

Development and Validity of a Nursing Intervention and Outcome: Compliance Behavior in Adults with Type 2 Diabetes Mellitus*

* Article derived from the doctoral thesis entitled “Efectividad de una intervención de enfermería para favorecer la adherencia terapéutica en el adulto con diabetes”, presented to the Graduate Program in Nursing, Universidad de Antioquia, 2025.

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Theme: Care processes and practices

Contribution to the nursing discipline: The study contributes to the advancement of the discipline by offering a rigorously developed and validated nursing educational intervention based on expert judgment and the validity of the compliance behavior outcome. This contribution strengthens care processes and practices by providing a standardized, theoretically grounded tool applicable in primary care settings. The proposed intervention promotes clinical decision-making, encourages self-care behaviors, and improves therapeutic adherence—all of which are essential elements for optimizing the health, well-being, and quality of life of people with T2DM. Thus, this study contributes to the nursing body of knowledge and supports the implementation of safe, effective, patient-centered practices.

Abstract

Introduction: Type 2 diabetes mellitus (T2DM) is a non-communicable disease, considered a public health concern due to its impact on global morbidity and mortality. **Objective:** To develop and validate a nursing intervention (Nursing Outcome Classification [NOC] outcome 1601) and outcome compliance behavior in adults with T2DM. **Materials and Methods:** Consensus study by specialists, delimited by the phase of development of the educational intervention and the validity of its content. The Content Validity Index (CVI) was used for data analysis, with a CVI ≥ 0.80 considered acceptable. **Results:** In total, twelve specialists validated the indicators and the nursing intervention. For the adherence behavior (NOC outcome 1601) nursing outcome, thirteen indicators were selected and validated by specialists, and a CVI of 0.91 was obtained. An individualized intervention, consisting of four sessions, was designed to increase knowledge and application of healthy behaviors in patients with T2DM. **Conclusion:** This study exposes the need for nursing approaches that integrate behavioral and educational components to optimize health outcomes that contribute to a more holistic and patient-centered management of T2DM.

Keywords (Source: DeCS)

Diabetes Mellitus, Type 2; validation study; Nursing Outcome Classification; medication adherence; nursing.

4 Desarrollo y validación de una intervención y resultado de enfermería conducta de cumplimiento en adultos con diabetes mellitus tipo 2*

* Artículo derivado de la tesis doctoral titulada "Efectividad de una intervención de enfermería para favorecer la adherencia terapéutica en el adulto con diabetes", presentada al Programa de Posgrado en Enfermería de la Universidad de Antioquia, 2025.

Resumen

Introducción: la diabetes mellitus tipo 2 (DM2) es una enfermedad no transmisible, que es considerada un problema de salud pública debido a su impacto en la morbilidad global. **Objetivo:** desarrollo y validación de una intervención y resultado de enfermería conducta de cumplimiento (1601) (NOC) en adultos con DM2. **Materiales y métodos:** estudio de consenso por especialistas, delimitado por la fase de desarrollo de la intervención educativa y validación del contenido de la misma. Para el análisis de datos se utilizó el índice de validez de contenido (IVC), considerado como aceptable el $IVC \geq 0,80$. **Resultados:** En total, 12 especialistas realizaron la validación de los indicadores y la intervención de enfermería. Para el resultado de enfermería conducta de cumplimiento (1601), 13 indicadores fueron seleccionados y validados por los especialistas; se obtuvo un IVC de 0,91. Se diseñó una intervención para aumentar el conocimiento y la aplicación de conductas saludables en pacientes con DM2, individualizada, compuesta por cuatro sesiones. **Conclusión:** este estudio sugiere la necesidad de enfoques de enfermería que integren componentes conductuales y educativos para optimizar los resultados de salud, contribuyendo a un manejo más holístico y centrado en el paciente con DM2.

Palabras clave (Fuente DeCS)

Diabetes mellitus tipo 2; estudio de validación; clasificación de resultado de enfermería; adherencia al tratamiento; enfermería.

Desenvolvimento e validação de uma intervenção e de um resultado de enfermagem sobre a adesão ao tratamento em adultos com diabetes mellitus tipo 2*

*Artigo derivado da tese de doutorado intitulada “Efectividad de una intervención de enfermería para favorecer la adherencia terapéutica en el adulto con diabetes”, apresentado ao Programa de Pós-Graduação em Enfermagem da Universidad de Antioquia, em 2025.

Resumo

Introdução: O diabetes mellitus tipo 2 (DM2) é uma doença não transmissível, considerada um problema de saúde pública devido ao seu impacto na mortalidade global. **Objetivo:** desenvolver e validar uma intervenção e o resultado de enfermagem “Adesão ao tratamento” (1601), da Classificação dos Resultados de Enfermagem (NOC), em adultos com DM2. **Materiais e métodos:** estudo de consenso por especialistas, delimitado pela fase de desenvolvimento da intervenção educacional e validação de seu conteúdo. Para a análise de dados, foi utilizado o índice de validade de conteúdo (IVC), sendo considerado aceitável \geq IVC de 0,80. **Resultados:** No total, 12 especialistas realizaram a validação dos indicadores e da intervenção de enfermagem. Para o resultado de enfermagem “Adesão ao tratamento” (1601), 13 indicadores foram selecionados e validados pelos especialistas; foi obtido um IVC de 0,91. Foi formulada uma intervenção de enfermagem educativa, individualizada, composta por quatro sessões, com o objetivo de ampliar o conhecimento e a adoção de comportamentos saudáveis em pacientes com DM2. **Conclusão:** Este estudo sugere a necessidade de abordagens de enfermagem que integrem componentes comportamentais e educacionais para otimizar os resultados de saúde, contribuindo para um manejo mais holístico e centrado no paciente com DM2.

Palavras-chave (Fonte DeCS)

Diabetes *mellitus* tipo 2; estudo de validação; classificação dos resultados de enfermagem; adesão ao tratamento; enfermagem.

Introduction

Type 2 diabetes mellitus (T2DM) is a major public health problem worldwide, representing a significant burden of morbidity and mortality (1). According to the International Diabetes Federation (IDF), approximately 588 million adults aged 20-79 were living with diabetes in 2024. This figure is projected to increase to 852 million by 2050, which represents a 45 % increase. In 2024, over 3.4 million people in this age group died from diabetes-related causes. Direct healthcare expenditures from this disease exceeded one trillion U.S. dollars, and this figure is expected to continue rising in the coming years (2).

Due to the impact of this condition, various strategies have been employed to control and manage the disease. Among them, the involvement of an interdisciplinary team is particularly notable (3). Although studies have consistently identified the benefits of implementing educational interventions within the framework of primary healthcare for individuals with T2DM, patient commitment to self-care is crucial for the proper execution of the interventions (4).

From a nursing perspective, several issues in the management and control of T2DM have been identified. Notably, there is a lack of knowledge about the disease, as well as a limited understanding of the necessary actions to improve health. This affects adherence to treatment and can contribute to a decrease in quality of life (5). Therefore, acquiring knowledge about the disease is crucial for making informed decisions that align with one's needs and for following the pharmacological and non-pharmacological recommendations offered by healthcare professionals (4).

The American Diabetes Association (ADA) recently outlined recommendations for the care of patients with T2DM by multidisciplinary teams in primary healthcare in its 2025 Standards of Care for Diabetes. These recommendations are based on clear evidence from scientifically and theoretically thorough studies and the opinions of clinically experienced experts, which will positively impact patient outcomes (6).

Therefore, implementing scientifically supported interventions in nursing is crucial for taking professional action to prevent, treat, and recover from various health conditions. Likewise, using the Nursing Outcomes Classification (NOC) is relevant for assessing patients' conditions after nursing interventions (7).

In the specific case of T2DM, a chronic disease requiring continuous management, the development and validity of educational protocols can significantly impact therapeutic adherence and disease control (3). To properly develop and implement an intervention, it is essential to obtain consensus validity through expert or specialist judgment. This approach involves obtaining an assessment from a

group of experts on a specific object, instrument, educational material, or aspect. It is a fundamental methodology because it is often the only indicator of the content validity of the instrument used to collect data (8).

In this study, the validity of NOC outcome 1601 plays a fundamental role in the intervention because it ensures the selected indicators accurately reflect changes in therapeutic adherence after the educational intervention. This process strengthens the scientific evidence regarding the effectiveness of nursing interventions for managing T2DM. However, there is still a lack of standardized interventions aimed at promoting therapeutic adherence in patients with T2DM in the nursing field. Thus, this study aimed to develop and validate a nursing intervention and NOC outcome (1601) for adults with T2DM.

Materials and Methods

Study Design

The study focused on developing and assessing nursing interventions based on the NOC tag “Compliance Behavior” (1601), which is structured by thirteen indicators. The phases proposed by (9) were followed, with two additional phases.

Phase I. Nursing educational intervention development. The problem to be addressed in the study was understood through two approaches: theoretical and empirical. The theoretical approach involved reviewing the theory of salutogenesis to better understand the factors influencing therapeutic adherence in adults with T2DM. The aim was also to develop skills promoting healthy behavior and increasing knowledge to enhance therapeutic adherence (10). The empirical approach taken included a scoping review of the literature to map and synthesize the available evidence on educational interventions for adults with T2DM in primary healthcare settings. The process was developed based on the methodological stages proposed by Arksey and O’Malley (11) and the JBI’s recommendations, ensuring a systematic and transparent approach to identifying, selecting, and analyzing the studies. As a result, seventeen studies addressing different educational strategies applied in primary care were identified. These studies highlight the positive impact of educational interventions on therapeutic adherence, self-management, and disease knowledge in patients with T2DM within the primary care setting. Additionally, these interventions contribute to strengthening nursing care and health self-management. Further details can be found in the article derived from this review (4).

Phase II. Nursing intervention, outcome content, and indicator validity. The theoretical fidelity assessment was conducted by

creating a matrix, and the intervention's content validity was determined based on the judgment of a group of specialists. Specialists received the assessment information through an online form containing the following sections: 1) informed consent; 2) specialist socio-demographic characteristics; 3) guidelines for validating the content of the intervention; 4) aspects to be validated to assess the relevance, accuracy, feasibility, and acceptability of the intervention, and 5) a matrix with the essential elements of the intervention (active intervention ingredients, components, activities, and actions). The rigor and outcome of each NOC indicator (1601) were verified in two rounds. First, specialists assessed the accepted indicators for the intervention. Then, they assessed them using a Likert-type scale (1 = agree, 2 = partially agree, 3 = disagree). The criteria of coherence, representativeness, relevance, and sufficiency were considered. According to the suggested literature, eight to ten specialists were needed to validate the material by consensus. Specialists had to be nurses from clinical, academic, or research environments who met at least two of the following criteria: master's or doctoral degrees; training in areas related to the study; at least two years of practical experience; community teaching experience; demonstrated mastery of the NOC; scientific publications on the study's topics (12).

Data Analysis

To assess content validity, we used the Content Validity Index (CVI), which was proposed by Lawshe in 1975 (13). For this study, we considered a CVI of at least 0.80 to be acceptable. Data were collected using the SurveyMonkey platform in standardized formats and synthesized using Microsoft Excel. The database was stored in Mendeley Data.

Ethical Criteria

The study adhered to the ethical principles of research established by the Council for International Organizations of Medical Sciences and the Declaration of Helsinki. The study also received approval from the ethics committee of the participating institutions (2007/038-17).

Results

Phase I. Intervention development. the salutogenic theoretical approach (14), as described by (15), was used in constructing the intervention. This approach promotes identifying and using factors that improve or maintain health. This theory enables patients to actively participate by identifying and utilizing their psychosocial capacities and resources to maintain their health. The theory also explores the factors that link cognitive, behavioral, and motivational processes, known as the sense of coherence (SC). This SC, in reciprocal interaction with general resilience resources (GRR), helps individuals maintain their health.

From the perspective of the SC, the three dimensions are understood as follows: the dimension of meaning refers to the extent to which a person feels that life has emotional significance. It is about viewing the problems and demands as worthwhile investments of energy and challenges rather than burdens. This aspect constitutes SC's motivational component (16).

The comprehensibility dimension refers to the extent to which a person perceives the stimuli of their internal and external environments as meaningful, orderly, consistent, and clear. Those who score high in comprehensibility expect future stimuli to be predictable, organized, and explicit. This is the cognitive facet of SC. Comprehensibility also implies the belief that one understands challenges and life events (16).

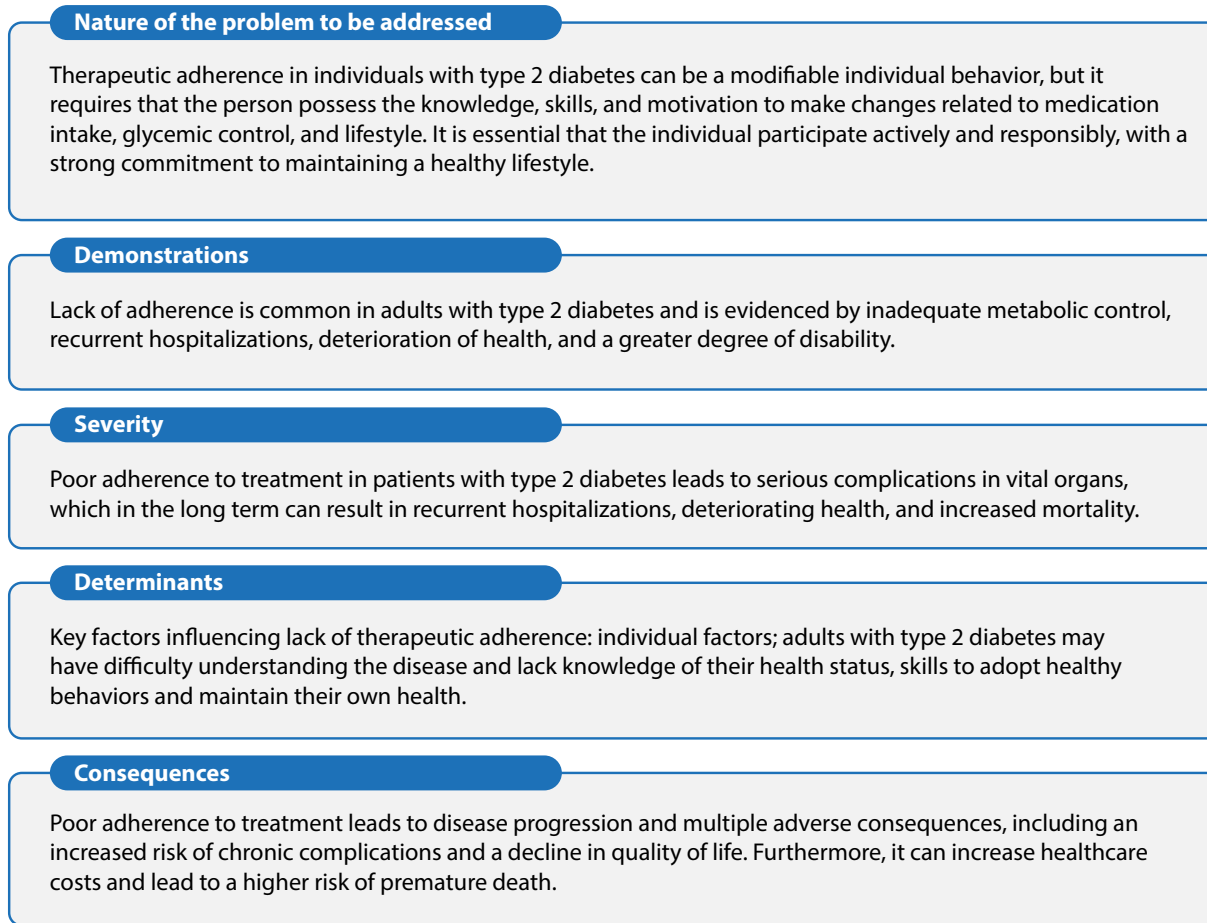
The manageability dimension refers to the extent to which a person believes they have the necessary resources to meet the demands of the situations they encounter. These resources can be under the person's direct control or legitimately controlled by others. This is the instrumental or behavioral aspect of SC, in which 'manageability' implies having the resources to act and perceiving situations as comfortable and under control (16). These dimensions converge in the concept of GRR: All the resources that help a person or group prevent or cope with psychosocial stressors.

From this perspective, the theory is based on an educational nursing intervention rooted in salutogenesis, in which nurses focus on identifying and resolving problems and locating support resources that help patients improve their health and overcome life's challenges (17). Considering the dynamic interaction between the individual, the environment, and the SC as a crucial factor in maintaining or regaining health, the theory assesses individual resources and capacities for promoting health. This allows for the recognition of therapeutic adherence or compliance in nursing as the conscious use of all resources that support positive health and well-being changes. Furthermore, an empirical approach mediated by a scoping review that synthesized evidence from studies with educational interventions for adults with T2DM in primary healthcare concluded that these interventions can positively impact adherence, self-care, and knowledge of the condition in patients with T2DM. The relevance of nursing professionals in the development and implementation of educational interventions within multidisciplinary teams was identified as crucial for achieving significant results (4). This ultimately led to a clearer understanding of the nature, manifestations, level of severity, causal factors, and consequences of the problem (Figure 1).

Once the active ingredients, method of administration, and dose of the intervention were defined, the characteristics in Table 1 were selected. The intervention was configured individually and face-to-face, using standardized educational material (a booklet)

and performing commitment and learning activities in each session. The study was adapted to the participants' schedules, and their appointments were mediated by reminders through telephone calls.

Figure 1. Conceptualization of the Health Problem Faced by Adults with Type 2 Diabetes Due to Lack of Therapeutic Adherence from a Salutogenic Perspective



Source: Prepared by the authors.

Table 1. Specific Characteristics of the Intervention

Characteristics	Description
Objective	To increase knowledge and application of healthy behaviors in patients with T2DM
Dose	4 sessions Once a week for one month Post-intervention nursing check-ups one month after completion
Duration	50 minutes
Delivery method	Individual In-person Delivery of educational materials
Ambient	Outpatient consultation at a top-tier health institution
Receiver	Adults diagnosed with T2DM who meet the study's inclusion criteria
Supplier	Nursing professional with training and experience in T2DM management

Source: Prepared by the authors.

The information used by specialists in the validity process to determine the relationship between the active principles, components, activities, and actions of the intervention is detailed in Table 2.

Phase II. Nursing intervention, outcome content, and indicator validity. To ensure the intervention content validity, the recommendations of (9) and the NOC 1601 were followed. A total of 12 specialists were included in the study, the majority of whom were female (75 %) with a mean age of 43 years. Regarding graduate studies, 91.6 % had obtained a master's degree and one held a doctoral degree. The mean years of experience in their field was 17.4, and the mean years of teaching experience in a community setting and of experience mastering the NOC was 8.9. All had published scientific papers on the topic.

Table 2. Fidelity Matrix of the “Diabetes Education: A Way to Promote Health, Well-Being and Quality of Life” Intervention

Objective	Active Component/ Ingredient	Activities	Actions
Motivate the participant to become interested in learning.	Motivational: Willingness and commitment to participate in maintaining one's own health. Meaningfulness.	Increase opportunities to adopt healthy behaviors.	Encourage participants to express their internal reference point for what they consider good or bad. Ask questions that lead participants to initiate change or continue maintaining their health. Help them find reasons for self-care.
Improve understanding of the current health situation.	Cognitive-comprehensibility: Understanding of the current health situation.	Educate the adult with T2DM about the course of the disease, complications, and warning signs and symptoms.	Describe the key concepts for understanding the disease. What is T2DM? Inform about the risk factors for developing T2DM. Identify the signs and symptoms of T2DM. Learn how to interpret blood glucose levels. Provide information about the complications of T2DM.
Promote skills for implementing specific actions related to adherence to pharmacological and non-pharmacological treatment.	Behavioral: Manageability, development of skills to adopt healthy behaviors.	Educate participants regarding the importance of adhering to pharmacological treatment managing the disease and the precautions that must be taken when using them.	Provide information about the importance and benefits of good adherence. Provide information about strategies for adhering to treatment. Understand the use of oral medications. Learn about the use of insulin. Provide information about the use of blood glucose monitoring.

Objective	Active Component/ Ingredient	Activities	Actions
Promote skills for implementing specific actions related to adherence to pharmacological and non-pharmacological treatment.	Behavioral: Manageability, development of skills to adopt healthy behaviors.	Actively participate in good adherence to non-pharmacological treatment to maintain good health.	<p>Learn about healthy eating.</p> <p>Learn about balanced portion sizes in a healthy diet.</p> <p>Learn about foods patients should avoid.</p> <p>Learn about the benefits and appropriate level of physical activity.</p> <p>Learn about the impact of stress on health and its triggers.</p> <p>Learn about stress management strategies.</p> <p>Learn about the effects of rest and sleep on health.</p>

Source: Prepared by the authors.

The NOC outcome 1601 and its thirteen indicators were validated by specialists and are described in Table 3.

Table 3. Selected Indicators of NOC Outcome (1601)

NOC tags (1601)
(160004) Accept diagnosis.
(160114) Seek reliable information about diagnosis.
(160115) Seek reliable information about treatment.
(160002) Discuss prescribed treatment regimen with a healthcare provider.
(160003) Follow the treatment regimen as prescribed.
(160005) Keep the appointment with a healthcare provider.
(160006) Modify the guidance guidelines as determined by a healthcare provider.
(160111) Report any changes in symptoms to a healthcare provider.
(160112) Monitor treatment response.
(160113) Monitor the therapeutic effects of the medication.
(160007) Perform self-monitoring when instructed.
(160008) Perform activities of daily living as prescribed.
(160009) Seek external help to implement healthy behavior.

Source: Prepared by the authors.

First, specialists reviewed the thirteen NOC tag 1601 indicators. As a result, all of them were approved and none were excluded. In the second part, specialists reviewed the conceptual and operational definitions, as well as the magnitude of each indicator. During this phase, they provided feedback on indicators 160115—Seek reliable information about treatment, and 160002—Discuss prescribed treatment regimen with a healthcare provider. These observations were considered and analyzed during the intervention, resulting in confirmation of all thirteen NOC outcome tag indicators. After completing the NOC tag and indicator validity process, specialists gave positive feedback on NOC outcome indicator 1601.

Intervention Validity

Following the reference framework (9), the intervention was developed and validated by twelve specialists, achieving a CVI of 0.80 or higher. One professional emphasized the importance of clearly defining patient autonomy to allow for a more in-depth understanding of the therapeutic regimen and the patients' right to express their opinion on professionals' recommendations. She also emphasized the importance of a multidisciplinary team for providing appropriate support. Based on these recommendations, the necessary adjustments were made, and the protocol was submitted for a second review. This review did not generate any additional recommendations, resulting in a CVI of 0.91.

Discussion

This study aimed to develop and validate a nursing intervention and its corresponding NOC 1601 outcome in adults with T2DM. Through rigorous expert assessment, the proposed intervention and NOC indicators were shown to meet the nursing discipline's established theoretical and scientific standards. Implementing these validated interventions can significantly improve disease management and patients' quality of life.

Studies agree that compliance behavior is essential for therapeutic adherence in patients with T2DM. A recent systematic review showed that interventions focused on behavioral changes were significantly more effective than those that were not. These findings underscore the importance of structured approaches, such as action planning and follow-up training, in interventions aimed at improving medication adherence (18).

The indicators that achieved 100 % approval are 160112—Monitor treatment response— and 160113—Monitor the therapeutic effects of the medication. Although several studies have demonstrated the effectiveness of pharmacological treatment for patients with T2DM, this effectiveness depends on each individual's adherence to the therapeutic regimen. Adherence depends

on each patient's ability to adapt to the treatment and fully implement other psychosocial components. Therefore, individualized interventions improve the effectiveness of pharmacological treatment and strengthen adherence by addressing patients' challenges. These interventions promote greater adherence and ultimately optimize health outcomes in patients with T2DM (19).

Similarly, indicators 160004—Acceptance of diagnosis—and 160115—Seeks reliable information about treatment—received unanimous approval from specialists. Recent research indicates that patients who quickly accept their diagnosis tend to take ownership of their condition and consequently seek information about their illness. This proactive behavior is associated with greater adherence to treatment because it promotes informed and responsible decision-making regarding self-care (20).

The behavior of adherence validated in this study is relevant due to its potential causal relationship with quality of life and therapeutic adherence. According to the literature, poor treatment adherence negatively impacts the quality of life of people with T2DM, creating a detrimental cycle in which poor adherence worsens health conditions and reduces perceived well-being. In this regard, intervention and NOC outcome 1601 validity provides evidence of the potential of nursing educational interventions to improve therapeutic adherence and the quality of life of patients with T2DM (21).

On the other hand, the results of this study align with previous findings that emphasize the impact of nurse-led educational interventions on improving therapeutic adherence and self-care among individuals with T2DM. A recently published meta-analysis of randomized controlled trials demonstrated that, in the medium and long term, educational interventions led by nurses effectively improve glycemic control, self-efficacy, self-management behaviors, other clinical outcomes, and overall patient satisfaction. These findings reinforce the idea that integrating nurse-led care models into T2DM management guidelines is essential for optimizing care and health outcomes (22).

This study has some limitations that should be considered when interpreting the results. First, the validity process relied exclusively on expert judgment. While this is a widely used strategy for establishing content validity, it does not allow for the assessment of the intervention's empirical effectiveness or the construct validity of a NOC outcome in a real-world population. However, since the study focused on the theoretical development and validity phase, the effects of the intervention on therapeutic adherence in patients with T2DM must be confirmed through future experimental or quasi-experimental research. Additionally, since the study was conducted in a specific primary care setting, the findings may be limited in their applicability to other healthcare settings or populations. However, the study involved nursing professionals with extensive experience in areas such as academic and research support and expertise in the use of the NOC.

Conclusion

In conclusion, the study developed and validated a nursing intervention and outcome (NOC 1601) for adults with T2DM. Specialists' validation of the indicators highlights the importance of the intervention for treatment adherence. These findings underscore the necessity of nursing approaches that integrate behavioral and educational components to optimize health outcomes for patients with T2DM. The validated intervention provides nursing professionals with an effective tool for managing this disease in a more holistic and patient-centered manner.

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