Original Article

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DEVELOPMENT AND VALIDATION OF AN EDUCATIONAL BOOKLET ON INSULIN THERAPY FOR ADULTS AND OLDER ADULTS IN THE HOME SETTING

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ABSTRACT

Objective: to develop and validate an educational booklet on home insulin administration based on the Health Belief Model (HBM).
Method: a methodological study conducted between December 2022 and February 2024 in Minas Gerais, Brazil, in four stages: an integrative review of knowledge among individuals with diabetes and their caregivers regarding insulin use; development of the material structured around the HBM domains (susceptibility, severity, benefits, barriers, cues to action, and self-efficacy); content and appearance validation by 14 specialists; and appearance validation with 32 Primary Health Care users. The Content Validity Index (CVI), Appearance Validity Index (AVI), and Binomial Test (agreement ≥85%) were used to assess the objective, structure/presentation, relevance, organization, writing style, appearance, and motivation indicators.
Results: the booklet *"Aplicação de insulina por pessoas com diabetes mellitus e seus cuidadores no ambiente domiciliar"* (24 pages) covered insulin types, preparation, administration, rotation, storage, disposal, and complications. The bibliographic stage identified technical and self-care gaps that informed the content development. In the specialists' validation, the total CVI was 1.00 and the AVI was .95 (p <.001). Qualitative suggestions included design adjustments, terminology revisions, and more detailed guidance on the mixing and rotation technique. After refinement, validation with the target population yielded an AVI of 1.00 (p <.001).
Conclusion: the booklet, grounded in the HBM, provides evidence of validity and establishes itself as a robust technology for Primary Health Care. The study demonstrates that translating theoretical frameworks into educational tools enhances self-management by addressing barriers, benefits, and self-efficacy. The tool strengthens autonomy and safety in home-based insulin therapy.

DESCRIPTORS: Educational technology. Diabetes mellitus. Self-care. Insulin. Primary health care. Nursing.

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CONSTRUÇÃO E VALIDAÇÃO DE CARTILHA EDUCATIVA SOBRE INSULINOTERAPIA PARA ADULTOS E IDOSOS NO AMBIENTE DOMICILIAR

RESUMO

Objetivo: elaborar e validar uma cartilha educativa sobre aplicação de insulina em ambiente domiciliar fundamentado no Modelo de Crenças em Saúde (MCS).
Método: estudo metodológico realizado entre dezembro/2022 e fevereiro/2024 em Minas Gerais, Brasil, em quatro etapas: revisão integrativa sobre o conhecimento de diabéticos e cuidadores sobre o uso da insulina; construção do material estruturado nos domínios do MCS (susceptibilidade, gravidade, benefícios, barreiras, sinais para ação e autoeficácia); validade de conteúdo e aparência por 14 especialistas; e validação de aparência com 32 usuários da Atenção Primária à Saúde. Utilizaram-se Índice de Validação de Conteúdo (IVC), de Aparência (IVA) e Teste Binomial (concordância ≥85%), avaliando-se os indicadores objetivos, estrutura/ apresentação, relevância, organização, estilo de escrita, aparência e motivação.
Resultados: a cartilha *"*Aplicação de insulina por pessoas com diabetes mellitus e seus cuidadores no ambiente domiciliar*"* (24 páginas) abordou tipos de insulina, preparo, administração, rodízio, armazenamento, descarte e complicações. Na etapa bibliográfica, identificaram-se lacunas técnicas e de autocuidado que direcionaram o conteúdo. Na validação por especialistas, o IVC total foi 1,00 e o IVA 0,95 (p<0,001). Sugestões qualitativas incluíram ajustes de *design,* terminologia e detalhamento da técnica de homogeneização e rodízio. Após refinamento, a validação com o público-alvo alcançou IVA 1,00 (p<0,001).
Conclusão: a cartilha, fundamentada no MCS, apresenta evidências de validade, consolidando-se como tecnologia robusta para a Atenção Primária à Saúde. O estudo demonstra que transpor referenciais teóricos para ferramentas tecnológicas qualifica a autogestão ao intervir em barreiras, benefícios e autoeficácia. Assim, a ferramenta fortalece a autonomia e a segurança na insulinoterapia domiciliar.

DESCRITORES: Tecnologia educacional. Diabetes mellitus. Autocuidado. Insulina. Atenção primária à saúde. Enfermagem.

CONSTRUCCIÓN Y VALIDACIÓN DE UNA CARTILLA EDUCATIVA SOBRE INSULINOTERAPIA PARA ADULTOS Y ADULTOS MAYORES EN EL ENTORNO DOMICILIARIO

RESUMEN

Objetivo: elaborar y validar una cartilla educativa sobre la aplicación de insulina en el entorno domiciliario fundamentada en el Modelo de Creencias en Salud (MCS).
Método: estudio metodológico realizado entre diciembre/2022 y febrero/2024 en Minas Gerais, Brasil, en cuatro etapas: revisión integradora sobre el conocimiento de personas con diabetes y cuidadores acerca del uso de la insulina; construcción del material estructurado en los dominios del MCS (susceptibilidad, gravedad, beneficios, barreras, señales para la acción y autoeficacia); validez de contenido y apariencia por 14 especialistas; y validación de apariencia con 32 usuarios de la Atención Primaria de Salud. Se utilizaron el Índice de Validación de Contenido (IVC), de Apariencia (IVA) y la Prueba Binomial (concordancia ≥85%), evaluándose los indicadores objetivos, estructura/presentación, relevancia, organización, estilo de escritura, apariencia y motivación.
Resultados: la cartilla "*Aplicação de insulina por pessoas com diabetes mellitus e seus cuidadores no ambiente domiciliar*" (24 páginas) abordó tipos de insulina, preparación, administración, rotación, almacenamiento, eliminación y complicaciones. En la etapa bibliográfica, se identificaron lagunas técnicas y de autocuidado que orientaron el contenido. En la validación por especialistas, el IVC total fue 1,00 y el IVA 0,95 (*p*<0,001). Las sugerencias cualitativas incluyeron ajustes de diseño, terminología y detalle de la técnica de homogeneización y rotación. Después del refinamiento, la validación con el público objetivo alcanzó un IVA de 1,00 (*p*<0,001).
Conclusión: la cartilla, fundamentada en el MCS, presenta evidencias de validez, consolidándose como una tecnología robusta para la Atención Primaria de Salud. El estudio demuestra que trasladar referentes teóricos a herramientas tecnológicas cualifica la autogestión al intervenir en barreras, beneficios y autoeficacia. Así, la herramienta fortalece la autonomía y la seguridad en la insulinoterapia domiciliaria.

DESCRIPTORES: Tecnología educativa. Diabetes mellitus. Autocuidado. Insulina. Atención primaria de salud. Enfermería.

INTRODUCTION

The management of pharmacological treatment for Diabetes Mellitus (DM), particularly insulin use, requires ongoing coordination between health services and patients' daily lives. In this context, primary health care (PHC) stands out as the strategic point of the Sistema Único de Saúde (Brazilian National Health System – SUS) for integrating clinical management with educational and preventive practices. However, the high demand for care, limited resources, and fragile professional-user relationships hinder educational activities, particularly in nursing, compromising individualized care, communication, and engagement in self-care and glycemic control[1–2].

Insulin therapy regimens are complex and associated with poor adherence and inadequate glycemic control[3–4], with systematic reviews indicating adherence rates in just over half of individuals with DM (52.6–56.7%)[3–4]. Barriers to adequate insulin use include difficulties in accessing health services, communication failures among healthcare providers, users, and their caregivers, insufficient understanding of the disease and treatment, and misconceptions about administration[1,4–7], as well as religious and cultural beliefs, caregiver dependence, lack of social support, and fear of adverse effects, injections, stigma, and therapeutic failure, particularly in low- and middle-income countries, which are factors that must be considered in care planning[8].

Insulin is classified as a high-alert medication (HAM) and, when administered incorrectly, can lead to serious outcomes, including glycemic dysregulation and life-threatening hypoglycemia[2,9]. Evidence indicates that home administration errors, including improper technique, incorrect storage and disposal, needle reuse, and unfamiliarity with injection timing, are associated with local complications (pain, inflammation, bruising) and recurrent hypoglycemic episodes, as well as glycemic variability resulting from injection into lipohypertrophic areas[10–11]. National studies report unsatisfactory home administration performance, particularly among older adults, individuals with comorbidities, and users of human insulin, reinforcing that insufficient knowledge increases the risk of errors and adverse events (AE)[1,11].

To address these barriers, educational technologies have been developed to support individuals with DM and their caregivers in the safe use of insulin, contributing to improved glycemic control, reduced risk of hypoglycemia, and better quality of life[2,12–13]. The development of such technologies promotes the synthesis, standardization, and dissemination of health guidance, while also fostering knowledge construction and adherence to self-care practices[14]. Robust evidence demonstrates that periodic educational training benefits individuals with DM using insulin at home by enhancing learning, therapeutic adherence, medication safety, and self-management, particularly when culturally adapted and facilitated by qualified healthcare providers[8]. In line with this, the American Diabetes Association (ADA) and the Sociedade Brasileira de Diabetes (Brazilian Diabetes Society – SBD) guidelines recommend systematic and ongoing education on the correct insulin administration technique for individuals with DM and their caregivers, with the aim of increasing safety, treatment efficacy, and glycemic control[15–16].

Primary health care professionals can employ methodological strategies as care management tools to strengthen motivation, enhance therapeutic engagement, and promote behavioral changes that support self-care among individuals with DM[2]. The success of self-care depends on the active participation of patients, family members, and the community, with family support being associated with greater access to information, health education, and favorable resources[17]. Considering that insulin use involves physical, psychological, social, and economic dimensions, its management goes beyond technical aspects, requiring a broader understanding of these factors when planning educational interventions[11].

Diabetes education promotes self-management autonomy by fostering knowledge and skill development aimed at behavioral change, with attitudes recognized as central determinants of this process[15,18]. In this context, adopting robust theoretical frameworks can enhance the use of educational technologies by accounting for the uniqueness and complexity of care, thereby contributing to the reduction of complications and healthcare costs[18]. The Health Belief Model (HBM) underpins this approach by guiding the development of educational materials capable of addressing the subjective challenges of home care, drawing on the constructs of susceptibility, severity, benefits, barriers, cues to action, and self-efficacy[19].

The HBM conceptualizes adherence to self-care in DM as a process influenced by individual risk perception, in which the recognition of vulnerability and disease severity, the assessment of therapeutic benefits, and the overcoming of barriers to insulin use guide the adoption of preventive and self-management behaviors[20]. Evidence supports the practical applicability of the HBM in promoting self-care among individuals with DM by enabling a comprehensive understanding of the multiple factors underlying health behavior[21–22]. Although Brazilian methodological studies have addressed this subject, a gap persists regarding the development of validated educational booklets grounded in the HBM and aimed at the safe use of insulin at home by family caregivers. Existing technologies focus primarily on materials targeted at healthcare providers or individuals with DM themselves, such as serial albums[23], registration tools linking diet and insulin use[12], educational media[24], and digital guides oriented by health literacy, without specifically addressing the family caregiver in this context[25].

The premise is that educational technologies grounded in theoretical models of behavior change, such as the HBM, are more comprehensible and relevant to the target population because they account for the psychosocial factors associated with adherence to insulin therapy. The absence of such theoretical frameworks in educational material development accordingly justifies the creation and validation of a booklet aimed at family caregivers, with the potential to promote greater safety and engagement among caregivers in home insulin administration. The study therefore aimed to develop and validate an educational booklet on home insulin administration based on the HBM.

METHOD

Study design, period, and setting

This is a methodological study conducted between December 2022 and February 2024 that describes the development and analysis of content and appearance validity evidence of an educational technology. The process involved four stages: 1) bibliographic review through an integrative review on the knowledge of individuals with DM and their family members/caregivers regarding home insulin administration; 2) development of the educational technology based on the HBM[19] (perceived susceptibility, severity, benefits, barriers, cues to action, and self-efficacy); 3) electronic content and appearance validation by a specialist committee; and 4) appearance validation by the target population (individuals with DM using insulin and caregivers/family members) at a PHC unit located in the municipality of Dores de Campos, Minas Gerais (MG), Brazil. This study followed the Revised Standards for Quality Improvement Reporting Excellence (SQUIRE 2.0) guidelines[26].

The study was conducted in a municipality in the Campos das Vertentes region (MG), with an estimated population of 10,313 inhabitants, a Human Development Index of 0.686, and a predominantly urban area. The local health network linked to the SUS comprises seven low- and medium-complexity services, including three PHC units, with high-complexity care provided through inter-municipal consortia.

Theoretical background

The development of the educational booklet was guided by the HBM[19,27], a social psychology framework that explains the adoption of health behaviors based on individual risk perception and motivational factors. The model encompasses four core dimensions, perceived susceptibility (perception of the risk of illness), perceived severity (assessment of the consequences of the disease), perceived benefits (expectation of gains from adopting the behavior), and perceived barriers (difficulties that may impede action), as well as two motivational stimuli: cues to action, which trigger decision-making, and self-efficacy, related to the individual's confidence in their ability to perform the recommended behavior. These constructs guided the selection, organization, and approach of the booklet's content, intending to support informed decision-making and the adoption of safe behaviors in insulin use within the home setting.

Bibliographic review

The objective of the booklet, the target population, and the learning needs were first defined. An integrative review was conducted exclusively to support the conceptual phase of the present study, as this approach allows the identification of scientific evidence, knowledge gaps, and educational practices that can inform the selection of current, relevant, and consistent information on the subject. It was conducted by two independent researchers across the MEDLINE/PubMed, SCOPUS, and LILACS (via the Virtual Health Library) databases and the SciELO library. The guiding question was: "What information do individuals with diabetes mellitus and their family members/caregivers need to know for the correct and safe administration of insulin at home?" The following descriptors were used: "Insulin therapy," "Insulin," "Injection device," "Diabetes Mellitus," "Educational technology," and "Nursing," integrated by the AND or OR connectors[1,5–7,28]. The search was conducted in January 2023, restricted to the years 2020–2023. This period was delimited because a review synthesizing the scientific literature on self-administration of insulin in adults with DM had already been published and was included in the present study[1]. The updated SBD and ADA guidelines were also consulted[15,16].

The information identified in the integrative review was analyzed interpretively and categorized in light of the HBM dimensions and stimuli, thereby informing the definition of educational content and the conceptual structure of the booklet. This process enabled the identification of content related to the perceived susceptibility and severity of DM and its complications, the benefits associated with safe and adequate insulin therapy, and the perceived barriers to correct home insulin administration. Cues to action were identified in studies that pointed to educational strategies, stimuli, alerts, practical guidance, or recommendations capable of triggering or reinforcing safe behaviors related to insulin use. Self-efficacy was addressed based on findings that highlighted the need to strengthen the confidence of individuals with DM and their caregivers to correctly perform the preparation, administration, and glycemic monitoring of insulin in the home setting.

Development of the educational booklet

In the second stage, illustrations and content derived from the integrative review were developed. Brief texts were used, written in clear, objective, and accessible language for the target population, in accordance with the recommendations of the Centers for Medicare and Medicaid Services[29].

The illustrations were selected from the public domain internet, and the Canva platform was used in the design of the educational booklet. The first version was then produced and evaluated by the authors, who made adjustments to the content and illustrations, resulting in a second version.

The HBM[19,27] guided the conceptual structure of the educational booklet, ensuring coherence between the adopted theoretical framework and the proposed educational messages. The four

dimensions of the model informed the definition of thematic axes, the organization of content, and the development of illustrations, with the aim of promoting adherence to safe behaviors in insulin use. The operationalization of the HBM was integrated with the pedagogical grounding of the booklet, anchored in principles of health education; content derived from the integrative review was rendered as clear, objective, and illustrated educational messages directed at individuals with DM and their family members/caregivers, with the goal of promoting understanding, autonomy, and informed decision-making in the home care context. Cues to action were incorporated through educational prompts, step-by-step guidance, visual alerts, direct language, and the educational character "Nurse Lina," serving as a stimulus for the adoption and maintenance of safe behaviors. Self-efficacy was addressed through the sequential presentation of insulin preparation and administration steps, the use of explanatory illustrations, practical examples, and encouraging messages, with the aim of strengthening the reader's confidence in self-care and shared care in the home setting.

Validation of the educational booklet by a specialist committee

In this stage, content and appearance validation of the educational booklet was conducted through consultation with a specialist committee in the field. Specialists who met at least two of the following criteria proposed by Jasper[30] were included: expertise in DM and insulin therapy; knowledge and skills acquired through a minimum of one year of professional experience (clinical, teaching, or research); and experience in the development of educational health technologies. Professionals who did not complete the validation instruments within the data collection period or were unable to participate fully in the study were excluded from the sample. Specialists were then selected from a network of contacts established through the Plataforma Lattes of the Conselho Nacional de Desenvolvimento Científico e Tecnológico (National Council for Scientific and Technological Development – CNPq) portal, using the terms "diabetes mellitus," "insulin," and "health technology." Snowball sampling was used to obtain referrals to other eligible professionals.

Through email, 29 specialists received an invitation letter to participate in this stage. Of these, 18 agreed to participate and were then sent the consent form, the booklet in Portable Document Format (PDF), a questionnaire for professional characterization (initials, sex, age, time since graduation, academic degree, occupation, work setting, and clinical and teaching experience), and the booklet analysis instruments: the Instrumento de Validação de Conteúdo Educativo em Saúde (IVCES)[31] and the Instrumento de Validação de Aparência de Tecnologias Educacionais em Saúde (IVATES)[32], both developed and validated in Brazil. The IVCES[31] is an instrument for evaluating the content of health educational materials, comprising 18 items distributed across the domains of objectives (five), structure/presentation (ten), and relevance (three). It demonstrates good internal consistency (.877) across its domains. The items assess aspects such as clarity and relevance of the objectives, organization and presentation of content, language appropriateness for the target population, and relevance of the information for health promotion. Responses are structured on a three-point Likert scale: disagree, partially agree, and fully agree. The IVATES[32] assesses the appearance and communicational quality of educational materials, comprising 12 items organized in the domains of objectives, organization, writing style, appearance, and motivation. The items address aspects related to textual clarity, logical sequencing of information, visual attractiveness, adequacy of illustrations, and the motivational potential of the educational material. Responses are presented on a five-point Likert scale: strongly disagree, disagree, partially disagree, agree, and strongly agree. It was developed for use with populations with low literacy and demonstrated content validity (CVI = .93) and convergent validity, as well as a strong correlation with the other instrument (*r* > .3, *p* < .05). Both instruments were administered in their full versions, as proposed in the original validation studies, without adaptations.

At the end of the quantitative evaluation, the specialists also provided qualitative feedback for improving the educational booklet. After a period of 30 days, 14 specialists returned the completed instruments, yielding a satisfactory sample size in accordance with literature recommendations[33]. The specialists' suggestions were analyzed to produce the pre-final version of the booklet with the appropriate adjustments.

Target population validation

Following the adjustments suggested by the specialists, the appearance validation stage with the target population was conducted. Twenty individuals with DM using insulin and 12 family members/caregivers recruited by convenience at a PHC unit in the municipality of Dores de Campos, Minas Gerais, Brazil, participated in this stage. A minimum sample of 30 participants was established, in accordance with the recommendation of a previous study[34]. The inclusion criteria for individuals with DM were: age over 18 years, ability to read and write in Brazilian Portuguese, insulin use for at least two months, and preserved visual, auditory, and cognitive capacity; for family members/caregivers: age over 18 years, ability to read and write in Brazilian Portuguese, at least two months of experience administering insulin to individuals with DM as part of their routine, and preserved visual, auditory, and cognitive capacity. Participants (individuals with DM and family members/caregivers) who were unable to fully evaluate the educational booklet, experienced difficulties that compromised their understanding of the material, or did not complete the evaluation instruments were excluded from the study.

With the assistance of the health team at the PHC unit, the principal researcher accessed the medical records of individuals with DM using insulin and compiled a list of potential participants with contact information. The researcher then made telephone calls to invite the participants. Those who agreed to participate had a home visit scheduled for data collection. On the selected day, after explaining the study objective and obtaining the signed consent form, an interview was conducted to collect sociodemographic and clinical characteristics from the participants (sex, age, marital status, education, family arrangement, time since diagnosis, and type of insulin prescribed) and/or from family members/caregivers (sex, age, marital status, education, family relationship, family arrangement, and tasks performed involving insulin use). The educational booklet was then provided in printed form, with participants instructed to read the material and complete the IVATES instrument[32] at the end.

Analysis of results and statistics

Sociodemographic and clinical data were analyzed using descriptive statistics. The Shapiro-Wilk test was used to assess the normality of variables. For the analysis of IVCES responses[31], the Content Validity Index (CVI) was calculated based on two mathematical equations: the I-CVI to assess agreement for each evaluated item (obtained by dividing the number of specialists who partially or fully agreed with the item by the total number of specialists); and the total CVI, obtained by calculating the mean of all I-CVI values. Disagreements among specialists were noted when responses indicated "disagree"; such items were individually analyzed for clarity, relevance, and appropriateness for the target population, in order to inform possible adjustments to the educational material. For the analysis of IVATES responses[32], the Appearance Validity Index (AVI) was also calculated using two mathematical equations:[35] the AVI-I to assess agreement for each evaluated item (obtained by dividing the number of specialists or target population members who fully agreed or agreed with the item by the total number of specialists or target population members); and the total AVI, obtained by calculating the mean of all AVI-I values. The Binomial Test was applied to determine whether the observed agreement proportion for each item was statistically higher than the minimum expected proportion, with a significance level of 5% ($p < .05$), for both the specialist committee and the target

population. Items with a mean equal to or greater than .85 were considered validated.[35–36] IBM SPSS Statistics, version 21, was used for all analyses.

Ethical aspects

The study was approved by the Research Ethics Committee of the proposing institution and complied with the requirements of Resolution 466/2012 of the Conselho Nacional de Saúde (National Health Council – CNS). All participants signed the consent form in two copies and were informed of the guarantee of anonymity and the exclusive use of data for scientific purposes. The records and data obtained were stored with the principal investigator and will be permanently deleted five years after the conclusion of the study.

RESULTS

Integrative review and development of the educational booklet

In the integrative review, 223 publications were identified, of which seven articles and guidelines comprised the final sample. The selected studies were organized into thematic axes and articulated with the HBM dimensions and stimuli, directly guiding the definition of content, the pedagogical organization, and the language of the educational booklet. The findings evidenced barriers and difficulties related to insulin use and the occurrence of glycemic imbalances resulting from improper administration, supporting the perception of susceptibility to illness. Understanding the negative impacts of the disease and the complications associated with low adherence, particularly hypoglycemia, underpinned the perceived severity dimension. The identification of insulin types, materials, preparation and administration techniques, and guidance on storage, transport, disposal, and glycemic monitoring supported the perceived benefits dimension. Technical, cognitive, and operational difficulties in the home setting were interpreted as perceived barriers, informing the adaptation of language, pedagogical sequencing, and the use of visual resources. Educational materials and facilitating strategies constituted cues to action, while empowerment, autonomy, and confidence for treatment continuity were understood as expressions of self-efficacy. The conversion of review findings into booklet items was carried out systematically: difficulties in insulin preparation and administration informed illustrated sections with step-by-step guidance; risks and complications grounded warning content and sign recognition; and evidence on empowerment guided the inclusion of encouraging messages, glycemic monitoring logs, and strategies for strengthening self-efficacy. Accordingly, from a pedagogical standpoint, each thematic axis yielded specific content organized according to the HBM, with progressive organization, accessible language, and visual resources aimed at reducing cognitive barriers and strengthening autonomy for self-care.

The first version of the educational booklet entitled "*Aplicação de insulina por pessoas com diabetes mellitus e seus cuidadores no ambiente domiciliar*" was developed in A5 format (148 × 210 mm), comprising 24 pages in portrait mode, compatible with both print and digital versions. The design prioritized legibility, portability, and visual comfort, with a color palette of blue, green, and white.

The cover features an illustration related to insulin administration, followed by a technical data page and table of contents, promoting organization and reader autonomy by anticipating the material's core content. The content is mediated by the character "Nurse Lina," who bridges the technical information with the home care context. The material begins by addressing difficulties related to insulin use, encouraging the recognition of vulnerabilities and the perception of risk. Insulin types, materials, preparation, and administration are then presented, along with guidance on storage, transport, and disposal of sharps, emphasizing safe practices aligned with the perceived benefits dimension. This

content was organized progressively, highlighting practices that contribute to the reduction of risks and AE, such as hand hygiene and adequate mixing of Neutral Protamine Hagedorn (NPH) insulin vials and pens.

The booklet also covers injection sites, subcutaneous pinching, timing, and rotation, along with guidance on storage, transport, and disposal, with the aim of minimizing operational barriers. Insulin therapy complications, particularly hypoglycemia, are addressed with a focus on recognizing signs and management strategies, engaging the perceived severity dimension. This approach seeks to minimize the technical and operational difficulties described in the literature, related to perceived barriers in the home setting. The potential complications of insulin therapy, with emphasis on hypoglycemia, are presented with a focus on recognizing signs and symptoms and on prevention and management strategies, engaging the perceived severity dimension of the HBM. Encouraging glycemic monitoring with recording of values as directed by healthcare providers reinforces the understanding of therapeutic goals and supports treatment adherence and continuity.

Throughout the material, step-by-step guidance, visual alerts, direct language, and the educational character serve as cues to action, encouraging the adoption of safe behaviors. The sequential presentation of insulin preparation and administration steps, combined with explanatory illustrations and encouraging messages, strengthens the reader's self-efficacy for self-care and shared care in the home setting. Figure 1 presents selected pages from the final version of the educational booklet.

Validation of the educational booklet by the specialist committee

Fourteen nurses participated in the validation, predominantly female (*n* = 13; 92.9%), with a mean age of 38.5 years (±5.7) and a mean time since graduation of 15.1 years (±4.8). A high level of academic qualification was observed, with a predominance of doctoral degrees in health science fields (*n* = 13; 92.9%), the majority being faculty at public higher education institutions (*n* = 11; 78.6%) and some working in PHC (*n* = 3; 21.4%), which conferred scientific consistency and practical applicability to the material evaluation. The assessment by the specialist committee evidenced high convergence regarding the clarity, relevance, and organization of the booklet's content. The absence of items with low agreement suggests that the core content of the booklet was aligned with the scientific evidence and the theoretical framework from the first version, indicating prior conceptual adequacy of the material (Table 1).

The homogeneity of agreement among evaluators, combined with the academic profile and professional experience of the group, supports the robustness of the validation process. The application of the Binomial Test confirmed that the agreement observed among the specialists was statistically significant and exceeded the pre-established criterion, indicating that the results did not occur by chance. The convergence of these findings, along with the absence of critical items, supported the completion of the validation process in a single round, without the need for structural or conceptual reformulations of the educational booklet.



Figure 1 – Selected pages from the educational booklet "*Aplicação de insulina por pessoas com diabetes mellitus e seus cuidadores no ambiente domiciliar*". Divinópolis, MG, Brazil, 2024.

Note: The educational booklet was structured based on the Health Belief Model (HBM). Link to access the full material: https://drive.google.com/file/d/1Zdqs_HVp-3wpVPJ60mFJzie5CshDS5pO/view?usp=sharing.

Table 1 – Distribution of Content and Appearance Validity indexes for each item, according to the specialist analysis. Divinópolis, MG, Brazil, 2024 (n=14).

Evaluation items – IVCES	Agree Fully	Agree Partially	Disagree	I-CVI †
	n (%)*	*n* (%)*	*n* (%)*	
Objectives				
1 Addresses the proposed subject	13 (92.9)	1 (7.1)	–	1
2 Appropriate for the teaching-learning process	14 (100)		–	1
3 Clarifies questions about the subject matter	13 (92.9)	1 (7.1)	–	1
4 Promotes reflection on the subject	13 (92.9)	1 (7.1)	–	1
5. Encourages behavioral change	11 (78.6)	3 (21.4)	–	1
Structure/Presentation				
6. Language appropriate for the target population	6 (42.8)	8 (57.2)	–	1
7. Language appropriate for educational material	12 (85.7)	2 (14.3)	–	1
8. Interactive language	12 (85.7)	2 (14.3)	–	1
9. Accurate information	12 (85.7)	2 (14.3)	–	1
10. Objective information	12 (85.7)	2 (14.3)	–	1
11. Clarifying information	13 (92.9)	1 (7.1)	–	1
12. Necessary information	14 (100)		–	1
13. Logical sequence of ideas	13 (92.9)	1 (7.1)	–	1
14. Current subject matter	14 (100)		–	1
15. Appropriate text length	12 (85.7)	3 (21.4)	–	1
Relevance				
16. Stimulates learning	13 (92.9)	1 (7.1)	–	1
17. Contributes to knowledge in the field	14 (100)		–	1
18. Arouses interest in the subject	13 (92.9)	1 (7.1)	–	1
Evaluation items – IVATES	**Agree Fully***	**Agree***	**Disagree***	**AVI-I ‡**
	n (%)*	*n* (%)*	*n* (%)*	
1. The illustrations are appropriate for the target population	7 (50)	7 (50.0)	–	1
2. The illustrations are clear and easy to understand	7 (50)	7 (50.0)	–	1
3. The illustrations are relevant for target population understanding of the content	12 (85.7)	2 (14.3)	–	1
4. The illustration colors are appropriate for the type of material	7 (50.0)	6 (42.9)	1 (7.1)	.93
5. The illustration shapes are appropriate for the type of material	6 (42.9)	7 (50.0)	1 (7.1)	.93
6. The illustrations depict the daily life of the target population	12 (85.7)	2 (14.3)	–	1
7. The arrangement of figures is in harmony with the text	10 (71.4)	2 (14.3)	2 (14.3)	.86
8. The figures used clarify the content of the educational material	8 (57.1)	6 (42.9)	–	1
9. The illustrations support the presentation of the subject and follow a logical sequence	11 (78.6)	3 (21.4)	–	1
10. The illustrations are present in adequate quantities in the educational material	10 (71.4)	2 (14.3)	2 (14.3)	.86
11. The illustrations are of adequate size in the educational material	9 (64.3)	4 (28.6)	1 (7.1)	.93
12. The illustrations support behavioral and attitudinal change in the target population	12 (85.7)	2 (14.3)	–	1

*Agreement percentage per item; † I-CVI – Item-Level Content Validity Index; ‡AVI-I – Item-Level Appearance Validity Index.

To complete this stage, only one round of evaluation was necessary. The specialists' suggestions focused on linguistic, pedagogical, and visual adjustments aimed at improving accessibility and comprehension for the target population, including the simplification of technical terms, the detailing of insulin therapy procedures, graphic adaptations, and the expansion of illustrations. These adjustments encompassed, among other aspects, the terminology used, the presentation of insulin preparation and administration steps, the visual organization of the material, and glycemic monitoring records. The contributions did not reveal conceptual inconsistencies but strengthened the operationalization of the HBM dimensions and stimuli, particularly in reducing perceived barriers, stimulating self-efficacy, and reinforcing cues to action in the home care context.

After incorporating these recommendations, the booklet maintained theoretical coherence and methodological consistency, establishing itself as a validated educational technology to support the safe use of insulin. These adjustments reinforced the pedagogical function of the booklet by expanding instructional clarity and the operationalization of the HBM, particularly in addressing perceived barriers and strengthening self-efficacy.

Target population validation

All participants had type 2 DM (T2DM); the majority (*n* = 13, 65%) were women, with a mean age of 68.5 years (±9.4), a median of 3.0 years of schooling (interquartile range = 2.0), and married (*n* = 12, 60%). Regarding occupation, 12 (60%) were not economically active. The mean time since diagnosis was 14.4 years (±9.8); all used NPH insulin (*n* = 20, 100%), characterizing a population with high susceptibility and potential barriers to insulin therapy management.

Family members/caregivers (*n* = 12) were predominantly women (66.7%), with a mean age of 58.3 years (±15.8) and low educational attainment of 3.1 years (±1.2). Regarding family relationship, six (50%) were spouses or children, three (25%) were siblings, and three (25%) were other family members. Half lived in the same household as the person with DM, and all were responsible for preparing and administering insulin, highlighting their central role in home care. The appearance evaluation confirmed high adequacy of language, organization, and visual presentation of the booklet for the target population, with statistically significant agreement among participants (Table 2).

The absence of modification suggestions indicates that the material met the perceived needs, contributing to the reduction of barriers, the strengthening of self-efficacy, and the activation of cues to action. The unanimous expression of interest in reading and ability to follow the guidance reinforces the educational booklet's potential to support safe behaviors in home insulin use. These findings indicate that the booklet fulfilled its pedagogical function by fostering comprehension of the guidance and confidence in its application in the home setting, serving as a support for safe behavior in insulin therapy.

Table 2 – Target population evaluation of the booklet's objectives, organization, writing style, appearance, and motivation. Divinópolis, MG, Brazil, 2024 (n = 32).

Evaluation items	Agree Fully	Agree	AVI-I †
	n (%)*	*n* (%)*	
1. The illustrations are appropriate for the target population	32 (100)	–	1
2. The illustrations are clear and easy to understand	32 (100)	–	1
3. The illustrations are relevant for the target population's understanding of the content	32 (100)	–	1
4. The illustration colors are appropriate for the type of material	32 (100)	–	1

Table 2 – Cont.

Evaluation items	Agree Fully	Agree	AVI-I †
	n (%)*	*n* (%)*	
5. The illustration shapes are appropriate for the type of material	32 (100)	–	1
6. The illustrations depict the daily life of the target population	32 (100)	–	1
7. The arrangement of figures is in harmony with the text	32 (100)	–	1
8. The figures used clarify the content of the educational material	32 (100)	–	1
9. The illustrations support the presentation of the subject and follow a logical sequence	32 (100)	–	1
10. The illustrations are present in adequate quantities in the educational material	32 (100)	–	1
11. The illustrations are of adequate size in the educational material	29 (90.6)	3 (9.4)	1
12. The illustrations support behavioral and attitudinal change in the target population	32 (100)	–	1

*Agreement percentage per item; † AVI-I – Item-Level Appearance Validity Index.

DISCUSSION

The present study indicates that the systematic integration of scientific evidence, an explicit theoretical framework, and rigorous methodological validation constitutes a consistent pathway for the development of educational health technologies. The HBM-grounded booklet translated the gaps and demands identified in the integrative review into pedagogically organized content, aligned with the psychosocial determinants of safe home insulin use and the PHC context. Multi-stage validation demonstrated conceptual consensus and communicational adequacy of the material, requiring only linguistic and visual adjustments, indicating theoretical and pedagogical maturity from the initial version.

Content and appearance validation was conducted by a committee composed of nurses. Although the literature indicates that multiprofessional participation can broaden evaluative perspectives, the high agreement observed in this study reflects nursing expertise in health education, care for individuals with DM, and the development of educational technologies[35–36]. Previous methodological studies corroborate the validity of processes conducted exclusively by nurses, recognizing their technical-scientific, pedagogical, and clinical competence in the evaluation of health educational materials[12,14,23].

The high CVI and AVI values observed, including items with maximum I-CVI, indicate consensus regarding the clarity, relevance, and conceptual adequacy of the content, as recommended in the methodological literature, where maximum values reflect full agreement among experienced evaluators. The application of the Binomial Test complemented these analyses by demonstrating that the observed agreement was statistically superior to the reference criterion and not attributable to chance, strengthening the robustness of the validation[35,37]. The absence of items with agreement below the cutoff point supported the methodological decision to conclude the process in a single round, without the need for structural reformulations[35,37].

In contrast, items related to appearance, such as language, graphic formatting, and the teaching-learning process, presented relatively lower agreement, an expected aspect in evaluations involving more subjective dimensions. From the HBM perspective, these elements are directly related to cues to action, as visual clarity, sequential organization, and language accessibility serve as stimuli

that promote attention, comprehension, and engagement[21,38]. They also influence self-efficacy by strengthening the individual's confidence in their ability to correctly perform the steps of insulin therapy[22].

The qualitative recommendations focused on pedagogical and communicational adjustments incorporated in a single round, including textual revisions, reorganization of the page sequence, and simplification of language. In light of the HBM, these adaptations contributed to the reduction of perceived barriers[39], particularly those related to content complexity, and reinforced cues to action[17,21,38] and self-efficacy,[17,21–22] by facilitating decision-making and the adoption of safe practices. The effectiveness of these adjustments was corroborated in the target population validation, which confirmed the material's adequacy to the needs of individuals with DM and their caregivers in the home setting.

A lack of knowledge and limited health literacy among individuals with DM using insulin and their family members/caregivers can represent a barrier to self-care, which increasingly justifies investment in the development of educational technologies that support the teaching-learning process for the population. Health education through educational technology promotes the socialization of knowledge and provides a scientific foundation for clinical care by the multiprofessional team, including individuals with lower levels of health literacy and educational attainment[40]. The presentation of coherent, organized, and visually attractive information contributes to effective reading of the booklet and facilitates the adoption of health behaviors[7,12,40].

The findings converge with national studies that developed and validated educational technologies for insulin therapy, which also report high agreement regarding the clarity and organization of materials. However, most of these technologies are based primarily on informational approaches or health literacy, with limited systematic incorporation of theoretical models of behavior change, restricting their potential to promote sustained adherence to insulin therapy[12,23–25].

Unlike these materials, the present booklet was entirely structured from the HBM, operationalizing its dimensions and stimuli from content selection to final validation. This distinction allowed for addressing not only the insulin administration technique but also the cognitive and motivational determinants that influence adherence in the home setting, particularly among family caregivers. International evidence[41–42] corroborates this approach by demonstrating that theoretically grounded educational interventions support the strengthening of self-efficacy, engagement, and the adoption of safe behaviors, with an impact on clinical outcomes.

Studies conducted in different international contexts demonstrate that HBM-based interventions contribute to improved glycemic control, reduction of glycated hemoglobin, enhanced self-management skills, and strengthened self-efficacy[21–22]. In contrast, national production of interventional studies explicitly grounded in this model remains incipient, although educational programs with behavioral and motivational components have demonstrated a positive impact[43]. These findings reinforce that technical knowledge alone is insufficient to promote sustained behavioral change, with health belief-mediated approaches being a central element for self-care[17,21–22].

Educational interventions grounded in HBM adjust beliefs to promote improvements in self-care practices, particularly in older adult populations and contexts of greater social vulnerability[21–22]. Qualitative research reinforces that individual beliefs modulate insulin use in individuals with DM who present complex self-care learning demands, and that perceptions of severity, susceptibility, barriers, and benefits directly influence management practices, reinforcing the need for contextualized and theoretically grounded educational technologies[39].

The HBM considers factors such as the perception of DM severity, susceptibility to disease complications, perceived barriers including fear of needles, social stigma, or lack of knowledge about administration, and the expected benefits of correct insulin use. It also highlights the importance of stimuli that motivate behavior, such as the user's connection with healthcare providers and services, family support, and positive self-care experiences[21]. By applying this model, it is possible to identify

misconceptions, develop more targeted educational strategies, personalize clinical follow-up, and increase patient satisfaction and confidence in treatment. The model also enables the strengthening of the individual's autonomy and responsibility in DM management.

The present study contributes to the nursing field by demonstrating the feasibility of systematically integrating a theoretical behavior change model into the development and validation of an educational technology aimed at the safe use of insulin at home. Within the PHC context, the booklet has the potential to support nursing practice in individualized and systematized care by informing the identification of specific beliefs, barriers, and needs, and guiding educational interventions aligned with clinical guidelines and the nursing process.

Nursing practice with individuals with DM must be grounded in qualified communication, bonding, and recognition of individual needs, fostering the shared construction of care and adherence to guidance. In this context, the use of HBM-grounded educational technologies supports more individualized and systematized interventions that are sensitive to beliefs, barriers, and motivations, strengthening safe self-care and adherence to home insulin therapy[11]. Future studies are recommended to evaluate the implementation of the booklet in real home care settings, using experimental or quasi-experimental designs, in order to analyze its applicability, acceptability, and potential impact on self-care, insulin use safety, and clinical outcomes in individuals with DM and their caregivers.

As limitations, the absence of individuals with type 1 DM (T1DM) in the target population validation stage, stemming from the predominance of children and adolescents in the local setting, restricts the generalization of findings to this specific group, although the content is relevant to both types of DM. Additionally, the absence of a formal comprehensibility pretest prior to appearance validation is acknowledged, as this could have refined the language in preliminary stages. From a theoretical-methodological standpoint, the non-use of a detailed specification matrix demonstrating the direct and systematic connection between the integrative review findings, the HBM constructs, and each final booklet item represents a limitation in the process of transposing the theoretical framework to the instrument. Finally, the reliance on Likert scales, while validated, may have limited the capture of subjective nuances and deeper participant perceptions, which complementary qualitative methods could have elucidated more comprehensively.

CONCLUSION

The educational booklet on home insulin administration, grounded in the HBM, provides evidence of content and appearance validity, establishing itself as a robust technology for clinical practice in PHC. For nursing science, the study demonstrates that the translation of classical theoretical frameworks into technological tools allows for an approach that transcends technique by focusing on the subjective determinants of adherence. The material effectively enhances self-management by sensitizing users to the susceptibility and severity of complications, while reinforcing the benefits of treatment and offering strategies for overcoming operational barriers. The use of this resource accordingly strengthens autonomy and specialized support, constituting a strategic tool for promoting safety in insulin therapy.

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CONFLICT OF INTEREST
The authors declare there are no conflicts of interest.

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