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

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 cartailla 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 cartilla 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.

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

Descritores
Traumatismos da medula espinal; Sexualidade; Educação em saúde; Materiais de ensino; Ensaios de validação

Descritores
Traumatismos de la médula espinal; Sexualidad; Educación en salud; Materiales de enseñanza; Estudios de validación

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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.\textsuperscript{(13,14)} Publication selection was in accordance with the PRISMA recommendations (Appendix 1).\textsuperscript{(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.\textsuperscript{(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%.\textsuperscript{(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.\textsuperscript{(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.).\textsuperscript{(18)}

The consulted literature advocates a sample of 30 people to validate an educational booklet with the target audience.\textsuperscript{(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,\textsuperscript{(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). 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. 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.

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

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

<table>
<thead>
<tr>
<th>Aspects</th>
<th>Alterations based on recommendations of referees and members of the target audience</th>
</tr>
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<tbody>
<tr>
<td>Language</td>
<td>- The subtitle of the booklet, displayed on the cover, was changed from “what you would like to know” to “what you must know”.&lt;br&gt;- 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.&lt;br&gt;- 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.&lt;br&gt;- The abbreviation “AVC” (Portuguese initialism for cerebrovascular accident) was removed.</td>
</tr>
<tr>
<td>Layout and design</td>
<td>- 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.&lt;br&gt;- The layouts of the captions of the illustration about erogenous areas were organized.&lt;br&gt;- The font color of a word was changed from red to black.</td>
</tr>
<tr>
<td>Illustrations</td>
<td>- The illustration on the cover was altered so the characters would hold hands.&lt;br&gt;- An illustration was reformulated to remove the spinal cord center.&lt;br&gt;- A family figure was included about the physical activity topic.&lt;br&gt;- The illustrations about the signs and symptoms of autonomic dysreflexia were redesigned because the original ones were not self-explanatory.&lt;br&gt;- The contrasts in the illustrations about classification of spinal cord injuries were altered.</td>
</tr>
<tr>
<td>Language</td>
<td>Comments on the evaluation of the booklet by the target audience</td>
</tr>
<tr>
<td>Layout and design</td>
<td>- 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).</td>
</tr>
<tr>
<td>Illustrations</td>
<td>- “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). “The organization is clear” (Participant 27). “The size is excellent to encourage the search for more information” (Participant 35).</td>
</tr>
<tr>
<td>Evaluation of the booklet</td>
<td>- “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 13).</td>
</tr>
</tbody>
</table>

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 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).

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).
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 re-written. 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.

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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.

References


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