimated incidence is 40 new cases per year per one million people, with 80% of the victims being men and 60% between 10 and 30 years old.[3]

Sexual function rehabilitation is one of the main concerns of paraplegic people. For tetraplegic patients, this worry is secondary, because regaining the motor function is their priority, given the greater impairment of motricity and mobility they suffer.[2,4-6]

Sexual satisfaction is an important aspect of the life of people with spinal cord injury, and different treatment methods for sexual dysfunctions and adaptations in sex life must be considered to improve the quality of life of these people.[6,7]

Healthcare professionals have the responsibility to promote sex education of people with spinal cord injury to reduce the impact of the condition on sexuality and the sexual function and improve the quality of life of these patients. It is necessary to encourage the maintenance of the sexual identity to preserve the basic human needs, since the first hospital admission until the outpatient follow-up.[8]

To achieve this goal, it is essential that people with spinal cord injury receive guidance on possible changes and adaptation methods, because information may effectively contribute to clarifying doubts and reducing fears regarding the new health condition.[1]

There is a lack of educational materials oriented to the sexuality of people with spinal cord injury. It has been observed that studies focused on sex education have been overlooked by those centered at the care to the patients, treatment for the injury, and adaptations to the changes in the acute phase which follows the trauma.[1]

In this scenario, the design of a printed educational booklet may add to this discussion and improve the quality of life of people living with spinal cord injury. Printed educational materials are known to be widely used to disseminate health messages and facilitate the teaching and learning processes, given that the apprehension of information occurs according to the learning pace of each person. In addition, the cost of production per unit is relatively low.[9]

Therefore, the objective of the present paper is to describe the development and validation of an educational booklet about the sexual activity of people with spinal cord injury.

Methods

This was a methodological and development study carried out in four steps: 1. documentary search in blogs, 2. integrative review, 3. development of the educational technology, and 4. material's content and technical face validation by referees and members of the target audience.[10]

In the first step of the study, carried out in June 2016, a documentary search was performed in 16 blogs to determine the educational interests and needs of the target audience. The choice of the blogs was intentional and followed the suggestion of some authors of the present investigation. The focus was to select websites that addressed the sexuality and sexual function of people with spinal cord injury, with posts between 2006 and 2016, in Portuguese, available for free on Google.[11,12] Five blogs with commercial purposes were excluded.

The second phase consisted of an integrative review with six stages: identification of the subject and guiding question of the study, establishment of sampling criteria for inclusion and exclusion of investigations, evaluation of the selected publications, examination of the investigations included in the review, categorization and interpretation of the extracted information, and presentation of the review

and the synthesis of knowledge.[13,14] Publication selection was in accordance with the PRISMA recommendations (Appendix 1).[15]

The search for publications occurred from September to October 2016 in four databases [Cumulative Index to Nursing and Allied Health Literature (CINAHL), Scopus/Elsevier, Medical Literature Analysis and Retrieval System Online (PubMed/MEDLINE), and ScienceDirect/Elsevier] and three virtual libraries [Virtual Health Library (VHL), Scientific Electronic Library Online (SciELO), and Cochrane Library] using the controlled descriptors "sexuality" and "spinal cord injury". The selection covered manuscripts published in peer-reviewed journals between 2006 and 2016, available online as full texts, in Portuguese, English, and/or Spanish. Editorials, letters to the editor, reflexive studies, duplicated publications, and studies which did not address the subject directly were excluded. A search on Google was also carried out. The initial selection had 315 manuscripts, from which 22 were chosen for reflexive reading and synthesis of knowledge.

The third step focused on implementing the development of the booklet following three aspects: language, illustration, and layout and design, which are recommended in the preparation of printed health educational materials.[10] First the texts to be included in the booklet were written, with an objective language, culturally adapted to the target audience. To ensure these characteristics, the authors measured the Flesch readability index (FRI) in all the sentences and paragraphs of the booklet by using the automatic grammar review tool for Portuguese available at the Microsoft Word software. The FRI value considered acceptable was between 70% and 100%, with the defined ranges fairly easy reading from 70% to 80%, easy reading from 80% to 90%, and very easy reading from 90% to 100%.[16] Subsequently, a specialist in graphic design was consulted to create the illustrations and diagramming with the Adobe Illustrator CS3 and Adobe Indesign CS6 (Windows) programs, respectively. The booklet was conceived from October to November 2016 and reviewed in May 2017 after validation.

The fourth step was divided into content validation of the booklet by 11 healthcare professional referees, among whom nine were nurses (four clinical nurses, three rehabilitation nurses, and two professors), one psychologist (clinical), and one physical educator (professor); technical face validation of the booklet by three graphic design referees; and face validation by 37 members of the target audience. The validation by referees occurred from December 2016 to February 2017, and by people from the target audience between March and April 2017.

The selection of referees was carried out through the non-probabilistic convenience snowball method, as suggested by other studies.[17] The professionals identified by this sampling technique were invited to participate in the study, and met adapted preestablished criteria of the field literature: having a minimum professional experience of five years (clinical, teaching, or research); presenting scientific production in the areas of spinal cord injury, neurology, or sexuality; and having an academic degree (specialist, master's, or Ph.D.).[18]

The consulted literature advocates a sample of 30 people to validate an educational booklet with the target audience.[19] Initially, 50 people were selected by convenience, of whom 13 did not send material back within the established deadline of 30 days. Consequently, 37 members of the target audience participated in the study.

The eligibility criteria of the target audience were: people who had a spinal cord injury at least six months earlier (this time gap was important for sexual adjustments), 18 years old or older, literate and with at least four years of formal education,[20] living in the metropolitan area of the city of Fortaleza, state of Ceará, Brazil. Discontinuity criteria were: dropping out of the study, moving to other municipality, and dying.

Three instruments were used in data collection. All of them had a free and informed consent form, an identification form, a clinical data form (for members of the target audience only), and items to evaluate the booklet. The first tool was filled out by referees who were healthcare professionals for content validation, with 46 items organized in eight evaluation aspects (objectives, content, lan-

guage, relevance, illustrations, layout, motivation, and culture). The second instrument was oriented to referees who were graphic designers to validate the technical face and had 28 items distributed into seven evaluation aspects (structure, presentation, illustration, layout, functioning, usability, and efficiency). The third tool, aimed at the target audience and designed for face validation, contained 47 items grouped into five evaluation aspects (objectives, organization, language, face, and motivation).

The validation process used the content validity index (CVI), which was calculated based on three variants: the CVI of individual items (item-level content validity index or I-CVI), the CVI of each evaluated aspect (scale-level content validity index, universal agreement or S-CVI-UA), and the CVI of all the evaluated items (scale-level content validity index, average calculation method or S-CVI-AVE).[17] The items which reached a minimum level of agreement of 80% among referees or members of the target audience and had a binomial test with $p<0.05$ were considered valid, as suggested by experts in the field.[9] This method employed a Likert scale with a score ranging from 1 to 5 points regarding the level of agreement in each item. The answer by referees and members of the target audience could be classified as: (1) Totally disagree, (2) Disagree, (3) Neither agree nor disagree, (4) Agree, and (5) Totally agree.[21]

The study met the ethical aspects advocated by Resolutions 466/2012 and 510/2016 of the Brazilian National Health Council and was approved under report no. 1,615,777.

Results

Booklet development

The content of the booklet was designed from a documentary search and an integrative review. The former consisted of the analysis of 16 blogs of people with spinal cord injury, 168 publications, and 32 comments regarding sexuality and sexual function from which the authors identified interests, educational needs, type of language, and expressions used by the target audience. The latter examined 22 manuscripts, resulting in the synthesis of knowledge of the following subjects: sexuality, sexual function and spinal cord injury, sexual desire in people with spinal cord injury, rehabilitation and sex education, sexual satisfaction, male and female sexual dysfunction, and autonomic dysreflexia.

The educational booklet was entitled "Sexuality in spinal cord injury: what you must know", and the content organized into six chapters: Presentation, Sexuality, Spinal cord injury and sexual function, Treatment for sexual dysfunctions, Male sexual dysfunctions, Female sexual dysfunctions, Promotion of healthy and satisfactory sexual activity for people with spinal cord injury, and Conclusion.

The following phases were followed in designing the material: text development, illustration, layout and design, and diagramming. The authors opted to use a popular language in writing the text of the booklet. When technical words and expressions had to be mentioned, they were defined before being inserted in the text. A few examples of words and expressions that had to be introduced to the audience are: paraplegia, tetraplegia, psychogenic and reflex vaginal vasocongestion, psychogenic and reflex erection, ejaculation, vibrostimulation, and autonomic dysreflexia.

After the elaboration process, the booklet was printed on both sides of the paper, with colored ink, in A4 paper, with landscape orientation, and booklet format. The final version had 148 mm x 210 mm, 44 pages (including the external parts), and was bound as a stapled brochure. Figure 1 presents the cover, presentation, and an example of the booklet content.

Figure 1. Representative illustration of the cover, contents, and diagramming of the booklet "Sexuality in spinal cord injury: what you must know"

Booklet validation

The process of validation of the educational booklet followed its development.

The content validation presented an S-CVI-AVE of 0.88, and most evaluated aspects reached an agreement level higher than 0.80 among the referees. The exceptions were the language and culture aspects, which obtained an S-CVI-UA of 0.74 and 0.64, respectively (Figure 2A). The referees disagreed on the items that addressed clarity and understanding (I-CVI=0.55, p=0.01) and cultural adequacy of the language (I-CVI=0.64, p=0.069) because of the use of abbreviations and scientific expressions.

The technical face validation presented an S-CVI-AVE of 0.87, because most of the examined aspects reached a level of agreement higher than 0.80 among the referees. The only exception was the aspect efficiency, with an S-CVI-UA of 0.75, given that the items concerning the number and characterization of characters and use of visual resources obtained an I-CVI of 0.67 (p=0.386) (Figure 2B).

The face validation of the booklet showed an S-CVI-AVE of 0.94 and all the evaluated aspects ob-

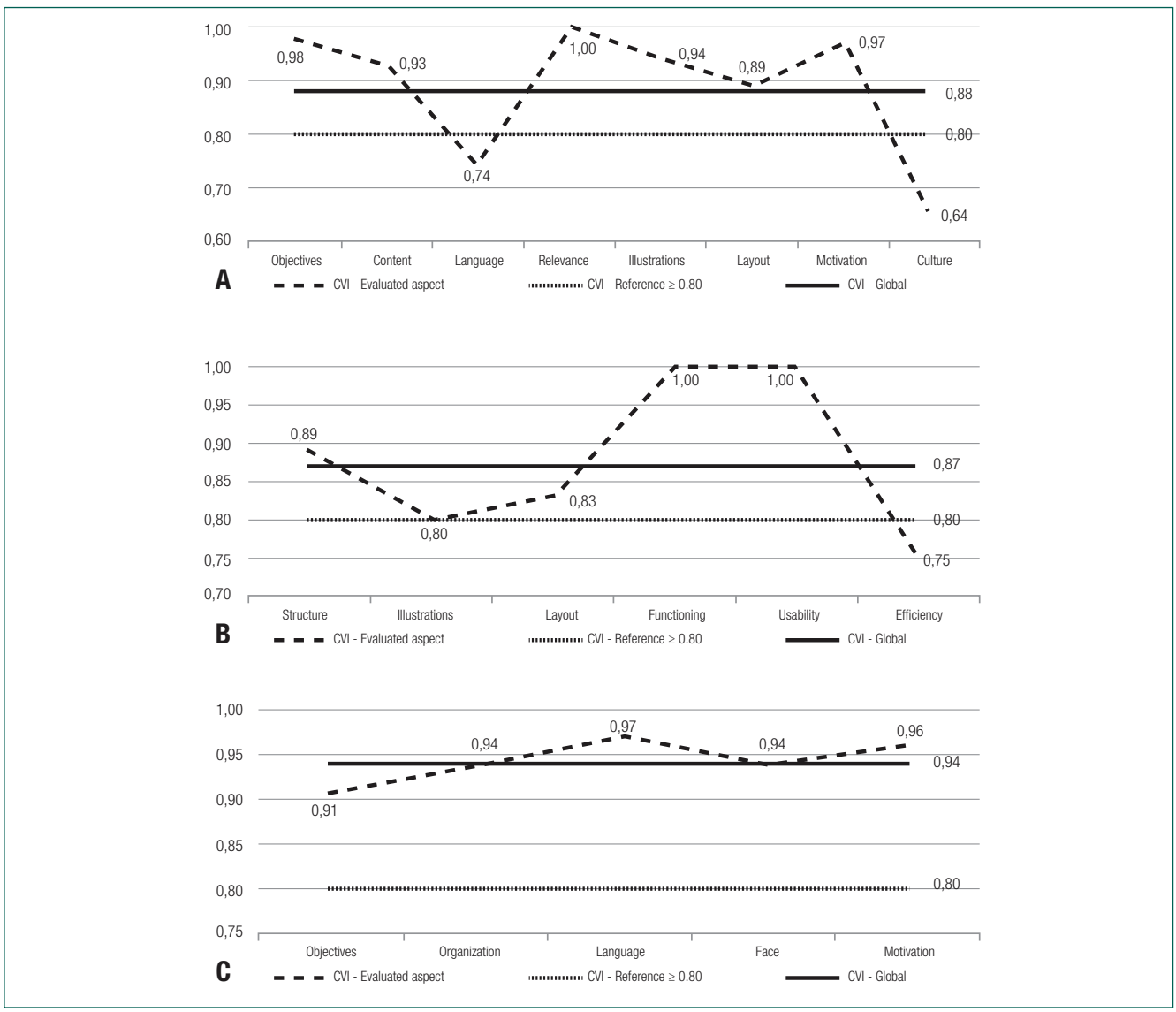

Figure 2 (A). Level of agreement among referees who were healthcare professionals as a function of evaluated content aspects. **(B).** Level of agreement among referees who were graphic designers as a function of evaluated face aspects. **(C).** Level of agreement among members of the target audience as a function of evaluated face aspects

Chart 1. Alterations made in the booklet after recommendations of referees and members of the target audience, and comments on the material by the target audience

Aspects	Alterations based on recommendations of referees and members of the target audience
Language	- The subtitle of the booklet, displayed on the cover, was changed from "what you would like to know" to "what you must know". - The authors reformulated contents and texts about spinal cord injury, classification of spinal cord injuries, changes in the sexual function, rehabilitation, menstruation, and autonomic dysreflexia. - Contents about intestinal control and exams to evaluate male fertility were included. - The expressions "vertebrae" and "dilated corpus cavernosum" were replaced with "spinal cord" and "corpus cavernosum full of blood". Names of active principles were replaced with commercial names of medications. - The abbreviation "AVC" (Portuguese initialism for cerebrovascular accident) was removed.
Layout and design	- The layouts of the charts regarding functions of the body affected by the spinal cord injury, classification of spinal cord injuries, types of erection, and types of vaginal vasocongestion were organized. - The layouts of the captions of the illustration about erogenous areas were organized. - The font color of a word was changed from red to black.
Illustrations	- The illustration on the cover was altered so the characters would hold hands. - An illustration was reformulated to remove the spinal cord center. - A family figure was included about the physical activity topic. - The illustrations about the signs and symptoms of autonomic dysreflexia were redesigned because the original ones were not self-explanatory. - The contrasts in the illustrations about classification of spinal cord injuries were altered.
Aspects	Comments on the evaluation of the booklet by the target audience
Language	*"The booklet is clear and fairly objective, goes straight to the point, no stalling. And it will help many people, for sure" (Participant 2). "The language is very clear and objective, making patients understand everything coherently" (Participant 1). "Yes, the explanations are clear" (Participant 27).*
Layout and design	*"I agree, because it is very organized with its structure, coherence, size, and logical titles for each item" (Participant 10). "The organization is coherent" (Participant 1). "Very well organized" (Participant 27). "The size is excellent to encourage the search for more information" (Participant 35).*
Illustrations	*"The figures are clear and objective, with good and proper appearance" (Participant 1). "All the figures are well illustrated and interesting" (Participant 27). "The figures are very important in the text, that helps to interpret" (Participant 36).*
Evaluation of the booklet	*"It is a great book, full of basic and concrete information" (Participant 36). "The booklet makes people informed to the point of accepting a sex life with another wheelchair user. The addressed information was adapted with much coherence" (Participant 1). "I agree, the booklet offers the possibility of sexual activities for people with spinal cord injury, addresses the necessary and important topics for people to have knowledge and feel fulfilled, ready to live in society" (Participant 10). "The booklet must always be used" (Participant 35). "The use of the booklet clarified many questions I had in my routine and my life" (Participant 36). "Clear and explicit reading, useful for patients, relatives, and other people" (Participant 21). "The material is extremely important and clear to help any person with spinal cord injury" (Participant 17). "What each alteration promotes and how it impacts on sex life is very relative, for both men and women, respecting their limits" (Participant 10).*

tained a level of agreement higher than 0.80 among the target audience (Figure 2C).

Regarding the socioeconomic characterization of the target audience, there was a predominance of men (67.7%), with an average age of 35.8 years (with a standard deviation of 12.2). The most numerous age group was from 20 to 29 years (40.5%), and the average member of the target audience had brown skin (62%). Most members (51.4%) had up to ten years of formal education, 59.5% were Catholic, 62.2% single, 62.2% unemployed, 51.4% retired, and 45.9% had an average income of one minimum wage.

The clinical characterization of the members of the target audience revealed that most of the sample was made up of people with complete paraplegia (54.1%), followed by incomplete paraplegia (40.5%). Two participants were tetraplegic (5.4%). Concerning the level of spinal cord injury, there was a predominance of the thoracic segment of the spinal cord (73%). The main causes of the injuries were perforations by firearms (43.2%) and car accident (37.8%). The average time of spinal cord injury was 12.6 years (with a standard deviation of 7.7 years).

Chart 1 presents the main changes carried out in the booklet after the suggestions of referees and members of the target audience, and the results of the evaluation of the material by the target audience.

Discussion

The development and validation of the educational technology "Sexuality in spinal cord injury: what you must know" followed methodological rigor to ensure that scientific information was accessible and easy to understand by the target audience, according to recommendations in the field literature.[9,10,12,16,21]

The results of the validation process revealed a high level of agreement among referees (S-CVI-AVE>0.80). It means that the experts considered the content, language, layout and design, and illustrations accessible to people with spinal cord injury. Other studies describing the development of health educational booklets also showed similar results regarding the CVI and face evaluation.[9,22,23]

However, in addition to the objective assessment represented by the calculation of the CVI, the authors also valued the subjective aspects of

the evaluation process. The suggestions by referees and members of the target audience were considered a relevant contribution, because they allowed to adapt the material to the preferences and culture of participants and the professional judgment of experts. The changes in language, layout and design, and illustrations were compatible with the used theoretical framework.[10]

In the language domain, abbreviations and scientific expressions were replaced or inserted in the text after being defined, and some excerpts were rewritten. The development of educational materials requires that technical and scientific information is presented with a plain and clear writing, with short and objective messages to facilitate the reading and understanding of the transmitted ideas.[10,23,24]

The layout and design were adjusted regarding organization, colors, and contrasts. Some illustrations were redrawn to picture the reality better and new illustrations were included. The changes were based on the literature that indicates the use of visual resources to introduce extensive and complex concepts didactically, and that they must help understand texts and facilitate the reading, making it more attractive and creative.[10,23,24]

The design of new educational technologies in different health contexts and settings shows that the use of the CVI together with the subjective evaluation of referees and members of the target audience allows the development of high-quality educational material.[9,10,12,16,21,22]

The sample of the target audience evaluated the educational booklet positively, considering its information clear and objective, presented in an organized and coherent arrangement, and complemented by illustrations adequate to the context. In addition, the participants stressed the importance of the sexuality and sexual activity subject to people with spinal cord injury, their relatives, partners, and whoever shows interest in the theme. According to literature, health educational materials must address scientific production, but also take into account the professional judgment and the preferences and culture of participants.[9,10,12,16,21,22] Consequently, a comparison between results of different studies regarding this aspect must be performed with caution, given that people undergoing sexual rehabilitation related to spinal cord injury may express special sexual desires and preferences.

It is important that people with spinal cord injury be informed that there are therapeutic possibilities for sexual dysfunctions and these may vary according to the level and extension of the injury and difficulties experienced by each individual.[25] In this regard, the booklet addresses the concepts of sexuality, spinal cord injury, sexual dysfunction, and treatments, which involve the physical, psychological, and emotional aspects, and relationship and self-care issues.

The reorganization of the sexuality of people with paraplegia or tetraplegia who have neurogenic sexual dysfunction must occur within a comprehensive and multiprofessional perspective, and take into consideration the physical, psychological, and interpersonal circumstances and cultural and gender differences. These aspects are significantly emphasized in the booklet.[1,3,7,8,25]

The booklet stresses the relevance of the participation of partners, when they exist, in the sexual rehabilitation, because their learning process before the new health condition may contribute to a more satisfactory sexual life for the couples. Both people with spinal cord injury and their partners must have the opportunity to address this topic unreservedly with healthcare professionals.[26]

Faced with this scenario, nurses, as members of the healthcare team and professionals responsible for care, have an important role to play regarding this topic. They have to understand the whole process and physical and emotional changes experienced by people with spinal cord injury when sexual activities are resumed to identify, guide, and help these people to cope with problems and overcome them. Additionally, nurses must identify diagnoses, arrange interventions, and elaborate results that help them solve or reduce concerns, to improve the sexual performance of patients and prevent complications.[1,26]

Therefore, offering people with spinal cord injury an easy access to educational materials about sexuality, such as the booklet "Sexuality in spinal cord injury: what you must know", may favor the

awakening of people with this health problem to care in sexual health and promote knowledge, behavior change, and practice of proper health care, notably when the booklet is used with the guidance of healthcare professionals as a tool for sexual health education, facilitating the interaction between professionals and patients. Patients may access the material afterwards, and partners and relatives can benefit from the information in the publication.

The present study had some limitations. One of them was the convenience sampling, which makes results and conclusions applicable to the people in the examined sample, and their interests and needs. The generalization of results must be limited to some circumstances. Another limitation was the lack of pedagogues in the validation process. The number of participants and services could have been higher if more funding were available to develop the investigation.

Conclusion

The objective of the present study was fully met in the description of the process of development and validation of an educational booklet about the sexual activity of people with spinal cord injury. To the best of the authors' knowledge, this educational material is the first focused on this subject and oriented to this specific public. The booklet was validated regarding content and technical face by referees, and technical face by members of the target audience. In the context of health education, the booklet was considered a valid educational material and proper to promote healthy and satisfactory sexual activity in people with spinal cord injury. It may be used in the teaching, research, extension, and specialized clinical care spheres. Regarding the latter, the authors believe that the material may help train professionals and make them reach an effective clinical practice, especially in the sexual rehabilitation of people with spinal cord injury. It is important to stress that researchers who aim at the development and validation of educational materials or research in this area should mind to use theoretical and methodological frameworks that provide the tools with a solid basis and increase their chances to be validated.

Acknowledgments

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Contributions

Silva RA was responsible for the study conception, design, and execution; data collection, analysis, and interpretation; manuscript writing; relevant critical review of its intellectual content; and final approval of the version to be published. Carvalho ZMF contributed to the study conception and design; relevant critical review of the intellectual content of the manuscript; and final approval of the version to be published. Araújo MFM, Ximenes LB, Andrade LM, and Studart RMB contributed to data analysis and interpretation and relevant critical review of the intellectual content of the manuscript. Cruz AG participated in the study's scientific and intellectual conception and data analysis and interpretation. Serra MAAO contributed to the writing, preparation, and approval of the version to be published. All the authors contributed to technical procedures.

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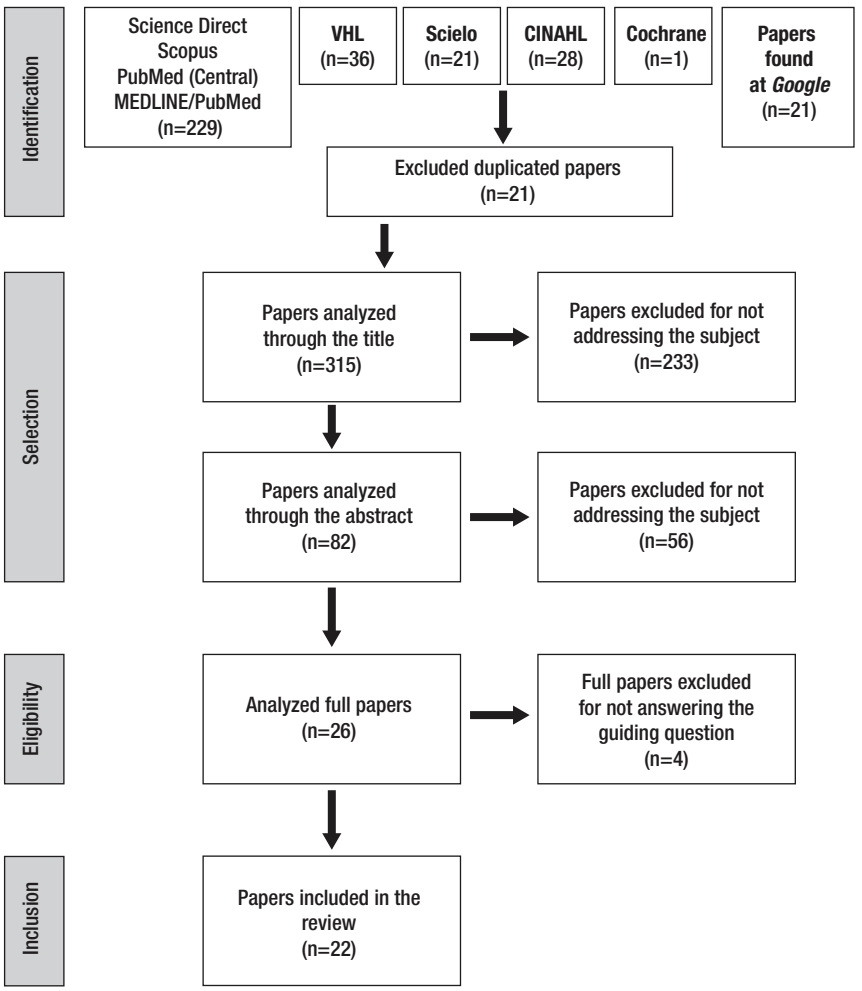
Appendix 1. Chart flow of the process of selection of studies for inclusion in the integrative literature review, carried out based on PRISMA recommendations



ACTA 30 YEARS 1988 - 2018

Original Article

Reliability and validity of the Lasater Clinical Judgment Rubric – Brazilian Version

Confiabilidade e validade da Lasater Clinical Judgment Rubric – Brazilian Version

Confiabilidad y validez de la Lasater Clinical Judgement Rubric – Brazilian Version

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Keywords
Psychometry; Nursing education; Nursing students; Validation studies

Descritores
Psicometria; Educação em enfermagem; Estudantes de enfermagem; Estudo de validação

Descriptores
Psicometría; Educación en enfermería; Estudiantes de enfermería; Estudio de validación

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Abstract

Objective: To evaluate the reliability and validity of the Lasater Clinical Judgment Rubric - Brazilian Version in a sample of nursing students.

Methods: Methodological design study conducted at a public institution of higher education in the southeast region of Brazil. Preliminarily, was analyzed the clarity of behaviors described by eight students in each level of the 11 dimensions of the instrument. Next, was collection of data on the evaluation of psychometric properties with self-application by 179 students. Participants were grouped in junior (1st and 2nd terms n=115) and senior (3rd and 4th terms n=64) students. The following psychometric properties were analyzed: discriminant validity, reliability and dimensionality.

Results: Through the Brazilian version of the rubric were differentiated the two groups of students (p-value <0.05) in the 11 dimensions evaluated. Stability was verified by test-retest (Intraclass Correlation Coefficient – ICC: 0.88). Internal consistency was obtained for the global instrument (Cronbach's alpha: 0.899) and for phases of Noticing (α=0.75), Interpreting (α=0.64), Responding (α=0.78) and Reflecting (α=0.63). Dimensionality validity by confirmatory factorial analysis (CFA) obtained results of composite reliability (CR) above 0.7, and average variance extracted (AVE) higher than 0.5 in all phases. The discriminant validity of the factorial model by the Fornell-Larcker criterion and cross loadings confirmed the theoretical structure of the rubric original version.

Conclusion: The evaluation of the psychometric properties of the Brazilian version of the rubric showed evidence of reliability and construct validity of the instrument for measuring the development of nursing students' clinical judgment.

Resumo

Objetivo: Avaliar a confiabilidade e validade da Lasater Clinical Judgment Rubric – Brazilian Version em uma amostra de estudantes de enfermagem.

Métodos: Pesquisa com delineamento metodológico, realizado em uma instituição pública de ensino superior da região sudeste do Brasil. Preliminarmente, foi analisada a clareza dos comportamentos descritos em cada nível das 11 dimensões do instrumento, por oito estudantes. A seguir, deu-se a coleta de dados relativos a avaliação das propriedades psicométricas com auto aplicação a 179 estudantes. Os participantes foram agrupados em iniciantes (1ª e 2ª séries n=115) e concluintes (3ª e 4ª séries n=64). Foram analisadas as propriedades psicométricas: validade discriminante, a fidedignidade e a dimensionalidade.

Resultados: A versão brasileira da rubrica diferenciou os dois grupos de estudantes (p-valor <0,05) nas 11 dimensões avaliadas. A estabilidade foi verificada pelo teste-reteste (ICC de 0,88). A consistência interna foi obtida para o instrumento global (alpha de Cronbach, de 0,889) e para as fases de reconhecimento (α=0,75), interpretação (α=0,64), resposta (α=0,78) e reflexão (α=0,63). Validade da dimensionalidade pela análise fatorial confirmatória (AFC) obteve resultados de confiabilidade composta (CC) acima de 0,7 e a variância média extraída (AVE) superiores a 0,5, em todas as fases. A validade discriminante do modelo fatorial pelo critério de Fornell-Larcker e pelas cargas cruzadas confirmaram a estrutura teórica da versão original da rubrica.

Conclusão: A avaliação das propriedades psicométricas da versão brasileira da rubrica mostrou evidências de confiabilidade e validade de construto do instrumento para medir o desenvolvimento do julgamento clínico do estudante de enfermagem.

Resumen

Objetivo: Evaluar confiabilidad y validez de la Lasater Clinical Judgement Rubric – Brazilian Version en muestra de estudiantes de enfermería.

Métodos: Investigación metodológica realizada en institución pública de enseñanza superior del sudeste de Brasil. Previamente fue analizada la claridad de los comportamientos descriptos en cada nivel de las 11 dimensiones del instrumento por los estudiantes. Luego se realizó recolección de datos relativos a evaluación de propiedades psicométricas con auto aplicación por 179 estudiantes. Los participantes fueron agrupados en novatos (1º y 2ª año, n=115) y avanzados (3º y 4º año, n=64). Fueron analizadas las propiedades psicométricas: validez discriminante, fiabilidad y dimensionalidad.

Resultados: La versión brasileña de la rúbrica diferenció a ambos grupos de estudiantes (p-valor <0,05) en las 11 dimensiones evaluadas. Estabilidad verificada por test-retest (ICC de 0,88). Consistencia interna obtenida para el instrumento global (alfa de Cronbach de 0,889) y para las fases de reconocimiento (α=0,75), interpretación (α=0,64), respuesta (α=0,78) y reflexión (α=0,63). La valides de dimensionalidad por análisis factorial confirmatorio (AFC) obtuvo resultados de confiabilidad compuesta (CC) mayores a 0,7 y varianza extraída media (AVE) superiores a 0,5 en todas las fases. La validez discriminante del modelo factorial por criterio de Fornell-Larcker y por cargas cruzadas confirmaron la estructura original de la versión original de la rúbrica.

Conclusión: La evaluación de las propiedades psicométricas de la versión brasileña mostró evidencias de confiabilidad y validez de constructo del instrumento para medir el desarrollo del juicio clínico del estudiante de enfermería.

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Conflicts of interest: nothing to declare.

Introduction

Nursing training for accurate care practice and safe care requires that professionals have assertive mental attitudes in clinical reasoning, judgment and decision making. The development of cognitive and technical ability and improvement of these actions are fundamental to identify individuals' needs through diagnostic reasoning and the direction of the care plan for therapeutic reasoning.[1,2]

When dealing with clinical reasoning, particularly the processes by which nurses and other professionals make their judgments, in the process of generating hypotheses, Tanner[3] considers the deliberation on evidences and the use of reasoning by recognition of pattern and intuitive understanding. Clinical judgment is a complex activity that requires professionals' flexibility and ability for recognizing important aspects in an undefined clinical situation for a proper interpretation of findings and a satisfactory answer. It also requires nurses' knowledge of pathophysiology, of patients' clinical manifestations, and the understanding of patients' and family's experiences of illness, their physical, social and emotional strengths, and coping resources.

Thus, when nurses initiate care, their clinical judgment is influenced by previous experiences, knowledge about patients and their pattern of response, the context in which the situation occurs, and the culture of the health unit. Moreover, by standards of reasoning, whether analytical, intuitive and/or narrative, and reflection on practice.[3] According to the Clinical Judgment model proposed by Tanner[3], the actions developed by nurses go through four phases, namely: Noticing ; Interpreting; Responding, and Reflecting.

The complexity of cognitive ability, whether from clinical reasoning and/or clinical judgment, has generated some questions in the academic community about which teaching strategies favor the acquisition of this skill and which types of assessment tools can be used. These concerns have encouraged researchers from different teaching contexts and countries to investigate this issue.[4-6] Thinking about an assertive nurse care practice leads to a review of the way of teaching, monitoring and evaluating the cognitive development process. A view on how nursing students identify and interpret individual needs for directing actions is critical for safe care.

The interest in nursing graduates' training and the need to use instruments for performance evaluation of the teaching-learning process, explains the choice for the Lasater Clinical Judgment Rubric (LCJR). It was developed by Lasater[7] and adapted to the Brazilian culture[8] as Lasater Clinical Judgment Rubric- Brazilian Version (LCJR-BV). This instrument allows a continuous and formative evaluation of the level of development of nursing students' clinical judgment.

The formative evaluation method allows the monitoring of learning in an individualized way, identification of gaps, self-assessment, and regulation of the knowledge acquisition process.[9] For this purpose, the monitoring and evaluation of learning requires the use of a reliable and valid instrument.

In Brazil, some studies on validation of instruments in the nursing area have been directed to health education in clinical practice[10] and educational practices in clinical simulation,[11] among others. However, there is still lack of research on valid instruments for the Brazilian culture that evaluate clinical judgment.

The aim of this study was to evaluate the reliability and validity of the LCJR-BV in a sample of nursing students.

Reference model of Tanner and the LCJR

In the LCJR, was used the Tanner model[3] that assesses clinical judgement performance in four phases, namely: Noticing; Interpreting; Responding; and Reflecting. The first three are part of thinking-in-action skills, and the last one comprises thinking skills about the action, which is a reflection occurring after responding to the situation.

In the Noticing phase, are evaluated the focused observation, recognizing deviations from expected patterns, and information seeking. In the Interpreting phase, is considered the prioritization and understanding of data. The Responding phase

reflects dimensions targeted for calm and confident performance, clear communication, well planned intervention/flexibility and being skillful. In the last phase, Reflecting, are considered aspects related to evaluation/self-analysis and commitment to improvement.[7]

For each phase, the LCJR describes two to four dimensions, totaling 11. In each dimension, students' behaviors can be evaluated during the learning process, in the following four levels: beginning, developing, accomplished and exemplary. At each level, 1 point is assigned for beginning; 2 points for developing, 3 points for accomplished; and 4 points for exemplary. The minimum score is 11 and the total score is 44 points.[7]

In several studies, the Tanner model[3] and the LCJR[7] have been applied as a guide for structuring students' reflection in the development of clinical judgment skills and for monitoring their progress throughout their clinical experience. They have been used in educational simulation programs for the improvement of clinical judgment capacity of experienced and newly formed nurses.[6,12-15]

The rubric is a method of guided reflection for evaluating the development of clinical judgment and an instrument used by students for assessment of their own progress by identifying areas that need improvement in order to be successful.[16] Additionally, using the LCJR allows a common language between teacher and student, the collaborative work for improving the performance of clinical skills, and helps students to feel more confident and competent for initiating care practices.[15]

In the professional environment, the LCJR allows nurses' performance evaluation in the conclusion of an educational activity by favoring the definition of performance criteria and self-assessment of strengths and weaknesses regarding the competence in the ability of clinical judgment during reflective practice.[17]

The cultural and semantic validation of the LCJR was performed in Brazil, and the instrument was named LCJR-BV. It was used to analyze five videos in a situation of high-fidelity simulation regarding performance of nursing students' clinical judgment. Three independent judges participated in this analysis and obtained satisfactory results in both intraobserver concordance (Kappa= 0.834; p≅00.000; Kappa = 0.764; p≅0.00; kappa 0.823; p≅0.00, respectively) in two analyzes with 15-day intervals, as in interobserver concordance (Kappa= 0.828; p≅ 0.00). However, the author recommends tests for evaluation of other psychometric properties of the instrument, the purpose of this study.[18]

The assessment and follow-up of the development of nursing students' clinical judgment is essential to ensure consistent clinical training. To this end, it is necessary to guarantee the availability of an instrument with accurate psychometric characteristics. If such an instrument is valid, it is expected to contribute with students' self-assessment and reflection in relation to their performance, and be a sign of what is expected from them in terms of developing clinical judgment of excellence throughout their training.

Methods

This is a methodological design study addressing the development, validation and evaluation of research instruments and methods[19] with the aim of evaluating the psychometric properties of the LCJR-BV instrument. It was initiated after the agreement of using the Lasater Clinical Judgment Rubric by the Brazilian version authors[8] and the American original.[7] Nursing students of a public institution located in the southeastern region of Brazil participated in the study.

In order to evaluate a suitable instrument for participants, nursing students' comprehension of the rubric items was preliminary investigated regarding the clarity of behaviors described in each level of the 11 dimensions of the LCJR-BV. Eight students participated in this process (two by term), and this was a convenience sample.

For each of the 11 LCJR-BV dimensions, the participant was asked to mark 'yes' or 'no' for clarity, and include a suggestion or comment for the corresponding item in case of a negative answer. They following responses emerged: in the dimension 'recognizing deviations from expected patterns', the

term 'obvious deviations' was considered unclear by a student, and it was changed to 'evident deviations'. Other students suggested changes in domains definitions: 'calm confident manner' and 'well planned intervention/flexibility' at developing level; 'being skillful', 'evaluation/self-analysis' and 'commitment to improvement' at beginning level. However, these suggestions were disregarded because they reflected changes in content and contained personal interpretations of value judgments. In view of these findings, the LCJR-BV was considered suitable for the investigation of psychometric properties.

Data collection with the purpose of evaluating the discriminant validity, reliability and dimensionality of the LCJR-BV occurred in October and November 2016, after approval of the institution and the ethics committee. The invitation to participants was made in the classroom, when were presented the study objectives, the instruments for demographic characterization, and the Lasater Clinical Judgment Rubric - Brazilian Version. Eligibility criteria were age above 18 years, and having some practical experience with outpatient or hospital nursing care. Participants involved in the previous phase of the study did not participate.

For descriptive and statistical data analysis, was used the SPSS software, version 18.0. The Shapiro-Wilk test was used to check the normality of data. Participants were included in two groups, namely: juniors, those enrolled in 1st and 2nd terms; and seniors, those in 3rd and 4th terms. Discriminant validity was assessed using the non-parametric Mann-Whitney test by comparing the scores of junior and senior students. A significance level of 5% was adopted.

The instrument trustworthiness or reliability was assessed through internal consistency by Cronbach's alpha and simple correlation by test-retest. For the test-retest, was adopted the period of two weeks after the first application, and it was measured by intraclass correlation coefficient (ICC).[20] Values higher than 0.75 are indicative of excellent agreement;[21] values 0.4≤ICC<0.75, satisfactory agreement; and ICC< 0.4 weak agreement.[22]

For evaluation of the LCJR-BV dimensionality, was used the Confirmatory Factor Analysis (CFA) for verification of the number of latent traits (theoretically defined). Structural equation models were used by considering Partial Least Squares (PLS) as an estimation method, and using the Smart PLS 2.0 software.[23] The factorial model analysis comprised the following two steps: analysis of convergent and discriminant validity of the LCJR-BV.

In the convergent validity analysis of the factorial model, were evaluated the AVE (Average Variance Extracted) results for each of the model factors. AVE values higher than 0.5 indicate that the model converges to a satisfactory result.[23] Subsequently, were evaluated the values of factorial load between items and their respective factors. Items with loads lower than 0.5 are considered as candidates to leave the factorial model. It is defined that loads should be at least greater than 0.5 and ideally greater than 0.7.[24] Another precision indicator used was the composite reliability that evaluates the quality of an instrument structural model. It was a more robust indicator when compared to Cronbach's alpha.[25] The result above 0.7 is considered as satisfactory.[23]

In the evaluation of discriminant validity, was adopted the Fornell-Larcker method[26]. It compares the square roots of AVEs with the correlation values between factors. This model has discriminant validity if the square roots of AVEs are larger than correlations between factors. Another criterion to evaluate discriminant validity was cross loadings analysis. In this case, it was observed if the factorial load of a given item was higher in the factor in which it was initially allocated than in the other factors of the model.

The study was approved by the institution and the Research Ethics Committee under CAAE protocol number 56124216.1.0000.5505. The ethical and legal aspects of Resolution number 466/2012 were respected.

Results

Of the 179 participants, 161 (89.94%) were female, 115 were classified as juniors (1st and 2nd terms) and 64 were seniors (3rd and 4th terms). The mean age was 22.1 years (minimum of 18 years old; maximum of 49 years old). Of the nursing students,

76.54% experienced practical activities in the outpatient clinic and 95.53% in the hospital setting.

Discriminant validity is used to verify if the instrument differentiates the two distinct groups. In the comparison test between the evaluated grades/terms (Table 1), the difference (p-value <0.05) in all evaluated dimensions became evident. The distribution comparison test was significant in all domains evaluated (p-value <0.001), which indicates the evaluation of the senior group is significantly higher than that of the junior group in all domains under study.

Table 1. Distribution of scores (mean and standard deviation) of LCJR-BV dimensions according to nursing students grouped in juniors and seniors (n=179)

Evaluated dimension	Grade/term		*p-value**
	Juniors	Seniors	
1.Focused observation	2.68±0.81 §	3.36±0.65 §	<0.001
2.Recognizing deviations from expected patterns	2.53±0.68 §	3.17±0.52 §	<0.001
3.Information seeking	3.04±0.84 §	3.58±0.53 §	<0.001
Noticing	8.25±1.86#	10.11±1.20 §	<0.001
4.Prioritizing data	2.68±0.78 §	3.17±0.58 §	<0.001
5.Making sense of data	2.61±0.75 §	3.19±0.43 §	<0.001
Interpreting	5.29±1.30 §	6.36±0.78 §	<0.001
6.Calm confident manner	2.74±0.75 §	3.28±0.60 §	<0.001
7.Clear communication	2.92±0.76 §	3.56±0.50 §	<0.001
8.Well planned intervention/flexibility	2.99±1.02 §	3.69±0.47 §	<0.001
9.Being skillful	2.74±0.69 §	3.20±0.44 §	<0.001
Responding	11.39±2.44#	13.73±1.30#	<0.001
10.Evaluation/self-analysis	2.79±0.74 §	3.33±0.54 §	<0.001
11.Commitment to improvement	3.17±0.70 §	3.47±0.53 §	<0.013
Reflecting	5.97±1.24 §	6.80±0.84 §	<0.001
Total	30.9 ± 5.7#	37 ± 2.85#	<0.001

p-value obtained by Mann-Whitney test; # Shapiro-Wilk test p≥0.05; § Shapiro-Wilk test p<0.05

The overall internal consistency of the LCJR-BV obtained Cronbach's alpha value of 0.889, and values in the phases were the following: Noticing (α=0.75), Interpreting (α=0.64), Responding (α=0.78) and Reflecting (α=0.63). Regarding stability verified by the test-retest with 27 participants of the 2nd term, there was a total correlation of 0.88. In the different phases of development of clinical judgement, results were the following: Noticing (ICC=0.57); Interpreting (ICC=0.61); Responding (ICC=0.85); and Reflecting (ICC=0.88).

In order to evaluate the dimensionality validity of the LCJR-BV, the measurements of composite reliability (CR) and average variance extracted (AVE) were initially calculated with the purpose of evaluating the convergent validity of the factorial model. The AVE values of each of the model factors were greater than 0.5 (Noticing=0.66; Interpreting=0.73; Responding=0.60; and Reflecting=0.73), and composite reliability results were higher than 0.7 (Noticing=0.85; Interpreting=0.84; Responding=0.86; and Reflecting=0.84), which indicates the model converges to a satisfactory result.

In the analysis of discriminant validity of the factorial model by means of the Fornell-Larcker criterion, square root values of the AVEs were higher than the correlations between factors (Table 2) thereby showing a satisfactory result.

Table 2. Discriminant validity of the LCJR-BV by the Fornell-Larcker criterion

	Fornell-Larcker criterion			
	Noticing	Interpreting	Responding	Reflecting
Noticing	**0.81**			
Interpreting	0.65	**0.85**		
Responding	0.68	0.69	**0.77**	
Reflecting	0.44	0.58	0.65	**0.85**

Note: Diagonal values highlighted in bold indicate the square root of the average variance extracted (AVE)

In the cross loading analysis (Table 3), the factorial loads of the LCJR-BV items were more expressive in the factor in which they are allocated in the instrument than in the other factors of the structural model evaluated.

Table 3. Discriminant validity of the LCJR-BV by cross loadings

	Cross loadings			
	Noticing	Interpreting	Responding	Reflecting
Dim1	0.76	0.50	0.50	0.25
Dim2	0.83	0.58	0.53	0.35
Dim3	0.85	0.51	0.61	0.45
Dim4	0.46	0.80	0.46	0.40
Dim5	0.63	0.91	0.69	0.57
Dim6	0.46	0.41	0.70	0.40
Dim7	0.52	0.56	0.83	0.52
Dim8	0.60	0.62	0.81	0.53
Dim9	0.51	0.52	0.75	0.55
Dim10	0.44	0.51	0.61	0.87
Dim11	0.30	0.48	0.49	0.83

Note: Diagonal values highlighted in bold indicate factorial loads of the most significant LCJR items in the factor in which they are allocated in the instrument

Discussion

Studies in different countries have evaluated the LCJR construct validity in order to demonstrate if the instrument actually measures what it is proposed to measure through discriminant validity and factorial analysis. By considering discriminant va-

lidity, the study by Adamson[27] evidenced that the LCJR instrument differentiated nursing students into three levels of proficiency (low expectation, in expectation and above expectation) when evaluated by the examiner in simulation scenarios. The Brazilian version described above was considered valid when differentiating the level of performance of clinical judgment between junior and senior students (Table 1).

The reliability of the LCJR was verified through internal consistency analysis and test-retest, and studies indicate the instrument reliability through Cronbach's alpha presented values between 0.810 and 0.974.[27-31] In the LCJR version for the Korean culture (K-LCJR), was obtained a Cronbach's alpha value for the total instrument (0.910), and for phases of Noticing (α=0.736), Interpreting (α=0.722), Responding (α=0.807) and Reflecting (α=0.683).[31] The Korean study also pointed that 152 students participated in three simulation scenarios (nurses-father-son interaction; febrile child and emergency measures for newborn). Of these, the febrile child scenario was used for data analysis. Students watched the videos recorded during the simulation for self-assessing their performance by using the K-LCJR.[31] In the initial validation study for the Brazilian version,[8] authors obtained a Cronbach's alpha of 0.892, and the following values in the phases: Noticing (α=0.816), Interpreting (α=0.714), Responding (α=0.795) and Reflecting (α=0.655). In the present study, Cronbach's alpha was 0.899 for the total value of the instrument. In the phases, values were the following: Noticing (α=0.75), Interpreting (α=0.64), Responding (α=0.78), and Reflecting (α=0.63). Findings of this study and those of the other studies allow to conclude the existence of a satisfactory level of internal consistency for the measurement instrument.[23] The analysis of composite reliability was not available in the aforementioned studies, but indicated the LCJR-BV has good quality in the proposed structural model

In the present study, in the test-retest, were obtained ICC values below 0.75 in the clinical judgment phases (observation and interpretation). This fact may be related to the influence of internal or external factors of subjects by considering these domains require cognitive ability for the analysis and synthesis of objective and subjective data, which are still in progress in this phase of participants' academic development. However, the total ICC value of 0.88 indicated an excellent reliability score.[21]

In the confirmatory factorial analysis, was confirmed the original theoretical framework of the LCJR proposed by Lasater[7] in four phases of clinical judgement development. Three dimensions were confirmed in the Noticing phase, namely: focused observation, recognizing deviations from expected patterns and information seeking; in the Interpreting phase, two dimensions: prioritizing data and making sense of data; in the Responding phase, four dimensions: calm confident manner, clear communication, well-planned intervention/flexibility and being skillful; and in the last phase, Reflecting, two dimensions: evaluation/self-analysis and commitment to improvement.[8,18]

In the face of results of the present study and those of Nunes,[8] the LCJR-BV can be considered validated for the Brazilian culture and recommended as an instrument to monitor the evolution of clinical judgment development. This can be done in an observational way by the teacher or self-applied by students themselves in activities of the training process in the different care contexts.

In spite of the good results evidenced in the present study, and given the statistical analyzes, coherence of the proposed instrument and the theory adopted in its construction, in our field, studies correlating the results of the rubric with another instrument measuring the same phenomenon have not been identified yet. In this study, students used the LCJR-BV in the mode of self-assessment of clinical practice performance.

Conclusion

The analysis of the LCJR-BV psychometric properties, that is, discriminant validity, reliability and dimensionality, has demonstrated evidence of reliability and validity of the instrument for evaluating the development of nursing students' clinical judgment.

Collaborations

Morais SCRV, Nunes JGP, Lasater K, Barros ALBL and Carvalho EC contributed to the project design, data analysis and interpretation, article writing, critical review of the intellectual content and final approval of the version to be published.

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Original Article

Deciding "case by case" on family presence in the emergency care service

Decidindo "caso a caso" a presença familiar no serviço de atendimento emergencial

Decidiendo "caso por caso" la presencia familiar en el servicio de atención de urgencias

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Keywords
Family; Health personnel; Emergency medical services; Emergency nursing; Family nursing

Descritores
Família; Pessoal de saúde; Serviços médicos de emergência; Enfermagem em emergência; Enfermagem familiar

Descriptores
Familia; Personal de salud; Servicios médicos de urgencia; Enfermería de urgencia; Enfermería de la familia

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Abstract
Objective: To understand how physicians and nurses experience and perceive the presence of families in the emergency care service.
Methods: This was a qualitative study that used symbolic interactionism as a theoretical reference, and grounded theory as a methodological reference. Twenty professionals participated – equally representing physicians and nurses - working in two emergency rooms located in the south of Brazil. Data were collected between October of 2016 and February of 2017, by means of interviews.
Results: The existence of a social culture of family exclusion was identified, widely diffused and practiced by professionals. However, families sometimes remain with their loved ones in the emergency room, since professionals analyze and decide "case by case", considering different aspects throughout the care process.
Conclusion: Multiple aspects are related in determining family presence during emergency care for physicians and nurses. Thus, a single directive on the presence of the family is not prudent. In fact, it is suggested that each health unit develop its protocols, considering local particularities.

Resumo
Objetivo: Compreender como médicos e enfermeiros vivenciam e percebem a presença da família no serviço de atendimento emergencial.
Métodos: Estudo qualitativo que utilizou o Interacionismo Simbólico como referencial teórico e a Teoria Fundamentada nos Dados como referencial metodológico. Participaram 20 profissionais – divididos equitativamente entre médicos e enfermeiros – que atuavam em duas Salas de Emergência localizadas no Sul do Brasil. Os dados foram coletados entre outubro de 2016 e fevereiro de 2017, por meio de entrevistas.
Resultados: Identificou-se a existência de uma cultura social de exclusão familiar, amplamente difundida e praticada pelos profissionais. Contudo, às vezes, as famílias permanecem com seus entes queridos na Sala de Emergência, visto que os profissionais analisam e decidem "caso a caso", considerando diferentes aspectos ao longo do processo assistencial.
Conclusão: Para médicos e enfermeiros múltiplos aspectos estão relacionados na determinação da presença familiar durante o atendimento emergencial. Assim, não é aconselhável uma diretiva única para a presença da família. Em realidade, sugere-se que cada unidade de saúde elabore seus protocolos considerando as particularidades locais.

Resumen
Objetivo: Comprender cómo médicos y enfermeros experimentan y perciben la presencia familiar en el servicio de atención de urgencias.
Métodos: Estudio cualitativo, aplicando el Interaccionismo Simbólico como referencial teórico, y la Teoría Fundamentada en los Datos como referencial metodológico. Participaron 20 profesionales –equitativamente divididos entre médicos y enfermeros– actuantes en dos Servicios de Urgencias del Sur de Brasil. Datos recolectados de octubre 2016 a febrero 2017 mediante entrevistas.
Resultados: Se identificó la existencia de una cultura social de exclusión familiar, ampliamente difundida y practicada por los profesionales. Igualmente, a veces, las familias permanecen con sus seres queridos en el Servicio de Urgencias, dado que los profesionales analizan y deciden "caso por caso", considerando diferentes aspectos a lo largo del proceso de atención.
Conclusión: Para médicos y enfermeros, múltiples aspectos se relacionan con la determinación de la presencia familiar durante la atención de urgencia. Por ello, no es aconsejable una directiva única sobre presencia familiar. En realidad, se sugiere que cada unidad de salud elabore sus protocolos considerando sus propias características.

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Introduction

The presence of the family in emergency care, during invasive procedures - including maneuvers of cardiopulmonary resuscitation - has been studied in several parts of the world.[1-5] However, despite the scientific evidence suggesting that this presence is positive for professionals, family and patients,[6,7] and, with the endorsement and encouragement of scientific critical care societies increasing, health professionals continue to strongly oppose this practice.[2]

Sometimes, the presence of the family is not allowed because the professionals fear that the relatives will: be impacted by the scenes occurring in the emergency service; interfere with the performance of procedures; prosecute institutions and professionals for misinterpreting clinical decisions; breach confidentiality of information relating to care; and hamper the teaching of resident staff.[2,4]

Other factors that negatively influence this practice include: lack of policies and specific guidelines to support the health professionals; and lack of infrastructure and support staff that welcome family members in the emergency room (ER).[3] Thus, in several units, the presence of the family is informal, unsystematic and inconsistent, depending mainly on the professional's self-confidence.[1] This triggers unfavorable outcomes in supporting family members, and causes negative perceptions on those involved with the family presence.[2]

In this sense, studies demonstrate potential disadvantages of this practice from the professionals' perspectives[7,8] or, at the most, dichotomize the understanding of the phenomenon into benefits versus limitations/losses.[9] The multifaceted perceptions and experiences of professionals who experienced emergency care, witnessed by the relative of an adult patient, are minimally explored [1,10] This limits the understanding of the reasons why physicians and nurses invite/allow families to accompany the patient during the care provided.

As nurses and physicians work collaboratively in emergency care, both can benefit from a better understanding of this phenomenon.[1,10] Based on the evidence presented, the objective of the study was to understand how physicians and nurses experience and perceive family presence in the emergency care service.

Methods

This was qualitative research with symbolic interactionism as a theoretical reference, and grounded theory (GT) as a methodological reference. It was conducted in the ER of two public institutions that did not have institutional policies or systematic routines involving the presence of family in the service, with the decision left to the professionals. The two units allow the entrance of two people during the visiting period, which occurs twice a day, for 30 minutes.

These units were chosen due the differences in their physical structure, professional profile, and type of clinical patients, which provided greater data variability. For example, one of them is linked to a university hospital that is a high complexity reference for the 30 municipalities of the 15th Regional Health District of Paraná, attending to more serious, complex cases, and victims of trauma and violence; the other is part of the Municipal Emergency Care Unit, which mainly attends patients with clinical conditions and acute chronic diseases.

The data were collected between October of 2016 and February of 2017, with interviews that lasted 20 to 45 minutes, performed by the first author, who had no relationship with the interviewees, although he had worked in emergency services, as had the other authors. The interviews were guided by the following guiding question: *What is your experience/perception of the presence of family during the provision of emergency care?*

The only inclusion criterion adopted was to be a physician or nurse working in one of the ERs. Those who worked in the sector for less than three months were excluded, because it was believed that their contributions would be greater only after this period. As recommended by authors of GT,[11] theoretical sampling guided the data collection, and theoretical saturation determined the number of participants in each group. Twenty professionals were interviewed. The sample groups are shown in chart 1.

Chart 1. Presentation of the sample groups participating in the study

Sample group	Participating professionals
G1	Three nurses and two physicians working at ER1, located in a Emergency Care Unit (ECU), who pointed out the precarious infrastructure and management conditions as interfering with the invitation of the families. Analyzing the information of these participants showed that it was necessary to seek professionals who experienced different infrastructure conditions, with a better technological contribution and greater number of beds and professionals in the service.
G2	Three nurses and six physicians working at ER2, at a university hospital. Although to a lesser extent, for these professionals the aspects related to the management of the service also acted as intervenient variable in the presence of families. Thus, when identifying the saturation of the initial categories of this group, expanding the understanding of the phenomenon by including the managers of each of the participating units was attempted.
G3	Two nurses, each of whom was a manager of the unit, who were approached to expand knowledge regarding the management of the service in relation to the potentialities and fragilities for the realization of the family presence in the ER.
G4	Two nurses and two physicians, a physician and a nurse from each unit, acted as validators of the theoretical construct. Validation occurred after the completion of data analysis, and identification of the central category.

In agreement with the constant comparative method, the interviews were performed concomitantly with data analysis and the development of the sample groups.[11] All statements were audio-recorded. As the interview was transcribed, and the lines were edited, floating readings were performed, in order to understand the content of the text; an open codification began thereafter, using QDA Miner® software and the development of memos and diagrams.

The axial codification allowed a grouping of codes by conceptual similarities and differences, beginning with the identification of the categories' properties, with the establishment of provisional concepts. Finally, the integration process allowed the densification of the categories and the aggregation of the concepts (Chart 2).

Chart 2. Representation of the data analytical process

Part of the analysis corpus	Sub-category	Category
The climate of the emergency room is complicated; it is a busy environment, with aggressive procedures, where everything happens very fast. Maybe, the scenario may seem very unusual for the family, which distances the family from the emergency service (G4, Health Professional 20 - Nurse).	Climate in the emergency space	Analysis of aspects concerning the environment and context
[...] *Sometimes, you do not even see the family around you, just because your focus is the patient* (G2, Health Professional 7 - Physician).	Philosophy of care	
We need a structure that enables greater privacy, because I believe that if the person is there, he/she is there to accompany her loved one and not the patient next door. So, this privacy is needed. If the structure does not provide this, the family will experience the care and suffering of the other one, as well (G1, Health Professional 1 - Nurse).	Physical structure	
Today, we had a patient in the emergency room and no monitor was working! The nurses tried to change it, they messed around, but nothing worked. Will the patient die for lack of a monitor? Of course not! But, if the family witnesses this, not having materials, will they understand that? Without materials there is no way to put the family in the room (G1, Health Professional 5 - Physician).	Medical and hospital supplies	
A little is related to the protagonist of the subject. He, as a professional, chooses whether he will maintain a posture for bringing the family closer or if will further alienate the family [...] So, it depends on the professional's attitude (G3, Health Professional 16 - Nurse manager).	Human resources	
[...] *But you also have to remember the issue of contamination. Placing everyone inside the emergency room is critical, everything can be found there, for example, every now and then a patient suspected of having meningitis or tuberculosis* (G1, Health Professional 3 – Physician).	Infection related to health care	
The critical patient, terminally ill, you have to argue, "Am I going to invest? Will I do cardiac compression on this patient who had a cardiac arrest? " The family member may say, "My father always said that he did not want to be intubated, that he did not want to go to an ICU." The physician says, "Look, I need to do this" and the family says, "No, but he didn't want to." So we stopped here! It would be the family itself helping in clinical decisions (G2, Health Professional 14 - Physician).	Level of complexity of the clinical condition	Analysis of aspects concerning patients and procedures
Sometimes the family does not disturb. The fact that they are present, does not disturb a simple procedure. As long as we evaluate and see that the parents will not be a problem. But in extreme procedures I believe that they should not be around, because it would disturb us. Here, three times I had to perform an open thoracotomy. I have the impression that no family member would want to be in an environment where this is likely to happen (G2, Health Professional 11 - Physician).	Level of complexity of the invasive procedures	
[...] *The family must be with a child patient. The mother or father should be present, and this is quite common. When attending a child is with the family on the side, it is all in front of the family* (G2, Professional 07 - Physician). [...] *For elderly patients, there are cases that we cannot restrain. In many cases we let them stay, so we can get information, and the elderly become less restless* (G1, Health Professional 2 - Nurse).	Patient age	
There are cases in which I am no longer very strict in order to force the patient to be alone. Because, I know this is going to cause very great stress, and possibly it will have a worsening effect on the general health. So I leave it for a moment, but if I see that the family is not collaborating, I ask them to leave (G1, Health Professional 4 - Nurse).	Possibilities of benefit for the patient	
I think the emotion stands out. We have to be more technical and do the medicine; we cannot involve emotion and medicine. The family presence, in a sense, puts pressure on the health professionals, the family ends up getting very emotional, very upset, and this sensitizes everybody (G2, Health Professional 10 - Physician).	Psycho-emotional impact for the team	Analysis of aspects concerning health professionals
[...] *My clinical attitudes do not change at all, whether it is the mother, the father, or whoever. I always make the same decision. We have to be professionals prepared to act in situations of stress* (G1, Health Professional 5 - Physician).	Education and preparation of professionals	
The presence of the family gives more confidence, even for the physician, about some procedures, for example, he can ask the family member to explain to the patient what is going to happen, in an easier language (G3, Health Professional 15 - Nurse manager).	Possibility of helping professionals	
[...] *It is fundamental [the family's presence] for them to also see that we do everything we can, everything that was to be done for the patient, we did* (G2, Health Professional 8 - Nurse).	Meeting the family needs	Analysis of aspects concerning the family
Many times, it's a very aggressive relative. In this case it may be more disruptive than helpful, because we never know the reaction of a relative in a moment of stress. He/she may become violent, wanting to assault a staff person (G1, Health Professional 4 - Nurse).	Family profile	
Usually the companions are lay people, then, when you perform a more invasive procedure, for example, intubation, I think it's something that affects the person watching, to see it all, I think it's a bit traumatizing (G1, Health Professional 2 - Nurse).	Family preparation	

The study was approved by the Ethics Committee of the State University of Maringá, opinion number 1,888,327 (Certificate of Presentation for Ethical Assessment - CAAE: 62787916.4.0000.0104).

Results

Twenty professionals (ten physicians and ten nurses) participated, of which 12 were female. The age ranged from 24 to 60 years, time after graduation ranged from six months to 37 years, and time working in the ER ranged from six months to 32 years.

Deciding "case by case": searching for support to deliberate family presence/absence in the emergency service

Professionals usually do not allow families to accompany patients during emergency care. In addition, there is a social culture of family exclusion, which, even if not formalized in institutional protocols/policies, is symbolic and widely accepted and shared by the staff. However, considering different aspects, families can stay with their loved ones. Thus, the expression "case by case" is recurrent in the professionals' statements.

The phenomenon "deciding case by case" leads to the *presence* or *absence* of the family. The causal, intervenient and contextual conditions are related to four major aspects: environment/context; relatives; patients/procedures; and, health professionals. The situation of allowing or refusing family presence is not crystallized, because during the care process, professionals tend to act, interact and evaluate constantly, leading them to review the decision to allow the presence of the family or not. Therefore, relatives who are present, sometimes depending on the clinical evolution of the patient and the activities/procedures to be performed, are asked to wait outside, while others, depending on how the patient evolves, are invited to be close to him (Figure 1).

Six **aspects related to the environment and the context** of the ER to allow or refuse family presence were noted. The climate in the emergency space, in general, is configured as highly stressful, agitated and troubled, making the place uninviting/nonreceptive to families. The frenetic sector routine also does not provide time to establish prior and welcoming contact with families - important for development of a family-professional bond, and to allow for the follow-up of care.

Family exclusion is also a reflection of the *philosophy of care* practiced in the emergency units. The care is exclusively focused on the patient needs, although it focuses mainly on those of physiopatho-

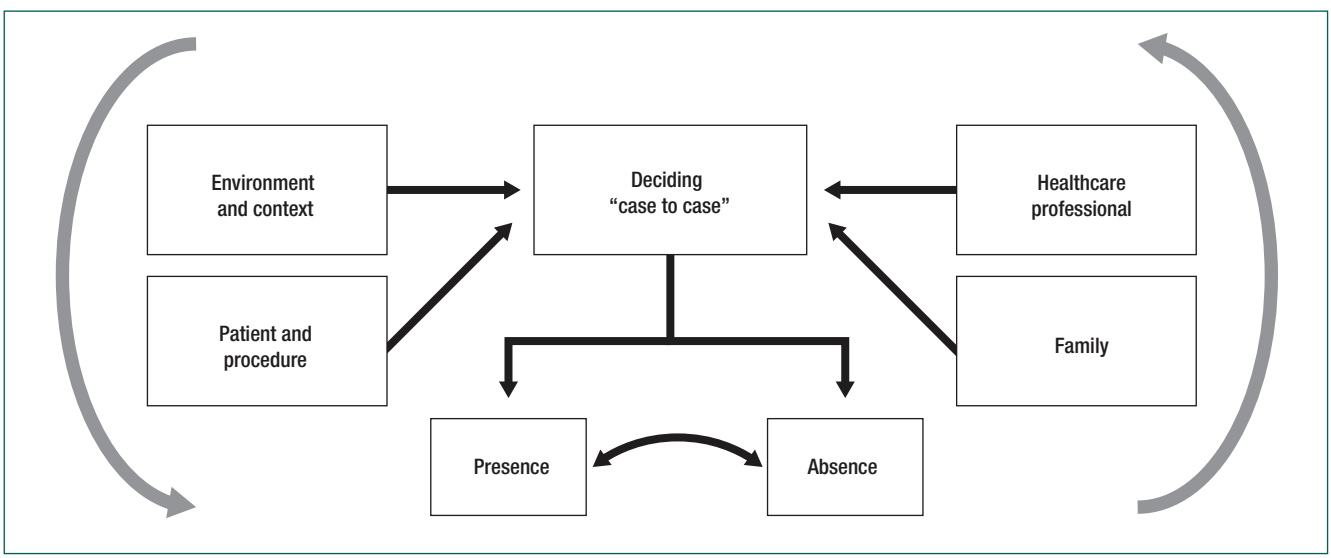

Figure 1. Relationship between the central category "Deciding case by case": searching for support to deliberate family presence/absence in the emergency service" and its categories

logical order; the family, when present, is often not even perceived by the professionals.

According to the professionals, the physical structure also does not allow the staff to perform its functions with the presence of the family, nor does it provide privacy for patients and their families, preventing them from experiencing the suffering from the disease and its care. There is also professional discomfort with the fact that, sometimes, the family members observe the care of other patients.

It was stated that, sometimes, due to the lack of medical and hospital supplies, it is necessary to adapt the care and rescue protocols and, consequently, there is a fear of the families understanding the situation as a neglect of service. The lack of materials was cited as limiting only in ER1. However, the practice is not more common in ER2, showing that a sufficient amount of materials, per se, does not boost family presence.

The professionals stated a need for *human resources* prepared for work focusing on families, who are available full time and who are responsible for them, providing the emotional and informational support they need. However, managers believe that, in addition to the number of professionals, the welcoming and receptive attitude of staff are relevant so that the families can be invited/allowed to remain in the ER.

Physicians are concerned about the possibility of raising infection rates in health care, due to the unrestricted presence of the family in the ER, which is a “contaminated environment” because it treats patients with communicable diseases that may or may not be diagnosed.

Permission for family presence is also related to aspects concerning patients. For example, in relation to the clinical condition, the professionals better accept the family presence in cases of minor *clinical complexity*, because control of the situation is greater, the outcome is more predictable, and there is little possibility of death. For critical patients there are divergent understandings about the presence of the family. Some professionals identify it as unnecessary for unconscious patients - as they do not realize the closeness of these families. Others, in turn, understand that terminally ill patients should have the opportunity to die close to their families, including allowing family members to participate in end-of-life therapeutic decisions, and to say goodbye to loved ones.

As for the *complexity of invasive procedures*, professionals tend to allow the presence of families during those which are minimally invasive and/or that do not violate the patient’s modesty and intimacy. On the other hand, it is not well accepted/practiced when greater psychomotor skill and attention of the professionals is necessary, because stress hinders manual dexterity.

Regarding the *age of the patients*, in the case of children and the elderly, the family presence is understood as necessary, well accepted, and even usual in the emergency sector, because they are perceived as more fragile physically and emotionally. In addition, professionals often need family information to better provide care.

Finally, they consider the *possibilities of benefit for the patient* with more comfort; calmness, security, and receipt of individualized care. At times, family absence triggers stress and anxiety in the patient, worsening his/her clinical condition. Thus, professionals allow the family to be present, even for a short period of time, but enough for the patient feel more familiar in the environment and, consequently, calmer.

To allow or refuse the presence of families, **aspects concerning to health professionals** were analyzed. One of the barriers was related to the fact that professionals may be touched by family suffering, or feel pressured by the requirement of immediately decisive behavior. This psycho-emotional impact cooperates to emotionally stress the professional.

There were also aspects related to the *education and preparation of professionals*. Many of them do not feel empowered to act with families during emergency situations. Those who call themselves self-trained, realize that their clinical behaviors and psychomotor skills are not influenced by the presence of the family, and in these cases, they decide in favor of family presence.

Finally, the presence of the family is also conditioned by the *possibility of helping the professionals*,

as they can be seen as a potential collaborator in the communication process between the patient-team, offering useful information to establish the diagnosis, and transmitting the professional message in accessible language to the patient.

With regard to the **aspects concerning the family**, to allow the family presence, the professionals stated that they wish to meet family needs. These needs include: obtaining information about the patient's clinical condition/prognosis; feeling they are part of the care; transmitting strengths to the patient; understanding the critical health situation; identifying that everything possible was done; and accompanying the patient's last moments of life, enabling the farewell, which facilitates the beginning of the mourning process.

But to allow their presence, it is necessary that the family member have an adequate profile and prior preparation. In relation to the family member profile, the level of relationship with the patient, the fact of not being elderly, having good physical and mental health, and emotional self-control was analyzed. The need for *family preparation* is due to the fact that care is too technical and procedural. Without preparation, the family members may become traumatized by the scenes, which occur, get sick, become aggressive, or even blame the professionals for death, possibly triggering lawsuits.

Discussion

The data presented enable us to understand the experiences and perceptions of professionals on family presence in the emergency service. Usually, families are barred from being with their family in the ER. However, in daily practice, a conditioned permission occurs, because of "case by case" analysis. This has already been identified in relation to cardiopulmonary resuscitation.[3] However, the present study advances this understanding, because it reveals that this conditional permission extends to different types of emergency care, and also because it indicates that the final decision is influenced by aspects related to the context, family members, patients, and professionals.

Physical space, for example, was considered inappropriate for receiving/welcoming the family. Similarly, an Australian study of emergency physicians showed that organizational factors, such as lack of space and support for families, as well as excessive workload, were the main reasons for not allowing family members to witness care.[1]

The environment of the ER, as a result of the type of care provided, is considered violent and aggressive for the family.[4,12] Therefore, people who work in that scenario, feel themselves to be clothed with authority and even legitimate power, in the name of protecting the families, excluded them from the space of care.[3] In addition, professionals refer to focusing their attention on the critical ill patient, in an attempt to save their life.[5] The patient is therefore, the center of care.

It is believed to be opportune and urgent to discuss and encourage the possibility of adopting the philosophy of Family-Centered Care (FCC) in emergency units. Professionals from different countries recognize the innumerable challenges to implementing this idea in these sectors, but they perceive it as the driving force for qualification of care for critical patients and their families, by humanizing care.[7,13,14] In the Brazilian context, FCC is still very incipient, not implemented in health services, or discussed in vocational education.[15,16]

In this investigation, the professionals emphasized that the complexity of the invasive procedures, the severity of the clinical condition, and the possibility of death were determinants for the family's withdrawal from the ER, which is in line with the results of studies conducted in Brazil[17] and Australia.[5] However, it is also understood that the family presence should be promoted when the patient has little chance of survival, so that they can say goodbye.[2,3]

The results also showed that professionals are more likely to accept the family presence when the patients are children or elderly, as demonstrated in other investigations.[1,3] In the case of children, the support for the presence of parents can be explained by nutritional dependence and by the close relationship between parents and young children,[3] in addition to the perception that ex-

cluding parents during hospitalization of a child is detrimental to their well-being.[18] However, if professionals are willing and able to overcome the personal and organizational barriers to facilitate the presence of parents during pediatric emergency care, the reluctance to adopting the same attitude for the adult patient must be analyzed.

The answer to the explicit question is not ready and it does not seem easy to construct/reach it. However, one clue may be in the identification of the existence of a culture of exclusion of the adult patient's family, which is widely accepted and shared by the professionals of this investigation. Similarly, another GT study identified that practitioners in emergency services claimed ownership of the patient and, even without institutional policies prohibiting the family presence, they felt they held the position of authority to allow or deny it, which was widespread among colleagues, relatives and patients, as the families showed little resistance to exclusion.[3]

This professional understanding may be related to a lack of awareness of the family presence. In fact, in this study, professionals perceived the absence of education focused at the adequate welcoming of families. It is believed that changes in the process of initial education and continuing education of professionals may enhance the sense of self-confidence during the care provided under the eyes of family members, while at the same time they seem to be feasible strategies to be engendered.

Not including families during education is not an exclusively Brazilian problem. A study with Australian critical care nurses, for example, showed that education was considered to be inadequate to meet the needs of families in the moments preceding and following the death of patients.[19] On the other hand, there are encouraging examples of Denmark,[20] the United States[21] and Canada,[22] which recognize the importance of training generalist nurses with competencies, mainly attitudinal, that favor the welcoming and care of patients and their families.

Also, a study conducted in the United States showed an increase in permission for the presence of families after educational interventions with the professionals of an emergency unit.[23]

However, in South Korea, researchers have suggested developing and implementing an educational program to modify the negative perception of professionals about the presence of families in ER.[24] These studies, therefore, show that changes in the formative process collaborate to diminish the symbolic culture of professional exclusion.

Another relevant aspect is the possibility of developing strategies to raise awareness so that the professionals in the exercise of otherness can be strengthened. Sometimes, in this research, professionals assume the role of the other in the interactional process, facilitating the understanding of the desire to be with the loved one. The nursing team, for example, when witnessing the family's experience of death, can demonstrate feelings of compassion and solidarity and, in putting itself in the place of the family that suffers, can better understand their needs.[25] This has the potential to reduce the rigor used by professionals to select the ideal family profile that can accompany the patient during care.

Finally, it is highlighted that in the absence of structured protocols, decision-making and clinical practice is guided by the professional self-confidence, as well as individual perception, experiences, and beliefs about family presence in care. This explains the wide variations identified in this study and in the literature, culminating in an inconsistent and sporadic family presence.

The interviews were conducted during the participants' workday, which may have contributed to more superficial responses, as some participants were concerned about returning to their activities.

Conclusion

For physicians and nurses, the presence of the family in the ER is configured as a complex and multidetermined process. Aspects related to: environment/context; families; patients/procedures; and, themselves were considered in the decision. However, because the phenomenon is heterogeneous and has multiple facets, this decision is not crystallized, as it is constantly considered throughout the care, and performed in a different manner for each case.

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Collaborations

Barreto MS, Marcon SS, Garcia-Vivar C, Furlan MC, Rissardo LK, Haddad MCL, Dupas G and Matsuda LM declare that they contributed to the study design, analysis and data interpretation, relevant critical review of the intellectual content, and final approval of the version to be published.

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Original Article

Nursing diagnoses and interventions for the person with venous ulcer

Diagnósticos e intervenções de enfermagem para a pessoa com úlcera venosa

Diagnóstico e intervenciones de enfermería para la persona con úlcera venosa

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Keywords
Standardized nursing terminology; Nursing diagnosis; Nursing process; Varicose ulcer/ classification

Descritores
Terminologia padronizada em enfermagem; Diagnóstico de enfermagem; Processo de enfermagem; Classificação; Úlcera varicosa/classificação

Descriptores
Terminología normalizada de enfermería; Diagnóstico de enfermería; Proceso de enfermería; Clasificación; Úlcera varicosa/ clasificación

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Abstract
Objective: To develop and validate the terminological subset of ICNP® for the care of people with venous ulcer guided by Wanda Aguiar Horta's theory of Basic Human Needs.
Methods: Methodological study for the development terminological subsets of ICNP®. Initially, was conducted an integrative review in order to search for evidence in the literature for the nursing practice to people with venous ulcer, and answer the following question: What are the empirical evidences found in the person with venous ulcer? The accessed databases were the Medical Literature Analysis and Retrieval System Online (MEDLINE), the Latin American and Caribbean Literature on Health Sciences Information (LILACS), and the Cumulative Index to Nursing and Allied Health Literature (CINAHL). Inclusion criteria were the following: abstracts available in Portuguese, English or Spanish; and published between 2012 and 2016. Exclusion criteria were case reports, theses, monographs, manuals and papers that did not present clinical manifestations of venous ulcer.
Results: A group of nurse judges experienced in the treatment of venous ulcer validated 84 nursing diagnoses and outcomes, and 306 interventions. Of the diagnoses developed, 62 are included in ICNP® and 23 are new diagnoses, not included.
Conclusion: The ICNP® has proved to be a taxonomy that can be compatible and applicable to nurses' clinic with potential for organization of the work process, whether in the outpatient or hospital setting.

Resumo
Objetivo: Elaborar e validar o Subconjunto terminológico CIPE® para o cuidado à pessoa com úlcera venosa, orientado pela teoria das Necessidades Humanas Básicas de Wanda Aguiar Horta.
Métodos: Estudo metodológico para elaboração de subconjuntos terminológicos da CIPE®. Inicialmente, fez-se uma revisão integrativa, buscando evidências para a prática de enfermagem à pessoa com úlcera venosa dispostas na literatura, a fim de responder à seguinte pergunta: Quais as evidências empíricas apresentadas na pessoa com úlcera venosa? As bases acessadas foram o *Medical Literature Analysis and Retrieval System Online* (MEDLINE) e a Literatura Latino-Americana e do Caribe de Informação em Ciências da Saúde (LILACS), e também a *Cumulative Index to Nursing and Allied Health Literature* (CINAHL). Utilizaram-se os seguintes critérios de inclusão: ter resumo disponível nos idiomas português, inglês ou espanhol; e publicados entre 2012 e 2016. Como critérios de exclusão: relatos de casos, teses, monografias, manuais e trabalhos que não apresentavam manifestações clínicas da úlcera venosa.
Resultados: 84 diagnósticos, resultados de enfermagem e 306 intervenções foram validados por um grupo de juízes enfermeiros, expertises em tratamento de úlcera venosa. Dos diagnósticos elaborados, 62 são constantes na CIPE® e 23 são novos diagnósticos, não constantes.
Conclusão: A CIPE® evidenciou-se como uma taxonomia que pode ser compatível e aplicável à clínica do enfermeiro, com potencial para a organização do processo de trabalho, seja no âmbito ambulatorial ou hospitalar.

Resumen
Objetivo: Elaborar y validar el Subconjunto terminológico CIPE® para el cuidado de la persona con úlcera venosa, orientado por la teoría de las Necesidades Humanas Básicas de Wanda Aguiar Horta.
Métodos: Estudio metodológico para elaboración de subconjuntos terminológicos de CIPE®. Inicialmente, se realizó revisión integrativa, buscando evidencias de la práctica de enfermería a la persona con úlcera venosa dispuestas en la literatura, para responder la pregunta: ¿Cuáles son las evidencias empíricas presentadas en la persona con úlcera venosa? Se buscó en las bases *Medical Literature Analysis and Retrieval System Online* (MEDLINE), Literatura Latinoamericana y del Caribe en Ciencias de la Salud (LILACS) y *Cumulative Index to Nursing and Allied Health Literature* (CINAHL). Se utilizaron los siguientes criterios de inclusión: contar con resumen disponible en portugués, inglés o español; y publicación entre 2012 y 2016. Como criterios de exclusión: relatos de casos, tesis, monografías, manuales y trabajos que no expresaban manifestaciones clínicas de la úlcera venosa.
Resultados: 84 diagnósticos, resultados de enfermería y 306 intervenciones fueron validadas por un grupo de expertos enfermeros, especializados en tratamiento de úlcera venosa. De los diagnósticos elaborados, 62 constan en la CIPE® y 23 son nuevos.
Conclusión: La CIPE® se evidenció como taxonomía compatible y aplicable a la clínica del enfermero, con potencial para organización del proceso de trabajo, tanto en el ámbito ambulatorio como hospitalario.

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Introduction

Venous ulcers are a serious public health problem, since they cause disability, suffering, social isolation and are costly because they consume resources for care and cause damages to the quality of life.[1,2] Furthermore, treatments are long and have recurrence of 70%.[3] Prevalence in the world population is around 1% to 1.5%[4,5] and in Brazil, approximately 3% of the population is affected by venous ulcers.[6]

The professional's conduct is fundamental for the evolution or not of the wound, and the care choices can contribute to the improvement or worsening of the clinical picture.[7] From its conception, Nursing has the care of people with wounds in its routine practice. In the search for qualifying the care provided, the nursing process should be used as a methodological and systematic tool for providing care to people with venous ulcer.[8]

For implementation of the nursing process, should be used classification systems that help in the identification of nursing diagnoses, outcomes and interventions. Among taxonomies, the International Classification for Nursing Practice (ICNP®) is appropriate especially when directed at a specific population or health priority, and represented by terminological subsets.[9]

Terminological subsets are sets of nursing diagnostic statements, outcomes and interventions directed to specific health conditions, specialties or care contexts, or nursing phenomena with the aim to facilitate the documentation of practice and simplify the use of the ICNP® classification.[10] There is a growing need for the development of terminological subsets, and seven subsets have been published so far, although none is targeted to people with venous ulcers yet.

The approach to venous ulcer patients needs to be holistic and integral, since the etiology is complex and has several associated factors that directly interfere in the quality of life of these people.[3,6] In this perspective, Wanda Aguiar Horta's Theory of Basic Human Needs is an adequate theoretical contribution in the organization of nursing care to people with venous ulcers, because according to this theory, nursing respects and maintains uniqueness, authenticity and individuality of human beings.[11]

Hence the relevance of the present study with the aim to develop and validate the terminological subset of the ICNP® for the care of the person with venous ulcer guided by Wanda Aguiar Horta's Theory of Basic Human Needs.

Methods

A methodological study based on the method of Nobrega et al[12] for the development terminological subsets of ICNP®. Initially, was conducted an integrative review in the literature searching for evidence for the practice of nursing for people with venous ulcer in order to answer the following question: What are the empirical evidences found in people with venous ulcer?

The databases accessed were the Medical Literature Analysis and Retrieval System Online (MEDLINE), the Latin American and Caribbean Literature on Health Sciences Information (LILACS), and the Cumulative Index to Nursing and Allied Health Literature (CINAHL).

The search was performed in the portal of the Coordination for the Improvement of Higher Level Personnel using the Health Science Descriptors (DeCS), and by crossing two by two with the Boolean operator AND, as follows: *"Úlcera Varicosa"*, *"Enfermagem"* in Portuguese; "Varicose Ulcer", "Nursing" in English; and *"Úlcera Varicosa"*, *"Enfermería"* in Spanish. For the search in CINAHL, were used the following Medical Subject Headings (MESH) terms: "Varicose Ulcer", "Nursing". The inclusion criteria were abstracts available in Portuguese, English or Spanish and publication period between 2012 and 2016. Exclusion criteria were all case reports, theses, monographs, manuals and papers that did not have clinical manifestations of venous ulcer.

The searches and analyzes of titles and abstracts were performed by two researchers. After selection, the articles were read by two researchers, which allowed the manual extraction of empirical evidence.

Then, three researchers performed a process of analysis, grouping and standardization of the initial list that resulted in 88 evidences.

In the next stage of the study, began the construction of diagnostic statements and nursing outcomes by cross-checking the empirical evidence with terms of the ICNP®, version 2015. For each empirical evidence, was selected a term of the Focus axis and a term of the Judgment axis with inclusion of additional terms when necessary, which resulted in 73 diagnoses and outcomes. Twenty-three new diagnoses and nursing outcomes were created, as they were not included in ICNP®, version 2015. The ISO 18.104: 2014 norm was also considered - Health informatics: categorical structures for representation of nursing diagnoses and nursing actions in terminological systems, in which a diagnosis can be expressed by focus and judgment or a clinical finding.[13] In this same stage, were constructed operational definitions for each diagnosis by using the definitions of ICNP® for the constant terms, and of scientific articles, manuals, Nursing textbooks and dictionaries for non-constant terms. The established definition used for this construction is formed by the 'term representing the object' + verb to be + 'definite or indefinite article' + 'class to which the object belongs' + 'characteristics of species'.[14]

For each diagnosis, was developed a block of statements of Nursing interventions by using a term of the Action axis and an ICNP® Target term, which may belong to any of the axes, except the Judgment axis. The ISO 18.104: 2014 was also considered with a descriptor for action and at least one descriptor for target, except when the target is the own subject of the record.[13] In addition to cross-mapping with the ICNP®, version 2015, were used reference books in the area of venous ulcer[4] and Nursing,[15,16] besides the researchers' experience.

The terminological subset was subjected to content validation by consensus with nurse judges, and criteria were to work in a Basic Health Unit of the Municipality of Vitória (state of Espírito Santo) and attend people with venous ulcer. Nurse judges were chosen by convenience, indication of researchers and the stomatherapist nurse, who is reference in wounds and coordinator of the skin care group at the City Hall. For this stage, were invited 13 nurses by letter, in addition to the coordinator of the skin care group.

At the beginning of the meeting, was given orientation regarding the study, the Basic Human Needs Theory and ICNP®. Subsequently, nurses were given the subset, a questionnaire to characterize the judges, and the operational definitions of diagnoses. Nurses were asked to read the material and indicate agreements/disagreements with the subset. After that, were discussed only the items in which there was disagreement, and it was decided by consensus about the permanence, withdrawal or rewriting of the statement. Statements were considered valid when there was 100% consensus.

The validation meeting lasted three and a half hours. After that time, the proposed changes were written by the researcher, and shared with participants by email. Then, they had seven days to read and make comments about the writing.

In the absence of disagreement, the subset was restructured according to recommendations of the International Council of Nurses and guided by the theoretical framework of Basic Human Needs.

The study was approved by the Research Ethics Committee of the Universidade Federal do Espírito Santo under number CAAE 61423516.7.0000.5060.

Results

In the integrative literature review, were found 43 articles in LILACS, 56 in MEDLINE and one in CINAHL, the total of 100 articles. Of these, six were excluded because the abstracts were not available, and seven were excluded because they were repeated. After reading the 87 abstracts, 66 articles were excluded following the exclusion criteria. Finally, 21 articles were selected for reading in full (Figure 1).

Of these articles, 88 evidences were manually extracted. Besides the 'venous ulcer' term that was present in all articles, the most cited was 'pain', in

71.4% of publications, followed by terms related to venous insufficiency with 66.6%. The reduction of functional mobility was present in 61.9% of articles, and 'exudate', 'infection' and 'social isolation' were in 52.3% each; 'odor' in 42.8%; 'healing', 'hyperglycemia' and 'edema' in 38.9%. 'Decreased rest' and 'decreased ability to work' were in 33.3% of publications, 'necrosis', 'relapse', 'changes in sleep pattern' and 'low self-esteem' were cited in 28.5%. Other terms had five or fewer citations and, despite this fact, they were considered for the creation of diagnoses.

By means of cross-referencing the evidences extracted with terms included in the Focus axis of ICNP®, version 2015, were developed 73 nursing diagnoses and outcomes. In addition, were created 23 new diagnoses and nursing outcomes, as these evidences were not found in ICNP®, version 2015. There were 96 nursing diagnoses and outcomes in total, and operational definitions for each diagnosis were also provided.

For an easier clinical reasoning, diagnoses were organized within the fields of Basic Human Needs described by Wanda Aguiar Horta. For each nursing diagnosis, was developed a block of statements of nursing interventions (total of 306) by considering the 7 Axes Model of the ICNP®, version 2015.

The statements underwent content validation by consensus of 13 nurses, and 84 diagnoses and nursing outcomes were considered valid by 100% of judges. Of the 23 diagnoses not included in ICNP®, 16 remained unchanged, three were excluded, and four were changed in the writing of the statement. There were suggestions for changes and adjustments in some interventions. Thus, the final configuration of the subset is described in chart 1.

The distribution of nursing diagnoses and interventions by basic human needs is shown in chart 2.

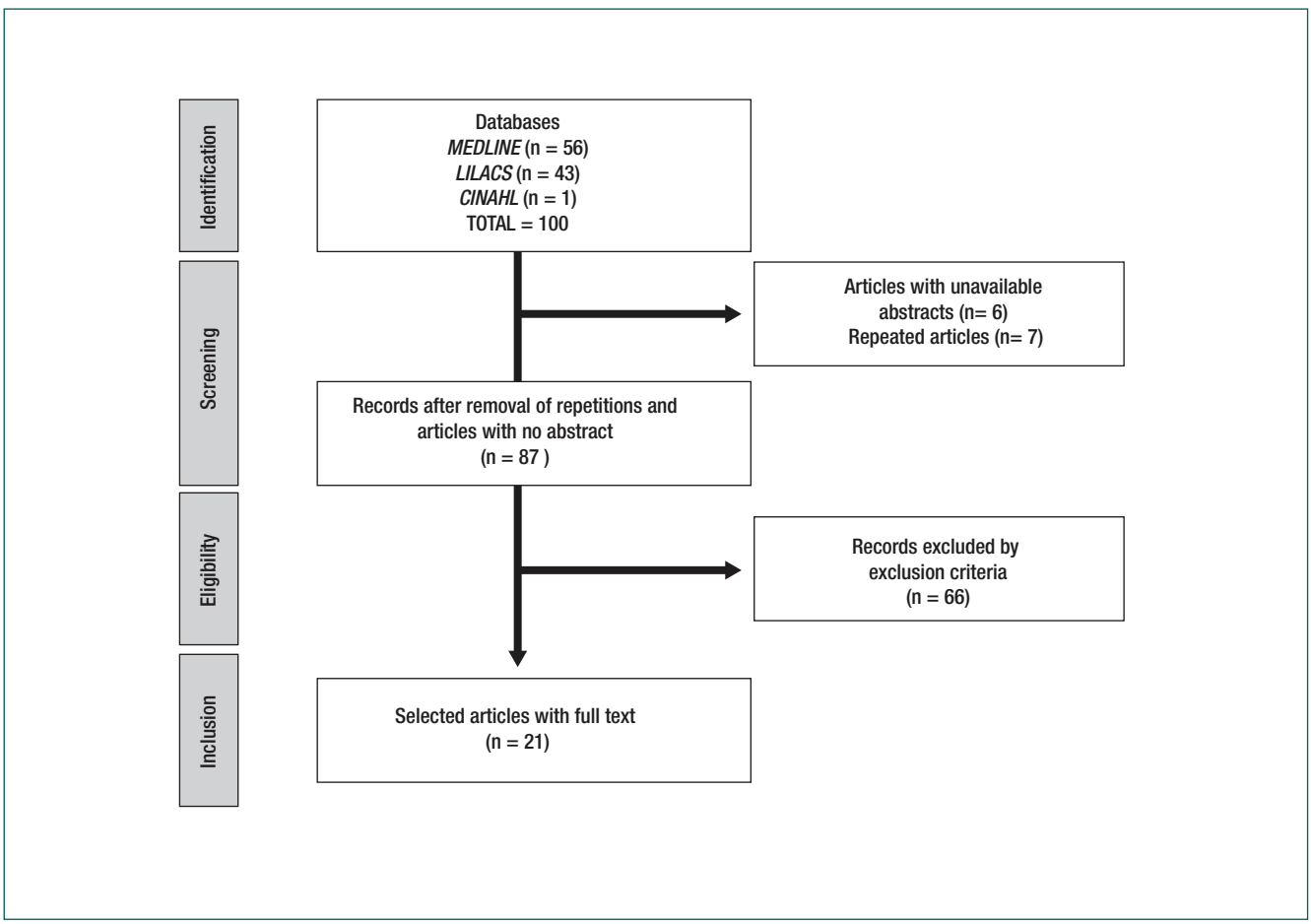

Figure 1. PRISMA flowchart of the search and selection process of studies included in the integrative review

Chart 1. ICNP® terminological subset for care of the person with venous ulcer

Psychobiological needs	
Psychobiological needs - skin and mucosal integrity	
Nursing diagnosis/outcomes	
Allergy White atrophy Irregular wound edges Regular wound edges Cellulitis Strange body in the wound Wound scab Desquamation of skin Eczema Epithelialization at wound edges Erythema Wound with slough Partial thickness wound	Full thickness wound Hyperemia Hypergranulation in wound Infiltration at wound edges Impaired tissues integrity Maceration at wound edges Necrosis Hyperpigmented skin Dry perilesional skin Granulation tissue Scar tissue Recurrent ulcer Venous ulcer
Nursing interventions	
· Applying compression/contention bandage. · Applying wound bandage. · Applying wound bandage that exerts slight pressure on wound. · Applying bandage. · Applying skin moisturizer. · Applying silver nitrate. · Evaluating wound healing. · Evaluating venous ulcer healing. · Evaluating wound in patient's return. · Evaluating wound for decision making regarding dressing. · Evaluating infection. · Evaluating need for antibiotics administration. · Evaluating need for protective dressing. · Evaluating need for wound debridement. · Evaluating Blood Pressure. · Evaluating skin temperature. · Evaluating skin turgor. · Evaluating ulcer for decision making regarding dressing. · Confirming allergy. · Describing wound characteristics. · Describing ulcer characteristics. · Describing wound size and depth. · Documenting ulcer history. · Referring to medical care. · Stimulating the establishment of daily habits of body and environmental hygiene. · Examining skin condition. · Performing debridement. · Measuring ankle-brachial index (ABI) in both legs by hand Doppler. · Identifying eczema-causing mechanism. · Identifying erythema-causing mechanism.	· Identifying hyperemia-causing mechanism. · Identifying the onset of allergic reactions resulting from topical treatment implemented. · Encouraging increased fluid intake. · Teaching about skin care. · Teaching about wound care. · Keeping the wound moist. · Monitoring skin condition. · Monitoring the appearance of edges. · Monitoring skin color. · Monitoring skin color, temperature, humidity and appearance. · Monitoring edema and moisture on edges. · Monitoring the infection. · Monitoring signs and symptoms of wound infection. · Monitoring signs and symptoms of ulcer infection. · Monitoring humidity at edges. · Guiding hygiene and restricted use of agressive soaps to the skin. · Guiding the patient about making the dressing at home. · Guiding the patient about care for preventing ulcer recurrence. · Guiding regarding the risk of infection. · Guiding regarding the importance of raising legs at constant intervals. · Guiding regarding the use of moisturizers. · Guiding regarding allergic reaction. · Prescribing the use of perilesional skin moisturizer. · Prescribing the use of skin moisturizer. · Removing strange body from the wound bed. · Removing wound debris with water spray or saline solution. · Requesting laboratory tests for evaluation. · Suspending use of possible allergen. · Treating allergic reaction.
Psychobiological Needs - nutrition	
Nursing diagnosis/outcomes	
Impaired nutritional status Hyperlipidemia status Obesity status Hyperglycemia	Insufficient food intake Excessive food intake Risk of nutritional deficit
Nursing interventions	
· Evaluating the need to change eating habits. · Assisting patient to receive help from appropriate nutritional programs of the community. · Evaluating the need to change eating habits. · Evaluating food acceptance. · Calculating Body Mass Index for nutritional status evaluation. · Discussing with patient a plan to change eating habits. · Referring for medical care. · Encouraging adherence to diet. · Encouraging adherence to a physical activity plan. · Encouraging adherence to a plan for changing eating habits. · Encouraging intake according to nutritional needs and food preferences. · Establishing a goal for weight control. · Identifying possible causes of hyperglycemia. · Identifying possible causes of hyperlipidemia. · Informing the patient about the importance of the plan for changing eating habits for glycemic control.	· Informing the patient about the importance of the plan for changing eating habits for lipemic control. · Investigating possible causes of obesity. · Investigating food preferences. · Measuring patient's height. · Monitoring nutritional status. · Monitoring capillary glycemia. · Monitoring weight. · Guiding the patient about response to medication. · Guiding the patient about possible complications of hyperglycemia. · Guiding the patient about possible complications of hyperlipidemia. · Guiding the patient about expected positive results of joining the plan of change of eating habits in the short, medium and long term. · Weighing the patient. · Requesting laboratory tests for evaluation.

Continue...

Continuation.

Psychobiological needs - regulation	
Nursing diagnosis/outcomes	
Impaired wound healing Peripheral edema Large/moderate/low volume exudate Purulent exudate Bloody exudate	Serous exudate Serous-bloody exudate Infection Lipodermatosclerosis Impaired vascular process Risk of fall
Nursing interventions	
· Applying wound dressing. · Evaluating evolution of wound healing. · Evaluating the wound on patient's return. · Evaluating the wound for decision making regarding the dressing. · Evaluating the need for antibiotics. · Evaluating the need for wound debridement. · Evaluating the occurrence of trauma. · Evaluating peripheral Tissue Perfusion. · Evaluating the presence of edema. · Evaluating the presence of pulse. · Evaluating the risk of ineffective capillary perfusion. · Evaluating tactile, thermal and painful sensitivity in lower limbs. · Describing wound characteristics. · Discussing possible domestic accidents. · Documenting the history of the wound. · Referring patient for medical consultation. · Referring for medical care. · Measuring ankle-brachial index in both legs by hand Doppler.	· Encouraging the use of assistive aid devices for ambulation (cane, walker, wheelchair). · Inspecting legs regarding integrity, hydration and color. · Teaching about wound care. · Keeping the wound moist. · Monitoring the infection. · Monitoring signs and symptoms of wound infection. · Monitoring signs and symptoms of infection. · Monitoring body temperature. · Guiding the organization of domestic environment. · Guiding the patient regarding care for preventing ulcer recurrence. · Guiding the patient on the importance of raising legs at constant intervals. · Prescribring leg elevation at constant intervals. · Prescribing the use of compressive therapy. · Tracking the risk of falls and other accidents. · Removing wound debris with water spray or saline solution. · Requesting laboratory tests for evaluation. · Suggesting safe shoes that make walking easier. · Using absorbent cover in dressing. · Checking possible causes of edema.
Psychobiological needs - perception	
Nursing diagnosis/outcomes	
Mild/moderate/severe pain Mild/moderate/severe wound pain Mild/moderate/severe fetid odor	Impaired tactile perception Mild/moderate/severe pruritus Risk of impaired peripheral neurovascular function
Nursing interventions	
· Administering pain medication before wound care. · Applying wound dressing. · Evaluating need for debridement. · Evaluating wound for decision making regarding dressing. · Evaluating pain intensity. · Evaluating response to pain management. · Evaluating tactile, thermal and painful sensitivity in lower limbs. · Describing wound characteristics. · Referring patient for medical evaluation in case of peripheral vascular changes. · Encouraging patients to discuss their pain experience. · Encouraging patients to monitor their own pain and interfere properly. · Examining the integrity of skin. · Examining feet and legs at each return: inspection and palpation of skin, nails, subcutaneous and structure, palpation of arterial pulse and evaluation of plantar protective sensation. · Explaining causes of pain. · Measuring ankle-brachial index in both legs by hand Doppler. · Managing wound odor control. · Identifying the cause of pruritus. · Encouraging participation of family and patient in pain control. · Indicating the use of compressive therapy.	· Teaching about wound care. · Investigating factors that increase pain. · Keeping the wound moist. · Wetting the dressing with saline solution or water before removal. · Monitoring response to analgesic. · Monitoring signs and symptoms of infection. · Guiding the patient regarding moisturizer application. · Guiding the patient to apply cold compresses for relief of irritation. · Guiding the patient to report changes of sensitivity and the appearance of any injury. · Guiding the patient to favor adequate rest/sleep for pain relief. · Guiding the patient to keep nails trimmed and not scratch the skin. · Guiding the patient not to use abrasive products on the skin. · Guiding the patient with feet changes regarding adjustments on the type of shoes, physical activity and use of assistive aid devices for ambulation (cane, walker, wheelchair) · Guiding the patient regarding body hygiene of the affected area. · Guiding the patient regarding hygiene habits. · Prescribing analgesy. · Providing alternative methods of pain relief. · Removing wound debris with water spray or saline solution.
Psychobiological needs – sleep and rest	
Nursing diagnosis/outcomes	
Impaired rest behavior	Impaired sleep
Nursing interventions	
· Evaluating the cause of altered sleep pattern. · Encouraging rest. · Teaching the patient about relaxation techniques. · Stimulating the patient to maintain adequate sleep pattern. · Alleviating pain. · Organizing activities of daily life in order to allow rest periods during the day.	· Guiding to keep the ulcerated leg elevated when at rest. · Guiding the patient to make changes in the environment (reduce lighting, noises, check bed and pillow conditions, check ventilation conditions). · Guiding the patient to plan medication schedule in order not to interrupt the sleep. · Guiding the patient regarding factors interfering in the sleep. · Planning rest/activity periods with the patient.
Psychobiological needs - sexuality	
Nursing diagnosis/outcomes	
Impaired sexual behavior	
Nursing interventions	
· Evaluating the patient's knowledge of his/her sexuality pattern. · Encouraging the patient's ability to adjust to his/her state of health. · Encouraging the patient to share his/her feelings about sexuality. · Stimulating the dialogue about the situation with the partner.	· Identifying determinants of unsatisfactory sexual activity. · Guiding regarding contraceptive methods. · Promoting the practice of safe sex with use of condoms. · Providing counselling by considering cultural and social aspects, myths and taboos.

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Continuation.

Psychobiological needs – physical activity	
Nursing diagnosis/outcomes	
Low physical exercise	Impaired mobility
Nursing interventions	
· Evaluating adherence to the proposed exercise plan. · Evaluating patient's ability to perform activities of daily life. · Evaluating the need for ambulation assistive devices.	· Encouraging the patient to perform preferred physical activity within safe limits according to his/her condition regarding the venous ulcer. · Planning rest/activity periods with the patient.
Psychobiological needs - hydration	
Nursing diagnosis/outcomes	
Impaired self-care in fluid intake	Inadequate fluid intake
Nursing interventions	
· Evaluating patient's knowledge about his/her need of fluid intake. · Encouraging self-care. · Encouraging the patient to inspect skin during the shower. · Stimulating the establishment of daily habits of body and environmental hygiene. · Monitoring hydration indicators.	· Guiding the patient regarding the need of fluid intake. · Guiding regarding hygiene care by considering cultural and social aspects, myths and taboos. · Planning a scheme for stimulation of fluid intake by considering specificities of the case. · Recording fluid intake.
Psychobiological needs – body care	
Nursing diagnosis/outcomes	
Impaired ability to perform hygiene Inadequate hygiene	Impaired self-care in hygiene
Nursing interventions	
· Evaluating self-care. · Evaluating family hygiene conditions in the home environment. · Encouraging bathing before the visit to perform the dressing. · Encouraging hygiene habits by considering cultural and social aspects, myths and taboos. · Encouraging the patient to bathe.	· Stimulating the establishment of daily habits of body and environmental hygiene. · Encouraging the patient to inspect skin during the shower. · Guiding family/caregiver regarding personal hygiene care. · Guiding regarding hygiene care by considering cultural and social aspects, myths and taboos.
Psychobiological needs – physical security	
Nursing diagnosis/outcomes	
Alcohol abuse	Smoking
Nursing interventions	
· Assisting patient in establishing a goal plan for reducing alcohol abuse. · Assisting patient in establishing a goal plan for reducing smoking. · Assisting patient in identifying triggers related to the desire and act of smoking and the way to overcome them. · Assisting patient in identifying the moments and attitudes related to the desire to drink and the way to overcome them. · Evaluating lifestyle and its relation with alcohol abuse. · Evaluating lifestyle and its relation with tobacco abuse. · Referring to a self-help group.	· Encouraging search for a self-help group. · Identifying the family and community support network. · Identifying the desire to quit smoking. · Providing support for times related to abstinence. · Guiding regarding the possibility of relapses and how to overcome them. · Guiding regarding abstinence crisis. · Guiding regarding doubts related to use together with drugs. · Guiding regarding harm caused by smoking.
Psychosocial needs	
Psychosocial needs – freedom and participation	
Nursing diagnosis/outcomes	
Impaired social condition Impaired family coping	Impaired work role
Nursing interventions	
· Helping with identification of positive personal attributes. · Evaluating social support and support network (work, church, family, friends). · Discussing with the family and patient about co-responsibility in treatment and adverse reactions during treatment. · Referring family and patient to self-help groups and/or psychological care. · Referring to multiprofissional team if necessary.	· Encouraging the patient to identify his/her strengths and abilities. · Indicating community social equipments for recreation and leisure. · Investigating the family's level of understanding and acceptance of the patient's current state of health. · Guiding regarding patient's current state of health. · Scheduling a home visit. · Reinforcing to the family about treatment adherence.
Psychosocial needs – emotional security, self-esteem	
Nursing diagnosis/outcomes	
Anguish Anxiety Low self-esteem Stress	Fear Risk of low self-esteem Sadness
Nursing interventions	
· Embracement of the patient according to his/her needs. · Helping with identification of positive personal attributes. · Evaluating attitudes towards therapeutic regimen. · Referring to psychological care if necessary. · Referring to multiprofessional team if necessary. · Encouraging the expression of perceptions, feelings and fear. · Encouraging the patient to explain his/her doubts, desires and difficulties. · Encouraging the patient to identify his/her strenghts and abilities. · Encouraging the patient to verbalize feelings, perceptions and fear. · Encouraging participation in recreational activities. · Establishing a relationship of trust with the patient.	· Identifying determinants of Anguish. · Identifying determinants of Anxiety. · Identifying determinants of Sadness. · Encouraging activities that promote their well-being. · Investigating patient's socio-familial context. · Motivating patient for self-care at home. · Guiding regarding stress management actions. · Promoting patient's confidence in the care provided. · Recognizing the different moments experienced by patient when receiving new treatment guidelines. · Checking with patient and caregiver the factors causing fear.

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Psychosocial needs – self-image	
Nursing diagnosis/outcomes	
Impaired body image	
Nursing interventions	
· Discussing body image changes with patient. · Referring to multiprofessional team if necessary. · Identifying with the patient the factors interfering with his/her self-image.	· Guiding patient, caregiver and families regarding possible predictable physical changes during treatment (use of bandages, large dressings, etc). · Strengthening self-care.
Psychosocial needs – gregarious and leisure	
Nursing diagnosis/outcomes	
Impaired ability to perform leisure activities	Social isolation Risk of social isolation
Nursing interventions	
· Embracement of the patient according to his/her needs. · Evaluating family and social context. · Referring to multiprofessional team if necessary. · Encouraging participation in recreational activities. · Identifying with the patient the determinants for social isolation.	· Identifying community social equipments for recreation and leisure. · Encouraging participation in social and community groups. · Planning a simple daily routine by including recreation and leisure concrete activities. · Scheduling a home visit.
Psicosocial needs - love and acceptance	
Nursing diagnosis/outcomes	
Lack of family support Lack of social support	Impaired affective bonding
Nursing interventions	
· Embracement of the patient according to his/her needs. · Embracement of patient, caregiver and family in their needs. · Evaluating family and social context. · Evaluating social support. · Discussing with the family and patient about co-responsibility in treatment and adverse reactions during treatment. · Referring the family to self-help groups or psychological care. · Referring to psychological care if necessary.	· Referring to multiprofessional team if necessary. · Encouraging the verbalization of feelings, perceptions and fears. · Identifying with patient the determinants for lack of social support. · Encouraging participation in social and community groups. · Investigating the family's level of understanding and acceptance of the patient's current state of health. · Guiding regarding the patient's current state of health. · Scheduling a home visit. · Reinforcing to the family about treatment adherence.
Psychosocial needs – self-achievement	
Nursing diagnosis/outcomes	
Disposition for coping	
Nursing interventions	
· Evaluating coping ability. · Providing pertinent information to the current state of health. · Referring to multiprofessional team if necessary.	· Guiding regarding the need of adaptation. · Scheduling a home visit.
Psychosocial needs - apprenticeship	
Nursing diagnosis/outcomes	
Low health knowledge Impaired communication between nurse and patient	Non-adherence to therapy
Nursing interventions	
· Adjusting therapeutic regimen to social and leisure activities. · Evaluating patient's tension. · Evaluating response to prescribed medication. · Describing therapeutic plan to patient in writing. · Providing pertinent information to the current state of health. · Establishing active listening. · Stimulating self-care. · Explaining actions and possible adverse effects of medication. · Facilitate access to treatment (scheduling appointments/return, adjusting inputs and available medications).	· Speaking calmly with short sentences of easy understanding. · Identifying the side effect of therapeutic regimen. · Encouraging treatment adherence. · Guiding regarding use of medication. · Guiding regarding doubts related to prescribed treatment. · Scheduling home monitoring with the nursing team. · Providing a calm environment (office or home). · Using a calm and safe approach. · Checking if patient understood the guidelines provided.
Psychospiritul needs	
Psychospiritual needs - religious	
Nursing diagnosis/outcomes	
Conflictual religious belief	
Nursing interventions	
· Supporting the person's spiritual practices. · Encouraging attendance at religious ceremonies.	· Identifying spiritual beliefs. · Respecting food restrictions related to religious beliefs.

Chart 2. Distribution of diagnoses and interventions by basic human needs

Needs	Diagnoses	Interventions
Psyichobiological needs		
Skin and mucosal integrity	26	59
Nutrition	07	28
Regulation	11	37
Perception	06	37
Sleep and rest	02	11
Sexuality	01	08
Physical activity	02	05
Hydration	02	09
Body care	03	09
Physical security	02	15
TOTAL	62	220
Psychosocial needs		
Freedom and participation	03	11
Emotional security, self-esteem	07	21
Self-image	01	05
Gregarious and leisure	03	09
Love and acceptance	03	15
Self-achievement	01	05
Apprenticeship	03	18
Total	21	84
Psychospiritual needs		
Religious	01	04
Total	01	04
Grand total	84	306

Discussion

Since the care of people with venous ulcer is complex, nurses must rely on a holistic perspective for a full approach to individuals, especially when considering they are particularly weakened and biopsychosocially impacted.[17] This fact corroborates the pertinence of chosing the Basic Human Needs Theory by demonstrating its applicability to meet the needs of this population and contributes to the organization of diagnoses in an integral and comprehensive way.

Most diagnoses were included in psychobiological needs with focus on skin and mucosal integrity. After all, venous ulcer is commonly characterized by its location in the lower part of the leg, of superficial depth or partial thickness, reaching only the epidermis and dermis, with granulation tissue in its bed, irregular edges, and medium to large amount of exudate of serous or serous bloody aspect.[6,18,19] The estimated recurrence rate for improved venous ulcers is about 70%.[3,20]

The main etiology of venous ulcer is Chronic Venous Insufficiency (CVI), which is the most prevalent of venous diseases and affects 2% of the western population.[21] Thus, in the psychobiological need for regulation, the venous stasis caused by CVI results in skin and microcirculation changes that cause edema, lipodermatosclerosis, varicose veins, hyperpigmentation, eczema, dermatitis and cellulitis or erysipelas, which will culminate in ulceration.[4,5]

In the psychobiological need for perception, pain is a frequent symptom in people with venous ulcer, and prevalence of around 80% in this population.[18,22,23] Its chronic condition bears a close relation to decreased functional and working capacity, sleep pattern disturbances, increased wound healing time and even social isolation, which significantly reduce the quality of life of these people.[3,18,22]

Regarding psychosocial needs, the presence of ulcers affects the body self-image, self-esteem, social and family life, the ability for work and daily activities, and causes important damages to those affected.[1,24]

Most of the evidence refers to psychobiological needs with a focus on the injury. Thus, it will be the nurses's role in the exercise of care to turn this thread of their practice (this subset) from a hard technology into a light technology by using criticality and mediation through dialogue with patients, and by considering people as subjects of learning for their self-care, understanding them as historical and autonomous subjects.

The validation of the nursing diagnoses allows the perfection and legitimization of the taxonomy, and enables the generalization and increase of its prediction.[25] A methodological proposal for validation of the subsets has not been defined by the ICN.[12]

The validation by consensus allows an exhaustive discussion in a potential group, the deepening of knowledge about it and greater use of the classification.[26] All nurses participated in the discussions about the permanence or withdrawal of some diagnoses and interventions, such as changing the writing of items of the subset in order to fit the professional practice.

The ICNP® subset for people with venous ulcer that was validated in the present study can qualify

nursing care for these people. Since this is a documentation instrument, it supports and improves clinical practice, and facilitates the incorporation of the ICNP® in nurses' practice. However, it is noteworthy that catalogs do not replace nurses' clinical judgment in decision making for individualized care.[12]

Despite the evident importance of the subset, some points must be considered: the validation process occurred in a small group of specific population, which may limit its applicability in other scenarios. Nonetheless, the scientific basis for its construction emerged from studies and national and international clinical guidelines published in indexed journals. Submitting this subset to clinical validation, as well as external validation that considers several cultural scenarios and extracts can improve its sensitivity and specificity.

Conclusion

The study allowed the development and validation of a terminological subset with 84 nursing diagnoses and outcomes, and 306 interventions for care of the person with venous ulcer from the ICNP®, and structured on the Basic Human Needs Theory. Besides supporting the organization of the subset, this theory provided theoretical-conceptual contribution to the study. The ICNP® proved to be a taxonomy compatible with nurses' clinical practice given its usual vocabulary in professional practice. This terminology has perceptible potential for the organization of nurses' work process both in the outpatient and hospital setting. The proposed instrument is expected to be the subject of further studies for its inclusion in the professional practice of nurses caring for people with venous ulcer in order to be a mechanism for improvement of the care provided.

Collaborations

Grasse AP, Bicudo SDS, Primo CC, Zucolotti C, Belonia CSFO, Bringuente MEO, Araújo TM and Prado TN contributed with conception of the study, analysis and interpretation of data, relevant critical revision of intellectual content and approval of the final version to be published.

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ACTA 30 YEARS 1988 - 2018

Original Article

Effect of an educational intervention on pregnancy: a cluster-randomized clinical trial

Efeito de uma intervenção educativa na gravidez: ensaio clínico randomizado em cluster

Efecto de una intervención educativa en el embarazo: ensayo clínico randomizado en clúster

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Abstract
Objective: To evaluate the effects of an educational intervention on the knowledge, attitudes, and practices of pregnant women regarding the use of regional foods.
Methods: Single-blind cluster-randomized clinical trial with two parallel groups. The study was carried out from January to September 2013. Cluster random allocation was defined by the simple random allocation process. A draw was performed with the clusters, followed by a random allocation to choose the health units. Cluster A was part of the intervention group and cluster B was included in the control group. The intervention group had 91 pregnant women, who were introduced to an educational booklet, and the control group had 94 pregnant women, who attended regular prenatal appointments.
Results: The effect of the educational booklet on the intervention group presented statistical significance ($p < 0.001$) on the seventh and thirtieth days after the intervention when compared to the results of the control group, and there was an increase in the prevalence of adequacy of knowledge, attitudes, and practices regarding the use of regional foods.
Conclusion: The educational booklet was an effective intervention to improve the knowledge, attitudes, and practices of pregnant women regarding the use of regional foods.

Resumo
Objetivo: Avaliar os efeitos de uma intervenção educativa no conhecimento, na atitude e na prática das gestantes sobre o uso dos alimentos regionais.
Métodos: Ensaio clínico controlado randomizado em cluster, unicego, com dois grupos paralelos. O estudo foi realizado no período de janeiro a setembro de 2013. Alocação randômica dos conglomerados foi definida pelo processo de alocação aleatória simples. Na ocasião foi utilizado um sorteio entre os conglomerados/cluster e depois foi realizada uma alocação aleatória para escolha das USs. Desta maneira, o conglomerado A fez parte do GI e o conglomerado B do GC. Participaram 91 gestantes no GI (cartilha educativa) e 94 gestantes no GC (consulta pré-natal de risco habitual).
Resultados: O efeito da cartilha educativa no grupo de intervenção apresentou significância estatística ($p<0,001$) no sétimo e trigésimo dia pós-intervenção, quando comparados com o grupo controle e aumento da prevalência com adequabilidade do conhecimento, atitude e prática quanto ao uso dos alimentos regionais.
Conclusão: A cartilha educativa foi uma intervenção eficaz para melhorar o conhecimento, atitude e prática das gestantes quanto ao uso dos alimentos regionais.

Resumen
Objetivo: Evaluar los efectos de intervención educativa en conocimiento, actitud y práctica de las embarazadas sobre uso de los alimentos regionales.
Método: Ensayo clínico controlado randomizado en clúster, simple ciego, con dos grupos paralelos. Estudio realizado de enero a setiembre de 2013. La asignación randomizada de los conglomerados fue definida por proceso de asignación aleatoria simple. Se aplicó un sorteo entre los conglomerados/clústeres, realizándose luego una asignación aleatoria para elección de las USs. De esta manera, el conglomerado A formó parte del GI y el conglomerado B del GC. Participaron 91 embarazadas en el GI (libreta educativa), y 94 en el GC (consulta prenatal de riesgo normal).
Resultados: El efecto de la libreta educativa en el grupo intervención presentó significatividad estadística ($p<0,001$) en el séptimo y trigésimo día postintervención al compararlo con el grupo control, hubo aumento de la prevalencia con idoneidad del conocimiento, actitud y práctica respecto del uso de alimentos regionales.
Conclusión: La libreta educativa demostró ser eficaz para mejorar el conocimiento, actitud y práctica de las embarazadas respecto al uso de los alimentos regionales.

Brazilian Clinical Trials Registry (ReBEC): RBR 7mhyzt.

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Introduction

The guarantee of positive outcomes in the health of pregnant women and fetuses is a priority subject in the World Health Organization. Scientific evidence has been accumulated to ground food and nutrition policies and nutritional interventions to achieve a healthy diet during pregnancy. Nutritional guidance can provide an adequate weight gain from healthy dietary habits, thus preventing pregnant women from putting on excessive weight and consequently reducing the chances of maternal health problems and undesirable fetal outcomes.[1,2]

To promote a healthy diet in the Brazilian population, the Brazilian Ministry of Health developed a manual entitled Brazilian Regional Food. The objective of the publication is to disseminate the consumption of fruits, vegetables, tubers, and legumes and confirms the commitment to promote healthy dietary practices and prevent nutritional complications related to food and nutrition insecurity.[3]

International agencies recognize pregnancy as a phase with increased nutritional needs to support the maternal development and fetal growth[4] and recommend an increment in the ingestion of carbohydrates, fibers, proteins, and micronutrients, including vitamin A, complex B vitamins, folate, and iron.[5] However, an investigation carried out in Canada showed an inadequacy in the consumption of micronutrients from food sources with high prevalence for ingestion of iron (97%), vitamin D (96%), and folate (70%).[6] Authors pointed that in Brazil 90% of pregnant women present a high energy consumption, with an excessive ingestion of calories, and inadequacy of nutrients.[7] Consequently, it is recommended that primary healthcare professionals develop food and nutrition education strategies to promote a healthy diet based on the valorization of food culture.[2]

Food and nutrition education is a fundamental tool to promote health and aims to encourage the autonomy of individuals to value and respect cultural specificities and empower these people regarding their health care.[8] Authors consider that nurses, by developing health education actions, have the objective to improve the health and life conditions of the population. Therefore, educational programs must be implemented constantly and effectively to achieve their goal of improving the health of the society.[9]

Studies show that educational strategies have been proved efficient for adapting knowledge, attitudes, and practices (KAP) of some populations.[10,11]

This scenario sets the need to know the behavior of the assisted population from the KAP diagnosis and offer healthcare professionals the basis to develop health education strategies.

Considering the relevance of this subject to promote healthy eating habits during pregnancy, the objective of the present study was to evaluate the effects of an educational intervention on the KAP of pregnant women regarding healthy dietary habits with the use of regional foods.

Methods

The present investigation was a controlled single-blind cluster-randomized clinical trial, with two parallel groups, carried out with pregnant women submitted to the intervention of an educational booklet (intervention group or IG) and pregnant women who received nutritional guidance in regular prenatal appointments (control group or CG) according to the recommendation of the primary healthcare booklet of the Brazilian Ministry of Health.[2]

The study was blind when both pregnant women and nurses from health units did not have knowledge of the use of the educational booklet. Data collection occurred from January to September 2013, which allowed to reach the number of participants suggested by the sample size calculation. The confidence interval was 95% and the statistical power was 80%.

The political-administrative regions of Recife, state of Pernambuco, Brazil, were divided into clusters, with their respective health units. Cluster random allocation was defined by the simple random allocation process. A draw was performed with the clusters, followed by a random allocation to choose

the health units. As a result, cluster A was part of the IG and cluster B was included in the CG.

It is noteworthy that the random assorting of the health units to make up the IG and the CG in the same conglomerate followed the Consolidated Standards of Reporting Trials 2010 guideline, this procedure implies a high contamination risk of pregnant women from health units from each branch, that is, pregnant women from the CG could be affected by the intervention and hence the experiment would have been contaminated.

The pregnant women included in the study where those 18 years old or older who received prenatal care in health units and had a landline or a cell phone. Exclusion criteria were pregnant women with a gestational age higher than 36 weeks, or those who had difficulties to understand the questions of the questionnaire or the intervention, or had gestational or preexisting diabetes or gestational or chronic hypertension. Withdrawal or loss criteria were miscarriage or interrupted pregnancy or the impossibility to contact the patient by phone after ten attempts at different times and consecutive days. Initially, 294 pregnant women were eligible. The final analysis determined that the IG had 91 participants and the CG had 94. Figure 1 represents the sampling strategy to obtain the study sample.

Research assistants were trained before data collection to standardize collection procedures, addressed concepts, and execution of the pilot test, referring to tools and educational interven-

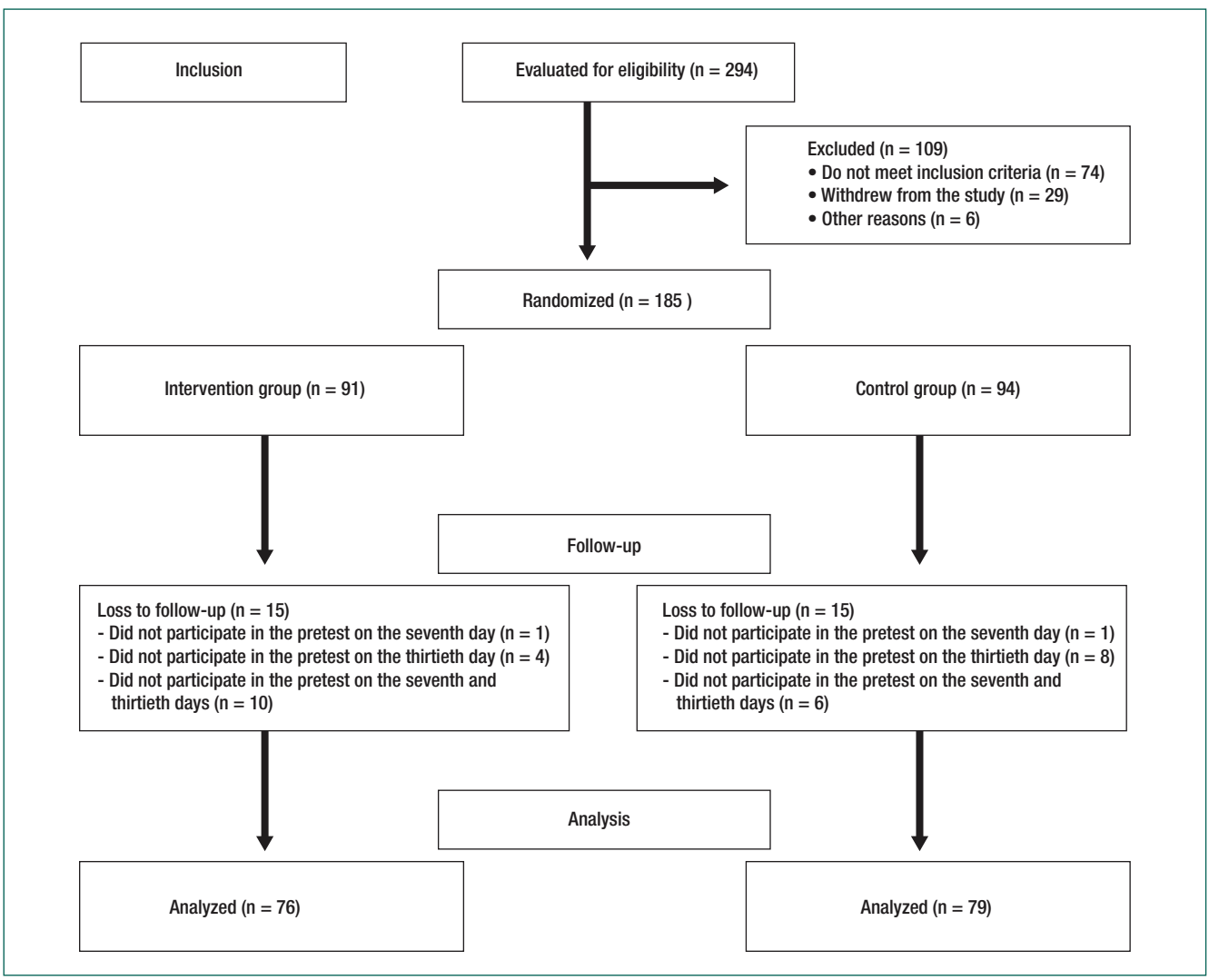

Figure 1. Sampling strategy to determine the study sample

tion. Collection took place in health units according to prenatal appointment days, analysis of inclusions, and active search of participants by phone contact.

A booklet entitled Healthy Diet during Pregnancy with Regional Foods (*Alimentação Saudável na Gravidez com os Alimentos Regionais*) was designed and validated to be applied in the intervention of the present study. The dimensions were 148 mm x 210 mm, and the publication had eight pages and was printed on both sides of the paper. The content is related to the concept of healthy nutrition, foods which are allowed and which should be avoided during pregnancy, the benefits of healthy dietary habits for mothers and babies, food hygiene, and recipes with regional foods.[12]

After a prenatal appointment, the women from the IG were invited to participate in the individual intervention in a private room, in a single session, with an average duration of 20 minutes. During this meeting, the booklet was introduced, read, and the patients kept a copy to take home.

The Brazilian Food Insecurity Scale (*Escala Brasileira de Insegurança Alimentar*) was used to assess the homogeneity of the sample and baseline of the IG and the CG in the pretest, before the prenatal appointment. This scale was developed and validated by researchers of the State University of Campinas, the Brazilian Ministry of Health, the Pan American Health Organization, and the São Paulo Research Foundation.[13]

The KAP survey was designed and validated for the present study to evaluate the primary outcome: analysis of the adequate and inadequate levels of knowledge, attitudes, and practices regarding regional foods. The instrument was applied on the seventh and thirtieth days to pregnant women from both groups. Follow-up was carried out by phone.

The authors created some definitions to analyze the KAP. The knowledge was considered adequate when used to prepare varied meals and/or juices, pregnant women referred to have heard of regional foods, knew three or more types of regional foods, and mentioned at least two types of meals prepared with regional foods. The attitude was considered adequate when pregnant women referred to be necessary to use regional foods in their meals and mentioned the importance of these items. The practice was considered adequate when pregnant women referred to have used regional foods in their meals and to use these items at least twice a day. For all the axes, inadequacy meant that pregnant women had negative answers to each situation mentioned in this paragraph.

Data were analyzed by the SSPS version 20 program. Pearson's chi-square test was used to compare qualitative variables between the intervention and control groups. When the expected frequencies were lower than 5, the Fisher's test was applied, or the Fisher-Freeman-Halton test, if the comparison involved variables with more than two categories. The odds ratio and its confidence interval were calculated to check the magnitude of the effect. In the comparison between quantitative measurements and intervention and control groups, the Mann-Whitney test was used. A level of significance of 5% was applied in all analyses.

The proposal was submitted to evaluation by the Research Ethics Committee of the Federal University of Pernambuco and approved under protocol no. 123,140/2012.

Results

There was no significant statistical difference between baselines in both IG and CG according to social and economic variables. The highest percentages referred to pregnant women with brown skin (IG = 68.4% and CG = 72.2%) who did not work (IG = 68.4% and CG = 64.6%) and had a family income of up to two minimum wages (IG = 73.7% and CG = 79.8%). Most pregnant women declared to have a partner and had complete elementary school and higher education (IG = 85.5% and CG = 86.1%). The age median was 24 years for the IG (CI = 23.90 – 26.31) and 25 years for the CG (CI = 24.27 – 26.75). The median gestational ages were 23 weeks and 5 days

(CI = 19.95 – 23.57) and 20 weeks (CI = 18.04 – 21.74) for the IG and CG, respectively. It is important to stress that the social and economic equivalence observed in the clusters minimized the so-called cluster effect.

The equilibrium between baselines of pregnant women from the IG and CG revealed the leveling of subjects in each branch of the experiment, thus decreasing the risk of bias. The evaluation of KAP showed no statistical difference ($p > 0.05$). In terms of percentage, the number of women who had an inadequate level in the pre-appointment was higher in both IG and CG in comparison with the adequate level. The values were, respectively: inadequate knowledge (93.4% and 93.4%), inadequate attitudes (69.7% and 57.0%), and inadequate practices (88.2% and 91.13%) (Table 1).

Table 1. Results of the baseline of knowledge, attitudes, and practices of pregnant women from the intervention and control groups regarding regional foods

KAP survey**		Intervention group (n = 76) n (%)	Control group (n = 79) n (%)	p-value*
Pre-appointment knowledge	Adequate	5 (6.6)	5 (6.3)	0.950
	Inadequate	71 (93.4)	74 (93.4)	
Pre-appointment attitudes	Adequate	23 (30.3)	34 (43.0)	0.099
	Inadequate	53 (69.7)	45 (57.0)	
Pre-appointment practices	Adequate	09 (11.8)	07 (8.86)	0.542
	Inadequate	67 (88.2)	72 (91.13)	

*The p-value was analyzed with Pearson's chi-square test; **Knowledge, attitudes, and practices

Regarding the effect of the intervention caused by the use of the educational booklet, the results indicate an adequate KAP level on the IG in the seventh and thirtieth days after the intervention in comparison with the level shown in the CG. The IG had $p<0.001$, with increased chances of adequate knowledge on the seventh (OR = 68.01 and CI = 24.48 – 188.97) and thirtieth days (OR = 83.57 and CI = 26.18 – 266.72). The results for adequate attitudes were OR = 13.16 and CI = 4.8 – 36.08 on the seventh day, and OR = 36.07 and CI = 8.27 – 157.23] on the thirtieth day for the IG. Analysis of adequate practices data revealed an OR = 6.61 and a CI = 3.13 – 13.98 on the seventh day, and an OR = 7.24 and a CI = 3.57 – 14.81 on the thirtieth day for the IG (Table 2).

Table 2. Effect of educational intervention on pregnant women according to the evaluation of knowledge, attitudes, and practices regarding regional foods

KAP survey		Intervention group (n = 76) n (%)	Control group (n = 79) n (%)	*Statistics
Knowledge Seventh day	Adequate	69 (90.8)	10 (12.7)	p < 0.001 OR = 68.01
	Inadequate	7 (9.2)	69 (87.3)	CI (24.48 – 188.97)
Knowledge Thirtieth day	Adequate	72 (94.7)	14 (17.7)	p < 0.001 OR = 83.57
	Inadequate	4 (5.3)	65 (82.3)	CI (26.18 – 266.72)
Attitudes Seventh day	Adequate	71 (93.4)	41 (51.9)	p < 0.001 OR = 13.16
	Inadequate	5 (6.6)	38 (48.1)	CI (4.80 – 36.08)
Attitudes Thirtieth day	Adequate	74 (97.4)	40 (50.6)	p < 0.001 OR = 36.07
	Inadequate	2 (2.6)	39 (49.4)	CI (8.27 – 157.23)
Practices Seventh day	Adequate	43 (56.6)	13 (16.5)	p < 0.001 OR = 6.61
	Inadequate	33 (43.4)	66 (83.5)	CI (3.13 – 13.98)
Practices Thirtieth day	Adequate	53 (69.7)	19 (24.1)	p < 0.001 OR = 7.28
	Inadequate	23 (30.3)	60 (75.9)	CI (3.57 – 14.81)

*The p-value was analyzed with Pearson's chi-square test and the statistical significance was $p < 0.05$. OR: odds ratio. CI: confidence interval (95%)

Discussion

The social and economic data collected in the present study revealed that most pregnant women in the sample were brown, did not work, and had a family income of up to two minimum wages. These results are compatible with the characteristics of the population that lives in the place where the investigation was carried out and the information from the State Plan for Food and Nutrition Security of Pernambuco, which pointed that the Brazilian regions with the lowest income are North and Northeast, with an average household income similar to that indicated by the present study.[14] Some authors declared that family income is a factor that directly interferes with the quality of the diet of the examined pregnant women, and that the higher the family income, the higher the adherence to a healthy eating plan.[15]

In this scenario, the consumption of regional foods is important to pregnant women because, in addition to their bioavailability and low cost, they are nutritious and enrich diet with fibers,

minerals, vitamins, and carbohydrates. The Northeast region of Brazil has a variety of regional foods, including fruits such as acerola, banana, and coconut, vegetables such as squash, watercress, and bur gherkin, roots such as yam and manioc, legumes such as green beans, in addition to tubers and cereals.[3]

Regarding the evaluation of inadequacy of knowledge, attitudes, and practices, most pregnant women in the CG had inadequate information regarding the use of regional foods, which may reinforce the limited access to the orientations about the consumption of these items, which are part of the eating culture of a region or community. These results also reveal the importance to emphasize the "regional foods" terminology during the guidance on healthy dietary habits. This would help pregnant women to develop adequate opinions about the importance of these foods. The women in the IG recognized this terminology with an adequate knowledge on the seventh (90.8%) and thirtieth (94.7%) days after the introduction of the educational booklet.

Similar findings were described in an investigation on the influence of an educational strategy on the promotion of the use of regional foods with preschool children. Most (96.8%) students began to recognize this terminology after the intervention. The authors of this study believed that the results should not be interpreted as if the examined population did not know nor consumed regional foods, but as an indication that it was not familiar with the used terminology.[16]

The findings of the present investigation reveal adequacy of knowledge, attitudes, and practices of pregnant women from the IG regarding the use of regional foods on the seventh and thirtieth days, with statistical significance, in comparison with the results obtained for the CG. It is valid to stress that the educational booklet presents illustrations of regional foods chosen by the pregnant women through a poll. Therefore, the publication respects local preferences and suggests recipes including regional foods with options for daily meals (mashed manioc, squash soup, tapioca, couscous, cooked banana, beans with squash, banana vitamin, etc.)

Authors consider that respecting regional eating habits is related to the recovery of a healthy dietary routine and has an important meaning for valuing the culture of the region. In addition, regional foods are commonly associated with a healthy diet and healthy people, which contributes to justifying their relevance in the promotion of healthy eating habits.[17]

Regarding the practice related to the use of regional foods, the IG obtained percentages of 56.6% on the seventh day and 16.5% on the thirtieth day in comparison with the CG ($p < 0.001$). This result corroborates what is observed in the reality of prenatal care, when healthcare professionals notice the difficulties pregnant women have to follow a dietary plan.

A healthy eating plan advocates the consumption of six portions per day of cereals, roots, and tubers, three portions per day of fruits and vegetables, one portion per day of beans and seeds, and one portion per day of sugars and sweets, whose daily ingestion is recommended for pregnant women.[2,3] These food groups encompass a significant number of regional foods and are sources of fibers, vitamins, and minerals.

Results of a Brazilian study revealed that only 10% of the population eat fruits and vegetables in accordance with the nutritional recommendations.[18] Another investigation compared the food consumption of pregnant and nonpregnant women and showed that there was no significant difference between these groups. The first group presented inadequate consumption of the nutrients iron, folate, and calcium, according to the daily intake recommendation of the Institute of Medicine.[19]

Authors stress the importance of health education to achieve a healthy diet during pregnancy, because in this phase most women are motivated to receive guidance on healthy eating habits and declare that changes in the diet have low cost and represent a lower risk to develop problems.[20]

The intervention in the present study was the booklet, applied as an educational material designed to impact on KAP. The findings pointed to an influence on the adequacy of the use of regional foods. A study emphasized that the use of booklets is a means to carry out actions oriented toward promot-

ing nutritional improvement in medical offices and an important part of the verbal communication between professionals and clients.[21] An investigation described a clinical trial with pregnant women using an educational activity based on the use of leaflets designed to improve dietary habits, increase the level of physical activity, and reduce obesity during pregnancy. The IG showed a significant increase in the consumption of vegetables in comparison with the CG.[22]

The pregnant women who participated in the present study attended regular prenatal appointments with primary healthcare nurses. To include nutritional changes more effectively, the educational booklet Healthy Diet during Pregnancy with Regional Foods (*Alimentação Saudável na Gravidez com os Alimentos Regionais*) was developed and validated.[12] Its effect was assessed by applying a KAP survey, and the results confirmed its applicability to increase knowledge, attitudes, and practices of the women in the sample. After the clinical validation performed in the present investigation, the booklet may be indicated as a health educational material, adding to prenatal appointments.

Prenatal monitoring is an important healthcare strategy and includes the promotion of health, screening, diagnosis, and prevention of diseases.[2] A study designed to compare the KAP of women who attended prenatal appointments with the KAP of women who did not identified a significant effect on the level of awareness of the quantity of foods, the proper ingestion of proteins, vegetables, fruits, milk, greens, and meat, prevention of anemia with the consumption of iron, and vitamin supplementation.[23]

Studies aim to assess KAP in several populations and on different subjects, and there is the consensus that the KAP method is relevant to obtain diagnoses of examined populations, with the objective to improve the development of interventions oriented toward promoting adequate levels of knowledge, attitudes, and practices.[10,24] Researchers seek to assess the effects of interventions on the change of knowledge, attitudes, and practices using the KAP method.[10,16,23,24] Results similar to those described in the present paper have been reported.

Printed educational materials have been used to improve the knowledge, satisfaction, adherence to treatments, and self-care of patients. Educational publications written by healthcare professionals are a tool to reinforce the orientations discussed verbally and may positively impact on the education of patients and be able to help them answer questions which may emerge when the interaction with professionals is not possible.[25]

Therefore, the authors emphasize the importance of nutritional guidance on primary health care during prenatal monitoring as a dynamic and participative process involving professionals, pregnant women, and their families. Nurses must work with these women to obtain behavior changes toward healthy and adequate eating habits during this phase. Nurses commonly have experience on strategies to promote health and are an important part of the primary healthcare team.[26]

The present study was carried out in a specific area of the metropolitan region of Recife, state of Pernambuco, Brazil. Consequently, the sample size may not be large enough to generalize the findings and be representative of Brazilian pregnant women.

Conclusion

The intervention design, based on the educational booklet, made possible the access of pregnant women to guidance on healthy eating habits. It was observed that pregnant women from the IG presented more adequate knowledge, attitudes, and practices regarding the use of regional foods in comparison with the women from the CG, with an increase in the prevalence of the level of adequacy on the seventh and thirtieth days after the intervention. The educational booklet was an efficient intervention to improve knowledge, attitudes, and practices of pregnant women regarding the use of regional foods.

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Contributions

Oliveira SC, Fernandes AFC, Vasconcelos EMR, Ximenes LB, Leal LP, Cavalcanti AMTS, and Lopes MVO declare to have contributed to the project conception, data analysis and interpretation, manuscript writing, relevant critical review of the intellectual content, and final approval of the version to be published.

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Original Article

Factors associated with non-compliance with antiretrovirals in HIV/AIDS patients

Fatores associados à não adesão dos antirretrovirais em portadores de HIV/AIDS

Factores asociados a la no adhesión a los retrovirales de portadores de VIH/SIDA

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Descritores
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Descriptores
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Abstract
Objective: To identify the factors associated to non-compliance with antiretroviral treatment in HIV / AIDS patients at a reference hospital in Manaus.
Methods: Hospital-based, quantitative, cross-sectional study developed with 100 participants with HIV / AIDS in outpatient follow-up. For the data collection, the self-administered "Questionnaire for the evaluation of compliance with antiretroviral treatment in people with HIV / AIDS" (CEAT-VIH) was used. Descriptive analysis was performed using the Pearson chi-square to obtain the p-value.
Results: Male participants were predominant (57%), age between 40 and 59 years (34%), secondary education (49%), without employment bond (84%), monthly income of one to three minimum wages (54%), unmarried (47%), heterosexual (76%), with sexual partner (56%), without active sexual life (61%), time since diagnosis between six months and five years (59%), no hospitalization (%). The predominant level of compliance was medium compliance (85%). The sociodemographic variables that revealed a statistically significant association with ARVT were sexual orientation ($p = 0.010$) and time since diagnosis ($p = 0.035$).
Conclusion: The study showed that people living with HIV comply with ARVT, but with medium compliance. The main factors associated with this result were sexual orientation and time since diagnosis.

Resumo
Objetivo: Identificar os fatores associados à não adesão ao tratamento antirretroviral em portadores de HIV/ AIDS em um Hospital de referência em Manaus.
Métodos: Estudo com abordagem quantitativa, transversal de base hospitalar, desenvolvido com 100 participantes com HIV/AIDS em acompanhamento ambulatorial. Para a coleta de dados foi utilizado o questionário autoaplicável, denominado "Questionário para a avaliação da adesão ao tratamento antirretroviral em pessoas com HIV/AIDS" (CEAT–VIH). Foi realizada análise descritiva, empregado o teste de qui-quadrado de *Pearson chi-square* para o valor de p.
Resultados: Predominou o sexo masculino (57%), faixa etária entre 40 a 59 anos (34%) escolaridade de 2º Grau (49%), sem vínculo empregatício (84%), renda mensal de 1 a 3 salários mínimos (54%), solteiros (47%), heterossexuais (76%), com parceiro sexual (56%), sem vida sexual ativa (61%), tempo de diagnóstico entre 6 meses a 5 anos (59%), nenhuma internação hospitalar (59%). O nível de adesão predominante foi a média adesão (85%). As variáveis sociodemográficas que tiveram associação estatisticamente significantes com a adesão TARV foram a orientação sexual (p=0,010) e o tempo de diagnóstico (p=0,035).
Conclusão: O estudo mostrou que pessoas que convivem com HIV aderem a TARV, porém com média adesão e os principais fatores associados a esse resultado foram a orientação sexual e o tempo de diagnóstico.

Resumen
Objetivo: Identificar los factores asociados a la no adhesión al tratamiento antirretroviral en portadores de VIH/SIDA en Hospital de referencia de Manaus.
Métodos: Estudio con abordaje cuantitativo, transversal, de base hospitalaria, desarrollado con 100 participantes con VIH/SIDA en seguimiento ambulatorio. Datos recolectados mediante cuestionario autoaplicable, denominado "Cuestionario para evaluación de la adhesión al tratamiento antirretroviral en personas con VIH/SIDA" (CEAT-VIH). Se realizó análisis descriptivo, utilizando el test de Chi-cuadrado de Pearson *Chi-square* para el valor de p.
Resultados: Predominio de sexo masculino (57%), faja etaria de 40 a 59 años (34%), educación secundaria (49%), sin trabajo fijo (84%), ingresos mensuales de 1 a 3 salarios mínimos (54%), solteros (47%), heterosexuales (76%), con pareja sexual (56%), sin vida sexual activa (61%), tiempo de diagnóstico de 6 meses a 5 años (59%), sin internaciones hospitalarias (59%). El nivel de adhesión predominante fue la mediana adhesión (85%). Las variables sociodemográficas con asociación estadísticamente significativa con la adhesión al TARV fueron la orientación sexual (p=0,010) y el tiempo de diagnóstico (p=0,035).
Conclusión: El estudio mostró que las personas que conviven con VIH adhieren al TARV, aunque con mediana adhesión, y los principales factores asociados a tal resultado fueron la orientación sexual y el tiempo de diagnóstico.

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Conflicts of interest: none to declare

Introduction

First described in 1981, the Human Immunodeficiency Syndrome went through several demographic and epidemiological changes.[1]

With the discovery of new drugs in recent years, advances have been achieved in the fight against HIV. This fact had an impact on the prognosis and epidemiology of the disease, causing a significant decrease in morbidity and mortality in people living with the virus in Brazil and around the world, but these drugs present new challenges to understand and cope with this disease.[2,3]

Despite these changes in the HIV / AIDS profile, the number of HIV-positive people is still high. According to UNAIDS - Joint United Nations Program on HIV / AIDS, controlling the disease will only be possible when all those infected are being treated. Therefore, the goal "90-90-90" was established, which aims to ensure that all infected people are treated by 2020, that 90% of people living with HIV know they have the virus, 90% receive ARVT - Antiretroviral Therapy and 90% of these have viral suppression.[4]

Treatment compliance being one of the greatest challenges in care for people living with HIV, it is one of the key pieces to reduce future complications and to improve and prolong the quality of life of individuals affected by the virus. The correct use of the antiretrovirals generates a reduction of costs with future hospitalizations due to complications of the infection, as well as of the necessity to exchange the drug for other more complex and expensive medicines.[5]

In order to achieve good rehabilitation and stability of the patient affected by HIV / AIDS, good treatment compliance is fundamental. In this sense, a universal treatment access policy is put in practice with studies on the identification of factors that lead to the interruption of drug therapy, being highly relevant for a better understanding of the problem and for the appropriate performance of health professionals, favoring a higher quality and life expectancy for these people.[6]

In this context, the objective of this study was to identify factors associated to non-compliance with antiretroviral treatment in HIV / AIDS patients at a reference hospital in Manaus.

Methods

This is a quantitative, cross-sectional, hospital-based study conducted at the Outpatient Clinic of the Foundation for Tropical Medicine Dr. Heitor Vieira Dourado. Data collection took place from October 2017 to January 2018. Participants were included in the study during the routine outpatient visit. The interviews were conducted inside the doctor's office, permitting the secrecy and confidentiality of the information obtained.

The sample was consecutive and non-probabilistic, in accordance with the inclusion criteria: male and female patients, aged 18 years or older; patients diagnosed with HIV for more than six months; being registered in the institution's UDM-Medication Dispensation Unit; being on antiretroviral therapy for at least six months in the I Doctor system. According to these criteria, 100 participants were included in the study.

The self-administered "Questionnaire for the evaluation of compliance with antiretroviral treatment in people with HIV / AIDS" (CEAT/VIH) was used to collect the data, which was validated for the Brazilian version by Remor, Milner-Moskovics and Preussler.[7] This questionnaire was used to assess the compliance level to antiretroviral treatment. It is multidimensional, covering the main factors that can modulate the treatment compliance behavior.[7] Consisting of 20 questions, CEAT-VIH evaluates the patients' compliance level to ARVT at three levels: low (d" 52 points or <50%); medium (53 to 78 points or 50 to 84%); and high (e" 79 points or> 85%). The minimum score is 17 and the maximum is 89. The higher the score, the higher the treatment compliance level.[7]

The sociodemographic data related to the patients were obtained through the application of a semistructured questionnaire, prepared by the researcher.

The collected data were organized and systemized in an Excel® spreadsheet and analyzed

in Statistical Package for Social Sciences (SPSS), version 2.0.

Descriptive statistics were used for sociodemographic characterization and descriptions of the domain scores. The variables were expressed in absolute and relative frequencies, independent of the measuring level. For the analysis, chi-square tests were performed, inferential analyses with $p < 0.05$ being considered statistically significant.

The development of the study met Brazilian standards of ethics for research involving human subjects and obtained approval from the research ethics committee under CAEE 74054217.4.0000.5016.

Results

In this study, 100 participants answered the questionnaire regarding the sociodemographic data and compliance with ARVT. First, the variables related to the sociodemographic aspects were analyzed, in which the male sex predominated (57%). The predominant age group was between 40 and 59 years old (34%), with secondary education (49%). With regard to employment status, 84% reported being unemployed, with monthly income of one to three minimum wages (54%). The majority of them reported being self-employed, single (47%). The predominant sexual orientation was heterosexual (76%), with a sexual partner (56%), no active sex life (61%), time since diagnosis between six months and five years (59%). The predominant hospitalization was none (59%) during the antiretroviral treatment of HIV patients attended during the study (Table 1).

Among the 100 interviewees, 85% were classified as medium compliance, 13% as high and only 2% as low compliance according to their answers and the total CEAT/HIV score. The minimum score in the study was 47 and the maximum 82, with an average score of 70.63 and a standard deviation of 7.67 (Table 2).

A statistically significant association was observed between two sociodemographic variables and the compliance levels with ARVT: sexual orientation (p=0.010) and time since diagnosis (p=0.035).

Table 1. Distribution of sociodemographic data of the 100 participants in the study population

Variables	n(%)
Sex	
Male	57(57.0)
Female	43(43.0)
Age Range	
18 to 29 years	10(10.0)
30 to 39 years	28(28.0)
40 to 59 years	34(34.0)
50 to 59 years	14(14.0)
>60 years	14(14.0)
Education	
Illiterate	2(2.0)
Primary	35(35.0)
Secondary	49(49.0)
Higher	14(14.0)
Employment	
Yes	16(16.0)
No	84(84.0)
Monthly income	
< 1 minimum wage	42(42.0)
1 to 3 minimum wages	54(54.0)
3 to 5 minimum wages	3(3.0)
> 5 minimum wages	1(1.0)
Marital Status	
Single	47(47.0)
Married	11(11.0)
Living with Fixed Partner	33(33.0)
Separated	4(4.0)
Divorced	1(1.0)
Widowed	4(4.0)
Sexual orientation	
Homosexual	18(18.0)
Bisexual	6(6.0)
Heterosexual	76(76.0)
Has a sexual partner	
Yes	56(56.0)
No	44(44.0)
Active sexual life	
Yes	39(39.0)
No	61(61.0)
Time since diagnosis	
6 months to 5 years	59(59.0)
6 years to 10 years	28(28.0)
11 to 15 years	7(7.0)
16 to 20 years	6(6.0)
Hospitalization antecedents	
None	59(59.0)
1 to 3 times	35(35.0)
3 to 5 times	2(2.0)
> 5 times	4(4.0)

Table 2. Classification of antiretroviral treatment compliance data

Compliance levels*	n(%)
Low	2(2.0)
Medium	85(85.0)
High	13(13.0)

*Levels defined according to classification of compliance with antiretroviral therapy of the version of the "cuestionario para la Evaluación de la Adhesión al tratamiento antirretroviral – CEAT/HIV" validated for Brazilian Portuguese

Table 3. Distribution of sociodemographic data and Compliance Level with Antiretroviral Therapy

Variables	High compliance n(%)	Medium compliance n(%)	Low compliance n(%)	Total n(%)	p-value*
Sex					
Male	9(16)	46(80)	2(4)	57(100)	0.274
Female	4(9)	39(91)	0(0)	43(100)	
Age Range					
18 to 29 years	1(10)	9(90)	0(0)	10(100)	0.438
30 to 39 years	3(11)	23(82)	2(7)	28(100)	
40 to 59 years	7(20)	27(80)	0(0)	34(100)	
50 to 59 years	1(7)	13(93)	0(0)	14(100)	
>60 years	1(7)	13(93)	0(0)	14(100)	
Education					
Illiterate	0(0)	2(100)	0(0)	2(100)	0.622
Primary	3(9)	31(88)	1(3)	35(100)	
Secondary	8(16)	41(84)	0(0)	49(100)	
Higher	2(14)	11(79)	1(7)	14(100)	
Employment					
Yes	2(12)	14(88)	0(0)	16(100)	0.819
No	11(13)	71(85)	2(2)	84(100)	
Monthly income					
< 1 minimum wage	2(5)	39(93)	1(2)	42(100)	0.443
1 to 3 minimum wages	11(20)	42(78)	1(2)	54(100)	
3 to 5 minimum wages	0(0)	3(100)	0(0)	3(100)	
> 5 minimum wages	0(0)	1(100)	0(0)	1(100)	
Marital Status					
Single	7(15)	39(83)	1(2)	47(100)	0.735
Married	1(9)	10(11.8)	0(0)	11(100)	
Living with Fixed Partner	3(9)	29(88)	1(3)	33(100)	
Separated	0(0)	4(100)	0(0)	4(100)	
Divorced	0(0)	1(100)	0(00	1(100)	
Widowed	2(50)	2(50)	0(0)	4(100)	
Sexual orientation					
Homosexual	6(33)	11(61)	1(6)	18(100)	0.010
Bisexual	2(33)	4(67)	0(0)	6(100)	
Heterosexual	5(6)	70(92)	1(2)	76(100)	
Has a sexual partner					
Yes	6(46.2)	49(57.6)	1(50.0)	56(100)	0.728
No	7(53.8)	36(42.4)	1(50.0)	44(100)	
Active sexual life					
Yes	6(15)	32(82)	1(3)	39(100)	0.800
No	7(11)	53(87)	1(2)	61(100)	
Time since diagnosis					
6 months to 5 years	6(10)	52(88)	1(2)	59(100)	0.035
6 years to 10 years	3(11)	25(89)	0(0)	28(100)	
11 to 15 years	3(43)	4(57)	0(0)	7(100)	
16 to 20 years	1(17)	4(66)	1(17)	6(100)	
Hospitalization antecedents					
None	6(10)	52(88)	1(2)	59(100)	0.781
1 to 3 times	7(20)	27(77)	1(3)	35(100)	
3 to 5 times	0(0)	2(100)	0(0)	2(100)	
> 5 times	0(0)	4(100)	0(0)	4(100)	

*_p-values_ calculated by means of Pearson's chi-square test, comparing the compliance level with each variable

When the variables sex, age range, education, employment, monthly income, sexual partner, active sexual life and hospitalization antecedents were considered, no statistically significant association was observed (Table 3).

Discussion

The precariousness of research on this topic in the North of Brazil is noted, where the mortality due to AIDS showed the highest growth rate in the past 10 years.[8]

The participants' sociodemographic characteristics confirm the profile of seropositive individuals in Brazil, with a predominance of males, between 40 and 59 years of age, secondary education level (high school), monthly income between one and three minimum wages, single and heterosexual, with sexual partner, but without active sex life.

Studies conducted in other regions indicated that 60% of infected individuals were male and 58.7% were between 40 and 59 years old.[9] Studies conducted outside Brazil found that female individuals were predominant though.[10]

In another study, results similar to the present study were found, with a predominance of secondary education and monthly income between 1 and 3 minimum wages.[11]

Studies show that, the higher the level of education, the better the people's perception, as well as the access to information about HIV / AIDS.[3] In this sense, the expected result regarding the education level was lower than that obtained, as in some studies where low education prevailed.[1] As noticed, the result of this study proves how the HIV profile in Brazil has been changing over time.

The results of this study corroborate those of other authors, where single individuals prevailed.[12] Studies have shown that single people have a lower chance of using condoms than married couples.[4] This may influence the increase of infection and transmission risks. They are more promiscuous and less careful about their health because they have to take care of themselves alone.[14]

In 2016, HIV / AIDS infection was predominant among heterosexuals in almost all regions of Brazil, except for the Southeast, where the infection was predominant among homosexuals.[15] These data further affirm the change in the profile of HIV / AIDS, which in the early phase of the disease prevailed among homosexuals.[12]

With regard to the employment bond, we can note some studies with results different from those found in this study, with a prevalence of people living with the virus and being formally employed.[9]

It is observed that most had sexual partners but did not have an active sexual life. Some participants reported having lost sexual pleasure after discovering the virus. In a study conducted in another region, people living with HIV reported restricting or suppressing their sexual practices because they had to reveal their HIV-positive status and were afraid of transmitting the disease, but they kept their sex life active,[16] which did not occur with the participants of this study, as sexual inactivity prevailed.

Regarding the time since diagnosis from six months to five years, our results differed from studies conducted in other regions, where the patients had been living with HIV ≥ 10 years.[9] Few studies are related to the time since diagnosis though, as most of them study the treatment time.

Regarding the hospitalization history, the results showed that no hospitalization prevailed in the study participants. No studies were found in the literature regarding this variable.

There were limitations in this study due to the short time of data collection. Because the data collection was performed in only one clinic and in a state with a high number of seropositives, the study population is considered small.

This study offers an important contribution in presenting the factors associated with non-compliance to ARVT and in measuring the level of compliance of seropositive individuals, making it possible to outline strategies to decrease these factors and to improve compliance with drug therapy.

Concerning the level of compliance with ARVT in the participants with a prevalence of medium compliance, similar results were also found using the same CEAT-HIV assessment tool, which is considered the most specific to assess the compliance level, despite its limitations.[17]

This result is worrisome as virologic failure can occur, making the viral load detectable during the treatment, representing a barrier to the success of the therapy, which can entail risks of disease progression, viral resistance and, consequently, the reduction of future therapies.[11]

For the sake of effective therapy, the patient needs to consume at least 95% of the prescribed medications, in order to keep the viral load undetectable and be able to reasonably reduce the possibility of virus transmission. Thus, the effectiveness of the ARVT depends on the compliance.[8]

On the other hand, other studies carried out in other parts of Brazil showed quite different results, where high compliance levels prevailed. This can be explained by lifestyle variation, access to quality treatment and early diagnosis.[9]

Because AIDS is classified as a chronic disease, we cannot judge this level of compliance as definitive because it can vary at any time during therapy. Therefore, it is important for health professionals to encourage compliance.[11]

Among the variables studied, those associated with ARVT compliance are sexual orientation, where studies with similar results were found in which sexual orientation was statistically significant.[18]

The other variable that presented statistical significance was the time since diagnosis. Some studies argue that, the longer the diagnosis, the better the compliance,[9] but the result of this study did not prove this, in view of variations in the results.

Conclusion

The study showed that people with HIV complied with antiretroviral therapy, but with medium compliance, and the main factors associated with this result were sexual orientation and time since diagnosis. This result is worrying, which may be related to the increase in the transmissibility of the disease and the increase in the number of HIV cases in the state of Amazonas. In this sense, it suggests the follow-up of ARVT compliance in people living with

the virus. Assuming that compliance is a continuous process involving not only the seropositive individuals, but also the family and health professionals, the active search of people who dropped out of the treatment is of utmost importance because they did not even enter the research as they were not monitored at the place of study.

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Collaborations

Menezes EG contributed to the project design and to the analysis and interpretation of the data. Santos SRF contributed to the project design and to the analysis and interpretation of the data. Melo GZS contributed to the relevant critical review of the intellectual content. Torrente G collaborated with the relevant critical review of the intellectual content. Pinto AS collaborated with the data collection and execution of the research. Andrade YNL cooperated with the writing of the article and with the relevant critical review of the intellectual content. Both approved the final version for publication.

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Original Article

Sexuality throughout all the stages of pregnancy: Experiences of expectant mothers

Sexualidade durante todas as fases da gravidez: experiências de gestantes

Sexualidad durante todas las fases del embarazo: experiencia de gestantes

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Abstract

Objective: To explore and understand the sexual experiences of expectant mothers during their pregnancy.
Methods: The study was carried out in two healthcare centers in the Almería Health District, in southern Spain. The participants included pregnant women who received prenatal care and/or maternity education. The inclusion criteria were being pregnant, maintaining sexual activity and agreeing to participate in the study. The exclusion criteria were having limitations on sexual activity by medical prescription. The sample consisted of 15 expectant women selected using a convenience sample, of which 5 took part in a focus group (FG) and 10 in in-depth interviews (IDI). Data was collected between the months of June and December 2016. Participants were contacted by the main researcher and an appointment was made to carry out the FGs or the IDIs.
Results: Three main categories emerged: False beliefs and a holistic approach to sexuality during pregnancy, which is related to the concept of sexuality, false beliefs, and limited sexual counseling during pregnancy. Limitations: From fear at the beginning to physical difficulty at the end, referring to the fluctuations in sexual desire as well as the physical changes that limit sexual activity. Adapting to changes: safe practices and satisfaction with one's body image, which encompasses concerns about the risks and the relationship between body image and self-esteem.
Conclusion: A lack of sexual counseling during pregnancy leads to the creation of false beliefs, which, together with physical changes, concerns about the risk, and fluctuations in sexual desire and interest, bring about a decrease in sexual activity. But sexuality remains an important aspect of pregnancy, toward which the participants must adopt a broader approach, not limited to intercourse, and adopt sexual practices that are adapted to the physical and emotional changes that happen during this time.

Resumo

Objetivo: Explorar e compreender as experiências sexuais de gestantes durante a gravidez.
Métodos: O estudo foi realizado em dois centros de saúde no Distrito Sanitário de Almería, sul da Espanha. Os participantes incluíram gestantes que receberam atendimento pré-natal e/ou educação para maternidade. Os critérios de inclusão foram estar grávida, manter atividade sexual e concordar em participar do estudo. Os critérios de exclusão foram ter limitações na atividade sexual por prescrição médica. A amostra foi composta por 15 gestantes selecionadas por meio de amostra de conveniência, das quais cinco participaram de grupo focal (GF) e 10 de entrevistas em profundidade (EP). Os dados foram coletados entre os meses de junho e dezembro de 2016. Os participantes foram contatados pelo pesquisador principal e foi realizada uma consulta para conduzir o GF ou EP.
Resultados: Três categorias principais emergiram: Falsas crenças e uma abordagem holística da sexualidade durante a gravidez, que está relacionada ao conceito de sexualidade, falsas crenças e aconselhamento sexual limitado durante a gravidez. Limitações: Do medo no início à dificuldade física no final, referindo-se às flutuações no desejo sexual, bem como às mudanças físicas que limitam a atividade sexual. Adaptação às mudanças: práticas seguras e satisfação com a imagem corporal, que engloba preocupações com os riscos e a relação entre imagem corporal e autoestima.
Conclusão: A falta de aconselhamento sexual durante a gravidez leva à criação de falsas crenças, que, juntamente com mudanças físicas, preocupações com o risco e flutuações no desejo e interesse sexual, provocam uma diminuição na atividade sexual. Mas a sexualidade permanece um aspecto importante da gravidez, em relação ao qual os participantes devem adotar uma abordagem mais ampla e não limitada ao ato sexual, além de adotar práticas adaptadas às mudanças físicas e emocionais que ocorrem durante esse período.

Resumen

Objetivo: Explorar y comprender las experiencias sexuales de gestantes durante el embarazo.
Métodos: Estudio realizado en dos centros de salud del Distrito Sanitario de Almería, Sur de España. Dentro de los participantes se incluyó a gestantes que recibieron atención prenatal y/o educación para la maternidad. Los criterios de inclusión fueron: estar embarazada, mantener actividad sexual y aceptar participar del estudio. Los criterios de exclusión fueron tener limitaciones de actividad sexual por prescripción médica. Muestra compuesta por 15 embarazadas seleccionadas mediante muestra de conveniencia, cinco de las cuales participaron del grupo focal (GF) y 10 de entrevistas en profundidad (EP). Datos recolectados entre junio y diciembre de 2016. Las participantes fueron contactadas por el investigador principal, realizando una consulta para incluirlas en el GF o en el EP.
Resultados: Surgieron tres categorías principales: Falsas creencias y un abordaje holístico de la sexualidad durante el embarazo, relacionada al concepto de sexualidad; falsas creencias y asesoramiento sexual limitado durante el embarazo. Limitaciones: Del miedo inicial a la dificultad física al final, refiriéndose a las fluctuaciones en el deseo sexual, así como a los cambios físicos limitantes de la actividad sexual. Adaptación a los cambios: prácticas seguras y satisfacción con la imagen corporal, que incluye preocupaciones con los riesgos y la relación entre imagen corporal y autoestima.
Conclusión: La falta de asesoramiento sexual durante el embarazo lleva a crear falsas creencias, que, conjuntamente con los cambios físicos, preocupaciones por riesgos y fluctuaciones del deseo e interés sexual, provocan una disminución de la actividad sexual. Pero la sexualidad continúa siendo un aspecto importante del embarazo, respecto del cual los participantes deben adoptar un abordaje más amplio y no limitado al acto sexual, además de adoptar prácticas adecuadas a los cambios físicos y emocionales típicos del período.

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Introduction

Gestation is the period that takes place between fertilization and childbirth, which causes physical, hormonal, emotional, psychological, social, and sexual changes in a woman.[1,2] As a result, pregnancy generates expectations and doubts about being able to deal with these changes and respond to this new situation.[3] In addition, pregnancy generates positive feelings, such a joy, but at the same time, negative feelings, such as depression,[4] fear and anxiety,[5] that can have negative repercussions on the expectant woman and her partners' sex life.[6] Along with the decrease in sexual desire, warnings about sex or limitations[7] and the fear of physically hurting the fetus,[8] can make pregnancy a period of low sexual activity. Expectant mothers have needs, doubts and concerns about their sexuality[8] that should be addressed during their prenatal care and education.[9]

Fluctuations in desire and sexual practices are normal throughout pregnancy[2,10] and post-partum.[11] In the first trimester, physical and emotional changes lead a a decrease in the frequency of sexual relations and sexual desire.[12] In the second trimester, sexual desire tends to come back,[13] associated with an improvement in an expectant mother's physical wellbeing,[14] less fear of losing the fetus,[15] better vaginal lubrication and ease of intercourse.[3] In the third trimester, physical limitations due to body size and shape and the pressure on the uterus limit sexual activity.[10,12] Although many studies focus on subjects such as reproductive health, miscarriage,[16] sexual education from a preventive standpoint[17,18] and the biological aspects of sexuality during pregnancy,[3] there is a lack of research about the subjective, emotional and experiential dimension of women during this period.[11]

The aim of this study is to explore and understand the sexual experiences of expectant mothers during their pregnancy.

Methods

Our study is a qualitative study based on Gadamer's hermeneutic phenomenology. Gadamer tells us that understanding a phenomenon is conditioned by the present, traditions, and history.[19] Our own experience creates prejudices which help subjects to understand themselves in their own context. Therefore, understanding and interpreting the narration of participants' experience involves a fusion of horizons between the interpreter's and participants' horizons.

The study was carried out in two healthcare centers in the Almería Health District, in southern Spain. The participants included pregnant women who received prenatal care and/or maternity education. The inclusion criteria were being pregnant, maintaining sexual activity and agreeing to participate in the study. The exclusion criteria were having limitations on sexual activity by medical prescription.

The sample consisted of 15 expectant women selected using a convenience sample, of which 5 took part in a focus group (FG) and 10 in in-depth interviews (IDI). Their sociodemographic data can be seen in table 1.

Table 1. Sociodemographic data of the participants (n=15)

Participant	Age	Weeks pregnant	Profession	Education level
FG-1	30	26	Accounting advisor	College
FG-2	28	32	Student	Vocational training
FG-3	31	36	Teacher	College
FG-4	35	32	Doctor	University
FG-5	27	24	Homemaker	High school
IDI-1	38	34	Clinical Psychologist	Master's
IDI-2	38	30	Economist	College
IDI-3	30	23	Teacher	University
IDI-4	31	30	Businesswoman	College
IDI-5	30	39	Teacher	College
IDI-6	34	40	Biologist	College
IDI-7	31	36	Waitress	High school
IDI-8	28	37	Psychologist	College
IDI-9	31	20	Student	Vocational training
IDI-10	34	28	Homemaker	Vocational training

FG - Participant in a Focus Group. IDI - In-depth Interview

Data was collected between the months of June and December 2016. Participants were contacted by the main researcher and an appointment was made to carry out the FGs or the IDIs. Before starting the conversation, the researcher reiterated the objectives of the study, informed participants about ethical issues, and asked for permission to record the conversation. The FG lasted 70 minutes and it was held in

a room in the health center where the patients went to maternity education. The moderator had an interview script that started with the question: "Tell me how your pregnancies are going," and later asked questions about their sexual experiences.

The IDIs were carried out at the participants' homes. The interview script was modified in order to dig deeper into more personal subjects that barely came up in the FG. When the interviewer perceived that the interviewees were comfortable with the questions being asked, she formed questions related to more intimate sexual activity, such as: "Tell me about the positions that prove to be most comfortable for you."

The recordings were transcribed by the interviewers immediately after finishing the FG and IDIs. When the researchers deemed that data saturation was reached, when new topics no longer emerged, they decided to conclude data collection. For the analysis, the following steps were followed, which are used in phenomenological research.[20]

Phase 1. Verifying the coherence between the question and the research method. Sexuality during pregnancy is a phenomenon of the life-world which it is possible to have experience in.

Phase 2. Identifying the pre-understanding of the researchers, derived from their clinical or research experience.

Phase 3. Gaining understanding through dialog with the participants. During the interviews, a spontaneous understanding was obtained, through what the participants shared, notes were taken and clarifying questions were also formulated.

Phase 4. Gaining understanding through dialog with the text (analysis). The researchers thoroughly read through the transcriptions and developed a general impression of the experiences. In this phase of the analysis, ATLAS-Ti software was used. (Version 8.0, Thomas Muhr, Berlin, Germany).

- The meaning of each sentence was analyzed and codified through an inductive analysis. This revealed units of meaning, subcategories and categories.
- As a consequence of moving from the text as a whole to its individual parts and from each part to the whole (hermeneutic circle), new questions arose throughout the interpretation of the data.
- Aiming to go beyond mere descriptions, the relationship between the themes and subthemes was established (pragmatic level).

Phase 5. Credibility was obtained by ensuring that all the participants' points of view were reflected. To reach confirmability, the transcriptions and the final list of categories and quotes were confirmed by the participants.

Participation was voluntary, anonymous and allowed after having signed an informed consent form. Participants were informed that they had the option to not respond to certain questions and that they could stop the interview process at any time, as well as that their conversations would be recorded for later transcription. The study was approved by the Research Ethics Committee of the heath district where data collection took place (2015-01/08).

Results

During the analysis process, 48 units of meaning, six subcategories, and three categories emerged. They reflected the perceptions of expectant mothers about their sexual experience during their pregnancy (Chart 1).

Chart 1. Categories, subcategories and units of meaning, resulting from the analysis

Categories	Subcategories	Units of meaning
False beliefs and a holistic approach to sexuality during pregnancy	False beliefs and advice during the pregnancy	Safety, information about positions during pregnancy, self-reporting, risk of miscarriage, fear of losing the fetus, giving in to pressure, moral limitations, uncertainty with their partner, harmful sex.
	Towards a broader concept of sexuality	Initiating the sexual act, broad concept, masturbation, other acts besides penetration, sexuality being important, relating to sex, intimacy with partner, erotic games.
Limitations. From fear at the beginning to physical difficulty at the end.	Fluctuations in sexual interest and desire	Fetal wellbeing, abstinence, stress, signs, being kind, discomfort, work, intensity, time, children.
	Physical changes that limit traditional sexual activity	Uncomfortable positions, lack of independence in certain movements, body size.
Adaptation to changes: safe practices and satisfaction with one's body image.	Concern about the risk and finding helpful positions	Intercourse, orgasm, Andromache position, comfortable position, oral sex, "69", intercourse from behind, penetration from behind, sideways position, heavy petting, tenderness.
	Relationship between body image and self-esteem. Feeling attractive and pampered	Feeling attractive, protective husband, body image, self-image, cuddling/pampering, thoughtful husband, loving, vaginal lubrication, smooth skin.

False beliefs and a holistic approach to sexuality during pregnancy

The participants hold false beliefs about sexuality during pregnancy, stemming from the absence of sexual education they receive during this period, which makes them unable to fully enjoy their sexuality throughout this time. At the same time, they take on a broad, holistic approach to sexuality, which makes adapting to the new limitations of the situation easier to handle.

False beliefs and the absence of sexual counseling during pregnancy

This subcategory refers to the mistaken ideas about the risks that sexual relations may entail during pregnancy. Guided by such beliefs, participants adopt fearful or hyper-protective attitudes that result in a decrease in the quantity and quality of their sexual relations. For example, some participants expressed that their partner was fearful and insecure about having sex with full penetration for fear of hurting the expectant mother and/or the fetus.

[…] my husband was hesitant, because he thought it was going to affect the baby (IDI-6).

[…] my partner…, I get the feeling that he is scared of hurting me and the baby (FG).

This fear was also common among the women, who expressed that they experienced fear of miscarriage, due to widespread false beliefs that are shared through advice from friends and acquaintances.

[…] they tell you that you have to be more careful with everything, because you could have a miscarriage in the first months. At that time, I was more scared, so I avoided doing it (IDI-2).

These false beliefs also generate hyper-protective behavior in the male partner, which can be interpreted either as a show of love or affection, or as over-zealous behavior that invalidates the pregnant woman as a person.

[…] he says, when I'm cleaning, that I should stop, that he'll do it. […] I tell him that I'm not sick, I'm not an invalid; sometimes it even makes me feel useless (IDI-8).

These false beliefs could be related to the the lack of sexual counseling in the maternity education sessions. For our participants, the sexual guidance that they received was scarce and they felt embarrassed asking about it, and thus, they turned to the Internet for information:

[…] I read about it on the Internet, which all of us know is sometimes not… (trustworthy). But the doctor didn't tell me anything about it (FG).

Some participants alleged that they didn't bring up the sexual topic because of moral reasons. Even nowadays many people consider it controversial to speak openly about sexuality, which is the reason why neither the patients nor health professionals bring it up:

Yeah, it probably would have been necessary, but, even today, in the society we live in, talking about that is not socially acceptable (FG).

Towards a broader concept of sexuality

Despite these widespread false beliefs, sexuality is considered by the participants as a very valuable thing, and they prioritize taking a broad approach and holistic understanding of the word, which goes beyond mere intercourse, but not excluding it either.

[Sexuality] is a very comprehensive thing, it doesn't have to do only with penetration. I don't know…, erotic games, penetration too, of course (FG).

Intimacy, autoeroticism (self-stimulation), masturbation and erotic games are not seen as an intermediate means to an end, rather, as pleasurable activities in themselves, that don't necessarily have to lead to intercourse.

I understand sexuality as…, seduction, flirting from the very beginning on, risqué lines you say to your husband, […] (FG).

Limitations: From fear at the beginning to physical difficulty at the end

The participants pointed out certain limitations on sexual relations throughout their pregnancy. These are related to fluctuations in interest and sexual desire throughout the different stages of pregnancy, and to the physical limitations that stem from from typical first-trimester symptoms (nausea, vomiting) at the beginning to the increase in body size at the end.

Fluctuations in sexual interest and desire

As the pregnancy progresses, we can see cases of abstinence and a decrease in sexual interest, which is shown, in the majority of our participants, in the first trimester.

[…] The first three months, I never really felt like it, but he did want to (FG).

On the other hand, some women explained that, in the second trimester, after their initial fear subsided, but before their physical limitations made it more difficult, they saw an increase in their sex drive:

[...] in the second trimester I did want to do it often…There's a certain time in which I feel like initiating more often than normal (IDI-3).

Once they are in their third trimester, the participants experienced feelings of pain and tension, factors that could lead to a decrease in their sex drive.

Right now, at 39 weeks…, I don't have sexual relations with penetration because it hurts, it hurts down below (IDI-10).

Physical changes that limit traditional sexual activity:

Among the physical changes that women undergo, we can find changes in the woman's body, which do not allow her and her partner to find a comfortable position in the third trimester, and other symptoms, such as nausea and vomiting during the first trimester, which also limit or hinder sexual relations during the pregnancy.

[…] now I only can do it in certain positions, I don't feel comfortable anymore in certain positions, I'm really limited with my belly being so big. (IDI-1).

At first, I only ever felt nauseated and like I was about to vomit, and I was sick all the time, (…). So, you can imagine, nothing at all, you are just barely getting by (FG).

Adapting to changes: safe practices and satisfaction with one's body image

Maintaining an active sex life in spite of the physical changes and the limitations caused the participants to undergo an adaptation process, based on looking for safe practices and comfortable positions. Also, the changes in their bodies caused greater satisfaction with their own body image.

Concerns about the risk and finding a comfortable position

Our participants explained that as their bellies grow, they look for adaptation through trying different (new) and more conducive sexual positions (woman on top, from behind and a sideways lying position). In this way, the increase in belly size does not avoid enjoying the intercourse:

With him lying down and me on top, because I'm scared of him putting pressure on me, (…) and if I'm on top, I can control it more so there is no pressure on my belly (IDI-7).

Oral sex was considered a risky sexual practice by some of the participants, who associated it with the possibility of catching oral infections and the consequent risk of miscarriage. Because of this, it is a practice that they avoid:

[…] we avoid oral sex lately, because of the risk…of infection or something, right? (…) even though I like it, I can live without it, I wouldn't want anything to happen from just a little sore in his mouth or something…, I don't want to take any risks (IDI-9).

Touching, kissing, and regular affection became the preferred sexual practice of many of the women, above any sexual practice more focused on the genitalia:

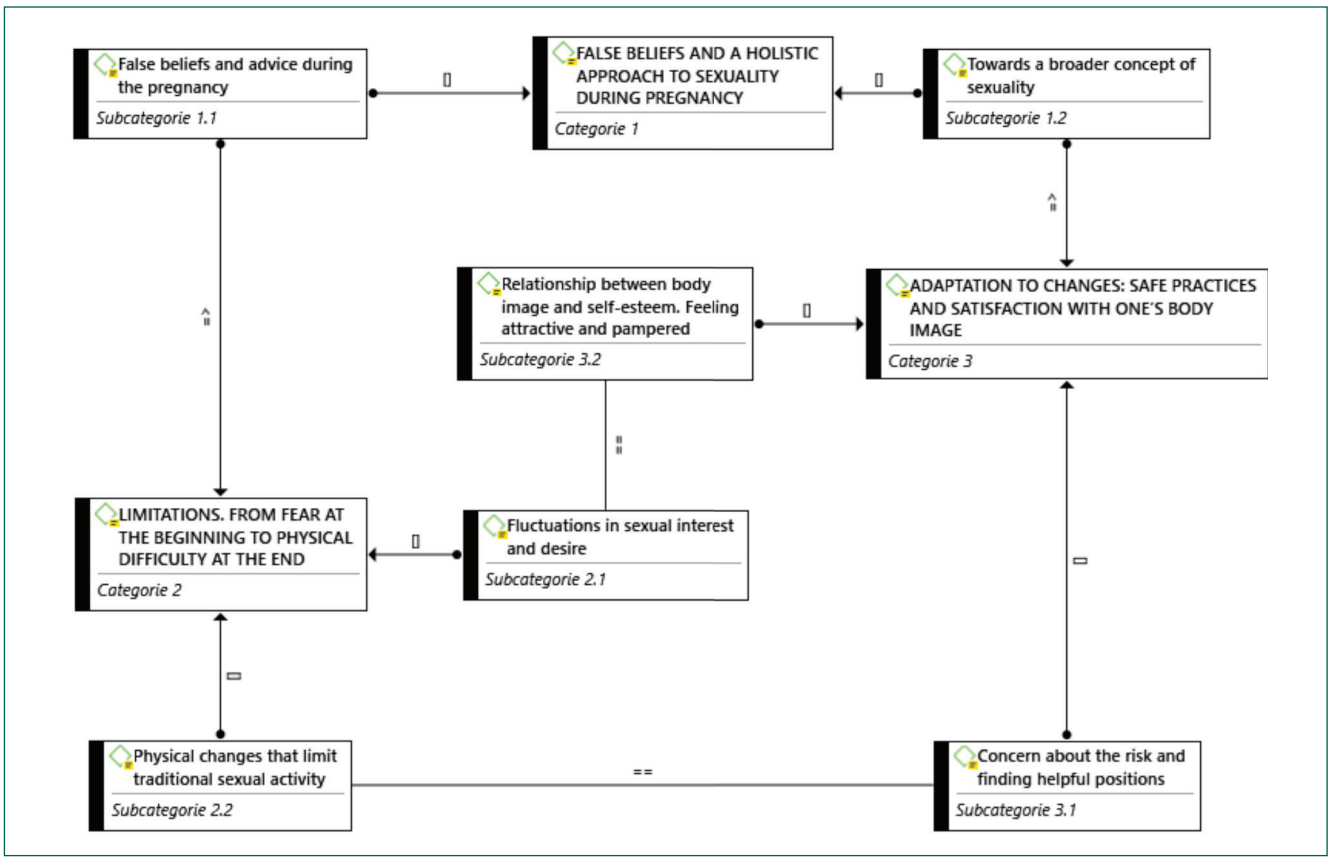
Now we look more for that, (…) to be hugged, kissed, to hear compliments and be told how beautiful we are, we don't go looking for that (penetration) (FG).

The relationship between body image and self-esteem. Feeling attractive and pampered

The physical changes that take place during pregnancy, also contribute to an increase in a woman's satisfaction with her body image, as she feels attractive and pampered by her partner, which generates an increase in self-esteem:

I like to see myself with my belly, wearing maternity clothes (…). I feel good in my own skin, and feel good about my pregnancy (IDI-3).

I find him more loving, and I can tell that with certain things he's more caring, I mean, Before, he didn't pay much attention to chores and to my things, but now he does (IDI-5).



Key: [] Is a part of. == Related to. => Contributes to. Prepared by the authors with ATLAS.Ti 8 software

Figure 1. Conceptual map created to show the relationships between categories and subcategories that emerged from the analysis

From the analysis of the relationships between the different categories (pragmatic level of analysis) a concept map was created (Figure 1). It represents how false beliefs contribute to the appearance of limiting factors that inhibit sexual activity in the initial stages of pregnancy. In more advanced stages, physical changes contribute to these limitations. A broad concept of sexuality, satisfaction with one's body image, and the search for comfortable positions that make it easier are all part of adapting to such changes, so that safe and satisfactory sexual activity can be maintained throughout the pregnancy.

Discussion

The main limitations in this study are related to the sample, since the majority of the participants have higher education degrees and planned pregnancies. All of them are young adults and we did not have adolescents nor women over 40 years old in our sample. The inclusion of a more varied sample may have yielded different results.

Including sexual health in the clinical evaluation of expectant mothers and sexual education in maternity (and paternity) education, could contribute to more fulfilling, satisfactory and unprejudiced sexual relations during pregnancy. Midwives and nurses that working with pregnant women and their partners should provide information about sexual activity during pregnancy.

In this study, sexual difficulties and issues related to pregnancy emerged. These have their base in limited sexual education, false beliefs, and myths that can have adverse effects on the relationship between the parents-to-be.[9] As in other studies,[21,22] beliefs that are socially and culturally accepted result in fears that have a negative impact on the sexuality of the expectant woman. Although some studies suggest that the connection between a couple does not change during pregnancy,[23] our participants confirmed that their partners expressed

concerns about intercourse. They fear hurting the fetus, which denotes a protective attitude.[24]

Our participants reported that the sexual education they received on behalf of health professionals was limited, and that many only received such information if they asked for it specifically, and noted that the information was also lacking in detail. Sexuality is not usually included in health professionals' agendas[20,25] nor in prenatal education programs.[25] Concurring with other studies, our participants resorted to friends or the Internet for information.[24] Some authors suggest that it should be the health professionals who advise pregnant women about psychosexual changes that take place during pregnancy.[11] Others have emphasized the importance of teaching sexual health interview skills in the undergraduate and continuing education of health professionals.[25,26]

Pregnancy significantly reduces a woman's sexual function, especially in the first and third trimesters,[12,27,28] and our study also found a marked decrease in sexual activity, especially intercourse, during these periods, due to fear and physical difficulties. On the other hand, the participants expressed an increase in self-esteem during the second trimester, linked to satisfaction with the changes their bodies were undergoing, which made them feel attractive and wanted. This reflects what was found in other studies, which found a positive correlation between self-esteem and satisfaction in sexual relations during and after the transition into maternity.[29] Nonetheless, other studies have showed that the higher the body mass, the lower satisfaction a woman has with her body image, regardless of whether she is pregnant or overweight for other reasons.[30] This suggests that it is not the pregnancy in itself but the excess weight in the third trimester that has a negative effect on sexual function.[31]

Conclusion

The absence of sexual counseling during pregnancy gives rise to false beliefs, which, together with physical changes, concerns about the risks, and fluctuations in sexual interest, cause a decrease in sexual activity. Nonetheless, sexuality remains an important aspect of pregnancy, toward which the participants must adopt a broader approach, not limited to intercourse, and adopt sexual practices that are adapted to the physical and emotional changes that happen during this time.

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Collaborations

Fernández-Sola C was responsible for the study design. Huankara-Kana D, Carmona-Samper E and López-Rodríguez MM performed the data collection. Granero-Molina J and Hernández-Padilla JM planned and carried out the analysis and interpretation of the results. Fernández-Sola C, Granero Molina J and Huankara Kana D drafted the manuscript and Hernández-Padilla JM, Carmona-Samper E and López Rodríguez MM revised it critically. All authors checked the manuscript for accuracy and completeness.

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Original Article

The teaching of gerontological nursing in Brazilian public higher education institutions

O ensino de enfermagem gerontológica nas instituições públicas brasileiras de ensino superior

Enseñanza de enfermería gerontológica en las instituciones públicas de enseñanza superior brasileñas

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Aged; Geriatric nursing; Nursing education; Teaching; Higher education institutions

Descritores
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Descriptores
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Abstract

Objective: To describe the current state of nursing education regarding the care of older adults in Brazilian public higher education institutions

Method: Documentary, descriptive research with qualitative approach, with data from July 2017 collected in the platform of the Ministry of Education. Information on nursing undergraduate courses in public universities was collected following three phases of access and data collection: identification, selection and eligibility. There was a descriptive analysis for characterization and qualitative Inductive Thematic Analysis using *Interface de R pour les Analyses Multidimensionnelles de Textes et de Questionnaires* (IRAMUTEQ). The project followed the ethical norms of Resolution 510/2016 of the National Health Council.

Results: The 87 universities selected offered 154 undergraduate nursing courses, mostly in the Northeast Region. Out of the total number of courses, 69 (44.8%) had mixed disciplines (covering care of older adults) and 53 (34.4%) had specific disciplines on health of the older adult. In the content of the syllabi, the terms most used in the construction of the word cloud were: health (162), older adult (154), nursing (113), adult (81), assistance (72), process (69) and attention (52). In the similarity analysis, three main organizing topics of the disciplines related to this theme were observed: health, nursing and older adult.

Conclusion: Nursing education needs to be aligned with current public policies and consistent with the health care model proposed. Therefore, the training offered must be consistent with the current demands of the labor market.

Resumo

Objetivo: Descrever o estado da arte da formação do enfermeiro em instituições públicas brasileiras de ensino superior no que se refere ao cuidado ao idoso

Métodos: Pesquisa documental, descritiva e de abordagem qualitativa, com dados da plataforma do Ministério da Educação de julho de 2017. Foram levantadas informações dos cursos presenciais de graduação em enfermagem das universidades públicas, seguindo três fases de acesso e coleta dos dados: identificação, seleção e elegibilidade. Houve análise descritiva de caracterização e Análise Temática Indutiva qualitativa, utilizando o *Interface de R pour les Analyses Multidimensionnelles de Textes et de Questionnaires* (IRAMUTEQ). O projeto seguiu as normativas éticas vigentes da Resolução 510/2016 do Conselho Nacional de Saúde.

Resultados: As 87 universidades selecionadas ofertavam 154 cursos de graduação em enfermagem, a maioria na Região Nordeste. Do total de cursos, 69 (44,8%) apresentavam disciplinas mistas (que abordavam o cuidado ao idoso) e 53 (34,4%) específicas de saúde do idoso. Nos conteúdos das ementas, os termos mais utilizados na construção da nuvem de palavras foram: saúde (162), idoso (154), enfermagem (113), adulto (81), assistência (72), processo (69) e atenção (52). Na análise de similitude, verificaram-se três principais eixos organizadores das disciplinas voltadas a essa temática: saúde, enfermagem e idoso.

Conclusão: O ensino da enfermagem precisa estar alinhado às políticas públicas vigentes e ser coerente com o modelo de atenção à saúde proposto. Portanto, é fundamental que a formação ofertada seja condizente com as atuais demandas do mercado de trabalho.

Resumen

Objetivo: Describir el estado del arte de la formación del enfermero en instituciones públicas de enseñanza superior brasileñas en lo atinente al cuidado del anciano.

Métodos: Investigación documental, descriptiva, de abordaje cualitativo, con datos del Ministerio de Educación de julio de 2017. Fue relevada información de los cursos de grado presenciales en enfermería de las universidades públicas, continuando con tres fases de acceso y recolección de los datos: identificación, selección y elegibilidad. Se realizó análisis descriptivo de caracterización y Análisis Temático Inductivo cualitativo, utilizando la *Interface de R pour les Analyses Multidimensionnelles de textes et de Questionnaires* (IRAMUTEQ). Proyecto respetando normativas éticas vigentes, Resolución 510/2016 del Consejo Nacional de Salud.

Resultados: Las 87 universidades seleccionadas ofrecían 154 cursos de grado en enfermería, mayoritariamente en Región Noreste. Del total de cursos, 69 (44,8%) presentaban disciplinas mixtas (abordando cuidado del anciano) y 53 (34,4%) específicas de salud del anciano. En los contenidos de los sumarios, los términos más utilizados en la construcción de la nube de palabras fueron: salud (162), anciano (154), enfermería (113), adulto (81), asistencia (72), proceso (69) y atención (52). El análisis de similitud verificó tres ejes organizadores principales de las disciplinas orientadas a dicha temática: salud, enfermedad y anciano.

Conclusión: La enseñanza de enfermería debe alinearse a las políticas públicas vigentes y ser coherente con el modelo de atención de salud propuesto. Consecuentemente, es fundamental que la formación ofrecida se condiga con las actuales demandas del mercado laboral.

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Conflicts of interest: none to declare.

Introduction

The worldwide increase in life expectancy along with the dramatic decrease in fertility rates have a direct impact on population ageing.[1,2] According to the World Health Organization (WHO),[3] by the year 2020, there will be approximately 200 million older adults and, by 2050, this number will reach approximately 310 million.

Considering the demographic transition and the aging process, several adjustments are necessary to meet the needs of the elderly population and to favor their autonomy and citizenship. These measures must guarantee fundamental human rights, such as: security, education, work and health.[4,5]

The process to ensure the right to health is complex and broad. The principles and guidelines supporting the construction of a care model must ensure that collective and individual demands are met in every step of health care, since entrance in the health system until exit, with the objective of preventing and treating illness and promoting health.[6] Thus, these actions will contribute to preserve the autonomy and maintain the functional capacity of older adults.[7]

In this context, nursing professionals assume a leading role in the organization of health services, due to their high representation in health care settings and to the functions they carry out in their daily work, since, besides acting directly in the care process, these professionals are also responsible for the management of processes and services.[8]

Given the above, the questions raised are: how is the nurse prepared by the Public Higher Education Institutions to care for older adults? Is the training aligned with the specific demands of the Brazilian demographic transition? Did these institutions consider the regional and global epidemiological profile of older adults during the training of nurses?

The Public Higher Education Institutions have a fundamental role in the construction of the profile of the nurse, since in the academic environment the students have the opportunity to develop and improve their competencies, abilities and attitudes for the exercise of the profession. This profile is decisive for the actions of the nurse in situations involving global health care issues and other issues specific to older adults, given the epidemiological transition in Brazilian society.[9]

In this sense, in article 5 of Resolution no. 3 of the National Council of Education/Higher Education Department of November 7, 2001, the National Curricular Guidelines for the Undergraduate Nursing Course establish the need to train nurses with specific abilities to "act professionally, understanding human nature in all its dimensions, expressions and evolutionary phases".[9]

The training of nurses must also be in line with the National Health Policy for Older Adults which, in its guidelines, values the permanent qualification in the area of health of older adults, in order to encourage teaching and research on the aging process.[7] The National Policy for the Older Adults reiterates these aspects and adds the need to include Gerontology and Geriatrics as curricular subjects in higher education courses in all areas of health.[10]

Despite the advances in public policies for the older adult, there are still many challenges in the academic education in the area of Gerontology and Geriatrics. The search for the theme in national and international literature revealed that there is still scarce research on the subject, which, given the demographic changes in the world and in Brazil, justifies the present research Given the expected increase of the older adult population, the life expectancy and the demands in health services, undergraduate courses in health, especially in nursing, must include disciplines related to Gerontology and Geriatrics, according to the policies established for this population. In this direction, the present study has as guiding question: What is the Brazilian panorama of nursing teaching in Public Higher Education Institutions regarding the care of older adults?

To answer this question, the following objective was defined: to describe the current state of nursing education regarding the care of older adults in Brazilian public higher education institutions.

Methods

This is a documentary, descriptive research with qualitative approach. Data were collected on the

platform of the Brazilian Ministry of Education in July 2017.

The sample was composed of active and face-to-face nursing undergraduate courses in the area of Health Sciences, of the Public Higher Education Institutions of Brazil. Bachelor's degree or Teaching License degree or both degrees were included.

Data collection included the phases of identification, selection and eligibility. In the first one, the Public Higher Education Institutions that offered the courses included were identified through the portal of higher education institutions and courses of the Ministry of Education (e-MEC).[11] Access to the official webpages of the Higher Education Public Institutions allowed to carry out the second phase and select the courses eligible for this study. In the third phase, the online access to nursing courses allowed identifying the curricular components related to the care of the older adult and those who addressed topics related to this topic, such as gerontology, geriatrics, gerontology and care/nursing care of the older adult were selected.

For the organization of the data, an analysis matrix was created using Excel software with the following information: "State"; "Higher Education Public Institutions"; "Courses"; "Type of curriculum", "In activity", "Online data availability", "Mixed discipline", "Specific discipline on care for the older adult" and "Discipline syllabus".

The numerical data were arranged in tables, according to simple and relative frequency, and grouped by region. The qualitative data were analyzed with the technique of Inductive Thematic Analysis[12] using the software IRAMUTEQ (*Interface de R pour les Analyses Multidimensionnelles de Textes et de Questionnaires)* 0.6 alpha 3, Brazilian version, which provides statistical analysis of text excerpts and tables composed by individuals and words.[13,14]

For the construction of the figures, similarity analysis based on the graph theory was used. This is an ideal mathematical model capable of identifying co-occurrences between words and its outcomes. This model indicates the connectivity between words, helping to identify the structure of a textual corpus and pointing out common parts and specificities in function of the descriptive variables identified in the analysis. In this phase, the word cloud was also used. The word clouds is a simpler lexical analysis that graphically groups and organizes words according to the frequency with which they are used.[14] In both analyzes, a frequency greater or equal to five was chosen in order to generate more understandable figures.

Since this study used free and public data available in the portal of the Ministry of Education, there was no need to submit the project to the Research Ethics Committee according to CNS Resolution no. 510/2016.

Results

In the e-MEC system, in 2017, 87 public higher education institutions which provided 154 nursing undergraduate courses were identified. The courses were distributed as follows: 144 (93.5%) Bachelor's degree and 10 (6.5%) Bachelor's and teaching license degree. The courses were offered predominantly in the Northeast and Southeast Regions. Fewer institutions were found in the Center-west and North regions (Table 1).

Of the total number of courses, 90 (58.4%) 69 (44.8%) disciplines were considered mixed (addressing care of older adults) and 53 (34.4%) courses had specific health disciplines on health of older adults (Table 1).

On the syllabi analyzed, the terms most cited and therefore most used in the construction of the word cloud were: health (162), older adult (154), nursing (113), adult (81), assistance (72), process (69) and attention (52). Figure 1 also shows the predominance of words such as care (50), aging (45), disease (40), surgery (40), aspect (37), practical (31) and political (33).

The similarity analysis allowed portraying the relationship between the words. At this stage, a total of 259 words were analyzed, those with frequency greater than or equal to five were selected: 147. With this analysis, it was possible to observe how

Note: It is a figure with clouds of words generated from the analysis of the software Iramuteq, in the Portuguese version.

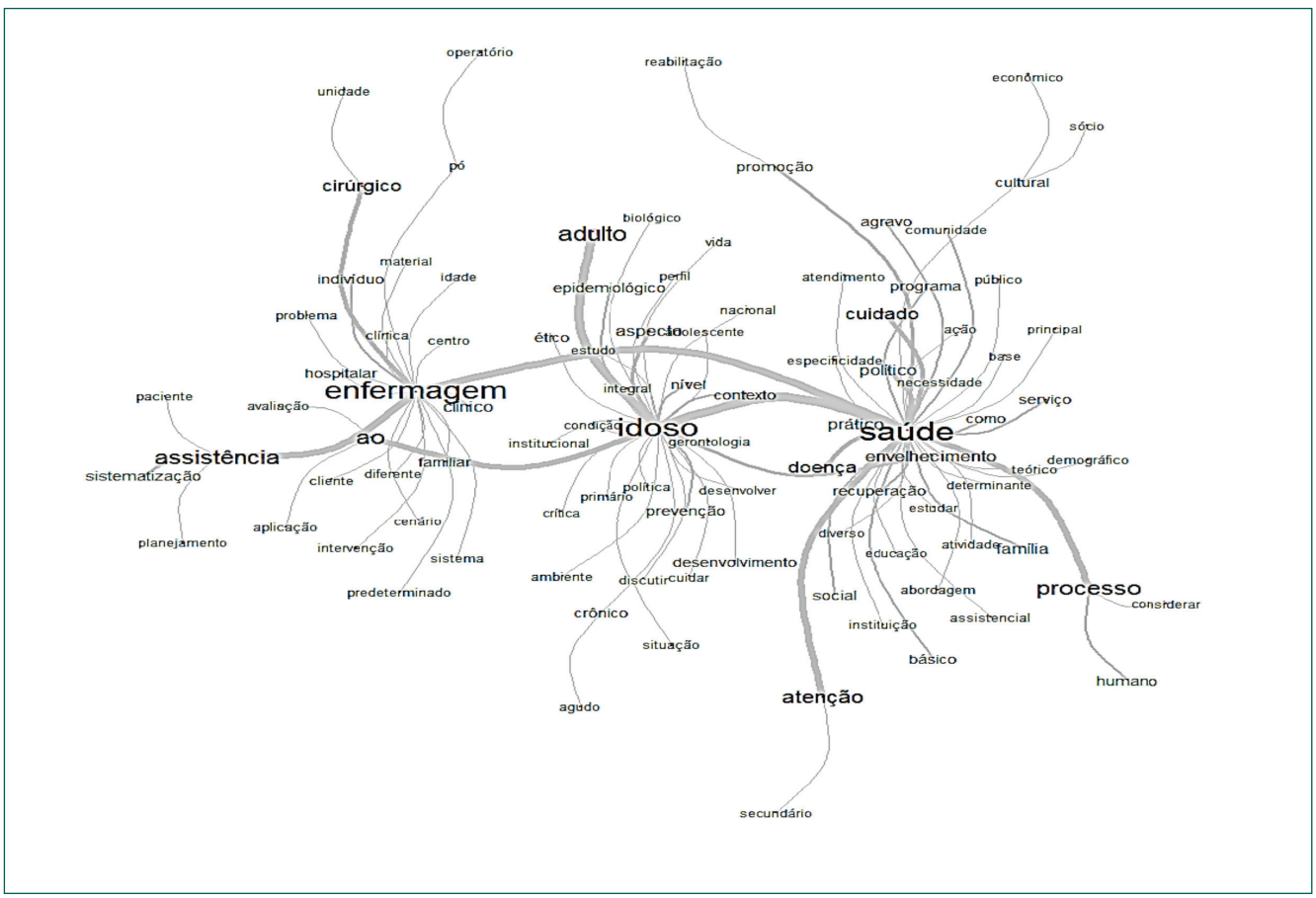
Figure 1. Word cloud built extracted from the syllabi of the disciplines that address the care of older adults and of specific disciplines on the health of the older adult

Table 1. Distribution of nursing courses and disciplines related to care for the older adult. Regions North, Northeast, Center-West, Southeast and South, Brazil

Variables	North	Northeast	Center-west	Southeast	South	Total
	n(%)	n(%)	n(%)	n(%)	n(%)	n(%)
Nursing Course	18(11.7)	62(40.3)	20(13.0)	33(21.4)	21(13.6)	154(100.0)
Disciplines that address the care of the older adult	4(5.0)	22(27.2)	9(11.1)	33(40.7)	13(16.0)	81(100.0)
Specific Discipline on Health of Older Adults	6(11.3)	23(43.4)	5(9.4)	14(25.5)	5(9.4)	53(100.0)

the syllabi related the various words to describe subjects related to the care of the older adult.

Figure 2 allows to identify the structure, the central nucleus and the peripheral system of the content of the syllabi analyzed. The figure also shows the three main organizing topics of the subjects related to care of the older adult: health, nursing and older adult.



Note: It is a figure with clouds of words generated from the analysis of the software Iramuteq, in the Portuguese version.

Figure 2. Similarity of words extracted from the syllabi of the disciplines that address the care of older adults and of specific disciplines on the health of the older adult

Discussion

The increase in the number of nursing courses in several Brazilian regions is a result of incentives and programs of the federal government. The Support Program for Restructuring and Expansion Plans of Federal Universities (REUni), for example, favored the approval of new universities and the expansion of existing ones through the opening of new campuses and courses.[15,16]

One of the proposals of this expansion was the interiorization of educational institutions, so that regions with few university places would be contemplated with new courses capable of improving social deficiencies and labor market issues. This way, new universities, campuses and courses have become part of a strategic for political, social and economic governance.[16]

This increase in places offering nursing undergraduate courses has also been identified in other countries, which implement development policies in the area of education. Besides the quantitative aspect, the quality of teaching in the area of nursing has also been undergoing modifications, aimed at meeting the technological advances in the health area and the changes in the population epidemiological profile resulting from the globalization process.[17,18]

This movement has the support of the World Health Organization, which seeks global strategies for valuing the nursing profession and proposes local guidelines for Latin America and the Caribbean, aiming to improve nursing study programs and qualify the professionals.[19,20]

Table 1 shows the distribution of nursing courses of public universities in each of the Brazilian regions after the expansion policies. The expansion process balanced the offer of courses throughout the country, except in the Northeast region, which still has a high number of courses compared to other regions. However, if private institutions are also considered, the increase in places in nursing courses is directly related to the degree of economic and social development of the region.[21]

This balance in the distributions of places in public nursing courses was possible because, in addition to the expansion and interiorization process, there was also an increase in investments to guarantee access and permanence of the students throughout the course. Thus, in addition to the creation of mechanisms that ensured access to low-income students, there was also assistance for the conclusion of the course. The resources allocated to the National Student Assistance Program have served this purpose, since they have guaranteed student housing, food, transport, health, digital inclusion, culture, sports, day care and pedagogical support.[22,23]

Regarding the disciplines, the topic of care of the older adult was present in all nursing courses analyzed, either by a description in topics, when it was an integrated curriculum, associated with another area, such as adult health, or specifically, as the discipline health of the older adult. These findings point to a transition period, also evidenced by changes in teaching methodologies, adoption of active methodologies or changes in approach to the topic. These changes are indicative of the need for a careful and comprehensive look at the specificities of the aging process and the consequent care needed.[24,25]

Active methodologies, such as aging simulation games, are able to favor empathy and good attitudes with the older adult and, therefore, may be essential in the student's preparation for the first contact with gerontology. In the future, this may improve the quality of the care provided.[26]

In addition to the simulation, the "Facilitated Learning to Advance Geriatrics" (FLAG) program aims to expand geriatric knowledge among professor Nurses, so that they can teach students the specificities of each phase of the aging process. After the implementation of this program, geriatrics studies were no longer limited or absent in the curriculum, and this motivated learning about the process of senescence and senility and the processes that are part of this trajectory.[27]

The frequency with which certain words were used in the syllabus of the disciplines demonstrates concern and zeal, considering the older adult as the center of care, and their health as a consequence of caring, with the nurse as the protagonist of this process. Thus, the central nuclei identified allow estab-

lishing guidelines for the disciplines that address the aging process and inferring values that will be incorporated into the professional identity of nursing students. This finding corroborates the curricular guidelines of nursing undergraduate courses, since it demonstrated that the older adult is regarded as essential in the training of nurses.[9]

The word "adult" was also prominent, perhaps because, historically, the health of the older adults has often been addressed in the discipline Adult Health. This way, this word appears quite frequently.

The other words that were frequently cited express the scope of the disciplines and the contextualization of the different environments in which the care of the older adult takes place. Thus, this care has been discussed from primary care to health institutions. Different actors were also identified in this care, which includes self-care, family or non-family caregivers and multi-professionals approaches.[25]

The word cloud also revealed that specific nursing subjects were included in the teaching-learning process, such as the elaboration of care protocols, systematization, organization of health services, and formulation of public policies for the older adult. The cloud suggests a proactive construction of the knowledge produced in undergraduate nursing courses in public institutions in Brazil, indicating an strengthening of the performance of the nurse and a possibility of interdisciplinary actions, in addition to the formation of political consciousness.[21]

The maximum tree confirms this possibility, since the analysis of similarity provides a hierarchical classification that puts the words older adult, health and nursing at the highest level. These three elements also establish a correlation with each other, forming the central structure of the tree. This perception is confirmed through the co-occurrence index in the maximum similarity tree,[28] where the elements health, older adult and nursing, for their symbolic value, are represented as the center of a star formation, which provides an understanding of the relationships between the elements and, consequently, gives meaning to the formulation of the syllabi of the disciplines.

The discussion about the data, based on these three basic elements of the syllabi, contributes to correlate teaching with nursing practice. The teaching-learning process suggests the composition of the work process in older adult care presents a structure in which nursing is the agent of care, health is the purpose of care and the older adult is the object of care. This relationship between teaching and work, in an objective or subjective way, is extremely important in the academic formation, as it contributes to the construction of an adequate professional identity and the development of essential skills for future professionals.[29]

A study carried out in Saudi Arabia confirmed the importance of curricula for the formation of attitudes and knowledge fundamental for nursing practice. However, the authors added the need to arouse in students the desire to care for and to dedicate themselves to the older adult, so that they become examples to follow. Thus, besides the insertion of curricular contents on the theme, the dedication and enthusiasm of the faculty are essential for education in gerontology.[30]

However, this study found that specific disciplines on geriatrics and gerontology, active methodologies and content guided by the current policies for older adults and aligned with the current model of care are present only sporadically and randomly in different institutions. Therefore, there is an evident need for a curricular guideline for nursing courses, establishing a solid articulation between academic education and policies addressing the care of the older adult.

This study found barriers during the course of this analysis that represented limitations. For example, the analysis was limited to data available online and some undergraduate courses did not provide their pedagogical projects in the university websites. Another limitation was the non-standardization of the data found, which led the researchers to a detailed search for information in additional links of Public Higher Education Institutions, such as Dean of Undergraduate Studies, Dean of Education, Resolutions of University Councils and other.

Conclusion

Considering that the aging process is contextualized in a demographic and epidemiological

transition, the teaching of gerontology and geriatrics in undergraduate nursing courses becomes a great challenge for coordinators and professors. In this study, the teaching of this subject was identified in models associated with active methodologies in integrated curricula, as well as in traditional models, without a specific learning space, including the subject as topics in mixed disciplines. Despite the presence of important theoretical contents, it is still necessary to broaden the knowledge on nursing interventions and to provide practical activities related to direct care for the older adult. Nursing courses in different regions of Brazil present different professors' profiles. These differences do not reflect regional demographic and epidemiological characteristics. However, they demonstrate differences in learning methodologies and the complexity with which the subject is treated.

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Collaborations

Rodrigues RAP, Bueno AA, Silva LM, Kusumota L, Almeida VC, Giacomini SBL and Reis NA declare that they contributed to the conception of the study, analysis and interpretation of the data, relevant critical review of the intellectual content and approval of the final version to be published.

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Original Article

Suicidal ideation and the use of illicit drugs in women

Ideação suicida e consumo de drogas ilícitas por mulheres

Ideas suicidas y consumo de drogas ilícitas en mujeres

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Descritores
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Descriptores
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Abstract

Objective: To analyze the relationship between suicidal ideation and illicit drug use in women.
Methods: An analytical study conducted with 369 women receiving care in the Basic Health Units, using the Non-Student Drug Use Questionnaire and the Self-Reporting Questionnaire for investigating suicidal ideation.
Results: Association between suicidal ideation and the use of tranquilizers without medical prescription (p=0.005), solvents (p=0.006), and marijuana (p=0.003) was identified. Utilization of tranquilizers increased the chances of suicidal ideation in women by 2.7 times (CI=1.372-5.608) when compared to those who did not use these drugs; the use of solvents increased it by 10.1 times (CI=2.197-46.967), and marijuana use by 3.3 times (CI=1.865-13.900).
Conclusion: The indicators indicate that illicit drug use by women has serious implications and, therefore, requires effective interventions that should focus above all on the prevention of suicidal ideation, as the progression of this ideation may converge in tragic outcomes that include attempted suicide, self-mutilation, and suicide.

Resumo

Objetivo: Analisar a relação entre ideação suicida e consumo de drogas ilícitas em mulheres.
Métodos: Estudo analítico realizado com 369 mulheres atendidas em Unidades Básicas de Saúde utilizando para investigação do consumo de drogas ilícitas o *Non-Student Drugs Use Questionnaire* e para investigação da ideação suicida o *Self-Reporting Questionnaire*.
Resultados: Verificou-se que existe associação entre ideação suicida e o uso de tranquilizantes sem prescrição médica (p=0,005), de solventes (p=0,006) e de maconha (p=0,003). O consumo de tranquilizantes aumenta em 2,7 vezes (IC=1,372-5,608) as chances de as mulheres terem ideação suicida quando comparadas com aquelas que não fazem uso das referidas drogas, bem como pelo uso de solventes em 10,1 vezes (IC=2,197-46,967) e o uso de maconha em 3,3 vezes (IC=1,865-13,900).
Conclusão: Os indicadores produzidos apontam que uso de drogas ilícitas pelas mulheres tem implicação grave e, portanto, necessita de intervenções efetivas que devem focalizar, sobretudo, na prevenção da ideação suicida, uma vez que a progressão dessa ideação poderá convergir para desfechos trágicos que incluem tentativa de suicídio, automutilação e suicídio.

Resumen

Objetivo: Analizar la relación entre ideas suicidas y consumo de drogas ilícitas en mujeres.
Método: Estudio analítico realizado con 369 mujeres atendidas en Unidades Básicas de Salud utilizando para investigación del consumo de drogas ilícitas el *Non-Student Drugs Use Questionnaire* y para investigar las ideas suicidas el *Self-Reporting Questionnaire*.
Resultados: Se verificó que existe asociación entre ideas suicidas y uso de tranquilizantes sin prescripción médica (p=0,005), solventes (p=0,006) y marihuana (p=0,003). El consumo de tranquilizantes aumenta en 2,7 veces (IC=1,372-5,608) las chances de que las mujeres tengan ideas suicidas, comparadas con las que no usan dichas drogas; así como el uso de solventes las aumenta en 10,1 veces (IC=2,197-46,967) y el uso de marihuana en 3,3 veces (IC=1,865-13,900).
Conclusión: Los indicadores elaborados establecen que el uso de drogas ilícitas por parte de mujeres tiene grave implicación, precisando de intervenciones efectivas que deben hacer foco, principalmente, en la prevención de ideas suicidas, toda vez que la progresión de tales ideas conduce a desenlaces trágicos, incluyendo tentativas de suicidio, automutilación y suicidio.

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Introduction

Illicit drug use has become more worrying, both for causing serious consequences for the individual's health and raising the morbidity and mortality indicators, as well as for its social, economic and criminal consequences.[1,2]

This consumption crosses several social groups, age groups, and gender. Regarding gender, although it is a common practice among men, the use among the female population has increased,[3] which is demonstrated by a meta-analysis performed which included135 primary studies, in which 21.5% of women were taking drugs.[4]

This increase was also described in a study conducted in Brazilian outlying communities, where women exceeded men in rates of illicit drug use, especially among sex workers. In these cases, the easy access, low cost of psychoactive substances (PAS), and the recognition of sex as a bargaining chip are considered to be facilitating factors for this practice.[5]

Given the presence of many women in this statistical scenario, and that consumption of illicit drugs is still associated with promiscuity and immorality, this exposes them to situations of violence, and promotes the emergence of comorbidities, including psychiatric disorders such as: depression, bipolar disorder, and personality disorders, among others.[6] These factors can contribute to the loss of existential value and, consequently, to suicidal behavior.[7]

The female population presents higher rates of suicidal ideation and attempts than the male population, and intoxication is the most commonly used method.[8] Suicidal ideation is characterized by ideas, planning, and the desire to end one's own life.[9]

In this scenario, discussion about these problems must be conducted, especially in the female universe, in which the expansion of illicit drug use is extremely recent and its outcomes still need to be studied, especially those involving suicidal behavior. Therefore, the objective of this study was to analyze the relationship between suicidal ideation and illicit drug use by women.

Methods

This was a cross-sectional and analytical study, conducted from August of 2015 to March of 2016, in five cities in the state of Piauí: Teresina, Bom Jesus, Floriano, Parnaíba, and Picos.

The sample was calculated using a population of 347,414 women, aged 20 to 59, residing in those cities as a reference.[10] The presumed 39% prevalence of alcohol consumption among women was adopted.[11] The level of confidence established was 95%, with a tolerable error of 5%. The sample consisted of 369 women. By proportional distribution, 232 women were selected in Teresina city, 36 in Parnaíba, 46 in Picos, 38 in Floriano and 17 in Bom Jesus. There were no losses from the calculated sample.

The inclusion criterion was women who participated in the Family Health Strategy (FHS) of their region. The exclusion criterion adopted in the study was women with a record of mental illness in their medical charts. When a woman met the exclusion criterion, she was recruited as a new participant.

The data collection occurred from August of 2015 to March of 2016. The women were recruited using a drawn lot. Microsoft Excel 2010 software was used, considering the numerical listing of the women receiving care in the respective cities that was available from the Basic Health Units (BHU).

Three instruments were used: one for sociodemographic characteristics (developed by the researchers to describe the variables of age, skin color/race, marital status, number of children, place of origin, education, and religion), the Non-Student Drug Use Questionnaire (NSDUQ) (for identification of illicit drugs), an instrument recommended by the World Health Organization (WHO), which was translated and tested in various countries,[12] and the Self-Reporting Questionnaire (SRQ-20), also recommended by the WHO for studies conducted in primary care, which is translated and validated for the Brazilian culture, and is composed of 20 objective questions that include four dimensions: depressive-anxious mood, somatic symptoms, vital energy decrease, and depressive thoughts. [13] This study focused on a specific question of the dimen-

sion "depressive thoughts", which asks if the participant "has had ideas of ending one's life".

A pilot test was performed with 10% of the sample (37 women), with the aim of testing the instruments and the researcher's ability. The information from this stage was not included in the database for analysis.

The Statistical Package for Social Science (SPSS) software, version 20.0, was used to analyze the data. The central tendency, dispersion, frequencies, and percentages were calculated, which allowed for the determination of the prevalence of illicit drug use by women. The Chi-square test was used to verify association between qualitative variables. When the frequency of the cells was less than 20%, or less than 5, an exact Fischer test was performed. The strength of associations between variables was calculated using the odds ratio (OR) and confidence intervals (95% CI). Logistic regression was performed with variables that presented p>0.010, with the purpose of verifying which illicit drugs best explain the effect on women's suicidal ideation. The stepwise forward modeling process was used.

The study was approved by the Research Ethics Committee of the Federal University of Piauí (Opinion No. 1,630,831). The participation of the women was voluntary, and only began after they read, received any clarifications, and signed the Terms of Free and Informed Consent form (FPIC).

Results

A predominance of women who were young adults (20 to 39 years old) (75.1%), with a mean age of 33.1 years (standard deviation=9.9), with a self-report of: brown skin color (59.4%), married/stable union (71.8%), Catholic (60.9%), having children (70.7%), and originating from the interior of the state (58.8%). On average, they had ten years of education (standard deviation=3.5).

Table 1 shows a statistically significant association between suicidal ideation and the use of non-prescription tranquilizers (p=0.005), solvents (p=0.006), and marijuana (p=0.003).

Table 1. Association between illicit drug use and suicidal ideation among women (n=369)

Independent variables	Suicidal ideation		*p-value*	OR	CI 95%
	No n(%)	Yes n(%)			
Non-prescription tranquilizer use			0.005*	2.774	1.372-5.608
No	279(75.6)	32(8.7)			
Yes	44(11.9)	14(3.8)			
Solvent use			0.006**	10.159	2.197-46.967
No	320(86.7)	42(11.4)			
Yes	3(0.8)	4(1.1)			
Marijuana use			0.003*	5.091	1.865-13.900
No	312(84.5)	39(10.6)			
Yes	11(3.0)	7(1.9)			
Cocaine and derivatives use			0.609**	1.1174	0.138-9.978
No	317(86.0)	45(12.2)			
Yes	6(1.6)	1(0.2)			
Total	323(100)	46(100)			

Pearson's chi-square test; ** Exact Fischer test; OR - Odds ratio; CI - Confidence interval

After logistic regression between the independent categorical variables (use of tranquillizers, solvents, and marijuana) with the dependent variable (suicidal ideation), this association was maintained. The use of tranquillizers increased by 2.7 times (CI=1.372-5.608), the chances of suicidal ideation when compared to those who did not use these drugs, as well as the use of solvents by 10.1 times (CI=2.197-46.967), and marijuana use by 3.3 times (CI=1.865-13.900) (Table 2).

Table 2. Logistic regression of illicit drug use with suicidal ideation (n = 369)

Independent variables	n	Suicidal ideation	
		OR(adj)*	CI** 95%
Tranquillizer use	58	2.772	1.328-5.786
Solvent use	7	10.179	2.05050.550
Marijuana use	18	3.334	1.128-9.858

* OR (adj) - adjusted odds ratio; ** CI - Confidence interval. The statistical significance established at 0.05, with the interval not passing the value 1.0

Discussion

The limitation of this study is the cross-sectional design which, although capable of demonstrating a relationship between the phenomena studied (suicidal ideation and use of illicit drugs), does not allow for the affirmation of the existence of causality. Although the instrument used is not specific for investigation of suicidal ideation, the evaluation of the participants regarding the dimension "depressive thoughts", of the SRQ-20, enabled the identification of ideation.

However, the results obtained are in addition to the statistical panorama to expand the discussion on drug consumption in the female universe, and its interface with suicidal ideation, as the knowledge produced on the subject is still limited, considering that the problem of PAS use by women is relatively recent.

The data from this research present socio-demographic and economic characteristics similar to the findings of other studies, also performed with women who: are receiving care in primary care, generally young, in an economically active and reproductive stage of life, unemployed, with a low purchasing power, and with a level of education below the expected level for their age.[14-17]

In addition to these characteristics, some particularities in the relationships established between women and drugs included the type of drug chosen, the purpose, and the expectations implied in that utilization.

In this context, the World Drug Report, published in 2016, shows a gender difference in the use of PAS; men are three times more likely to use marijuana, cocaine, and amphetamines, and women to use opioids and tranquilizers without a prescription.[18]

This reality ratifies the idea that the phenomenon of drugs is part of the daily life of women, although with symbolic values and distinct characteristics from a gender perspective. This scenario also expresses a risk of exposure to other situations of physical and mental vulnerability.

When analyzing the quality of life and the mental health of chemically dependent individuals, the results show that women present lower quality of life and mental health than men, although they start consuming later, for less time, and with a lower consumption pattern.[19]

In addition, the use of PAS in the female population is considered a risk factor for suicidal behavior.[20] The abuse of PAS interferes in, and may even increase the chances of such behavior.[21] A study conducted in Serbia indicates that the use of PAS by women can increase the risk of suicidal behavior from 6.5 to 9 times, when compared to women who do not use drugs.[22]

Suicidal behavior is a multifaceted problem, in which the presence of mental disorders increases their vulnerability.[23] Most people with this type of behavior (more than 90%) have diagnosed chronic mental disorders, with depression schizophrenia and abuse of PAS being more common. It is interesting to note that the association of suicidal behavior with the use of illicit PAS has been reported, specifically heroin, cocaine, and tranquillizers without medical prescription.[24]

In the present study, suicidal ideation is also associated with the use of tranquilizers. These, mostly the benzodiazepines, are depressants of the central nervous system. They are usually used by women, who are searching of relief for frustration and/or stress (49%).[25]

Although these substances act biologically on the mood and anxiety dimensions, recreational and indiscriminate use can generate physical and psychological dependence, in addition to the risk of paradoxical effects, such as depression and suicidal ideation.[26,27]

Another important finding of this research is on the use of solvents, whose use increases the chances of suicidal ideation among women. The literature indicate that the risk associated with solvent/inhalant utilization is erroneously considered low when, in fact, it may be responsible for tragic outcomes, including death.[28]

The misuse of solvents is among the most prevalent and pernicious forms of drug use in the Americas. These include a large group of substances with different utilities and consequences, with legalized use in industry/residences, and therefore readily available. Scientists and health professionals have neglected the repercussions of this practice on the female environment. However, one review study described recent advances in preclinical and clinical data on severe complications associated with this practice by women: sudden death and fetal solvent syndrome, neurotoxicity, cognitive impairment, headache, impaired sensory abilities (loss of vision, hearing and coordination), sleep disorders, and increased mental disorders, which even potentiate suicidal thoughts.[29]

Researchers at the University of Washington (USA) discussed the use of solvents and their interface with suicidal behavior. The authors found that, when

comparing users of solvents with non-users, a significantly higher rate of suicide in the users was identified, including ideation (52.1%, 32.2%, respectively) and attempts (25.8%, 12.5% respectively).[30]

This study indicated that the use of marijuana increases the chances of suicidal ideation among women. Although the use of this substance is of great epidemiological relevance, the natural course of the disorders caused by its use is still relatively unexplored.[31] In addition, as men constitute 75% of the population of marijuana users, women have been historically underrepresented in investigations of issues related to its use. Thus, the understanding of gender-specific risks and consequences are limited.[32]

Research states that women have advanced from experimentation to regular use more rapidly, and presented a larger decrease in quality of life, as a consequence of marijuana use.[33] A study conducted in Mexico describes that the use of marijuana by young people, in the last 12 months, increases the risk of suicidal ideation and attempted suicide. Other drugs are generally associated, but to a lesser extent.[34]

In the female context, specifically, a study with 600 participants found that women who seek treatment for compulsive use of marijuana, in late adolescence and in young adulthood, showed significantly higher rates of anxiety and suicide risk compared to men who sought treatment during the same stages of development.[35]

The indicators produced indicate that the use of illicit drugs by women has a serious implication and, therefore, requires effective interventions that should focus, above all, on the prevention of suicidal ideation, as the progression of this ideation may converge in tragic outcomes that include attempted suicide, self-mutilation, and suicide.

Conclusion

The findings of this study showed a predominance of young adult women, with brown skin color, married/stable union, Catholic, with children, and who were from the interior of the state. The women who used illicit drugs, such as non-prescription tranquilizers, solvents, and marijuana, were more likely to have suicidal ideation than those who did not report use.

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Collaborations

Silva Júnior FJG, Monteiro CFS, Veloso LUP, Sales JCS, Costa APC and Gonçalves LA declare that they contributed to the study design, analysis, data interpretation, and final approval of the version to be published.

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ACTA 30 YEARS 1988 - 2018

Original Article

Antiretroviral therapy: compliance level and the perception of HIV/Aids patients

Terapia com antirretrovirais: grau de adesão e a percepção dos indivíduos com HIV/Aids

Terapia con antirretrovirales: grado de adhesión y percepción de individuos con VIH/SIDA

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HIV; Acquired immunodeficiency syndrome; Anti-retroviral agents; Medication adhesion; Hospitalization

Descritores
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Descriptores
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Abstract
Objective: Understand the aspects related to HIV/AIDS patients' compliance level with antiretroviral drugs.
Methods: Qualitative study developed at two inpatient units of a university hospital in the interior of the State of São Paulo, Brazil. The data were produced between October 2017 and April 2018, interviewing 40 participants. The produced material was recorded and later transcribed. For the data analysis and processing, the Descending Hierarchical Classification technique was used for support, in the framework of the Collective Subject Discourse.
Results: After the analysis and processing, five word classes resulted: 1. Socioeconomic aspects as fundamental reasons for non-compliance with antiretrovirals; 2. Family support to cope with the condition and stimulate treatment compliance; 3. Consequences of the compliance level with antiretrovirals; 4. Difficulties to comply with antiretroviral therapy related to adverse effects and medicine format; and 5. Possible changes to improve compliance with HIV treatment.
Conclusion: The main difficulties people living with HIV/AIDS who are hospitalized and with irregular compliance face are socioeconomic aspects, family support and adverse effects.

Resumo
Objetivo: Apreender os aspectos relacionados ao grau de adesão de pessoas vivendo com HIV/aids aos antirretrovirais.
Métodos: Estudo com abordagem qualitativa desenvolvido em duas unidades de internação de um hospital universitário do interior paulista. A produção dos dados ocorreu no período de outubro de 2017 a abril de 2018 com 40 participantes entrevistados, cujo material produzido foi gravado e posteriormente transcrito. A análise e o processamento dos dados foram realizados com apoio na técnica da Classificação Hierárquica Descendente e base fundamentada no Discurso do Sujeito Coletivo.
Resultados: Após análise e processamento, obtiveram-se cinco classes de palavras: 1. Questões sócio-econômicas como motivos fundamentais da não adesão aos antirretrovirais; 2. O apoio familiar para o enfrentamento da condição e estímulo para a adesão ao tratamento; 3. Consequências do grau de adesão aos antirretrovirais; 4. Dificuldades de adesão à terapia antirretroviral relacionadas aos efeitos adversos e apresentação medicamentosa; e 5. Possíveis mudanças para melhorar a adesão ao tratamento do HIV.
Conclusão: As principais dificuldades enfrentadas por pessoas vivendo com HIV/aids hospitalizadas e que estão em adesão irregular são questões sócio-econômicas, apoio familiar e efeitos adversos.

Resumen
Objetivo: Comprender los aspectos relacionados al grado de adhesión de personas afectadas por VIH/SIDA a los antirretrovirales.
Métodos: Estudio con abordaje cualitativo, desarrollado en dos unidades de internación de un hospital universitario del interior paulista. Datos producidos de octubre de 2017 a abril de 2018 con 40 participantes entrevistados, cuyo material fue grabado y posteriormente transcripto. El análisis y procesamiento de datos se realizó con apoyo de la técnica de Clasificación Jerárquica Descendente, y la base, fundamentada en el Discurso del Sujeto Colectivo.
Resultados: Analizados los procesos, se obtuvieron cinco clases de palabras: 1. Cuestiones socioeconómicas como motivos fundamentales de no adhesión a los antirretrovirales; 2. Apoyo familiar para enfrentar la condición y estímulo para adherir al tratamiento; 3. Consecuencias del grado de adhesión a los antirretrovirales; 4. Dificultades de adhesión a la terapia antirretroviral relacionadas a efectos adversos y presentación de los medicamentos; y 5. Posibles cambios para mejorar la adhesión al tratamiento del VIH.
Conclusión: Las principales dificultades enfrentadas por personas afectadas por VIH/SIDA hospitalizadas y en adhesión irregular las constituyen cuestiones socioeconómicas, apoyo familiar y efectos adversos.

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Introduction

In the last 30 years, the AIDS (acquired immunodeficiency syndrome) epidemic has entailed negative consequences for families, communities and countries, representing one of the greatest contemporary challenges to public health. More than 7,000 people are infected with the Human Immunodeficiency Virus (HIV) every day.[1] Globally however, its transmission has declined by 16% since 2010 as a result of prevention and treatment programs.[2]

About 36.7 million people are living with HIV/AIDS worldwide, with approximately 1.8 million new cases registered in 2016.[2] Since the beginning of the epidemic in Brazil, from 1980 to June 2017, 882,810 cases of AIDS have been registered, with an average of 40,000 cases annually in the last five years.[3]

In order to address the problem, Brazil guarantees universal and free access to antiretrovirals through the Unified Health System (SUS).[4]

The 90-90-90 target, created by the United Nations program that contributes to end the AIDS epidemic worldwide,[5] sets forth that 90% of people living with HIV/AIDS (PLHA) be aware of their diagnosis, 90% already under treatment and 90% with an undetectable viral load. In Brazil, according to data for 2015, 60% of PLHA are being treated and approximately 54% are in viral suppression.[2]

Although access to antiretrovirals is free in Brazil, advances are still needed to achieve the goals of the 90-90-90 target. The distribution system of the therapy in the country is a prominent model in the international scenario, especially due to the universality of access.[6]

The objectives of antiretroviral therapy (ART) are to reduce morbidity and mortality and improve people's quality of life through viral suppression, which permits delaying or preventing the development of immunodeficiency.[7] Intermittent treatment is necessary though. In fact, ART changed the scenario of the problem, significantly reducing morbidity and mortality.[8,9]

A meta-analysis on ART in Latin America and the Caribbean showed a 70% compliance rate in the 25 countries surveyed. The following barriers to compliance were identified in the study: use of alcohol and other drugs, factors related to depression, unemployment and the number of tablets recommended in the therapy.[10]

In view of the above, further investigation is needed of what permeates the compliance with antiretrovirals of people living with HIV/AIDS. Based on the above considerations, the objective of this study was to understand the aspects related to the level of compliance of HIV/AIDS patients with antiretrovirals.

Methods

Qualitative research based on the collective subject discourse method, which is established in key expressions, structured and determined for the formation of essential ideas and similar to the participants' discourse, permitting the establishment of collective thinking.[11,12]

In total, 40 people living with HIV/AIDS participated in the study and were hospitalized at a referral hospital in an interior city in the state of São Paulo, with medical records of irregular compliance with antiretrovirals. Participants were selected by convenience sampling and met the inclusion criteria, namely: being 18 years of age or older, being aware of the diagnosis of AIDS and presenting pick-up rates of antiretroviral drugs inferior to 80% in the past 12 months in the Logistic Control system of Medicines (SICLOM), according to available evidence.[13]

Those in confinement situations (inmates and institutionalized patients) and those with undetectable viral load as reported in the electronic medical record were excluded.

The data were collected from October 2017 to April 2018, with completion based on theoretical saturation criteria. We conducted in-depth interviews with an average duration of 30 minutes, in a private room, guided by a semi-structured tool with open questions about compliance with antiretrovirals. The participants' discourse was recorded and later transcribed for the creation of a textual corpus.

The data were processed in IRaMuTeQ (R INTERFACE for multidimensional analysis of texts and questionnaires) by means of lexical analyses. The co-occurrences of words were calculated

that permit identifying topics of interest for the investigation. For the analysis of the textual data, the descending hierarchical classification (DHC) method was followed.[14]

After processing the data, classes predefined by the software were obtained, based on the organization of the most significant vocabulary in thematic axes. Then, the key expressions in the participants' discourse were organized to complement the CHD and to name the definitive classes based on the words contained in the CHD and the excerpts from the discourse.

The research received approval from the Research Ethics Committee of the University of São Paulo at Ribeirão Preto College of Nursing, CAAE: 57372416.7.0000.5393. The ethical premises for research involving human beings were complied with. All participants signed the Free and Informed Consent Form.

Results

In total, 40 people living with HIV/AIDS were included in the study, with a mean age of 41 years (median ± 42.62 / standard deviation ± 12.51) and mean HIV diagnosis time of ± 13.4 years (median 10 years / standard deviation ± 7.69).

Among the study participants, 17 (42.5%) were cisgender men, 21 (52.5%) cisgender women and 2 (5%) transgender / transsexual women. As for education, 7 (17.5%) were illiterate, 13 (32.5%) had not finished elementary education, 14 (35%) finished elementary school, 5 (12.5%) finished high school and 1 (2.5%) finished higher education. Twenty four (60%) gained an income, 26 (65%) had children and only 10 (25%) had active sexual partners. Regarding family support, 70% (30) reported having support.

In the processing of the statement, IRaMuTeQ recognized 39 initial context units (ICUs), 424 elementary context units (ECUs), and 15,180 occurrence records. The usage rate of the textual corpus was 80.42%. Based on the Descending Hierarchical Classification (DHC), the most relevant and most reported words were analyzed.

Five classes were obtained through the analysis: 1 - Socioeconomic issues as fundamental reasons for non-compliance with antiretrovirals; 2 - Family support to cope with the condition and stimulate treatment compliance; 3 - Consequences of irregular compliance with antiretrovirals; 4 - Difficulties of regular compliance with antiretroviral therapy, related to adverse effects and drug format and 5 - Possible changes to improve compliance with HIV treatment. These classes were identified in key terms and displayed in the final tree diagram (Figure 1).

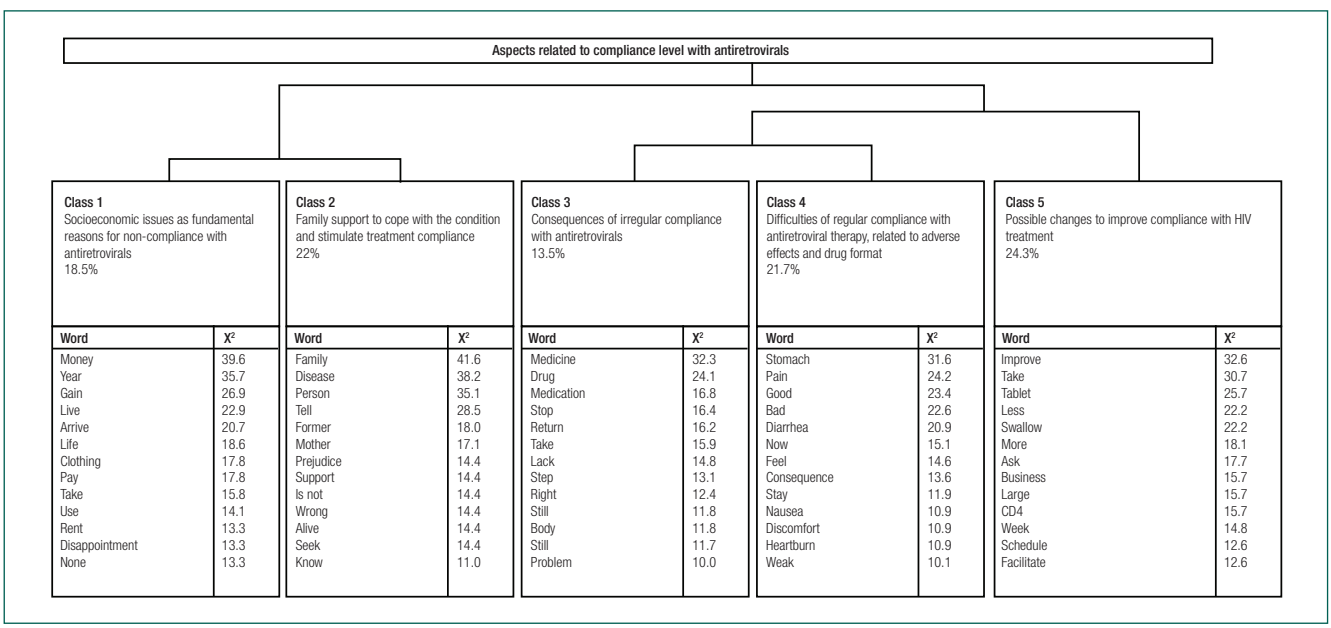

Figure 1. Graphical representation of aspects related to irregular compliance with antiretrovirals

Class 1: Socioeconomic issues as fundamental reasons for non-compliance with antiretrovirals

In this class, patients reported difficulties related to noncompliance with antiretrovirals, with emphasis on the lack of financial resources and drug use. Others reported that they stopped using antiretrovirals because they did not care about the correct time or forgot.

It is highlighted that the relevance of achieving maintenance and/or financial stability surpasses the concern with the clinical condition so that treatment is pushed to the background.

"I stopped on my own, because they were nauseating me and I needed to work". E-09

"I worked at night and stopped working because the back that was already rotting, it did not function anymore, so nobody helps me, I do not have social assistance". E-14

"I used drinks and drugs along with the medicines, so when I used them I did not take the medicine". (E-16)

"Sometimes, for example, if I missed the medication time, I did not worry. I was not going to run away and I did not have medicine in my pocket". (E-24).

In the case of some narrations, the discouragement with the treatment and having to deal with the disease daily entails giving up the therapy:

"I've been here so many times. I go there and stop and come back here again; laziness also, I am tired already of this patient life". (E-31)

Class 2: Family support to cope with the condition and stimulate treatment compliance

The participants reported social problems related to the disease. On the other hand, they also emphasized the importance of the family in the treatment process. It is known that family support for the treatment improves compliance with antiretrovirals significantly, as it highlights their relevance to the family group. In some cases, revealing the diagnosis to family and friends may have negative outcomes. Negative experiences can be observed:

"I told about my condition (to the affective partner) and it was very traumatic because I ended up being rejected, I even panicked". (E-35)

"A bit of family support too, lack of support. I come from the doctor and no one asks how my tests are, that's also what hurts me". (E-31)

Class 3: Consequences of irregular compliance with antiretrovirals

In this class, the consequences of abandoning the antiretrovirals were evidenced. The participants believe that the fact that they are hospitalized is somehow related to the interruption of treatment. The clinical symptoms were the most recurrent, considering that there is a drop in the count of defense cells of the immune system, making the patient susceptible to other diseases, mainly opportunistic conditions secondary to HIV.

"I'm here today because I got weak legs, shortness of breath, a problem in the lung, which is tuberculosis". (E-08)

"Because it's the third time I've changed the cocktail because I've stopped and come back, but it's the first time it hits one of my organs in 17 years". (E-13)

"I think this urine infection I had, which is already the third time, and the weakness is because I stopped with the medicine". (E-33).

Class 4: Difficulties of regular compliance with antiretroviral therapy, related to adverse effects and drug format

The amount and size of the tablets were noted as obstacles to regular treatment compliance. In addition, clinical manifestations such as epigastralgia, nausea and emesis predominate in this class and are strongly interconnected to reasons for poor compliance; as observed:

"I was taking those little ones that did me no harm then he came back with those huge ones he'll finish me off". (E-20)

"The size of the medicines and their effects, it destroys the stomach because they cure one thing and harm another". (E-04)

"I have a weak stomach for medicine in general and I have to take a medicine to be able to take the cocktail that harms me, it harms me a lot". (E-25)

"I stopped drinking because I cannot even see the bottle of medicine, just seeing the bottle already upsets my stomach". (E-33)

Class 5: Possible changes to improve compliance with HIV treatment

The participants pointed to aspects that may contribute to improve the compliance with HIV treat-

ment. Most indicated the use of smaller tablets and therapeutic regimens with fewer tablets for ingestion.

"If it were small I could even take it, but those huge tablets [...]". (E-06)

"Big pills that made me vomit, if it were less medicine and smaller, because I take 04 pills" (E-08).

"Something liquid because it does not hurt the stomach so much, you see, and it is easier to swallow" (E-21).

The irregular treatment compliance evidenced in this study is a source of concern, as the mean time of the participants' HIV diagnosis is little more than 13 years and it is expected that, the longer the diagnosis and treatment, the better the compliance with the antiretrovirals as a result of the routine.

It was observed that the five classes present relevant content to understand the irregular compliance with the HIV/AIDS treatment and can broaden the understanding of the subjectivities of the PLHA that involve the perception about their condition and the need for treatment.

Understanding these issues can contribute to the health professionals' practice, guiding them towards a broader approach to each individual's needs in an individualized way. The participants point out financial conditions, drug use, family support and difficulties with drug formats as factors to be considered.

Those factors influence the regular compliance with antiretroviral therapy. One of the great challenges the professionals involved in the care for these patients face is to develop strategies that are sensitive to the subjectivities of PLHA and that are capable of producing positive results in improving treatment compliance.

Discussion

It was identified that irregular compliance with antiretrovirals is related to aspects of the social, economic and cultural context of PLHA. Although the treatment in Brazil is free, the financial issues mentioned entail strong implications in daily social life and exert influence in the regular use of the medicine. Other conditions were reported: need for family support; use of alcohol and other drugs and difficulties to adapt to the drug format.

The HIV/AIDS therapy alone is a major challenge and adds up to the individual and collective aspects of PLHA. The complexity of the therapeutic scheme and the reactions to the medicines can be highlighted. In this sense, to manage the compliance, multiple factors need to be considered.[15]

Regarding the financial problems, there is evidence in the literature that the employment and income situation is a significant factor associated with non-compliance with the treatment.[16] In order to achieve better outcomes in antiretroviral treatment, managers and health professionals need to consider situations that pervade the free distribution of medicines, such as the sociocultural context the PLHA are inserted in. Efforts are needed to identify the difficulties in regular compliance with antiretrovirals, so that interventions capable of promoting positive change can be carried out.

Another highlight was the lack of family support, which the participants characterized as relevant for decision making on treatment abandonment. Studies show that the family exerts strong influence on treatment compliance, which goes beyond the financial aspect. The lack of emotional support and absence of family care were identified in a study involving people who abandoned HIV/AIDS treatment in Rio de Janeiro.[17]

Fear of being abandoned by the family as a result of the diagnosis of HIV infection is directly associated with treatment compliance.[18] Indeed, emotional support from the family to cope with the new condition is relevant at different times in the PLHAs' life, both for the acceptance of the diagnosis and the perception of the need to initiate the treatment and conduct it consistently.

As for alcohol and other drugs, the significant association between substance use and non-compliance with treatment was noteworthy in another study.[16] Similar results involving alcohol consumption were found among adolescents living with HIV in Malawi.[19]

Research in different realities has already shown that alcohol use decreases compliance with

antiretrovirals.[20-22] The reports obtained in this study demonstrate that participants decided to discontinue treatment to consume alcohol and/or other drugs.

Forgetfulness was one of the justifications for irregular compliance pointed out in this research. Another study showed that 32.9% of the subjects presented forgetfulness as the main cause of non-compliance.[23] A study conducted in South Korea between 2006 and 2015 found that 30% of the participants stopped taking antiretroviral drugs more than once month due to forgetfulness.[24]

In addition to the difficulties identified, the consequence of irregular compliance stand out, such as the drop in defense cells and the hospitalizations due to the worsening of the health condition. The immune system of ART users who do not comply with the treatment properly gets damaged, reflected in low levels of TCD4+ lymphocytes and, consequently, the progression towards Aids and the increased chance of opportunistic infections.[25,26]

As for difficulties to regularly comply with the antiretroviral therapy related to the adverse effects and medicine formats, in a Brazilian study, it was identified that, in a sample of PLHA, 24% of the participants reported adverse events.[27] In a study developed in East Africa, the presence of adverse effects negatively influence the antiretroviral therapy[28] and can affect different areas of human beings, ranging from the physical to the psychosocial.[29]

Possible changes to improve compliance with HIV treatment identified in this study were supported by an international study,[30] in which individuals undergoing injectable antiretroviral therapy reported better compliance due to the monthly or six-monthly application regimen.

A limitation in this study is that only people were investigated who were hospitalized due to the health complications the irregular compliance with the antiretrovirals had caused. Hence, PLHA who did not experience health complications and who for some reason were not hospitalized were left out. This means that people in other health conditions were not included in this research.

Conclusion

The main difficulties HIV/aids patients in hospital and showing irregular compliance with ART are socioeconomic and family support issues and the adverse effects of the treatment. The five classes present contents that contribute to understand the irregular compliance with the HIV/aids treatment and can guide the health professional's practices towards a comprehensive approach of the person's particularities.

Collaborations

Freitas JP, Sousa LRM, Cruz MCMA, Caldeira NMVP and Gir E declare that they contributed to the Project design, data analysis and interpretation, relevant critical review of the intellectual content and approval of the final version for publication.

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