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RESEARCH ARTICE (ORIGINAL)

Therapeutic guidelines for foot self-care in diabetes: A Delphi technique for a mobile application

Diretrizes terapêuticas para o autocuidado com os pés na diabetes: Técnica Delphi para uma aplicação móvel

Directrices terapéuticas para el autocuidado de los pies en la diabetes: técnica Delphi para una aplicación móvil

Geysa Santos Góis Lopes [1]
https://orcid.org/0000-0002-6801-1940

Maria José Lumini Landeiro [2, 3]
https://orcid.org/0000-0002-2951-8001

Maria Rui Miranda Grilo Correia de Sousa [2, 3]
https://orcid.org/0000-0002-6669-8339

[1] University of Porto, School of Medicine and Biomedical Sciences, Porto, Portugal

[2] Nursing School of Porto, Porto, Portugal

[3] University of Porto, Center for Health Technology and Services Research - Health Research Network (CINTESIS&RISE), Porto, Portugal

Corresponding author
Geysa Santos Góis Lopes
E-mail: geysagois@hotmail.com

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Abstract
Background: Mobile applications should include evidence-based content developed and validated by experts to ensure effectiveness and safety.
Objective: To validate therapeutic guidelines to promote foot self-care in people with type 2 diabetes mellitus for use in a mobile application, based on relevance and language.
Methodology: Delphi technique to validate guidelines developed from recent guidelines. Two rounds with 10 experts with proven clinical, research, or teaching experience. A minimum content validity index value of 0.8 was used. The modified guidance on Conducting and REporting DElphi Studies (CREDES) was used.
Results: Of the 128 guidelines related to comprehensive foot care, 125 reached a consensus, namely healthy maintenance and proper footwear and socks. The language was simplified to improve understanding.
Conclusion: The guidelines were found to be valid with clear language and can be incorporated into a mobile application to support foot self-care.

Keywords: validation study; Delphi technique; diabetic foot; diabetes mellitus, type 2; self-care; mobile applications

Resumo
Enquadramento: Para assegurar a eficácia e segurança, as aplicações devem ter conteúdos baseados em evidências, desenvolvidos e validados por especialistas.
Objetivo: Validar diretrizes terapêuticas para a promoção do autocuidado com os pés em pessoas com diabetes tipo 2, a serem implementadas numa aplicação móvel com base na sua relevância e linguagem.
Metodologia: Técnica Delphi para validação de orientações elaboradas a partir de guidelines recentes com duas rondas com 10 especialistas de comprovada experiência clínica, investigação ou docência. Considerou-se o índice de validade de conteúdo mínimo de 0,8. Utilizou-se a recomendação modificada para a condução e elaboração de relatórios dos estudos Delphi (CREDES).
Resultados: Das 128 orientações, 125 atingiram consenso, abrangendo cuidados integrais com os pés, incluindo a manutenção saudável, calçado e meias adequadas. A linguagem foi simplificada para facilitar a compreensão.
Conclusão: As orientações foram consideradas válidas, com linguagem adequada e poderão ser incluídas numa aplicação de suporte ao autocuidado com os pés.

Palavras-chave: estudo de validação; técnica Delphi; pé diabético; diabetes mellitus tipo 2; autocuidado; aplicações móveis

Resumen
Marco contextual: Para garantizar la eficacia y la seguridad, las aplicaciones deben tener un contenido basado en evidencias, desarrollado y validado por expertos.
Objetivo: Validar directrices terapéuticas para promover el autocuidado de los pies en personas con diabetes tipo 2, que se implementarán en una aplicación móvil en función de su relevancia e idioma.
Metodología: Técnica Delphi de validación de orientaciones basada en directrices recientes con dos rondas de 10 expertos con experiencia clínica, investigadora o docente demostrada. Se consideró un índice de validez de contenido mínimo de 0,8. Se utilizó la recomendación modificada para la realización y notificación de estudios Delphi (CREDES).
Resultados: De las 128 directrices, 125 llegaron a un consenso y abarcan el cuidado integral de los pies, incluido el mantenimiento saludable, el calzado adecuado y los calcetines. El lenguaje se ha simplificado para facilitar la comprensión.
Conclusión: Las orientaciones se consideraron válidas, con un lenguaje adecuado y que podrían incluirse en una app de apoyo al autocuidado de los pies.

Palabras clave: estudio de validación; técnica Delphi; pie diabético; diabetes *mellitus* tipo 2; autocuidado; aplicaciones móviles

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Introduction

Type 2 diabetes mellitus (T2DM) is a chronic disease that affects millions of people worldwide and can lead to serious foot complications such as infection and amputation if not properly managed (Schaper et al., 2023). Foot self-care is essential in the treatment of T2DM, but many people face challenges such as low self-efficacy and lack of knowledge (Dhandapani et al., 2022). This care, often carried out at home and without direct professional guidance, needs to be frequent and effective.

Technology offers a potential solution through mobile applications (Apps) that can provide personalized information and support regular self-care behaviors. It is essential that the app uses simple and reliable language to improve adherence (Bults et al., 2023). Creating a set of guidelines based on the most robust scientific evidence and evaluated by experts in the field will not only mitigate potential errors, but also make the app more reliable (Rose et al., 2019).

Therefore, this study aims to validate therapeutic guidelines to promote foot self-care in people with T2DM for use in an app based on their relevance and language.

Background

Diabetes-related foot disease is an area of concern in clinical practice due to its negative impact on quality of life and the financial costs for healthcare systems (Schaper et al., 2023). The lifetime risk of foot ulcer in people with diabetes ranges from 19% to 34% and is rising with increased longevity and the challenges of diabetes. After developing a foot ulcer, the recurrence rate is 65% at 3-5 years. In addition, 20% of people are at risk of amputation, and the 5-year mortality rate is 50-70% (McDermott et al., 2023). Therefore, focusing on effective prevention and treatment of diabetic foot ulcers is key to achieving good health outcomes.

More recently, a deeper understanding of the complications of DM has led to an important conceptual shift. In its most recent guidelines, the International Working Group on the Diabetic Foot (IWGDF) replaced the term diabetic foot with diabetes-related foot disease, which is the term used in this article (Netten et al., 2023). According to the IWGDF, this complication results from factors such as peripheral neuropathy, peripheral artery disease, infection, ulcer, neuro-osteoarthropathy, gangrene, or amputation (Netten et al., 2023).

In light of these implications, self-care is emerging as a central aspect of treatment. Self-care refers to the ability of individuals, families, and communities to promote health, prevent disease, manage health conditions, and cope with disability, with or without the support of professionals, as a complement to the health care system (WHO, 2022). Understanding that people can influence the development of diabetes-related foot disease through regular self-care practices is essential to effective management of this disease.

One study evaluated foot care education programs for people with DM and found that adopting self-care behaviors reduced the prevalence of risk factors for foot ulceration, such as dry skin, cracks, and calluses (Lira et al., 2023). These findings highlight the remarkable role of self-care in foot health.

Despite the importance of foot self-care, evidence shows that knowledge and practice are suboptimal (Manickum et al., 2021). A review found varying degrees of knowledge and practice, including foot inspection, foot hygiene, glycemic control, and foot protection (Manickum et al., 2021), underlining the need for interventions to improve foot self-care.

The need to improve self-care opens space for innovative strategies, such as the use of mobile apps. These apps, which are designed to run on mobile devices, provide health interventions and content (Rose et al., 2019). A systematic review found that while apps have a positive effect, they have a modest impact on health and can be useful to complement behavioral change (Iribarren et al., 2021). The International Diabetes Federation Europe recommends that diabetes self-management apps should be developed by healthcare professionals and validated by experts, ensuring their accuracy and effectiveness (Rose et al., 2019).

By validating the content to be included in an app, this study aims to comply with the recommendations in the literature and contribute to increasing the effectiveness of mobile technology to support foot self-care in people with T2DM.

Research question

What are the therapeutic guidelines for promoting foot self-care in people with T2DM for use in a mobile app based on their relevance and language?

Methodology

To answer the research question, the Delphi technique was used to collect data in a study conducted between September and December 2022 in Portugal. The process followed the modified guidance on Conducting and REporting of DElphi Studies (CREDES; Jünger et al., 2017). The technique was used to reach consensus on therapeutic guidelines to promote foot self-care through a structured and iterative process. It included careful selection of experts, development of a questionnaire, evaluation rounds, revision and reapplication of the questionnaire, analysis of responses, and compilation and documentation of consensus guidelines.

The experts were selected by purposive sampling based on a detailed curriculum analysis, including their scientific publications and history of clinical practice to ensure that they all had relevant experience in the field. This approach ensured the inclusion of experts with different perspectives, meeting the heterogeneity criterion of the Delphi panel. Inclusion criteria were a) being a health professional with at least two years of experience in monitoring/treating diabetes-related foot disease; and/or b)

having conducted research in the field; and/or c) being, or having been, a teacher in the field. Exclusion criteria were a) professionals willing to participate in all rounds of the study; b) specialists with a potential conflict of interest, that is, involvement in the development or promotion of foot self-care app or technologies, which could influence their responses or compromise the impartiality of the evaluations; and c) professionals with difficulty understanding European Portuguese. Thus, 10 multidisciplinary experts (nurses, podiatrists, teachers, and researchers) were identified. These experts completed both rounds of the Delphi process, ensuring data consistency and completeness. The sample was considered suitable for this method, providing balance and diversity of opinion without compromising the depth of the analysis. The fact that none of the experts dropped out increased the robustness and validity of the results. Participants were contacted by phone to explain the purpose of the study and the importance of their participation, which was then repeated by email.

Following Shang's guidelines (2023), two steps were taken to ensure the validity of the app's content: prior development of the content and then evaluation and quantification of the consensus.

In the development phase, an extensive literature search was conducted using a scoping review (Lopes et al., 2024) to map the recommendations of international guidelines on T2DM and foot health. The results of this review provided the theoretical basis for defining the content to be developed in this study. The researchers' team developed a set of statements for each topic to be included in the app, which were discussed iteratively and thoroughly reviewed for structure, organization, clarity, and relevance. The content was also evaluated by a teacher from outside the project team for comprehensibility and relevance of the recommendations, so that the final tool could be submitted to the expert panel for refinement. The final version of the content consists of 14 dimensions with 128 statements that, when combined, can support foot self-care. The following dimensions were included: T2DM and feet, Risk factors for diabetes-related foot disease, Foot self-examination, Frequency of foot assessment by a health professional, How to keep feet healthy, How to choose and wear appropriate footwear, How to choose socks, Foot health products, Foot wound care, Warning signs of foot infection, Foot problems, Specialists in foot care, Contact with health services, and Useful websites. It is important to note that the dimensions and statements were not ranked for relevance by the experts during the study, as the content was previously developed based on a scoping review to ensure comprehensiveness and substantiation of the proposed guidelines.

In the second phase, the Item-Level Content Validity Index (I-CVI) was used as a quantitative measure of consensus for each item. The I-CVI provides specific information about each statement that can be used to improve or exclude statements (Polit et al., 2007). The I-CVI was calculated by dividing the items with agreed rating of '4' or '5' (indicating relevance) by the total number of experts.

In addition, a qualitative analysis was conducted to integrate the suggestions provided by the experts. Textual responses were carefully reviewed, categorized according to emerging themes, and integrated into the existing dimensions. This process allowed valuable expert input to be incorporated and the final content to be refined, particularly with regard to the wording of the statements. In each round, consensus was reached on the parameters if the I-CVI was greater than or equal to 0.8. Statements with I-CVI between 0.7 and 0.79 had to be reformulated based on the suggestions. Finally, statements with I-CVI < 0.7 should be excluded depending on the relevance of the item (Polit et al., 2007). To assess the central point of the experts' responses, the median was calculated for each statement. In addition, the percentage of experts whose answers differed from the median was determined. A descriptive analysis was performed to characterize the experts.

In the first round, the Delphi process began with the experts evaluating the statements. A socio-demographic questionnaire and the questionnaire with the statements to be evaluated were sent to the participants by e-mail. The questionnaires were created using Microsoft Word. After 7 days, a reminder was sent to promote adherence. The questionnaire consisted of two parts. The first part included a description of the study, instructions on the rating scale, and a space for comments where participants could rephrase or add statements. The second part included the statements to be rated, with a final space for additional topics not on the original list.

Participants were asked to rate the degree of relevance and clarity of the information, based on the importance they attached to it and the relevance of the content to the objectives of the app. A 5-point Likert scale was used with the following options: 1 = *Strongly disagree*, 2 = *Disagree*, 3 = *Neither agree nor disagree*, 4 = *Agree*, and 5 = *Strongly agree*. The experts who answered in the first round were invited to participate in the second round to reach a consensus on content improvements. At this stage, the statistical data and a summary of the results obtained in the first round were presented to the experts as a basis for evaluation. The suggestions for content improvement made in the first round were included and the experts were asked whether they agreed with these recommendations. The experts were also given the opportunity to re-evaluate their considerations from the first round.

The steps described above were carried out as follows: the planning and development of the questionnaires took 3 weeks; the distribution, collection and analysis of the first round took 7 weeks; after adjustments based on the responses received, the second round took 3 weeks. The analysis of the responses and the compilation of the consensus guidelines took 3 weeks.

The ethical guidelines of the World Medical Association's Declaration of Helsinki were followed. All experts were informed of the nature of the research and were assured of anonymity and privacy by signing the informed consent form before being given access to the data collection instruments. This study was approved by the Ethics Committee of the University Hospital Center of São João (reference CHUSJ: 422/2021).

Results

The experts' mean age was 52 years (standard deviation = 10.47), 70% of whom were women. The majority were nurses (n = 7), followed by teachers who also worked as researchers (n = 2) and a podiatrist (n = 1). They had a mean of 17.2 years of professional experience in the field of diabetes-related foot disease. One had a Ph.D., five had master's degrees, two had specialist degrees, and two had bachelor's degrees.

In the first round, in terms of content, the results showed consensus on 114 of the 128 initial guidelines (I-CVI value > 0.80). Ten guidelines had an I-CVI value between 0.7 and 0.79 and four guidelines an I-CVI value < 0.7. Of these four guidelines, three were excluded and one, although meeting the exclusion criteria, was revised for relevance as it referred to the concept of diabetes-related foot disease. One of the guidelines that met the review criteria was recommended by the experts to be edited, refined, and split into two statements because the sentence was too long and could compromise its understanding. The How to keep feet healthy, How to choose and wear appropriate footwear, and How to choose socks dimensions were three of the eight sections that were unanimously deemed relevant and appropriate for inclusion in the app. However, the T2DM and feet and Foot health products dimensions had a lower degree of consensus, which led to the exclusion of more detailed information, namely on the use of leg elevation pillows to relieve foot pressure and the use of petroleum jelly. Table 1 shows the total number of statements per dimension, as well as the initial decisions made in the first round.

Table 1

Overview of the initial decisions in the first round

Dimensions	Total of statements	Recommend	Exclude	Revise
T2DM and feet	11	8	2	1
Risk factors for diabetes-related foot disease	1	1	0	0
Foot self-examination	16	15	1	0
How often should the feet be assessed by a health professional	5	3	0	2
How to keep feet healthy	30	30	0	0
How to choose and wear appropriate footwear	15	15	0	0
How to choose socks	4	4	0	0
Foot health products	8	5	1	2
Foot wound care	10	9	0	1
Foot infection: warning signs	2	2	0	0
Foot problems	6	6	0	0
Specialists in foot care	10	6	0	4
Contact with health services	5	5	0	0
Useful websites for healthy feet	5	5	0	0

Based on the quantitative analysis (statements without an I-CVI value > 0.80) and the content analysis of the panel's comments, the guidelines were revised, resulting in a total of 12 statements to be reviewed in the second round. In addition, the experts were also given the opportunity to read the other statements with an I-CVI value > 0.80 along with the comments of their peers so that they could review their ratings and, if they felt it appropriate, change their previous ratings. In the second round, 11 statements had an I-CVI value > 0.80. One statement related to the foot care team, specifically the radiologist as a foot care specialist, did not meet the pre-defined consensus threshold and was therefore excluded.

The median for all statements was equal to or greater than 4 (i.e., 4 or 5) on a 5-point Likert scale, indicating that the majority of experts rated the statements positively at the higher end of the scale. The variability of expert opinions in each dimension was analyzed by calculating the mean percentage of experts that differed from the median for each statement. Dimensions 5 (16%), 6 (16.6%), 9 (12%), and 10 (10%) showed high levels of agreement, indicating a relatively strong consensus in these areas. Dimensions 1 (38%), 4 (36.8%), 7 (20%), 11 (23.3%), 12 (23.2%), 13 (17.6%), and 14 (24.2%) showed moderate levels of agreement, reflecting a wider range of opinions. Dimensions 2 (40%), 3 (17.5%), and 8 (34.5%) showed greater disagreement among the experts, indicating areas of divergence.

With regard to language, the experts identified 25 statements that required adjustments to the syntax and words used in some statements. These changes aimed to simplify the language and make the content easier to understand and more accessible to the target audience. During the Delphi panel, the experts assessed three areas: (1) The writing style is suitable for the target audience; (2) The writing is attractive; and (3) The language is clear and

objective. The median response for these statements was above 4, indicating that the most experts found the language to be appropriate and easy to understand. However, some experts had additional comments and suggestions for improvement on the use of technical terms and the structure of the content. For example, some suggested including a glossary of terms such as *amputation* and *podiatrist*, making the text more assertive, and including illustrative images. Others suggested reducing and simplifying the content in some sections to make it easier to understand. They also suggested that some expressions should be adapted to the Portuguese context in which the app will be used. These comments were taken into account in the final revision to ensure that the language was clear, accessible, and culturally appropriate.

There was no third round because all guidelines were either fully accepted (meeting the consensus criteria) or fully rejected (not meeting the consensus criteria) at the end of the second round, leaving no items for further analysis. There were therefore 125 consensus statements in this study. The consensus statements are available and can be provided upon reasonable request.

Discussion

After the two Delphi rounds, the experts reached consensus on a wide range of guidelines to be included in a mobile app that, when combined, can promote foot self-care in people with T2DM. This study validated content consisting of 125 statements divided into 14 dimensions about comprehensive foot care. The large number of dimensions and statements reveals the need for a systemic and complex approach to promoting, maintaining, monitoring and managing foot health. None of the 14 dimensions were eliminated due to lack of consensus. The need for guidelines to develop skills and competencies to promote foot self-care is evident, with 57% of priority statements addressing this aspect. This result was expected given that self-care practices are fundamental to preventing complications and significantly reduce risk factors (Lira et al., 2023). The How to keep feet healthy, How to choose and wear appropriate footwear, and How to choose socks dimensions were unanimously agreed upon, highlighting the importance of practices that allow users to make informed decisions, especially at home. The IWGDF, recognized for its contributions, recommends the creation of structured educational programs to improve knowledge and self-protection behaviors and to promote adherence to self-care (Schaper et al., 2023). There was full consensus on the 15 statements related to choosing and wearing appropriate footwear. This agreement among experts is consistent with the scientific evidence that points to inappropriate footwear use or barefoot walking as major causes of foot injuries, often leading to ulcers (Schaper et al., 2023). It is therefore essential to provide therapeutic guidelines for the use of footwear adapted to biomechanical or structural changes in the feet. A literature review found that only a limited number of people with diabetes in low- and middle-income countries comply with international recommendations. It also highlighted the need for more practical strategies in resource-constrained contexts (Reddie et al., 2023). An app that provides validated guidance on the correct use of footwear can therefore help to prevent foot ulcers. Another priority is the How to keep feet healthy dimension, which also received unanimous support. These recommendations highlight the importance of daily self-care, including control of risk factors, hygiene, and what to do when signs and symptoms appear. Although the literature documents the positive impact of foot care (Schaper et al., 2023), one study revealed poor knowledge and preventive practices among people with diabetes (Dhandapani et al., 2022), highlighting the lack of interventions to meet self-care needs. Interventions based on best practices and ulcer prevention guidelines can reduce the morbidity and mortality rates associated with ulcer complications. Statements related to the Specialists in foot care and Foot health products dimensions received proportionally more recommendations from experts to be revised or excluded. The lack of consensus is partly due to the lack of clear and concise guidelines in these areas in international standards, reflecting the lack of a solid and established basis for this content. An analysis of available guidelines showed that only a few of them addressed these topics (American Diabetes Association Professional Practice Committee, 2022; National Institute for Health and Care Excellence, 2015; World Health Organization, 2020). The diversity of practices, the variety of products, and the constant evolution of knowledge may also explain the lack of standardized recommendations.

The second aim of this study was to evaluate the language of the guidelines, a key educational aspect (Barbosa et al., 2023), to ensure that they were accessible, attractive, and understandable to people with different levels of literacy. Creating recommendations that are understandable and motivating can be challenging. In addition, adjusting the language to eliminate irrelevant or redundant elements avoids information overload. Thus, validating the language reinforces the comprehensiveness of the guidelines and is essential for understanding the topic (Barbosa et al., 2023).

This study is a pioneer in the validation of guidelines for foot care education to be delivered through a self-care support app for the Portuguese population with T2DM. Although health professionals prioritize therapeutic education in their consultations, this information is usually provided verbally or through leaflets.

Although this study has provided validated guidelines for foot self-care, some limitations should be highlighted. The large number of recommendations (125) can make it difficult to define priorities, and the lack of consensus on certain dimensions indicates the need for further discussion. The literature recommends a panel of six to 20 experts, so a larger group could provide greater diversity and generalizability of the results. This study may also not capture all cultural and linguistic variations, limiting its applicability in other contexts. However, the study has strengths, such as the high response rate in the Delphi rounds, which reflects the experts' commitment.

Rigorous validation and active involvement ensure that the guidelines are scientifically valid and appropriate for the target audience. The panel's suggestions reinforce the commitment to developing guidelines that are scientifically valid and culturally appropriate.

Conclusion

This study identified essential therapeutic guidelines for a mobile app to support foot self-care in people with T2DM. The expert consensus reflects a high level of agreement and adds to the understanding of the topic. In terms of relevance of information and appropriateness of language, the validated recommendations provide support for self-care outside the clinical environment.

The guidelines cover multiple dimensions and confirm the need for a multi-level and systemic approach to the prevention of foot complications in DM, as established in the literature. This study provides a set of validated guidelines that can be used as a practical reference for people living with T2DM. Despite the challenges of implementation, the recommended care is low cost and low effort. These findings may assist researchers and health professionals in defining guidelines for foot self-care.

Future studies should validate the guidelines with experts from different cultural backgrounds to ensure the depth and breadth of self-care. It is also important to assess the level of acceptability of the content among people with T2DM. In addition, gathering feedback from users before finalizing the app will ensure that the guidelines meet the needs and expectations of the target audience. These steps can improve the guidelines and ensure their effectiveness in different contexts and populations.

Author contributions

Conceptualization: Lopes, G. S., Landeiro, M. J., Sousa, M. R.
Data curation: Lopes, G. S.
Formal analysis: Lopes, G. S., Landeiro, M. J., Sousa, M. R.
Investigation: Lopes, G. S.
Methodology: Lopes, G. S., Landeiro, M. J., Sousa, M. R.
Project administration: Lopes, G. S., Landeiro, M. J., Sousa, M. R.
Supervision: Landeiro, M. J., Sousa, M. R.
Validation: Lopes, G. S., Landeiro, M. J., Sousa, M. R.
Visualization: Lopes, G. S., Landeiro, M. J., Sousa, M. R.
Writing - original draft: Lopes, G. S.
Writing - review and editing: Lopes, G. S., Landeiro, M. J., Sousa, M. R.

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