







Methodological quality of validation of studies on simulated scenarios in nursing

Qualidade metodológica da validação de estudos sobre cenários simulados em enfermagem

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ABSTRACT

Objective: to evaluate the quality of the validation process performed in studies that developed simulated clinical scenarios for teaching and learning in nursing. **Methods:** the researchers conducted two steps: an integrative review in the Medical Literature Analysis and Retrieval System Online, Cumulative Index to Nursing and Allied Health Literature, Latin American and Caribbean Health Sciences Literature, Web of Science, SCOPUS, and Educational Resources Information Center databases; and the validation assessment, using the validated tool (Quality Assessment for Validity Studies). **Results:** 561 studies were identified, six of which comprised the sample, primary, methodological, available electronically and in full. Most showed good validation quality by meeting almost all the criteria required by the tool. **Conclusion:** the validation of studies on clinical scenarios was able to support reliable evidence for adoption in teaching through simulation in nursing. **Descriptors:** Nursing; Simulation Technique; Education, Nursing; Learning; Validation Study.

RESUMO

Objetivo: avaliar a qualidade do processo de validação realizado em estudos que desenvolveram cenários clínicos simulados para o ensino e aprendizagem em enfermagem. **Métodos:** os pesquisadores procederam à realização de duas etapas: uma revisão integrativa nas bases de dados *Medical Literature Analysis and Retrieval System Online*, *Cumulative Index to Nursing and Allied Health Literature*, *Literatura Latino-Americana e do Caribe em Ciências da Saúde*, *Web of Science*, *SCOPUS* e *Educational Resources Information Center*; e a avaliação da validação, adotando-se a ferramenta validada (*Avaliação da Qualidade para Estudos de Validade*). **Resultados:** identificaram-se 561 estudos, dos quais seis compuseram a amostra, primários, metodológicos, disponíveis eletronicamente e na íntegra. A maioria apresentou boa qualidade de validação ao cumprir quase todos os critérios exigidos pela ferramenta. **Conclusão:** a validação dos estudos sobre cenários clínicos foi capaz de sustentar evidências confiáveis para a adoção no ensino por meio da simulação em enfermagem.

Descritores: Enfermagem; Simulação; Educação em Enfermagem; Aprendizagem; Estudo de Validação.

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Introduction

Clinical simulation is defined as a teaching and learning strategy capable of obtaining effective educational results and fostering the development of competence⁽¹⁻²⁾ by translating real clinical situations into a safe environment⁽³⁾. The best practice standards for clinical simulation in nursing were developed by the International Nursing Association for Clinical Simulation and Learning and were last updated in 2021⁽⁴⁾.

Clinical simulation is composed of three stages entitled: preparation, participation, and debriefing⁽⁵⁾. The preparation stage is divided into pre-simulation, which includes activities to provide the participant with knowledge, such as lectures, reading of scientific material, books, and practice of skills⁽⁵⁻⁷⁾; and pre-briefing/briefing is configured as an orientation session, prior to the execution of the simulated scenario, regarding the learning objectives, characteristics of the scenario, and roles of the learners⁽⁴⁻⁵⁾.

The participation stage involves the development of the scenario, when the proposed clinical case is established⁽⁸⁻¹¹⁾; the debriefing is characterized by a discussion/reflection session about the simulated event, aimed at sustaining or improving the participant's future performance⁽¹²⁾. It is believed that simulated scenarios that provide high fidelity to the teaching and learning process can play a crucial role in patient safety^(10,13).

Even though the literature⁽¹²⁻¹⁵⁾ already explores research that proposed to develop simulated scenarios in nursing, there is still a lack of scientific production that synthesizes the knowledge produced about the methodological quality of the validation process of these studies and clarifies the ability of the developed scenarios to achieve the proposed learning objectives in the teaching and learning process through clinical simulation in nursing⁽¹²⁻¹⁵⁾.

Thus, for clinical simulation to represent an effective teaching and learning strategy, it is essential to obtain simulated clinical scenarios, prepared based on methodologically well-delineated studies

that promote an adequate validation process and clearly described, supporting the quality of the evidence identified in its results, to provide the development of clinical competence in nursing students and professionals⁽¹³⁻¹⁵⁾.

From this perspective, considering validation a fundamental criterion in methodological studies to ensure the reliability of the content developed^(1,4,13-15), this article aimed to evaluate the quality of the validation process carried out in studies that developed simulated clinical scenarios for teaching and learning in nursing.

Methods

Study conducted in two stages, a priori, an integrative literature review to identify the methodological studies that developed clinical scenarios in nursing, and then the evaluation of the quality of the validation process of the selected manuscripts.

The integrative literature review was conducted in October 2020 at a public university in the interior of São Paulo, Brazil, supported by the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) recommendation⁽¹⁶⁾ and configured by criteria arranged in a 27-item checklist and a four-step flowchart, which subsidized the rigor of this development.

The steps were as follows: (1) identification of the topic and guiding question; (2) search and selection of studies; (3) categorization; (4) analysis of the studies and (5) presentation of the review⁽¹⁷⁾.

The Patient-Intervention-Outcomes (PIO) strategy - a variation of the Patient-Intervention-Comparison-Outcomes (PICO) strategy⁽¹⁸⁾ - was adopted to develop the research question. The acronym P (population) was represented by nursing students and nursing professionals; the I (intervention) was configured by identifying studies that developed simulated clinical scenarios for nursing; and O (outcome) the nursing teaching and learning process. The following question was posed: what is the scientific evidence in

the literature on the development of simulated clinical scenarios for the teaching and learning process of nursing students and professionals?

An advanced search process was carried out in October 2020 with the help of the Portal of Periodicals, of the Coordination for the Improvement of Higher Education Personnel (*Coordenação de Aperfeiçoamento de Pessoal de Nível Superior/CAPES*), a virtual library that provides teaching and research institutions in Brazil with robust scientific production, made available to researchers free of charge by the University of São Paulo - Ribeirão Preto Nursing School, an institution associated by CAPES, via remote access entitled Federal Academic Community (CAFé).

The following sources of information were adopted: Medical Literature Analysis and Retrieval System Online (MEDLINE)/PubMed, Cumulative Index to Nursing and Allied Health Literature (CINAHL), Latin American and Caribbean Literature on Health Sciences (LILACS), Web of Science, SCOPUS, and Educational Resources Information Center (ERIC).

In PubMed/MEDLINE and SCOPUS we determined the indexed descriptors, in the English language, identified in Medical Subjects Headings (MeSH): Nurses; "Students, Nursing"; "Simulation Training"; "Validation Study" "Nursing Education", and the keyword: Scenario. An advanced search was performed using the strategy: ("nurses"[MeSH Terms] OR "nurses"[All fields]) AND "Students, Nursing"[All fields] AND "Simulation Training"[All fields] AND "Validation Study"[All fields] AND Scenario [All fields] AND "Nursing Education"[All fields] OR "Nursing Education"[All fields]).

In CINAHL the indexed descriptors were identified in Titles/Subjects, in English and in their Spanish and Portuguese versions: Nurse; "Students, Nursing"; Simulations; "Validation Studies", "Education, Nursing" and the keyword: Scenario. An advanced search was performed as follows: SU ((Nurse AND "Students, Nursing" AND Simulations AND "Validation Studies" AND Scenario AND "Education, Nursing")).

In the Web of Science, the descriptors indexed

in the Medical Subjects Headings (MeSH) in English were adopted: Nurses; "Students, Nursing"; "Simulation Training"; "Validation Study", "Nursing Education", and the keyword: Scenario. The advanced search occurred through the strategy: (Nurses AND "Students, Nursing" AND "Simulation Training" AND "Validation Study" AND Scenario AND "Nursing Education").

In LILACS, the descriptors were indexed under Health Science Descriptors (Decs) in Portuguese: "Enfermeiras e Enfermeiros"; "Estudantes de Enfermagem"; Simulation; "Estudo de Validação", "Educação em Enfermagem" and the keyword: Scenario, with the advanced search performed using the strategy: MH (("Nurses and Nurses" AND "Nursing Students" AND Simulation AND "Validation Study" AND Scenario AND "Nursing Education")), and their versions in English and Spanish.

In ERIC, the descriptors indexed in Medical Subjects Headings (MeSH) in English were: Nurses; "Students, Nursing"; "Simulation Training"; "Validation Study", Education and the keyword: Scenario. The advanced search was performed using the strategy: (Nurses AND "Students, Nursing" AND "Simulation Training" AND "Validation Study" AND Scenario AND Nursing Education).

Primary methodological studies that developed simulated scenarios in nursing and described the validation process, published in scientific journals, available electronically and in full were included. Literature reviews, case studies, dissertations, theses, monographs, abstracts published in annals of events.

The identified studies were submitted to the first stage of selection by two independent professionals, by reading the titles and abstracts, through a free, single-version web review program called Rayyan Qatar Computing Research Institute⁽¹⁹⁾. The researchers' evaluations diverged between 27 studies, which were forwarded to a third researcher, an *expert* in the scope of clinical simulation in nursing, responsible for deciding their inclusion or exclusion, and then a full reading was performed to define the sample.

The following information was extracted using a validated instrument⁽²⁰⁾: authors, year of publication, country of origin of the study, objective and type of study, results, conclusion. The level of evidence of the studies was also classified⁽²¹⁾. The findings were analyzed by Thematic Analysis⁽²²⁾ in three stages: pre-analysis, configured by floating reading of the evidence and organization of convergent information; exploration of the material with grouping of convergences and treatment of data, determining the categories.

In the second part of the study, the methodological quality of the selected studies was evaluated using the Quality Assessment for Validity Studies (QAVALS) tool. Despite being used in Brazil, this tool has

not yet been validated for Brazilian Portuguese, but we chose to adopt it because it is easy to interpret, manipulate, reliable, and does not generate a score. It is composed of 24 criteria that assess aspects about the methodological quality of validation studies, classified as “yes”, “no” or “other” (other= ND= cannot be determined; NA= not applicable; NR= not reported) and the more criteria are met by the study and are classified as “yes”, the better the validation quality⁽²³⁾.

The research was not submitted to the Research Ethics Committee since it is a literature review and does not involve human beings. The manuscript selection process is shown in Figure 1, based on the PRISMA recommendation⁽¹⁶⁾.

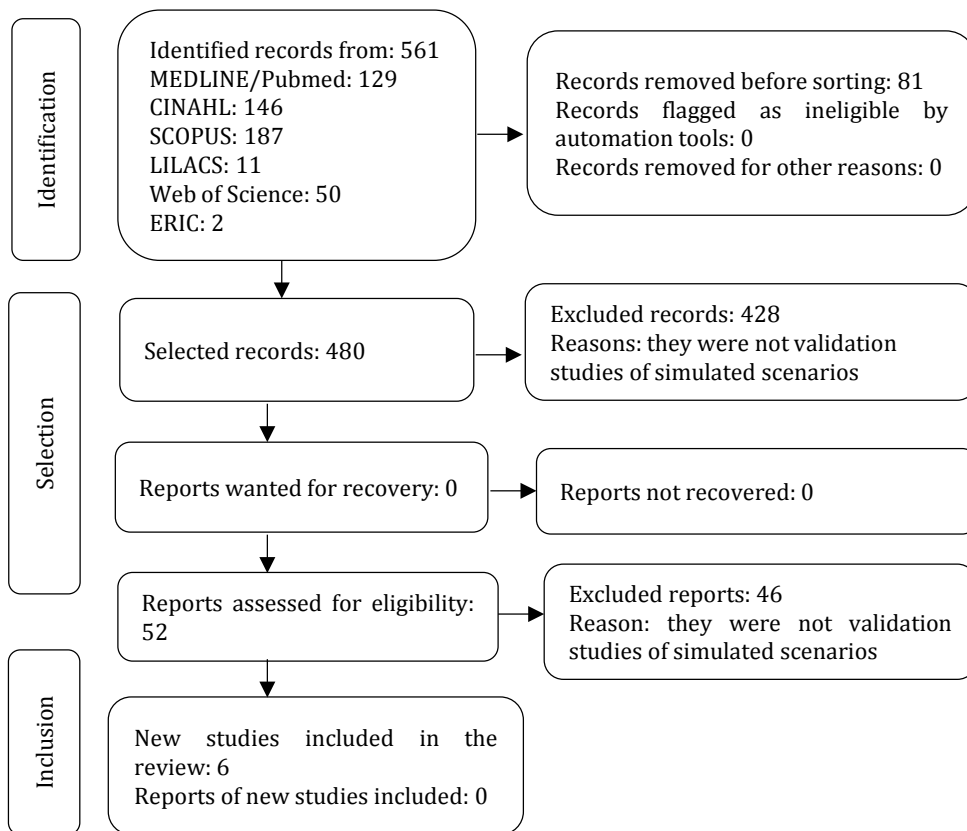


Figure 1 – Flowchart of identification, selection and inclusion of studies, prepared based on the PRISMA recommendation. Ribeirão Preto, SP, Brazil, 2020

Results

We identified 561 studies that were selected to

compose the final sample of the present research, six manuscripts, characterized in Figure 2.

Authors, year/origin	Objective, type of study and level of evidence	Results and conclusion
Jung et al. 2015/Coréia do Sul ⁽²⁴⁾	Develop and validate a simulation scenario to improve patient safety during asthma care. Methodological study. Level of evidence 6.	The identification of a Content Validity Coefficient higher than 0.80 for the scenario and an interobserver reliability of 0.95, indicated a good methodological quality in the development and validation of this construct.
Eduardo et al. 2016/Brasil ⁽²⁵⁾	Validate a scenario on the health care wastes management. Methodological study. Level of evidence 6.	100% agreement was obtained regarding the organization, comprehensiveness, objectivity, and relevance of the scenario. However, there was no clear description of the validation process.
Mazzo et al. 2018/Brasil ⁽¹³⁾	Describe the construction of a scenario of a patient with pressure injury. Experience report. Level of evidence 6.	Although the scenario developed can improve the cognitive, psychomotor, and affective aspects of caring for a patient with an injury, there was an absence of methodological criteria in its elaboration, such as, mainly, the description of the validation process.
Negri et al. 2019/Brasil ⁽²⁶⁾	Build and validate a simulation scenario on care of colostomy patients. Descriptive study. Level of evidence 6.	A total Content Validity Index of 1.0% was obtained in the interobserver evaluation regarding the quality of the developed scenario, which characterized it as valid, of good quality and feasible for the care of colostomy patients
Andrade et al. 2019/Brasil ⁽¹⁵⁾	Build and validate a clinical simulation scenario for postpartum hemorrhage. Methodological development research. Level of evidence 6.	The agreement on the validity of this scenario, supported by the quality of the methodological approach adopted, was satisfactory. This was clear when obtaining a Coefficient of Content Validity higher than 0.90 by the judges and 0.95 by the students involved. Thus, the construct was considered validated and appropriate for postpartum hemorrhage care.
Souza et al. 2020/Brasil ⁽²⁷⁾	To describe the process of content validation of a bloodstream infection prevention scenario. Methodological study. Level of evidence 6.	All requirements of the simulated clinical scenario achieved greater than 80% inter-rater agreement on their clarity and relevance, which demonstrated the methodological validity and quality of this construct.

Figure 2 – Characterization of the studies that comprised the sample of the integrative literature review. Ribeirão Preto, SP, Brazil, 2020

The studies date from 2015⁽²⁴⁾ to 2020⁽²⁷⁾, mostly national^(13,15,25-27) and with level of evidence 6⁽²¹⁾.

Given the findings, it was considered important, in addition to the presentation of the methodological quality of the validation, obtained by the studies that developed clinical scenarios, to structure a category called Actions recommended to develop a simulated scenario in nursing, composed of: 1) definition of those responsible for carrying out the steps of the scenario^(24,27); 2) establishment of the theme^(24,25); 3) description of the learning objectives⁽¹³⁻¹⁵⁾; 4) identification of the contents in the literature^(15,27); 5) preparation of the script based on references^(13,15,24); 6) definition of the target audience^(15,25,27); 7) definition

of the number of participants⁽²⁵⁻²⁷⁾; 8) establishment of prerequisites for participation⁽¹⁵⁾; 9) description of the clinical case, the patient characteristics, and whether they will be actors or simulators⁽²⁷⁾; adjustment to the participant's knowledge level⁽²⁶⁾; 10) description of the expected results^(13,15); 11) definition of the competencies to be developed⁽²⁴⁻²⁵⁾; 12) definition of the scenario fidelity⁽¹⁵⁾; 13) determination of the location⁽²⁶⁾; 14) establishment of the scenario duration⁽²⁷⁾; 15) establishment of the simulator^(13,15); 16) definition of equipment and materials^(15,24-25); 17) definition of the facilitators⁽¹⁵⁾; 18) script analysis of the simulated scenario⁽²⁵⁾; 19) training of facilitators and actors^(24,26); 20) pilot execution^(25,26); 21) pre-briefing/

briefing^(15,24-27); 22) scenario development; support to the participant during the execution with clues^(15,24); 23) scene videotaping⁽¹³⁾.

Next, the methodological quality of the validation studies was assessed using the Quality Assessment for Validity Studies (QAVALS) tool⁽²³⁾, as shown in Figure 3.

Item	Studies					
	13	15	24	25	26	27
1. Was the study design reported?	Yes	Yes	Yes	Yes	Yes	Yes
2. Is there a description of the validity type?	Yes	Yes	Yes	Yes	Yes	NR
3. Was the recruitment scenario and timeline described?	Yes	Yes	Yes	Yes	Yes	No
4. Are there selection criteria?	No	Yes	Yes	Yes	Yes	No
5. Does the sample represent the population?	NR	Yes	Yes	Yes	Yes	NR
6. Have the validated outcome measures been described?	Yes	Yes	Yes	Yes	Yes	No
7. Did the study provide a description of the procedures for validity?	No	Yes	No	Yes	Yes	Yes
8. Was the testing procedure standardized for everyone?	NR	Yes	NR	Yes	Yes	Yes
9. Was the sample size calculated to ensure power?	No	Yes	No	No	No	No
10. Did the study describe attrition?	NR	NR	NR	NR	NR	NR
11. Were statistical analyses used to test validity?	NR	Yes	NR	Yes	Yes	Yes
12. In multiple comparisons, did the adjustments control for type 1 error?	NA	NA	NA	NA	NA	NA
13. Were confounding variables identified and action taken?	NA	NA	NA	NA	NA	NA
14. Did you describe primary findings?	No	Yes	No	Yes	Yes	Yes
15. Did you report validity coefficients for primary findings?	No	Yes	No	Yes	Yes	No
16. Were there standard deviations or confidence intervals? If not, were there interquartile ranges?	No	Yes	No	No	No	Yes
17. Has the selection of experts and their qualifications been described?	No	Yes	Yes	Yes	Yes	Yes
18. Was justification provided for the selection of the reference standard?	NA	NA	NA	NA	NA	NA
19. When the index test was evaluated by more than one rater, were the raters blinded?	NA	NA	NA	NA	NA	NA
20. When the index test was evaluated by more than one rater, was reliability established?	NA	NA	NA	NA	NA	NA
21. Was there a gap between the reference standard and the test measure?	NA	NA	NA	NA	NA	NA
22. Were the individuals in different groups homogeneous?	NA	NA	NA	NA	NA	NA
23. Are the measures of convergent validity like the outcome measure?	NA	NA	NA	NA	NA	NA
24. Are the measures a different construct than the outcome of interest?	NA	NA	NA	NA	NA	NA

NA: not applicable; NR: not reported

Figure 3 – Evaluation of the methodological quality of the sample validation studies using the Quality Assessment for Validity Studies tool. Ribeirão Preto, SP, Brazil, 2020

Of the studies that comprised the sample, most^(13,25-27) showed good validation quality, since they met almost all the criteria proposed by the tool adopted⁽²³⁾, obtaining the classification “yes”. Only two studies^(15,24) were characterized as of low validation quality, as they did not fulfill most of the items that support this process.

It is important to clarify that the validation process performed in these manuscripts was face and content validation, therefore, the classification described as “not applicable”, obtained in the other valida-

tions, addressed by this tool, such as: criterion validity; construct validity for known groups; convergent construct validity and discriminant construct validity did not interfere in the methodological quality of the validation. It is also emphasized that because the scenarios developed are descriptive scripts, which do not propose to measure performance in each context, the other validations are unnecessary; only content validity is sufficient.

The criteria that showed weaknesses were the description of the type of validity adopted, the study

setting, and the timing of participant recruitment; clear description of the participant and expert selection criteria, primary findings, validity coefficients, and standard deviations or confidence intervals; performance of sample calculation; and description of some conflict during the process.

Discussion

The production of methodological studies on the development of simulated scenarios that clearly describe the route taken to validate the research is considered insufficient, an important limitation of this manuscript.

This manuscript contributes to nursing research, care and education by presenting a body of knowledge that indicates the quality of validation of studies that have developed scenarios for clinical simulation in nursing, demonstrates the main weaknesses in this area, and synthesizes a practical guide or step-by-step, based on scientific evidence, to support simulated scenarios and the excellence of this practice.

From this perspective, this study is unprecedented in nursing science because it compiles the knowledge produced about the quality of the validation process of methodological studies that proposed to develop scenarios for the teaching and learning process through simulation, and points to the good quality of most of the selected manuscripts, which indicates the reliability of the research produced on this topic, which is current, innovative and growing in the national and international scenario. In addition, it also synergizes in an objective way, a set of actions for the development of a simulated scenario, to direct the clinical simulation planning of nursing faculty members, simulation facilitators in other realities, and researchers.

Although it was not configured as the main object of this study, it was possible to compile a synthesis of the recommended actions to develop a simulated scenario in nursing, which can be useful for the development of a clinical simulation capable of mimicking reality.

A common error in clinical simulation is to interpret the simulated scenario considering only the description of a clinical case and minimizing fundamental criteria of its planning and development^(1,4,14,28). The absence of theoretical-methodological references that support the attainment of the scenario, learning objectives and other criteria identified in the sample of the present research^(15,24-25) negatively interferes in the learning outcomes of students and professionals and in the development of clinical competencies pertinent to nursing practice^(2,8).

This is like a qualitative study that analyzed 12 interviews with specialists in order to develop a theoretical and practical script/scenario to be used in simulated clinical activities, concluding that this resource can only enable an innovative and stimulating teaching experience if it is properly grounded in the relevant literature⁽¹⁴⁾.

A research of the validation methodological type corroborates the need to plan, execute and evaluate a simulated scenario for postpartum hemorrhage, performed with 22 expert judges and 30 students. This scenario was considered useful and appropriate for this reality because it was based on learning objectives, fidelity, assessment instrument, activities developed before the scenario and debriefing, considering the criteria required to maintain its quality⁽²⁶⁾.

The evaluation of the methodological quality of validation of the studies, the main object of exploration of the present research, provided support to indicate that most of the manuscripts^(13,25-27) evaluated presented validations of good quality and met almost all the requirements indicated to establish the reliability of this pathway. Obscurities in the description of certain criteria for the validation of scenarios, or the noncompliance with them, can weaken the validation performed and/or cause methodological biases⁽²³⁾.

A methodological research⁽¹⁵⁾ conducted in a public hospital in the countryside of São Paulo, Brazil, which aimed to validate the content of a scenario about the management of Health Services Waste did not perform, mainly, the description of the type of validity assessment adopted, the study scenario, the time

of recruitment of participants, considered important criteria for validation and a condition detrimental to the quality of the evidence produced⁽²³⁾.

It is already evident, for the recognition of the quality of a content validation, the clarity in the description of the type of validation adopted, of the primary findings, validity coefficients and sample calculation description, among other criteria, since they help sustain the credibility of the results and legitimacy of the study, a fundamental aspect to strengthen the proposed validation⁽²⁹⁾.

In this perspective, a study that reported the experience of describing a step-by-step description to develop a simulation scenario for nursing incorporated the validation of its content and due note of the type of validation adopted, criteria for selecting judges, and clear demonstration of results and validation coefficients, being considered of good methodological quality and useful for obtaining best practices for quality clinical simulation⁽¹⁰⁾.

On the other hand, the need to clearly describe the selection of experts translates the importance of recognizing that the content validation was performed by experts in the desired area, with the intention of improving the proposed scenario and sustaining its reliability before the teaching and learning process^(25,29). Thus, the validation by experts is configured by the careful evaluation of professionals, experts in the construct theme and able to adjust the consistency of the content⁽²⁹⁾.

It is recommended that randomized clinical trials be developed to test the effectiveness of simulated scenarios for nursing and present the methodological quality of the validation process adopted to foster science in this perspective and ensure a roll of reliable scenarios for use in the nursing teaching and learning process.

Conclusion

The quality of the methodological pathway of study validation that developed simulated scenarios for nursing was considered good in most of the inclu-

ded articles based on the analysis of 24 criteria supported by the Quality Assessment for Validity Studies tool, thus characterized as reliable as to the content developed.

Collaborations

Nascimento JSG, Pires FC, Nascimento KG, Regino DSG, Siqueira TV, and Dalri MCB contributed to the conception and design, data analysis and interpretation, writing of the article, relevant critical review of the intellectual content, and final approval of the version to be published.

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