Article

Development and Content Validation of an Instrument Covering Care for Pregnant Women with Sickle Cell Disease*

* Paper derived from the master's dissertation in Nursing: "Cuidado de enfermagem à gestante com doença falciforme: construção e validação de um protocolo de cuidados" presented at the Nursing School of Universidade Federal da Bahia, Salvador, in 2018.

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Theme: Healthcare technologies

Contribution to the field: This study contributes to the nursing team's scientific knowledge on the care of pregnant women with sickle cell disease, with the aim of preventing complications throughout the pregnancy-puerperium cycle.

Abstract

Introduction: The lack of discussions on nursing care for pregnant women with sickle cell disease in Brazil and the urgent need for intervention and improvements in the nursing care provided to these women sparked this study. In addition, validity is an essential attribute for instruments used in research and/or clinical practice. **Objective:** To develop and validate an instrument covering the care of pregnant women with sickle cell disease. **Materials and methods:** This is a methodological, content validation study conducted with specialist judges. The instrument was structured with 19 nursing diagnoses that addressed the biological, psychological, and social dimensions, as well as 126 nursing interventions. The Delphi technique was used with the participation of 18 judges. The results were analyzed using the content validity index and a level of agreement above 0.80. **Results:** Of the 145 items analyzed, 22 (15.17 %) scored a content validity index < 0.80, and the adjustments suggested by the judges were implemented. The instrument's general content validity index was calculated at 0.87. The instrument reached acceptable content validity parameters, according to the criteria used. **Conclusions:** The instrument's potential stands out, and it can be improved through its use as a resource for guiding nursing practices directed to pregnant women with sickle cell disease, both in primary health care and in hospital networks.

Keywords (Source: DeCS)
Validation study; nursing research; nursing diagnosis; nursing care; pregnant women; sickle cell anemia.

Desarrollo y validación del contenido de un instrumento para la atención de mujeres embarazadas con anemia de células falciformes*

* Artículo derivado de tesis de maestría en enfermería titulada "*Cuidado de enfermagem à gestante com doença falciforme: construção e validação de um protocolo de cuidados*" ("Atención en enfermería a mujeres embarazadas con anemia de células falciformes: construcción y validez de un protocolo de cuidados") presentada en la Escola de Enfermagem, Universidade Federal da Bahia, Salvador, en 2018.

Resumen

Introducción: la escasez de debates sobre la atención de enfermería a gestantes con anemia de células falciformes en el país y la urgente necesidad de intervención y mejora de los cuidados de enfermería prestados a esas mujeres motivaron la realización de este estudio. Además, la validez es un atributo esencial en los instrumentos para uso en investigación y/o práctica clínica. **Objetivo:** elaborar y validar un instrumento de atención a gestantes con anemia de células falciformes. **Material y método:** estudio metodológico, de validación de contenido con jueces/as expertos/as. El instrumento se estructuró con 19 diagnósticos de enfermería que abordaban las dimensiones biológica, psicológica y social, y 126 intervenciones de enfermería. Se utilizó la técnica Delphi, con la participación de 18 jueces/as. Los resultados se analizaron utilizando el índice de validez de contenido y un nivel de acuerdo superior a 0,80. **Resultados:** de los 145 ítems analizados, 22 (15,17 %) tenían un índice de validez de contenido < 0,80, y se aplicaron los ajustes sugeridos por los/las jueces/as. El índice global de validez de contenido del instrumento se calculó en 0,87. El instrumento alcanzó parámetros de validez de contenido aceptables, según los criterios utilizados. **Conclusiones:** se destaca el potencial del instrumento, que puede ser perfeccionado a través de su utilización como recurso para orientar las prácticas de enfermería dirigidas a gestantes con anemia de células falciformes, tanto en la atención primaria de salud como en la red hospitalaria.

Palabras clave (Fuente: DeCS)
Estudio de validación; investigación en enfermería; diagnóstico de enfermería; atención de enfermería; mujeres embarazadas; anemia de células falciformes.

Desenvolvimento e validação de conteúdo de instrumento para cuidados às gestantes com doença falciforme*

* Artigo derivado de dissertação de mestrado em enfermagem intitulada "Cuidado de enfermagem à gestante com doença falciforme: construção e validação de um protocolo de cuidados", defendida na Escola de Enfermagem, Universidade Federal da Bahia, Salvador, em 2018.

Resumo

Introdução: a escassez de debates sobre o cuidado de enfermagem às gestantes com doença falciforme no país e a urgente necessidade de intervenção e melhorias na assistência de enfermagem prestada às essas mulheres, motivaram este estudo. Além disso, em instrumentos para uso em pesquisa e/ou na prática clínica, a validade é um atributo essencial. **Objetivo:** desenvolver e validar um instrumento para cuidados às gestantes com doença falciforme. **Materiais e método:** estudo metodológico, de validação de conteúdo com juízas(es) especialistas. O instrumento foi estruturado com 19 diagnósticos de enfermagem que abordaram as dimensões biológica, psíquica e social, e 126 intervenções de enfermagem. Utilizou-se a técnica Delphi, com participação de 18 juízas(es). Os resultados foram analisados por meio do índice de validade de conteúdo e nível de concordância acima de 0,80. **Resultados:** dos 145 itens analisados, 22 (15,17 %) apresentaram índice de validade de conteúdo < 0,80, e os ajustes sugeridos pelas(os) juízas(es) foram implementados. O índice de validade de conteúdo geral do instrumento foi calculado em 0,87. O instrumento alcançou parâmetros aceitáveis de validade de conteúdo, segundo o critério utilizado. **Conclusões:** destaca-se o potencial do instrumento, que pode ser aprimorado a partir do seu uso, como recurso na orientação das práticas de enfermagem voltadas às mulheres grávidas com doença falciforme, nos âmbitos da atenção primária à saúde e da rede hospitalar.

Palavras-chave (Fonte DeCS)
Estudos de validação; pesquisa em enfermagem; diagnóstico de enfermagem; cuidados de enfermagem; gestantes; anemia falciforme.

Introduction

Sickle cell disease (SCD) is part of a group of chronic hereditary hemolytic diseases, with conditions that include frequent pain crises, anemia, and recurrent infections, among others, which significantly impact the quality of life of those affected (1). Recent data (2) from Africa estimate a global prevalence of 7.74 million people with SCD in 2021, while in Brazil the estimated mean prevalence is 2 % in the general population, and 6 to 10 % in black and mixed people (3).

Women with SCD face significant challenges when they become pregnant and require multi-professional care to maintain their health until the end of pregnancy (4). Prenatal care for pregnant women with SCD requires a monitoring protocol for normal risk and high-risk care, considering the potential for complications and the need for early intervention in the event of alterations during pregnancy (5).

In fact, studies show that the presence of SCD renders women more vulnerable to pre-eclampsia, intrauterine growth restriction, premature birth, and perinatal mortality (6), in addition to exacerbating the risks of pain crises, acute chest syndrome, and thromboembolism (4). The relative risk of maternal mortality in women with SCD was 18.5 (concordance index [CI] 95 %; 8.63-39.72) whilst the relative risk of perinatal mortality was 2.9 per 1000 deliveries compared to women without SCD in a cohort study conducted in the UK (7). Biosocial factors, such as socioeconomic status, nutritional status, and lack of access to healthcare and education, increase the severity of the condition and influence adequate management of the disease (8).

Care provided to pregnant women with SCD must be thorough and individualized, performed by an experienced multi-professional team to identify possible alterations early on and/or avoid complications that could lead to hospitalization, pregnancy loss, or even maternal and perinatal death (9, 10). The organization and maintenance of a care network, with preventive and health protection and promotion practices, is necessary for women with SCD (11). From this perspective, the focus on the promotion of self-care is essential for women with SCD to develop self-observation skills and competencies for measures intended to reduce the complications of the disease and improve their quality of life (12).

Countries in the European Union (13) and the United States (6) have made investments in the education and training of nursing teams, medical doctors, and other healthcare professionals who provide care to people with SCD, considering the lack of knowledge on the disease (14, 15) has been highlighted as an obstacle to the implementation of care lines for hemoglobinopathies. Therefore, it can be noted that the gap in knowledge on the management of SCD in pregnant women is not restricted to the nursing team, but to healthcare professionals in general. Studies similar to the present one will enable filling these gaps to reduce maternal and fetal morbidity and mortality in women with this disease, corroborating the achieve-

ment of the goals of the United Nations Sustainable Development Goals for the global reduction of this indicator (16).

It is worth noting that, as of December 2023, no validated instrument has been found in the literature for nursing care for pregnant women with SCD, highlighting the relevance and unprecedented nature of the results of this research for the health sector, nursing praxis, and the line of care for pregnant women with SCD.

In Brazil, it is vital to highlight the role of the nursing team in recognizing self-care deficits in women with SCD, especially during the pregnancy and puerperal stages. The absence of discussions on the subject nationwide and the urgent need for intervention and improvements in the nursing care provided to this group (11) sparked the present study, which aimed to develop and validate an instrument covering nursing care for pregnant women with SCD.

This is an instrument developed in Brazil by a Brazilian researcher, and its initial version consisted of 19 nursing diagnoses and 126 nursing care measures for pregnant women with SCD, stemming from qualitative research analyzed in the light of Orem's theory. As of December 2023, it has not been translated into other languages.

Materials and methods

Type of study

This is a psychometric study covering the creation and validation of an instrument, developed in two stages. First, the design of the instrument, based on data from Santos' research (17) as part of the development of her master's thesis; and second, the content validation, conducted with the participation of Brazilian judges.

Instrument design

The instrument, entitled "Nursing care for pregnant women with sickle cell disease", was developed for use in clinical practice and its design was based on Orem's self-care theory (18), applied to the findings of a previous qualitative study performed with 15 pregnant women diagnosed with SCD (17). In that study, pregnant women with SCD were interviewed using a semi-structured script divided into two parts. The first contained questions on sociodemographic data, SCD history, obstetric history, and current pregnancy; the second part covered universal self-care requirements (oxygenation and circulation; eating habits; fluid intake; bowel and bladder elimination; daily activities; rest; social interaction/participation; health promotion/well-being; sexual function; self-esteem; self-image), developmental self-care requirements, self-care requirements, health deviations, racial requirements, and gender requirements.

The content of the interviews with the pregnant women with SCD, in the light of Orem's theory, was used to formulate the nursing diagnoses that comprise this instrument, which covers the biological, psychological, and social dimensions. For each nursing diagnosis, the respective nursing care items were defined, and the first version of the instrument (13) consisted of 19 diagnoses and 126 nursing care items.

Content validity

Content validity consists of an evaluation performed by specialist judges who determine whether an instrument measures exactly what it is intended to measure (19). In instruments for use in research and/or clinical practice, validity is an essential attribute.

The study was conducted from March 2017 to February 2018. Potential study participants were identified through a curriculum search on the Lattes platform and in a multi-professional healthcare unit specializing in SCD care. Content validation was conducted using a round of the Delphi technique (20, 21) with judges who had been selected for convenience, following the following inclusion criteria: Having at least one year of professional knowledge and experience in the subject and clinical practice and/or health management; holding at least an undergraduate degree. A total of 24 invitations were sent to professionals who met the criteria for participating as judges, with a response rate of 75 %. The invitation letter and informed consent form (ICF) were sent by email, with 18 participants responding by returning the signed ICF and receiving a link to the Google Forms form to fill it in and send it back to the researcher within a deadline of 60 days.

The form consisted of three parts: Identification data of the judges; an instrument containing 19 nursing diagnoses and 126 proposed nursing interventions, and a final opinion on the instrument analyzed. Each judge rated the items (nursing diagnoses and interventions) regarding their permanence in the instrument's composition, using the response options on a Likert scale (22, 23) with scores ranging from 1 to 5, where 1 — irrelevant, 2 — not very relevant, 3 — relevant, 4 — very relevant, and 5 — extremely relevant. In addition, the judges answered two questions concerning the need to add other items to the instrument and the intelligibility (clarity, spelling, coherence) of all the items presented, where they recorded comments and/or suggestions. A validation round was performed with the judges.

To analyze the final opinion regarding the instrument in question, the following criteria were listed: Usefulness and relevance, consistency, clarity, objectivity, simplicity, feasibility, updating, accuracy, and instructional sequence of topics. The response options ranged from 0 to 4, where 0 — strongly disagree, 1 — disagree, 2 — neither disagree nor agree, 3 — agree, and 4 — strongly agree.

Data analysis

The agreement analysis of the judgment of the instrument's items was performed using the content validity index (CVI), calculated using the number of 4 and 5 responses on the Likert scale, divided by the total number of responses (24). To assess the agreement with the final opinion on the instrument analyzed, the CVI was calculated using the number of 3 and 4 responses obtained at this stage. For all the analyses, Polit and Beck's (25) criteria for analyzing the CVI were used, which establishes items with a CVI higher than 0.80 as relevant. The instrument's general CVI was also calculated from the sum of all the CVIs calculated separately, divided by the total number of items (24).

Ethical aspects

This study was approved by the Research Ethics Committee of the Nursing School of the Universidade Federal da Bahia under Opinion 2.242.672 and it complied with the ethical precepts of the Declaration of Helsinki, Resolution 466, of December 12, 2012, and Resolution 516, of June 3, 2016, of the National Health Council of Brazil.

Results

The instrument was developed based on a previous qualitative study conducted in clinical practice with pregnant women with SCD entitled "Nursing care for pregnant women with sickle cell disease." The instrument's content was organized in the form of nursing diagnoses, based on Orem's self-care theory, and was consolidated into an initial version with 19 diagnoses and 126 nursing cares, which was submitted for evaluation to the judges. Of the 24 judges who agreed to participate in the survey, 6 did not submit the completed form, even after extending the deadline for submitting it. This resulted in 18 responses to the validation form, of which 7 (38.89 %) were via Google Forms and 11 (61.11 %) via printed material. Nurses (61.11 %), psychologists (11.11 %), social workers (11.11 %), nutritionists (5.56 %), speech therapists (5.56 %), and anthropologists (5.56 %) participated as judges in the study, thus casting a holistic eye on the care of pregnant women with SCD. Considering that pregnant women require multi-professional assistance and comprehensive care, it was decided to include healthcare professionals in the sample who are part of the multi-professional team at a multicenter facility specialized in SCD. To ensure aspects related to the specific nursing language, over 60 % of the sample consisted of nurses.

Most participants were working in teaching, research and extension (61.11 %), and/or in outpatient clinics specializing in providing care to people with SCD (33.33 %), had between 1 and 5 years of professional experience (55.56 %), had experience with

SCD in care (61.11 %), and in teaching and research (61.11 %). The level of training ranged from undergraduate (22.22 %), to specialization (33.33 %), residency (5.56 %), master's (16.67 %), and doctorate (22.22 %). All the judges were living and working in the Northeast region of Brazil at the time of the study. Regarding content validation, the nursing diagnoses and nursing care that comprised the instrument and had a CVI higher than 0.80, as rated by the judges, are described in Table 1.

Table 1. Nursing Care for Pregnant Women with SCD — Items that Scored a CVI Higher than 0.80. Salvador, Bahia, Brazil, 2018 (n = 18)

Nursing Diagnosis	Nursing Care	CVI
Ineffective sexuality pattern, defined by reports of difficulties, limitations, and changes in sexual activities, related to discomfort, fear of pregnancy, incorrect information, and lack of knowledge	Reassure women that sexual behavior changes during pregnancy, from feeling a strong desire for sex to just wanting to be cuddled.	0.83
	Encourage honest communication with their partner regarding their desire or changes in interest.	0.89
	Provide guidance on how to recognize fatigue as an interfering factor, especially in the first three months, and again in the last month of pregnancy.	0.94
	Encourage pregnant women to discuss their emotions with their partners.	0.94
	Inform them that sexual intercourse is possible until labor begins unless there are any contraindications (premature labor, previous early abortion, bleeding, or rupture of the sac).	0.94
	Exploring misinformation, using anatomical charts to show how the baby is protected in the womb.	0.83
	Explore what type of pain is being experienced.	0.94
	Suggest different positions and the use of water-soluble lubricants for sexual intercourse.	0.83
Excessive fluid volume, characterized by peripheral edema, related to venous compression by the pregnant uterus	Explain the cause of edema (increased estrogen levels cause fluid retention).	0.83
	Provide guidance on moderately limiting salt intake (e.g., eliminating processed meats and snacks) and maintaining a minimum water intake of 2 liters per day, if there are no contraindications.	1.0
	Refer patients to a medical appointment if they present high blood pressure, proteinuria, facial edema, sacral edema, depressible edema, or weight gain greater than 1 kilogram per week.	1.0
	Advise patients to avoid reclining backward, sitting for long periods without elevating their feet, or standing for a long time.	0.83
	Advise them to lie on their left side for short periods throughout the day and to take a warm bath daily.	0.89

Nursing Diagnosis	Nursing Care	CVI
Ineffective breathing pattern characterized by dyspnea, related to the pregnancy condition secondary to increased use of respiratory muscle strength	Teach patients breathing exercises, with thoracoabdominal movements, that favor gas exchange.	0.89
	Advise them to maintain optimum hydration.	0.89
	Recommend gentle physical exercise and movements that promote lung expansion.	0.94
	Advise them to keep the bed head elevated by 30° unless contraindicated.	0.89
Sharp pain, characterized by spoken reports of pain, related to the vessel occlusion phenomenon	Sharp pain, characterized by spoken reports of pain, related to the vessel occlusion phenomenon.	0.94
	Provide health guidance to reduce or eliminate the factors that increase the experience of pain.	1.0
	Advise pregnant women on possible methods to be used to reduce pain intensity, such as discussing the use of hot water bottle applications, their effects, indications, and precautions.	1.0
	Provide guidance on distracting activities (e.g., guided imagery, music) and relaxation techniques, such as local massage.	0.94
	Provide guidance on the use of prescribed painkillers for pain relief.	1.0
	Investigate pregnant women's response to pain relief medication.	1.0
	Reduce or eliminate the common side effects of painkillers (sedation, constipation, nausea, vomiting, dry mouth).	0.89
	Assist their families in reacting positively to the pregnant women's experience of pain.	0.89
	Explain all procedures before they start.	0.89
	Provide comfort techniques as requested (walking, music, massage, acupressure, shower or bath, heat application, hypnosis, guided imagery).	1.0
	Evaluate the effectiveness of breathing techniques.	0.89
	If pain or anxiety is not reduced, check the possibility of changing the plan.	0.94
	Assess the level of fatigue.	0.83
	Stimulate ambulation and position changes every 20 to 30 minutes.	0.83
	Approach the women calmly and gently.	0.94
Intolerance to daily activities characterized by discomfort and dyspnea upon physical effort and reports of fatigue and weakness, related to an imbalance between oxygen supply and demand as well as inadequate social support	Monitor and record the pregnant women's response to the activities.	0.89
	Provide sleep advice.	0.83
	Advise them to do the activities at their own pace and only those that are essential.	0.94
	Discuss the possibility of social support for cooperation in daily activities.	0.89

Nursing Diagnosis	Nursing Care	CVI
Impaired social interaction, characterized by altered social interaction behaviors, related to changes in usual social patterns	Provide support to pregnant women to maintain basic social skills and reduce social isolation.	0.89
	Encourage participation in support groups, such as the Bahia Association of People with Sickle Cell Disease (*Associação Baiana de Pessoas com Doença Falciforme*).	0.94
	Assist their families and community members in understanding and offering support.	0.94
	Explore strategies for managing difficult situations in social interaction.	0.83
Unbalanced nutrition: a lower intake than what the body needs, characterized by a lack of interest in food, related to decreased appetite, nausea, and heartburn	Explain the need for an adequate intake of carbohydrates, fats, proteins, vitamins, minerals, and fluids.	0.94
	Refer patients to a nutritionist to establish daily nutritional requirements.	0.94
	Advise patients to eat small, frequent meals (every 3 hours) instead of small, large ones.	1.0
	Restrict the intake of fluids during meals and avoid drinking fluids one hour before and one hour after meals.	0.94
	Provide printed resources summarizing the nutritious diet.	0.83
	Teach them the importance of adequate calorie and fluid intake while breastfeeding, regarding the production of breast milk.	0.94
	Explain the physiological changes and nutritional needs during pregnancy.	0.94
	Discuss the effects of alcohol, caffeine, and artificial sweeteners on fetal development.	0.94
Constipation characterized by changes in intestinal pattern with decreased frequency, related to decreased peristalsis secondary to pregnancy	Investigate the contributing factors.	0.83
	Provide guidance on corrective measures, with a regular timetable for elimination (encouraging bowel movements), and suitable exercises (contracting the abdominal muscles several times a day, sitting down and standing up, keeping the heels on the floor with slightly bent knees).	0.83
	Provide guidance on a balanced diet, with a preference for foods rich in fiber (fresh fruit and vegetables with peel, bran, fruit juices, cooked vegetables, cereals, and whole wheat bread), while considering financial limitations (encourage the use of seasonal fruits and vegetables).	0.94
	Advise them on adequate fluid intake, of at least 2 liters a day; recommend a glass of lukewarm water half an hour before breakfast, which can act as a stimulant for bowel movements.	0.94
	Explain the risks of constipation in pregnancy and the postpartum period (decreased gastric motility, prolonged intestinal transit, increased uterine pressure, distension of the abdominal muscles in the postpartum period, and relaxation of the intestines in the postpartum period).	0.94
	Explain the aggravating factors for the onset of hemorrhoids (straining during bowel movements, constipation, prolonged standing, wearing tight clothes).	0.89
	If the woman has a history of constipation, discuss how to use bolus-forming laxatives to soften stools after childbirth.	0.94
	Advise them to take sitz baths and use cold astringent compresses for hemorrhoids.	0.89

Nursing Diagnosis	Nursing Care	CVI
Body image disorder characterized by reports of perceptions that reflect an altered view of one's own body image, related to developmental changes and the effects of pregnancy	Stimulate social interaction.	0.83
	Encourage women to share their concerns.	0.89
	Discuss the challenges and changes caused by pregnancy and motherhood.	0.94
	Encourage them to share their expectations: Their own and those of their significant others; help them find sources of love and affection.	0.89
	Stimulate spouses to share their concerns and anxieties.	0.89
Risk-prone health behavior, characterized by failure to prevent health problems and a negative mindset towards care	Provide health education simply and clearly, emphasizing the options for improving the health of pregnant women in terms of diet and the importance of water intake.	0.94
	Stimulate pregnant women's confidence in making changes.	0.89
	Set a realistic goal and action plan.	0.94
Impaired sleep pattern, characterized by reports of difficulty sleeping, not feeling fully rested, and a shifts in normal sleep pattern, related to discomfort secondary to pregnancy	Teach pregnant women to place pillows in the lateral decubitus position (one between the legs, one under the abdomen, one under the arm that is above, and one under the head).	0.89
	Provide guidance on how to eliminate environmental distractions and sleep interruptions.	0.89
	Set up a schedule with the pregnant women for daytime activities.	0.89
	Promote a sleep ritual or routine, as it prepares the mind, body, and spirit for rest.	0.89
	Advise them to take a warm bath before bed, eat a small snack before bed (avoid foods with a lot of spice and that produce a lot of waste) and drink warm milk, as it contains tryptophan, a sleep inducer.	0.94
	Recommend the use of herbs that promote sleep (e.g. chamomile).	0.83
	Recommend listening to soft music; back massages; relaxation and breathing exercises.	0.89
Low situational self-esteem, characterized by negative reports of their self-worth, related to this condition and the alterations caused by pregnancy	Help the pregnant women to identify and express positive feelings and self-assessments.	0.83
	Help them to identify distortions that increase negative self-assessments.	0.83
	Investigate and mobilize their current support system.	0.89
	Help the pregnant women to learn new coping skills.	0.94
	Help them to manage specific problems that may be aggravating this diagnosis.	0.89
	Refer them to psychology services if necessary.	0.83

Nursing Diagnosis	Nursing Care	CVI
Impaired teeth, characterized by toothache and cavities, related to ineffective oral hygiene and lack of access to professional care	Provide guidance on the importance of adequate oral hygiene following each meal.	0.89
	Refer to a dental professional.	1.0
	Encourage dental care follow-up.	0.94
	Address and guide self-care practices for the oral health of pregnant women and children.	0.94
	Debunk the fear and the impossibility of receiving dental treatment at this stage.	0.94
Impaired urinary elimination, characterized by dysuria and altered urinary frequency, related to urinary tract infection	Provide guidance on personal hygiene habits.	0.89
	Encourage fluid intake.	1.0
	Teach them the signs and symptoms of urinary infection.	1.0
	Evaluate abnormal laboratory findings, especially cultures and sensitizations, in addition to complete blood counts.	1.0
	Check for abnormal signs and symptoms, including frequency, urgency, burning, abnormal color and odor.	1.0
	Refer them to medical appointments for evaluation.	1.0
Risk of infection related to increased vulnerability due to poor knowledge to avoid exposure to pathogens	Reduce pregnant women's susceptibility to infections.	0.83
	Provide continuous and dynamic health education to women and their partners during prenatal care, focusing on the causes, risks, and forms of transmission.	0.94
	Refer them to a medical appointment in the event of an altered test.	0.94
	Establish a relationship of trust to assure the quality of the counseling process and adherence to treatment and to the service.	1.0
	Provide an environment of privacy for appointments, as well as time and availability for dialogue, ensuring the confidentiality of information.	0.89
	Emphasize adherence to treatment and advise patients to complete treatment even if symptoms or signs have disappeared.	0.89
	Abstain from sexual relations until the treatment is completed and the symptoms disappear.	0.94
	Offer condoms and encourage their use to reduce the risk of HIV transmission and other sexually transmitted diseases.	1.0
Impaired knowledge, characterized by inadequate information reporting, related to information misinterpretation	Clarify to pregnant women that SCD is a genetic and hereditary disease that is not contagious and cannot be prevented by healthy eating practices or prenatal care.	0.83
	Clarify to them what the chances of the child being born with the disease are.	0.89
	Provide guidance to them on how to adopt healthy eating practices and do prenatal care to benefit their health and contribute to the child's growth.	1.0
	Check whether the pregnant woman understood the instructions.	0.89

Nursing Diagnosis	Nursing Care	CVI
Fear characterized by reports of concern, lowered self-assurance, dread, and increased alertness, related to the uncertainties stemming from pregnancy	Create coping strategies together with the pregnant women, their partners and/or family members.	0.83
Lack of adherence to folic acid treatment, characterized by its incorrect use, related to failure to follow the recommended therapy regimen	Determine the pregnant women's understanding of the importance of using vitamin supplements and the risks of maternal and fetal health problems if they fail to adhere to the regimen.	0.94
	Investigate their reasons for not adhering to the therapy regimen.	0.94
	Encourage positive thinking regarding new health-related behaviors.	0.83
	Review medication therapy and vitamin supplementation for pregnancy in SCD.	0.89

Source: Prepared by the authors.

The 9 diagnoses and their respective forms of nursing care (22) that did not score a CVI higher than 0.80 were checked against the literature to exclude or adjust them, depending on the presence or absence of suggestions from the judges. They also analyzed the need to insert new guidelines for the proposed diagnoses, and only the "ineffective respiratory pattern" and "risk of infection" diagnoses did not have new items added to them. Some items were adjusted based on the judges' suggestions (Table 2).

Table 2. Care Suggested by the Judges to be Incorporated into the Instrument. Salvador, Bahia, Brazil, 2018 (n = 18)

Nursing Diagnoses	Care Suggested by the Judges
Ineffective sexuality pattern	Investigate the feelings generated by the pattern of ineffective sexuality, as they may indicate the causal factor.
Excessive fluid intake	Provide guidance on the importance of walking to promote venous return, as well as wearing comfortable clothes and shoes and compression stockings.
	Refer them for assessment by a medical professional if there are any changes in their breathing pattern.
Sharp pain	Explain the trigger factors for pain crises to the women.
	Advise them on the importance of hydration as an essential precaution to avoid pain.
	Investigate self-reported pain intensity using standardized pain scales (e.g., Wrong-Baker Faus scale, visual analogue scale, numerical rating scale).
Intolerance to physical activities	Advise them to reduce the pace and intensity of their physical activities.

Nursing Diagnoses	Care Suggested by the Judges
Impaired social interaction	Identify the person/agent with whom the pregnant women have a close bond and encourage their presence and care for the pregnant women.
	Discuss possibilities for incorporating pleasure and leisure activities into their routine.
	Investigate the cause, such as lower limb ulcers.
Unbalanced nutrition: A lower intake than what the body needs	Advise them to avoid fried, spicy, strong-smelling, fatty, or gas-forming foods, as well as avoiding being on an empty or overloaded stomach.
Constipation	Provide guidance on how to observe their daily bowel rhythm and beware of long periods without bowel movements and signs of discomfort.
Body image disorder	Encourage conversation with other pregnant women and/or participation in pregnancy groups so that they can share similar experiences.
	Encourage the pregnant women to touch and look at their own bodies. Guide them to focus on their body parts.
Impaired sleep pattern	Provide advice on relaxation techniques and massages.
Low situational self-esteem	Create/provide an atmosphere of trust between professionals and pregnant women, by listening to them in a qualified way, without using their own judgments or generalized teachings and statements.
Impaired teeth	Check for gingivitis.
Impaired urinary elimination	Investigate if there is a previous history of urinary infection.
Limited knowledge	Refer them for an appointment with a geneticist, if necessary.
Fear	In case of worsening, refer to the psychology department.
	Identify their fears and anxieties, propose a discussion on each situation presented so that the pregnant women themselves can resolve their issues. Suggest participating in conversation circles and pregnant women's groups.

Source: Prepared by the authors.

In terms of nursing interventions, the judges provided contributions, suggesting emphasis on the following aspects: The social determinants of health should be emphasized to prompt a consistent reflection on who women with SCD are; to consider the existence of triple discrimination (being black, being a woman, having SCD); to encourage the participation of the partner in childcare; to use accessible language, without technical terms; to consider healthy eating, but also the socio-economic conditions of these women; to refer them to the psychology service, in light of the effects of racism and discrimination, and the possibility of the loss process. The result of the final opinion on the instrument: Nursing Care for Pregnant Women with Sickle Cell Disease was evaluated satisfactorily by the judges, based on the evaluation criteria, form of presentation, and total score of the instrument (Table 3).

Table 3. Summary of the Final Evaluation of the Instrument: Nursing Care for Pregnant Women with Sickle Cell Disease, Evaluated by the Judges. Salvador, Bahia, Brazil, 2018 (n = 18)

Criteria	CVI	
Usefulness and relevance	1.0	
Consistency	1.0	
Clarity	0.83	
Objectivity	0.94	
Simplicity	0.83	
Viability	1.0	
Updated	0.94	
Accuracy	0.72	
Instructional sequence of topics	0.83	
Presentation format	% (n=18)	
Printed	16.67 (n=3)	
Electronic	0.0 (n=0)	
Printed and electronic	83.33 (n=15)	
General CVI	0.87	
Total score	Mean 8.72	Median 9.0

Source: Prepared by the authors.

After assigning the total score, the judges issued their final opinion on the instrument as a whole (Table 4).

Tabela 4. Summary of the Judges' Considerations on the Final Evaluation of the Instrument. Salvador, Bahia, Brazil, 2018 (n = 18)

Intelligibility	Review spelling, clarity, and coherence.
	Suitability of the instrument's language for pregnant women.
Rearranging items	Divide the pain diagnosis (sharp pain and labor pain).
	Discussion of sexual practice should be addressed after other topics of a more general nature.
Health determinants	Consider the real possibilities of access, such as food, for instance.
	Consider the health determinants in care.
	Consider the existence of triple discrimination against these women.
Specificity of SCD	Include an assessment of pregnant women for the risk of hemolysis.
	Refer them to the psychology service.

Source: Prepared by the authors.

After the content validation process, the instrument presented 19 diagnoses and 127 forms of nursing care in the final version. In general, the judges presented positive comments on the proposed instrument, stating it addresses the health of pregnant women with SCD, establishing an interface between biological, social, and health education, as well as being a way of directing and promoting important items for maternal and fetal well-being to be addressed by nursing professionals in their health care. Furthermore, they found that the instrument can guide nurses' practice. It is deemed that this instrument is a prototype that can guide the care provided to pregnant women with SCD and, in its use, it can be further improved.

Discussion

The results indicated that there was acceptable agreement between the judges' evaluations, with the general CVI being higher than that of other health instrument validation studies (26, 27). Content validation was important for reaching an agreement among the judges, correcting possible inconsistencies, and providing methodological rigor for the use of technologies such as booklets and protocols (24). The use of the Delphi technique helped to reach a consensus among the judges regarding the instrument, corroborating other studies (23, 28-30) which found similar results when using the same technique.

It is worth highlighting the importance of validating the instruments that will be used in the health field, so that they are reliable and suitable for a given population, with the content validation process being an essential stage in the development and adaptation of various instruments, such as questionnaires and scales (24). In addition to the evaluation of the instrument's items, the considerations registered by the judges emphasized the importance of the social determinants of health in the process of chronic diseases, which should be more closely understood and monitored during the health care of pregnant women with SCD.

The ethnic-racial discussions that have been raised are extremely important, especially considering the origin of SCD in sub-Saharan Africa (6) and the prevalence of cases of the disease and sickle cell trait in the black population (31) in Brazil. This fact implies a stigma that the disease has developed over a period of just over a hundred years since its first case was discovered. Brazil is a country with a high percentile of black population, but pregnant women with SCD still suffer racism in healthcare services. In a study performed in Bahia, a Brazilian state that ranks first in terms of number of people with SCD nationwide, researchers demonstrated the presence of institutional racism during the stay of black women with this condition in healthcare services, with unfair, discourteous, and humiliating treatment provided by the healthcare team (32), which seems to be a naturalized phenomenon, compromising healthcare measures. The authors of the study also found indirect racial discrimination against this group in healthcare units.

Considering women with SCD, the literature indicates they suffer triple discrimination based on race, gender, and social status, and that the discrimination they suffer is reflected in the care they receive in healthcare units, such as prenatal care, which has its quality compromised (33). This can lead to various maternal and fetal complications as a result of iatrogenic and negligent care. Healthcare professionals should deepen their knowledge of the aspects surrounding the reality of these women and offer care to pregnant women with SCD in a conscious and comprehensive way, adapting the language used to their level of education, with economically accessible guidelines and investigating signs of racism in their coping with the disease or emotional and psychological aspects.

Gender, class, and race inequalities (34) lead to difficulties in accessing healthcare services for black women with SCD, as well as having reduced access to education, which is why they are employed in occupations that require fewer qualifications for the job market (32). It is therefore essential that the judges make the necessary adjustments to the language of the educational resources for all women, including those who are not literate, allowing them equal opportunities to build the knowledge they need to implement self-care measures.

The instrument is an assistive technology, but nursing care has a living dimension, and each appointment is special and unique, as it brings the professionals and patients face to face, with numerous possibilities for experiences and exchanges. According to Orem (18), the nurse is the main healthcare professional responsible for care and developing health education activities to help people cope with self-care deficits. In this sense, the aim of nursing care is to improve quality of life through guidance and encouragement for self-care, considering the chronic nature of SCD and its prognosis, which requires changes in lifestyle habits and health management at all stages of life.

The use of this instrument in care practice by the nursing team should be the guiding object of nursing actions, but it is worth considering the importance of the individuality and integrality of care for pregnant women with SCD. These pregnant women have specific characteristics stemming from the disease that require special attention, as highlighted by the judges in the study when they recommended referral to the psychology service as a nursing intervention. This recommendation can be understood by the frequent occurrence of spontaneous abortion in pregnant women with SCD (10, 34) and the increased risk of maternal death due to exacerbated complications during pregnancy and puerperium (4, 6, 35).

Thus, considering the complications caused by the disease, even though it is not a deterrent to pregnancy, the possibility of miscarriage is a sensitive issue for these pregnant women, gen-

erating feelings of anguish, anxiety, and fear over the outcome of the pregnancy. Faced with pregnancy losses caused by miscarriage and stillbirth, the emotional state of these women is altered in the process of miscarriage, and the absence of a qualified team and the presence of institutional racism intensify these feelings in the process of loss, but the support of their partner and family generates the strength to endure the process of loss (10).

Limitations of the study include technical difficulties in filling out the online validation form through the Google Forms platform, as well as the delay of some participants in responding to the form sent, considering that their participation is voluntary and requires time. Another limitation may be the presence of judges from a single region of the country.

Conclusions

The creation and validation of the guiding instrument: Nursing Care for Pregnant Women with Sickle Cell Disease, is intended to enable the management of care for pregnant women with SCD, based on scientific knowledge, to become accessible in the clinical practice of healthcare professionals. Pregnant women with SCD require comprehensive care with a biopsychosocial perspective, which goes beyond the disease, including the particularities of race and class, as well as social and cultural factors, given the specificities that are inherent to women with this disease. The dissemination of information and guidance on SCD among the population and healthcare professionals is particularly necessary in the context of pregnancy to preserve the health of pregnant women and their babies, from conception to puerperium.

Furthering the knowledge on SCD and its nuances during pregnancy, even during professional training in undergraduate nursing and healthcare courses, is a key strategy for ensuring the long-term quality of care for this group of pregnant women. More importantly, the existence of a specific nursing care instrument for pregnant women with SCD is within the limits of nurses' professional practice and should guide pertinent clinical conduct. It is worth noting the existing gap in care for people with SCD, which, despite having protocols defined by the Brazilian Ministry of Health, lacks the availability of instruments in clinical practice.

The instrument's potential stands out, and it can be improved through its use as a resource for guiding nursing practices directed at pregnant women with SCD, both in primary health care and in the hospital network; thus, contributing to the scientific knowledge of nurses for the care of pregnant women with SCD to prevent complications throughout the pregnancy-puerperal cycle.

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